
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

**FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

ProKidney Corp.

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)
2000 Frontis Plaza Blvd., Ste 250
Winston-Salem, NC 27103
Telephone: (336) 999-7028

98-1586514
(I.R.S. Employer
Identification Number)

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Tim Bertram, Ph.D.
Chief Executive Officer
ProKidney Corp.
2000 Frontis Plaza Blvd., Ste 250
Winston-Salem, NC 27103
Telephone: (336) 999-7028

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Todd C. Girolamo, Esq.
ProKidney Corp.
2000 Frontis Plaza Blvd., Ste 250
Winston-Salem, NC 27103
Telephone: (336) 999-7028

Megan N. Gates, Esq.
Jason S. McCaffrey, Esq.
Matthew T. Simpson, Esq.
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
One Financial Center
Boston, Massachusetts 02111
Telephone: (617) 542-6000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. The selling securityholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission becomes effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED AUGUST 8, 2022

PRELIMINARY PROSPECTUS

PROKIDNEY CORP.

Up to 232,530,000 Class A Ordinary Shares

This prospectus relates to the resale from time to time by the selling securityholders named in this prospectus (the “Selling Securityholders”) of up to (i) 50,000 Class A ordinary shares, par value \$0.0001 per share (“Class A ordinary shares”) of ProKidney Corp. (formerly known as Social Capital Suvretta Holdings Corp. III, the “Company”), collectively held by certain holders of the Company’s securities (the “Holders”) party to that certain Amended and Restated Registration Rights Agreement, dated as of July 11, 2022, by and among the Company, SCS Sponsor III LLC, and the Holders (the “Amended and Restated Registration Rights Agreement”), their permitted transferees and certain Additional Holders (as defined in the Amended and Restated Registration Rights Agreement); (ii) 180,000,000 Class A ordinary shares issued or issuable pursuant to that certain Exchange Agreement, dated as of July 11, 2022, by and among the Company, ProKidney LP, and certain holders of the Company’s securities party thereto (the “Exchange Agreement”); and (iii) 52,480,000 Class A ordinary shares, purchased by certain investors at a purchase price of \$10.00 per share, pursuant to subscription agreements with the Company.

This prospectus provides you with a general description of such securities and the general manner in which the Selling Securityholders may offer or sell the securities. The prospectus supplement may also add, update or change information contained in this prospectus.

We will not receive any proceeds from the sale of Class A ordinary shares by the Selling Securityholders. However, we will pay the expenses, other than any underwriting discounts and commissions, associated with the sale of securities pursuant to this prospectus.

We are registering the securities for resale pursuant to the Selling Securityholders’ registration rights under certain agreements between us and the Selling Securityholders. Our registration of the securities covered by this prospectus does not mean that either we or the Selling Securityholders will issue, offer or sell, as applicable, any of the securities. The Selling Securityholders may offer and sell the securities covered by this prospectus in a number of different ways and at varying prices. We provide more information about how the Selling Securityholders may sell the shares in the section entitled “*Plan of Distribution*.”

You should read this prospectus and any prospectus supplement or amendment carefully before you invest in our securities.

Our Class A ordinary shares are listed on the Nasdaq Capital Market under the symbol “PROK.” On August 5, 2022, the closing price of our Class A ordinary shares was \$7.40.

Investing in our securities involves a high degree of risk. See “[Risk Factors](#)” beginning on page 6 of this prospectus and in the other documents that are incorporated by reference in this prospectus.

None of the Securities and Exchange Commission, any state securities commission or any other regulatory body has approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2022.

TABLE OF CONTENTS

CERTAIN DEFINED TERMS	ii
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS	vi
SUMMARY OF THE PROSPECTUS	1
THE OFFERING	5
RISK FACTORS	6
USE OF PROCEEDS	80
MARKET PRICE, TICKER SYMBOL AND DIVIDEND INFORMATION	81
UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION	82
NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION	88
BUSINESS OF PROKIDNEY	96
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	141
DESCRIPTION OF PROKIDNEY SECURITIES	152
SECURITIES ACT RESTRICTIONS ON RESALE OF SECURITIES	164
BENEFICIAL OWNERSHIP OF SECURITIES	165
SELLING SECURITYHOLDERS	168
MANAGEMENT	173
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS	192
CERTAIN MATERIAL U.S. AND NON-U.S. FEDERAL INCOME TAX CONSIDERATIONS	199
PLAN OF DISTRIBUTION	205
LEGAL MATTERS	207
EXPERTS	208
WHERE YOU CAN FIND MORE INFORMATION	209
INDEX TO FINANCIAL STATEMENTS	FS-1

You should rely only on the information contained in this prospectus. No one has been authorized to provide you with information that is different from that contained in this prospectus. This prospectus is dated as of the date set forth on the cover hereof. You should not assume that the information contained in this prospectus is accurate as of any date other than that date.

For investors outside the United States: We have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

CERTAIN DEFINED TERMS

In this document:

“*Amended and Restated Registration Rights Agreement*” means the Amended and Restated Registration Rights Agreement, dated as of July 11, 2022, by and among ProKidney, the Sponsor, certain ProKidney Unitholders and the other parties thereto;

“*BLA*” means Biologics License Application;

“*Board*” means the board of directors of ProKidney;

“*Business Combination*” refers to the transactions contemplated by the Business Combination Agreement;

“*Business Combination Agreement*” means the business combination agreement, dated as of January 18, 2022 by and between SCS and ProKidney LP;

“*Cayman Islands Companies Act*” means the Companies Act (as amended) of the Cayman Islands;;

“*CBER*” means Center for Biologics Evaluation and Research;

“*cGMP*” means current good manufacturing practices;

“*Charter*” means the second amended and restated memorandum and articles of association of the Company adopted by special resolution on 11 July 2022;

“*CKD*” means chronic kidney disease;

“*Closing*” means the closing of the Business Combination;

“*Closing ProKidney Unitholders*” means (i) the ProKidney Unitholders (other than PMEL) and (ii) the PMEL Post-Combination Unitholders;

“*CMS*” means the Centers for Medicare & Medicaid Services;

“*eGFR*” means the estimated glomerular filtration rate;

“*EMA*” means the European Medicines Agency;

“*Exchange Act*” means the Securities Exchange Act of 1934, as amended;

“*Exchange Agreement*” means the exchange agreement, dated as of July 11, 2022, by and among SCS, ProKidney LP and the Closing ProKidney Unitholders;

“*FCA*” means the federal False Claims Act;

“*FCPA*” means the U.S. Foreign Corrupt Practices Act;

“*FDA*” means the U.S. Food and Drug Administration;

“*FTC*” means the Federal Trade Commission;

“*GAAP*” means accounting principles generally accepted in the United States of America;

“*GCPs*” means Good Clinical Practices;

Table of Contents

“GP” means ProKidney Corp. GP Limited, which replaced Legacy GP as the general partner of ProKidney LP upon the Closing;

“GP Board” means the board of directors of GP;

“HIPAA” means the Health Insurance Portability and Accountability Act of 1996;

“HITECH” means the Health Information Technology for Economic and Clinical Health Act;

“Legacy ProKidney Class A Units” means the units of ProKidney LP designated as “Class A Units” pursuant to the ProKidney Limited Partnership Agreement;

“Legacy ProKidney Class B Units” means the units of ProKidney LP designated as “Class B Units” pursuant to the ProKidney Limited Partnership Agreement;

“Legacy GP” means ProKidney GP Limited, a private limited company incorporated under the laws of Ireland, which acted as the general partner of ProKidney LP prior to the Closing;

“Legacy GP Board” means the board of directors of Legacy GP;

“Paired Interest” means one Post-Combination ProKidney Common Unit and one ProKidney Class B ordinary share, which are together exchangeable for one ProKidney Class A ordinary share or the cash equivalent thereunder under certain circumstances and subject to certain conditions pursuant to the Exchange Agreement;

“PIPE Investment” means the purchase of SCS Class A ordinary shares and/or Post-Combination ProKidney Common Units pursuant to the Subscription Agreements;

“PIPE Investment Amount” means the aggregate gross purchase price received by SCS and ProKidney LP in the PIPE Investment;

“PIPE Investors” means those certain investors that participated in the PIPE Investment pursuant to the Subscription Agreements;

“PIPE Shares” means SCS Class A ordinary shares purchased in the PIPE Investment, or in the case of the ProKidney Related PIPE Investors, the Post-Combination ProKidney Common Units (together with a corresponding number of SCS Class B ordinary shares, if applicable) purchased in lieu of SCS Class A ordinary shares in the PIPE Investment;

“PMEL” means ProKidney Management Equity LLC, a Bermuda limited liability company;

“PMEL Existing Holders” means certain persons who, as members of PMEL, held an indirect interest in the Legacy Class B Units held by PMEL prior to the Closing;

“PMEL Post-Combination Unitholders” means the PMEL Existing Holders, as well as their designees, or one or more holding persons or nominated persons who received Post-Combination ProKidney Common Units or PMEL RCUs on behalf of the PMEL Existing Holders in connection with the Business Combination;

“PMEL RCUs” means the Restricted Common Units of ProKidney designated as “PMEL RCUs” pursuant to the Second Amended and Restated ProKidney Limited Partnership Agreement;

“Post-Combination ProKidney Common Units” means the units of ProKidney designated as “Common Units” pursuant to the Second Amended and Restated ProKidney Limited Partnership Agreement;

Table of Contents

“*ProKidney*” means (unless otherwise indicated) SCS after the Business Combination, including its name change from Social Capital Suvretta Holdings Corp. III to “ProKidney Corp.,” as applicable;

“*ProKidney Bermuda*” means ProKidney LLC, a limited liability company incorporated under the laws of Bermuda in December 2018, which is currently a wholly owned subsidiary of ProKidney;

“*ProKidney Class A ordinary shares*” means ProKidney’s Class A ordinary shares, par value \$0.0001 per share;

“*ProKidney Class B ordinary shares*” means ProKidney’s Class B ordinary shares, par value \$0.0001 per share;

“*ProKidney Class B PMEL RSRs*” or “*PMEL RSRs*” means the Restricted Stock Rights of ProKidney designated as “Class B PMEL RSRs” that were issued pursuant to the Business Combination Agreement;

“*ProKidney Employee Stock Purchase Plan*” means the ProKidney Corp. Employee Stock Purchase Plan;

“*ProKidney Incentive Equity Plan*” means the ProKidney Corp. 2022 Incentive Equity Plan;

“*ProKidney-KY*” means ProKidney (formerly known as RegenMed (Cayman) Ltd. (d/b/a inRegen)), a clinical-stage cellular therapeutics company incorporated under the Cayman Islands Companies Act focused on the treatment of chronic renal disease and acquired by ProKidney in January 2019;

“*ProKidney Limited Partnership Agreement*” means the First Amended and Restated Limited Partnership Agreement for a Limited Partnership Called ProKidney LP, dated as of January 17, 2022, by and among Tolerantia, LLC, Control Empresarial de Capitales, S.A. de C.V. (formerly Inversora Carso, S.A. de C.V.), PMEL and Legacy GP;

“*ProKidney LP*” means ProKidney LP, a limited partnership organized under the laws of Ireland;

“*ProKidney ordinary shares*” means the ProKidney Class A ordinary shares and the ProKidney Class B ordinary shares;

“*ProKidney Promissory Notes*” means the two promissory notes entered into by ProKidney LP on January 18, 2022, concurrently with the execution of the Business Combination Agreement, with certain ProKidney Unitholders pursuant to which such ProKidney Unitholders agreed to fund up to \$100,000,000 in the aggregate to support the operational and financing needs of ProKidney LP prior to the Closing;

“*ProKidney Related PIPE Investors*” means certain existing directors, officers and unitholders of ProKidney LP and/or its affiliates that participated in the PIPE Investment;

“*ProKidney Unitholders*” means any person who held units of ProKidney LP immediately prior to the consummation of the Business Combination;

“*ProKidney-US*” means ProKidney, LLC (formerly known as Twin City Bio LLC), a Delaware limited liability company that provides contract development and manufacturing service for pharmaceutical and biotech companies focused on cell-based therapies and that was acquired by ProKidney LP in January 2019;

“*REACT*” means Renal Autologous Cell Therapy, the lead product candidate of ProKidney;

“*Restricted Common Units*” means the units of ProKidney LP designated as “Restricted Common Units” pursuant to the Second Amended and Restated ProKidney Limited Partnership Agreement;

Table of Contents

“*Restricted Stock Rights*” means restricted stock rights in respect of ProKidney Class B ordinary shares;

“*RMAT*” means regenerative medicine advanced therapy;

“*Sarbanes-Oxley Act*” means the Sarbanes-Oxley Act of 2002, as amended;

“*SCS*” means Social Capital Suvretta Holdings Corp. III, a Cayman Islands exempted company limited by shares (which, after the Closing, is known as ProKidney Corp.);

“*SCS Class A ordinary shares*” means Class A ordinary shares in the share capital of SCS, par value \$0.0001 per share;

“*SCS Class B ordinary shares*” means Class B ordinary shares in the share capital of SCS, par value \$0.0001 per share;

“*SEC*” means the U.S. Securities and Exchange Commission;

“*Second Amended and Restated ProKidney Limited Partnership Agreement*” means the second amended and restated limited partnership agreement of ProKidney LP, which went into effect upon the completion of the Business Combination;

“*Securities Act*” means the Securities Act of 1933, as amended;

“*Sponsor*” means SCS Sponsor III LLC, a Cayman Islands limited liability company;

“*Sponsor Related PIPE Investor*” refers to certain existing directors, officers and equityholders of, or investment funds managed by Suvretta Capital Management, LLC, SCS, the Sponsor and/or their respective affiliates that participated in the PIPE Investment (together with their permitted transferees);

“*SRC*” means selected renal cell;

“*Subscription Agreements*” means the subscription agreements entered into by and between SCS and certain investors;

“*Tax Receivable Agreement*” means the Tax Receivable Agreement, dated as of July 11, 2022, by and among SCS, the TRA party representative (as defined in the Tax Receivable Agreement) and the Closing ProKidney Unitholders;

“*Third Party PIPE Investment*” means any PIPE Investment made by a Third Party PIPE Investor;

“*Third Party PIPE Investment Amount*” means the aggregate gross purchase price received by SCS in the Third Party PIPE Investment;

“*Third Party PIPE Investor*” means any PIPE Investor who is not (i) a Sponsor Related PIPE Investor or (ii) a ProKidney Related PIPE Investor; and

“*Voting Agreement*” means the Deed of Undertaking, dated February 14, 2022, made by Control Empresarial de Capitales, S.A. de C.V. (formerly Inversora Carso, S.A. de C.V.), a Mexican corporation.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements regarding, among other things, our plans, strategies and prospects, both business and financial. These statements are based on the beliefs and assumptions of management. Although we believe that our plans, intentions and expectations reflected in or suggested by these forward-looking statements are reasonable, we cannot assure you that we will achieve or realize these plans, intentions or expectations. Forward-looking statements are inherently subject to risks, uncertainties and assumptions. Generally, statements that are not historical facts, including statements concerning possible or assumed future actions, business strategies, events or results of operations, are forward-looking statements. These statements may be preceded by, followed by or include the words “believes,” “estimates,” “expects,” “projects,” “forecasts,” “may,” “will,” “should,” “seeks,” “plans,” “scheduled,” “anticipates” or “intends” or similar expressions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the anticipated benefits of the Business Combination;
- our ability to maintain the listing of our Class A ordinary shares on the Nasdaq Capital Market (“Nasdaq”);
- our ability to manage our growth effectively;
- the success, cost and timing of our product development activities;
- the potential attributes and benefits of our product candidates, and if approved, our products;
- our ability to manufacture REACT, our lead product candidate;
- our ability to obtain and maintain regulatory approval for our products, and any related restrictions and limitations of any approved product;
- our ability to identify, in-license or acquire additional technology;
- our ability to maintain our existing license, manufacturing and supply agreements;
- our reliance on third parties to conduct, supervise and monitor a certain portion of our research and nonclinical testing and clinical trials for REACT;
- our ability to compete with other companies currently marketing or engaged in the biologics market and in the area of treatment of kidney disease, many of which have greater financial and marketing resources than us;
- the size and growth potential of the markets for our products, and the ability of each to serve those markets, either alone or in partnership with others;
- changes in applicable laws or regulations;
- our estimates regarding expenses, revenue, capital requirements and needs for additional financing;
- our ability to raise financing in the future;
- our financial performance;
- our intellectual property rights;
- security breaches with respect to computer systems;
- economic downturns and political and market conditions beyond our control;
- the impact of the COVID-19 pandemic on our business; and
- other factors detailed under the section titled “*Risk Factors*.”

[Table of Contents](#)

These forward-looking statements are based on information available as of the date of this prospectus, and current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Important factors could cause actual results to differ materially from those indicated or implied by forward-looking statements such as those contained in documents we have filed with the SEC. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. For a discussion of the risks involved in our business and investing in our ordinary shares, see the section titled “*Risk Factors.*”

Should one or more of these risks or uncertainties materialize, or should any of the underlying assumptions prove incorrect, actual results may vary in material respects from those expressed or implied by these forward-looking statements. You should not place undue reliance on these forward-looking statements.

SUMMARY OF THE PROSPECTUS

This summary highlights selected information included in this prospectus and does not contain all of the information that may be important to you in making an investment decision. This summary is qualified in its entirety by the more detailed information included in this prospectus. Before making your investment decision with respect to our securities, you should carefully read this entire prospectus, including the information under “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements included elsewhere in this prospectus.

The Company

We are a clinical-stage biotechnology business with a transformative proprietary cell therapy platform that is capable of treating multiple chronic diseases of the kidney using a patient’s own cells. Our approach seeks to redefine the treatment of CKD by restoring kidney function and preventing or delaying the progression of CKD, rather than managing kidney failure. Our lead product candidate, REACT, is designed to stabilize or improve renal, or kidney, function in patients with chronically diseased kidneys. REACT is a product composed of a patient’s own SRCs, formulated into a product that is reinjected into the kidney by a minimally invasive outpatient procedure that can be repeated if necessary. Because REACT is a personalized treatment composed of a patient’s own, or autologous, SRCs, there is no need for treatment with immunosuppressive therapies, which are required during a patient’s lifetime when a patient receives a kidney transplant from another donor, or an allogeneic transplant. We are currently conducting a Phase 3 clinical trial and multiple Phase 2 clinical trials for REACT in patients with moderate to severe CKD caused by diabetes mellitus or congenital anomalies of the kidney and urinary tract.

Recent Developments

Business Combination Agreement

The Company was originally known as Social Capital Suvretta Holdings Corp. III. On July 11, 2022, we consummated the Business Combination pursuant to the terms of the Business Combination Agreement, dated as of January 18, 2022, by and between SCS and ProKidney LP, a limited partnership registered under the laws of Ireland, acting through its general partner ProKidney GP Limited, a private limited company incorporated under the laws of Ireland. In connection with the Business Combination, SCS changed its name to “ProKidney Corp.”

As a consequence of the Business Combination, each SCS Class B ordinary share that was issued and outstanding as of immediately prior to the effective time of the merger was converted, on a one-for-one basis, into ProKidney Class A ordinary shares.

In addition, concurrently with the execution of the Business Combination Agreement, on January 18, 2022, SCS entered into the Subscription Agreements, pursuant to which the PIPE Investors purchased, immediately prior to the Closing, an aggregate of 57,480,000 Class A ordinary shares at a purchase price of \$10.00 per share.

In connection with the Business Combination, each issued and outstanding Class B unit (each, a “ProKidney Class B Unit”) in ProKidney LP that had not vested pursuant to the terms of the applicable award agreement was recapitalized into one PMEL RCU, which would, when vested in accordance with the applicable award agreement, automatically convert into a Post-Combination ProKidney Common Unit (and the associated ProKidney Class B PMEL RSR would vest), and all other issued and outstanding Legacy Class A Units and Legacy Class B Units in ProKidney were recapitalized into an aggregate number of Post-Combination ProKidney Common Units equal to (x) 175,000,000 minus (y) the number of PMEL RCUs issued as described above.

At the Closing, (i) ProKidney LP issued to SCS a number of Post-Combination ProKidney Common Units equal to the number of fully diluted outstanding SCS ordinary shares as of immediately prior to the Closing (but

after giving effect to all redemptions of SCS Class A ordinary shares and the purchase of SCS Class A ordinary shares and/or Post-Combination ProKidney Common Units pursuant to the PIPE Investment), in exchange for (a) (x) ProKidney Class B ordinary shares, which shares have no economic rights but entitle the holders thereof to vote on all matters on which shareholders of ProKidney are entitled to vote generally, and (y) ProKidney Class B PMEL RSRs, which convert into ProKidney Class B ordinary shares upon the vesting of the associated PMEL RCUs, (b) an amount in cash equal to the aggregate proceeds obtained by SCS in the PIPE Investment and (c) an amount in cash equal to the aggregate proceeds available for release to SCS from SCS's trust account (the "Trust Account") (after giving effect to all redemptions of SCS Class A ordinary shares and after payment of any deferred underwriting commissions that were held in the Trust Account and payment of certain transaction expenses); (ii) ProKidney distributed to the Closing ProKidney Unitholders the ProKidney Class B ordinary shares and ProKidney Class B PMEL RSRs received pursuant to clause (i)(a) (x) and (y) above; and (iii) holders (the "Earnout Participants") of Legacy ProKidney Class A Units received an aggregate of 17,500,000 Restricted Common Units (the "Earnout RCUs") and 17,500,000 Restricted Stock Rights (the "Earnout RSRs") (collectively, the "Earnout Rights"), which Earnout Rights will vest in three equal tranches upon the achievement of certain ProKidney share price milestones or certain change of control events. When vested, the Earnout RCUs will automatically convert into Post-Combination ProKidney Common Units and the associated Earnout RSRs will automatically convert into ProKidney Class B ordinary shares, respectively.

Stock Exchange Listing

Our Class A ordinary shares are listed for trading on Nasdaq under the symbols "PROK."

Summary of Risk Factors

Investing in our securities involves risks. You should carefully consider the risks described in "Risk Factors" beginning on page 6 before making a decision to invest in our securities. If any of these risks actually occurs, our business, financial condition and results of operations would likely be materially adversely affected. Some of the risks related to our business and industry are summarized below.

- We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future;
- Having completed the Business Combination, we will continue to require substantial additional capital to finance our operations;
- We have a limited operating history and have not generated any revenue to date, and may never become profitable;
- Our business is highly dependent on the success of our lead product candidate, REACT, as well as any other future product candidates that we may advance into clinical development. REACT and our future product candidates will require significant additional clinical development and funding before we may be able to seek regulatory approval for and launch a product commercially;
- REACT is based on a novel technology, which makes it difficult to predict the time and cost of product development and of subsequently obtaining regulatory approval;
- Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome, and the results of nonclinical studies, previous clinical trials, or interim results of ongoing clinical trials of REACT and any of our future product candidates may not be predictive of future results. Further, we may encounter substantial delays in completing the development of REACT and any of our future product candidates;
- Negative public opinion and increased regulatory scrutiny of autologous cell therapy using REACT may adversely impact the development or commercial success of our current and future product candidates;

- We are conducting our first Phase 3 clinical trial and may be unable to successfully complete it or any future clinical trials;
- The design or execution of our ongoing and future clinical trials may not support marketing approval;
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success;
- Due to our limited resources and access to capital, we must make decisions on the allocation of resources to certain programs and product candidates;
- Cell therapies are complex and difficult to manufacture, and we could experience manufacturing problems that result in delays in the development or commercialization of REACT, our lead product candidate, or otherwise harm our business;
- Our autologous cell therapy products are patient-specific, and we need to ensure that the correct product is administered to the correct patient;
- Delays in obtaining regulatory approval of the manufacturing process and facility to produce REACT or disruptions in the manufacturing process may delay or disrupt our commercialization efforts;
- Managing an autologous ex vivo cell therapy supply chain is highly complex;
- Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could adversely affect our financial condition and results of operations;
- Because we are a “controlled company” within the meaning of the Nasdaq rules, our shareholders may not have certain corporate governance protections that are available to shareholders of companies that are not controlled companies;
- Required payments under the Tax Receivable Agreement may be substantial, and in certain cases, payments under the Tax Receivable Agreement may exceed the actual tax benefits that we realize or may be accelerated; and
- Because we are a Cayman Islands exempted company, the rights of our shareholders may be different from the rights of shareholders governed by the laws of U.S. jurisdictions.

Corporate Information

SCS was incorporated on February 25, 2021 as a Cayman Islands exempted company. It was formed for the purpose of entering into a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses. As an exempted company, we have received a tax exemption undertaking from the Government of the Cayman Islands to the effect that, in accordance with Section 6 of the Tax Concessions Act (as amended) of the Cayman Islands, for a period of 30 years from the date of the undertaking, no law which is enacted in the Cayman Islands imposing any tax or duty to be levied on profits, income, gains or appreciations, or any tax in the nature of estate duty or inheritance tax, will apply to any property comprised in or any income arising under the company, or to the security holders thereof, in respect of any such property or income.

On July 11, 2022, SCS and ProKidney LP completed the Business Combination, and SCS’s corporate name was changed to “ProKidney Corp.”

The combined structure was organized in an umbrella partnership-C corporation (a so called “Up-C” structure). ProKidney Corp. is a holding company, and our direct assets consist of Post-Combination ProKidney Common Units and all of the issued and outstanding equity interests of GP, which became the general partner of ProKidney LP upon the Closing. ProKidney Corp. controls GP, with the rights of management specified in the Second Amended and Restated ProKidney Limited Partnership Agreement.

Our principal executive offices are located at 2000 Frontis Plaza Blvd., Ste 250, Winston-Salem, North Carolina, and our telephone number is (336) 999-7028.

Controlled Company

Under the Nasdaq Listing Rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a “controlled company.” Pursuant to the terms of the Voting Agreement, Tolerantia, LLC (“Tolerantia”) effectively controls a majority of the voting power of all of our outstanding ordinary shares with respect to the election, appointment or removal of any director. As a result, we are a “controlled company” within the meaning of the Nasdaq Listing Rules. A controlled company may elect not to comply with certain corporate governance standards, including the requirements that (i) a majority of its board of directors consist of independent directors, (ii) subject to the exception pursuant to Nasdaq Listing Rule 5605(b)(2), its board of directors have a compensation committee that is composed of at least two members, each of whom is an independent director, with a written charter addressing the committee’s purpose and responsibilities and (iii) director nominees must be selected, or recommended for the board’s selection, either by independent directors constituting a majority of the board’s independent directors in a vote in which only independent directors participate, or by a nominating and corporate governance committee comprised solely of independent directors with a written charter addressing the committee’s purpose and responsibilities. Under the Business Combination Agreement, a majority of the directors on the Board were required to be “independent” directors for the purposes of the Nasdaq Listing Rules, but for at least some period following the Business Combination, we may utilize the other exemptions described above. If any of these exemptions are used, you may not have the same protections afforded to shareholders of companies that are subject to all of these corporate governance requirements. If we cease to be a “controlled company” and our shares continue to be listed on the Nasdaq, we will be required to comply with these standards and, depending on the Board’s independence determination with respect to our then-current directors, we may be required to add additional directors to the Board in order to achieve such compliance within the applicable transition period.

Emerging Growth Company

Section 102(b)(1) of the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”) exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a registration statement under the Securities Act declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with those of another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

We will remain an emerging growth company until the earlier of: (1) the last day of the fiscal year (a) following the fifth anniversary of the Closing of SCS’s initial public offering, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common equity that is held by non-affiliates exceeds \$700 million as of the end of the prior fiscal year’s second fiscal quarter; and (2) the date on which we have issued more than \$1.00 billion in non-convertible debt securities during the prior three-year period. References herein to “emerging growth company” have the meaning associated with it in the JOBS Act.

THE OFFERING

Issuer	ProKidney Corp.
Resale of Class A ordinary shares	
Class A ordinary shares offered by the Selling Securityholders (representing the PIPE Shares purchased by certain PIPE Investors, shares issued or issuable pursuant to the vesting of restricted stock units, and shares issued or issuable pursuant to the Exchange Agreement)	232,530,000 shares
Use of proceeds	We will not receive any proceeds from the sale of the Class A ordinary shares to be offered by the Selling Securityholders.
Lock-up agreements	Certain of our shareholders are subject to certain restrictions on transfer until the termination of applicable lock-up periods. See “ <i>Plan of Distribution — Lock-Up Agreements</i> ” for further discussion.
Ticker Symbol	“PROK” for the Class A ordinary shares.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks described below before making an investment decision. Our business, prospects, financial condition, or operating results could be harmed by any of these risks, as well as other risks not known to us or that we consider immaterial as of the date of this prospectus. The trading price of our securities could decline due to any of these risks, and, as a result, you may lose all or part of your investment.

Unless the context otherwise requires, references in this section to “we,” “us,” “our” and the “Company” refer to ProKidney Corp. and its subsidiaries following the Business Combination and to ProKidney LP and its subsidiaries prior to the Business Combination, as the case may be.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses since our inception. We continue to incur significant research and development and other expenses related to our ongoing operations. For the three months ended March 31, 2022 and 2021 and for the years ended December 31, 2021 and 2020, we reported a net loss of \$67.5 million, \$11.6 million, \$55.1 million and \$26.7 million, respectively. As of March 31, 2022 and December 31, 2021, we had an accumulated deficit of \$229.0 million and \$161.5 million, respectively. We have devoted substantially all of our resources and efforts to research and development, and we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we receive marketing approval for and commercialize our lead product candidate, Renal Autologous Cell Therapy (“REACT”), we expect that we will continue to incur substantial research and development and other expenses to develop and market additional potential product candidates. These conditions raise substantial doubt about our ability to continue as a going concern for a period of at least one year from the date our financial statements are issued, and our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included elsewhere in this prospectus.

Our product candidate, REACT, is still in clinical testing. We expect to continue to incur significant losses for the foreseeable future, and we anticipate that our expenses will increase substantially if, and as, we:

- advance the development of REACT and any other future product candidates through clinical development, and, if successful, later-stage clinical trials;
- experience delays or interruptions to any future preclinical studies, our current clinical trials, our receipt of services from our third-party service providers on whom we rely, or our supply chain, including delays due to the COVID-19 pandemic, other health crises or events or circumstances beyond our control;
- seek regulatory approvals for any future product candidates that may successfully complete clinical trials;
- commercialize REACT and any future product candidates, if approved;
- increase the amount of research and development activities to discover and develop product candidates and line extensions;
- manufacture the materials needed for clinical trials or, following receipt of necessary regulatory approvals, commercial sales, at our manufacturing facilities;
- establish and validate commercial-scale cGMP manufacturing facilities and partner with Contract Manufacturing Organizations (“CMOs”);

[Table of Contents](#)

- establish a commercialization infrastructure and scale up internal and external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- hire additional executives in clinical development, regulatory, manufacturing, quality control, quality assurance, scientific, public / investor relations general and administrative and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development and manufacturing efforts, general and administrative functions and our operations as a public company;
- establish domestic and global sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;
- maintain, expand and protect our intellectual property portfolio; and
- invest in or in-license other technologies or product candidates.

To become and remain profitable, we must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing non-clinical studies and clinical trials, obtaining marketing approval for REACT and any future product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Having completed the Business Combination, we will continue to require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and product development programs, future commercialization efforts or other operations.

Developing biopharmaceutical products, including conducting clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials of REACT and any future product candidates that we may develop, seek regulatory approvals for REACT and our future product candidates, and manufacture, launch and commercialize any products for which we receive regulatory approval. We also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and product development programs or future commercialization efforts.

As of March 31, 2022, we had approximately \$29.8 million in cash, cash equivalents and short-term investments. Based on our current operating plan, and having completed the Business Combination and accounting for \$574.8 million received in the PIPE Investment, we believe that our cash, cash equivalents and short-term investments will be sufficient to fund our operating expenses and capital expenditure requirements through 2024. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital to complete clinical development of any of our current programs.

[Table of Contents](#)

Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of REACT and any future product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of clinical trials for REACT and any future product candidates;
- the clinical development plans we establish for these product candidates;
- the timelines of our clinical trials and the overall costs to finish the clinical trials due to the COVID-19 pandemic;
- the number and characteristics of product candidates that we develop;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable foreign regulatory authorities;
- whether we are able to enter into and maintain collaboration agreements, including the terms of and timing of payments under any such agreements;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us, REACT or any of our future product candidates;
- the effect of competing clinical, technological and market developments;
- the costs of maintaining our own commercial-scale cGMP manufacturing facility;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the revenue, if any, received from commercial sales of REACT and any of our future product candidates for which we receive marketing approval; and
- the costs of operating as a public company.

Following the Business Combination, we currently do not have any committed external source of funds or other support for our development efforts, and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. Further, to the extent that we raise additional capital through the sale of ordinary shares or securities convertible or exchangeable into ordinary shares, your ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to REACT and any future product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also may be required to seek collaborators for REACT or any of our future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to REACT and any future product candidates or technologies that we otherwise would seek to develop or

[Table of Contents](#)

commercialize ourselves. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of REACT or any of our future product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our ordinary shares to decline.

Risks Related to Research and Development of REACT and Our Future Product Candidates

We have a limited operating history and have not generated any revenue to date, and may never become profitable.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were founded in 2018, have no products approved for commercial sale and have not generated any revenue. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, undertaking non-clinical studies, conducting clinical trials, developing a network of key opinion leaders, and performing research and development of REACT. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. REACT and any other product candidates we develop will require substantial additional development and clinical research time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have not yet demonstrated the ability to progress any product candidate through later-stage clinical trials leading to successful marketing authorization. We may be unable to obtain regulatory approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, achieve market access, and acceptance with insurers and health care providers, or conduct sales and marketing activities necessary for successful product commercialization.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. If and when one of our product candidates were to receive regulatory approval, we would need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving and complex fields. Consequently, we have no meaningful history of operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing medical products.

Due to the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable could decrease the value of our shares and impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

The market for biologics and for the treatment of kidney disease is highly competitive. If we fail to effectively compete, our business, financial condition and operating results will suffer.

We face significant competition in the biologics market and in the area of treatment of kidney disease. We face competition from companies that develop and manufacture cell therapies, including major and specialty

[Table of Contents](#)

pharmaceutical and biotechnology companies, developers of tubular and glomerular cell drug modulators, antifibrosis medications, induced pluripotent cells, other autologous mesenchymal stem cells and mechanical renal assist devices such as implantable and wearable renal dialysis machines, and advances in peritoneal dialysis and home dialysis. Cell-based clinical trials by other companies are underway globally with umbilical, adipose and bone marrow derived mesenchymal stem cells for CKD. Early-phase human induced pluripotent stem cell therapies for kidney diseases are ongoing in Japan. We believe that our principal competitors include developers of SGLT2 inhibitors and Mineral Receptor Agonists (“MRAs”), which are small-molecule therapies recently approved to lower risks of CKD progression.

Many of our current competitors may have competitive advantages over us, including significantly greater financial resources and expertise in research and development, pre-clinical testing, clinical trials, manufacturing, and marketing than we do.

We believe that the principal competitive factors in its target markets include:

- accuracy, including sensitivity and specificity, and reproducibility of results;
- reputation among customers;
- innovation in offerings or products, if approved;
- efficacy and safety profile;
- cost;
- effectiveness of promotional support;
- intellectual property protection;
- the intended patient population; and
- relative convenience of dosing and administration.

We cannot assure you that our products, if approved, will compete favorably or that we will be successful in the face of increasing competition from new products and technologies introduced by existing competitors or new companies entering our target markets. In addition, we cannot assure you that our competitors do not have or will not develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

Our business is highly dependent on the success of our lead product candidate, REACT, as well as any other future product candidates that we may advance into clinical development. REACT and our future product candidates will require significant additional clinical development and funding before we may be able to seek regulatory approval for and launch a product commercially.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. REACT, our lead product candidate, is in Phase 3 clinical development. We cannot offer any assurances or predict with any certainty that such Phase 3 clinical development will be successfully completed, that positive clinical data will be obtained from such Phase 3 clinical development efforts or that regulatory authorities will grant marketing approval for REACT, in any such case on the expected timelines. Furthermore, regulatory approvals for REACT, even if obtained, may limit the type of patients in which REACT may be used for CKD or otherwise require specific warning or labeling language, each of which may reduce the commercial potential of REACT. Even if approved, we might not be successful in commercializing REACT. Should we fail to obtain regulatory approvals for REACT or fail to successfully commercialize REACT upon such regulatory approvals, our business and financial condition could be materially harmed and we may be more heavily dependent on the success of our other therapeutic programs.

[Table of Contents](#)

As an organization, we have not previously conducted any later stage or pivotal clinical trials, have limited experience in preparing, submitting and pursuing regulatory filings and have not previously submitted a BLA for any product candidate. Before we can generate any revenue from sales of our lead product candidate, REACT, or any of our future product candidates, we must complete clinical development, regulatory review and approval in one or more jurisdictions. We also need to obtain substantial additional funding to support our continuing operations and pursue our growth strategy. In addition, if REACT or any of our future product candidates is approved, we must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and we may not have the financial resources to continue development of REACT or any of our future product candidates.

We may experience setbacks that could delay or prevent regulatory approval of, or our ability to commercialize, REACT and any of our future product candidates, including:

- negative or inconclusive results from our clinical trials or positive results from the clinical trials of others for product candidates similar to ours leading to their approval, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or to abandon a program;
- product-related side effects experienced by patients or subjects in our clinical trials or by individuals using medicines or therapeutics that we, the FDA, other regulators or others view as relevant to the development of REACT or any of our future product candidates;
- delays in submitting Investigational New Drug Applications (“INDS”) or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials, including our clinical endpoints, and any requirement for additional confirmatory trials;
- delays in enrolling subjects in clinical trials, including due to the COVID-19 pandemic, and completion of clinical trials, including under the FDA’s GCPs, the guidelines from International Conference on Harmonization (“ICH Guidelines”), Good Laboratory Practices (“GLP”), and current Good Tissue Practices (“cGTPs”);
- inability to maintain compliance with regulatory requirements, including cGMPs, and complying effectively with other procedures;
- high drop-out rates of subjects from clinical trials;
- inadequate supply or quality of REACT or our future product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- poor efficacy of REACT or our future product candidates during clinical trials;
- trial results taking longer than anticipated;
- trials being subjected to fraud or data capture failure or other technical mishaps leading to the invalidation of our trials;
- the results of our trials not supporting application for conditional approval in the European Union, the Asia-Pacific region, and Latin America;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;

Table of Contents

- delays related to the impact of the spread of the COVID-19 pandemic, including the impact of COVID-19 on the FDA's ability to continue its normal operations;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical development generally or with respect to our technology in particular;
- varying interpretations of data by the FDA and similar foreign regulatory agencies;
- the completion of Health Technology Assessment ("HTA") procedures with governmental authorities;
- any policy level review of REACT by CMS;
- the financing on our other ongoing or future programs;
- evolving scientific discovery and technology of cell-based therapies and bioprocessing; or
- obsolescence of manufacturing automation which could require a re-design of parts or equipment to ensure quality replacement component, the delays of which could cause significant delays in manufacturing and loss of sales.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator.

Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.

Our business and operations may be adversely affected by the effects of the evolving COVID-19 virus, which was declared a global pandemic by the World Health Organization ("WHO"). The COVID-19 pandemic has resulted in travel and other restrictions to reduce the spread of the disease, including public health directives and orders in the United States and the European Union ("EU") that, among other things and for various periods of time, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings and events and ordered cessation of non-essential travel. Future remote work policies and similar government orders or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity and may disrupt our ongoing research and development activities and our clinical trials and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Further, such orders also may impact the availability or cost of materials, which would disrupt our supply chain and manufacturing efforts and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities.

Although we have been able to effectively manage our supply chain and manufacturing capabilities despite the COVID-19 pandemic to date, we may experience related disruptions in the future that could severely impact our clinical trials, including:

- delays or difficulties with patient enrollment in clinical trials;
- delays, difficulties or a suspension in clinical trial site initiation, including difficulties in recruiting investigators, proceduralists and clinical staff;
- interruptions in our ability to manufacture and deliver the required supply of REACT or future product candidates for clinical trials;
- diversion of health care resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- potential cancellation or postponement of elective procedures scheduled at our clinical trial sites and reduction in operating hours at a significant number of our clinical trial sites;

Table of Contents

- changes in local regulations as part of a response to the COVID-19 outbreak that among other things (i) may interrupt our ability to manufacture REACT and (ii) may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruption of key clinical trial activities, such as clinical trial site monitoring, and the ability or willingness of subjects to travel to trial sites for scheduled visits and laboratory testing due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- refusal of the FDA and other regulatory agencies to accept data from clinical trials in these affected geographies; and
- decreases or shifts of government funding from regulatory agencies, university research and education.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our securities.

The global COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this prospectus, such as the ultimate geographic spread of the disease, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, health care systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this “*Risk Factors*” section.

REACT is based on a novel technology, which makes it difficult to predict the time and cost of product development and of subsequently obtaining regulatory approval.

The clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates.

Regulatory requirements in the United States and in other countries governing cell therapy products are evolving and the FDA or other regulatory bodies may change the requirements, or identify different regulatory

pathways, for approval for REACT or any of our future product candidates. For example, the FDA has established the Office of Tissues and Advanced Therapies within CBER to consolidate the review of cell therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its review when called upon. It is possible that over time new or different divisions may be established or be granted the responsibility for regulating cell therapy products, including regenerative cell-based products, such as ours. Further, additional regulatory involvement from FDA advisory bodies, including the Cardio-Renal Advisory Committee, may delay review or make additional recommendations requiring further investigation. As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the non-clinical and clinical development and manufacture of, and obtain regulatory approval for, REACT or any future product candidates. Changes in regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of REACT or any future product candidates or lead to significant post-approval limitations or restrictions.

We have concentrated our research and development efforts on utilizing regenerative renal cell-based therapies. To date, the FDA has approved a relatively small number of cell-based therapies for commercialization and no regenerative renal-based cell therapy has been approved for commercial use by any regulatory authority. The processes and requirements imposed by the FDA or other applicable regulatory authorities may cause delays and additional costs in obtaining approvals for marketing authorization for REACT or any future product candidates. Because our platform is novel, and cell-based therapies are relatively new, regulatory agencies may lack experience in evaluating product candidates like REACT. This novelty may lengthen the regulatory review process, including the time it takes for the FDA to review our IND applications if and when submitted, increase our development costs and delay or prevent commercialization of REACT. Additionally, advancing novel CKD therapies creates significant challenges for us, including:

- educating medical personnel regarding the potential side-effect profile of REACT and, as the clinical development program progresses, on observed side effects with REACT;
- training medical personnel on the proper use and delivery of REACT;
- enrolling sufficient numbers of subjects in clinical trials; and
- continuing to develop a manufacturing process to support the clinical development of REACT.

We must be able to overcome these challenges in order for us to develop, commercialize and manufacture REACT.

As we advance REACT, we will be required to consult with the FDA and other regulatory authorities, and REACT will likely be reviewed by an FDA advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of REACT. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenues to maintain our business.

In addition, adverse developments in preclinical studies or clinical trials conducted by others in the field of cell therapy products may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for approval of any product candidates we may develop, and may otherwise negatively affect our ability to develop and commercialize REACT or future product candidates. Similarly, the European Commission may issue new guidelines concerning the development and marketing authorization for cell therapies and require that we comply with these new guidelines, which could require additional studies or clinical trials to support the marketing approval of REACT or any product candidates we may develop in the future or which could make our product candidates unable to successfully obtain approval.

[Table of Contents](#)

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop.

Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome, and the results of nonclinical studies, previous clinical trials, or interim results of ongoing clinical trials of REACT and any of our future product candidates may not be predictive of future results. Further, we may encounter substantial delays in completing the development of REACT and any of our future product candidates.

Our product candidate, REACT, is in clinical development, and its risk of failure is high. The clinical trials, manufacturing and marketing of REACT or any of our future product candidates, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market REACT and any of our future product candidates. Before obtaining regulatory approvals for the commercial sale of REACT or any of our future product candidates, we must demonstrate through lengthy, complex and expensive testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because REACT is subject to regulation as a biological product, we will need to demonstrate that it is safe, pure and potent for use in its target indication and lacks latent untoward cell effects. REACT and any other product candidate we may develop must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The process of administration of REACT involves taking a small biopsy of tissue from the kidney. The risks associated with a biopsy include bleeding, pain and hematoma, or bruising.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new therapeutic modality can include dispositive data from two well-controlled, Phase 3 clinical trials of the relevant product in the relevant patient population. Our Phase 3 development program may involve one to two thousand patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier nonclinical studies or clinical trials. The outcome of nonclinical studies and early clinical trials of REACT and our future product candidates may not be predictive of the success of the Phase 3 registrational development program, and interim results of a clinical trial do not necessarily predict final results. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as therapeutic products and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of REACT or any of our future product candidates. Product candidates and delivery methods for cellular therapeutics and tissue engineered products that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- nonclinical or preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities associated with the product or delivery method;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful and relevant;
- failure to receive the necessary regulatory approvals;

[Table of Contents](#)

- manufacturing costs, formulation issues, pricing or reimbursement issues, mechanism of action, logistical constraints or other factors that make a product candidate uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized.

In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, our earlier stage trials are open-label studies, where both the subject and investigator know whether the subject is receiving REACT or standard of care therapy. Most typically, open-label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations and biases that may exaggerate any therapeutic effect as subjects in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which subjects have received treatment and may interpret the information of the treated group more favorably given this knowledge. Given that our earlier stage trials include an open-label dosing design, while we believe our trials utilize objective assessment measures for measuring our endpoints and therefore are unlikely to be influenced in any manner by subject or investigator bias, it is unknown whether the open-label design may not be predictive of future clinical trial results with this or other product candidates for which we conduct an open-label clinical trial when studied in a controlled environment or with only objective endpoints.

Furthermore, the standards that the FDA and comparable foreign regulatory authorities use when regulating REACT require judgment and may change over time, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from nonclinical and clinical activities is subject to validation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. Specifically, some countries, such as China, have enacted or are considering enacting restrictions on the import and export of human genetic materials, cells and tissues. Such laws and regulations could impair our ability to import and export human cells and cell-based therapies, which could have a material adverse impact on our business. We cannot predict whether legislative changes will be enacted, whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop.

To date, we have not completed any pivotal trials required for the approval of REACT. We may experience delays in conducting any clinical trials, need to be redesigned, recruit and enroll subjects on time or be completed on schedule, or at all. Clinical trials can be delayed suspended or terminated for a variety of reasons, including in connection with:

- delays in sufficiently developing, characterizing, standardizing or controlling a manufacturing process and quality criteria suitable for advanced clinical trials;
- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- delays in reaching agreement with the FDA, EMA or other regulatory authorities as to the design or implementation of our clinical trials;
- obtaining additional regulatory authorizations to conduct future clinical trials;

Table of Contents

- reaching agreements on acceptable terms with additional/future clinical trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- obtaining institutional review board (“IRB”) or Ethics Committee approval at each additional/future trial site;
- recruiting suitable patients to participate in a clinical trial;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold;
- clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;
- failure to perform in accordance with the applicable regulatory requirements, including FDA’s GCP requirements, or applicable regulatory requirements in other countries;
- addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate or the delivery procedure that are viewed to outweigh its potential benefits;
- adding a sufficient number of clinical trial sites;
- manufacturing sufficient quantities of a product candidate for use in clinical trials;
- disruptions in our supply chain, which could result in improper storage, transport or development conditions for our product components, whose treatment is time-sensitive and temperature-sensitive and which are patient-specific; or
- interruption of our manufacturing processes, which could lead to our inability to properly administer treatment.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize REACT or any of our future product candidates or significantly increase the cost of such trials, including:

- changes in regulatory requirements or guidance, or receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of REACT or our future product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of subjects required for clinical trials of REACT or our future product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of REACT or our future product candidates for various reasons, including non-compliance with regulatory requirements, a finding that REACT or our future product candidates have undesirable side effects or other unexpected characteristics, or a finding that the subjects are being exposed to unacceptable health risks;
- the cost of clinical trials of REACT or our future product candidates may be greater than we anticipate and we may not have funds to cover the costs;
- the supply or quality of REACT or our future product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

Table of Contents

- regulators may revise the requirements for approving REACT or our future product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of REACT or any of our future product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of REACT or our future product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for REACT or any of our future product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings or Risk Evaluation and Mitigation Strategy (“REMS”);
- be subject to additional post-marketing testing requirements;
- be subject to changes in the way the product is administered; or
- have regulatory authorities withdraw or suspend their approval of the product or to impose restrictions on its distribution after obtaining marketing approval.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board (“DSMB”) for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using REACT or one of our future product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

REACT, our lead product candidate, will require extensive clinical testing before we are prepared to submit a BLA or MAA for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for REACT and submit a BLA or MAA for regulatory approval of REACT or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, EMA or other regulatory authorities on our clinical development program, and the FDA, EMA or such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

We are currently conducting clinical trials in foreign countries, as well as in the United States. If we continue to seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval from foreign regulatory agencies may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

[Table of Contents](#)

Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business.

Any topline data or interim analyses from our nonclinical studies and clinical trials that may be announced or published from time to time may change as more data becomes available and will remain subject to audit and verification procedures that could result in material changes in the final data.

We have disclosed interim analyses of certain ongoing clinical trials and may continue to disclose publicly interim or topline data from its nonclinical studies and clinical trials in the future. These interim updates will be based on a preliminary analysis of then-available data, and the results and related findings and conclusions will be subject to change following a more comprehensive review of the data related to the particular study or trial. We will be required to make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim or topline results that we may report might differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim and topline data will remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. As a result, any interim or topline data should be viewed with caution until the final data are available. Interim data from clinical trials that we may complete will be subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and us in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, investors or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim or topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidate may be harmed, which could harm our business, operating results, prospects or financial condition.

The regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for REACT, our lead product candidate, or any of our future product candidates, our business may be materially and adversely affected.

The time required to obtain approval or other marketing authorizations by the FDA, EMA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, and the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for any product candidates we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any biologic product candidates in the United States until we receive regulatory approval of a BLA from the FDA, and we cannot market it in the European Union until we receive approval from the FDA or approval for a MAA from the EMA, or other required regulatory approval in other

[Table of Contents](#)

countries. To date, we have had only limited discussions with the regulatory agencies of the United States, the European Union, Argentina, Israel, Canada and Brazil regarding clinical development programs or regulatory approval for any product candidate within such jurisdictions.

Prior to obtaining approval to commercialize any biologic product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, EMA or other foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical or preclinical studies and clinical trials may be interpreted differently by different regulatory agencies. Even if we believe the nonclinical or clinical data for REACT are promising, such data may be insufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for REACT either prior to or after approval, or it may object to elements of our clinical development programs.

REACT could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities of third-party suppliers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of product candidates developed by biologics manufacturers, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market REACT or any of our future product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We have invested a significant portion of our time and financial resources in the development of REACT. Our business is dependent on our ability to successfully complete nonclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize REACT and any future product candidates in a timely manner.

Even if we eventually complete clinical testing and receive approval of a BLA or foreign marketing application for REACT or any future product candidates, the FDA, EMA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA, EMA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA, EMA or applicable foreign regulatory agency may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

[Table of Contents](#)

In addition, the FDA, EMA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future product candidates on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Our nonclinical studies and clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of REACT or our future product candidates, or serious adverse or unacceptable side effects may be identified during the development of REACT or any of our future product candidates, which could prevent, delay or limit the scope of regulatory approval of REACT or any of our future product candidates, limit their commercialization, increase our costs or necessitate the abandonment or limitation of the development of REACT or our future product candidates.

To obtain the requisite regulatory approvals for the commercial sale of REACT and any of our future product candidates, we must demonstrate through lengthy, complex and expensive nonclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication. Nonclinical testing and clinical trials are expensive and time consuming, and their outcomes are inherently uncertain. Failures can occur at any time during the development process. The outcome of nonclinical studies and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

We may fail to demonstrate with substantial evidence from adequate and well-controlled trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that REACT is safe and potent for its intended uses.

Possible adverse side effects that could occur with treatment with autologous cell therapy products include thrombocytopenia, chills, anemia, febrile neutropenia, diarrhea, neutropenia, vomiting, hypotension, dyspnea, cytokine release syndrome and neurotoxicity. Side effects may be unrecognized and mismanaged by medical personnel and considered unrelated due to unfamiliarity with REACT. REACT treatment necessitates a renal biopsy to obtain tissue to manufacture the bioactive component and injections to deposit the REACT into the kidney. Each intervention poses the risk of adverse events from renal bleeding that may require hospitalization, blood transfusion or surgical intervention.

A severe bleed was observed in one patient which led to the adoption of a noncutting needle design for the REACT procedure. Since then, no injection-related adverse events have been observed. If, however, any other adverse events, or other unexpected serious adverse events, occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events experienced by subjects enrolled in our current and planned clinical trials were not caused by our product candidate, the FDA, EMA or other foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidate for any or all targeted indications. Even if we are able to demonstrate that any serious adverse events experienced by subjects enrolled in our current and planned clinical trials are not product-related, such occurrences could affect patient recruitment or the ability of enrolled subjects to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

Furthermore, if REACT or any of our future product candidates is associated with undesirable effects in nonclinical studies or clinical trials or have characteristics that are unexpected, we may decide or be required to

[Table of Contents](#)

perform additional nonclinical studies or to halt or delay further clinical development of our product candidates or to limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, if approved. The FDA, EMA, Paul-Ehrlich-Institut, an Agency of the German Federal Ministry of Health, Medical Products Agency, the government agency in Sweden, Brazilian Health Regulatory Agency, an IRB, or an independent ethics committee (“IEC”) may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the product candidate.

Additionally, if REACT or any of our future product candidates receives marketing approval, and we or others identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or other requirements subject to a REMS;
- we may be required to change the way the product is administered or conduct additional nonclinical studies or clinical trials;
- we could be sued and held liable for harm caused to patients;
- we may decide to remove the product from the market;
- we may not be able to achieve or maintain third-party payor coverage and adequate reimbursement;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties; and
- our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or foreign regulatory agencies in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Negative public opinion and increased regulatory scrutiny of autologous cell therapy using REACT may adversely impact the development or commercial success of our current and future product candidates.

The clinical and commercial success of REACT will depend in part on public acceptance of the use of autologous cell therapy for treatment of kidney disease. Any adverse public attitudes about the use of REACT may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of REACT or any of our future product candidates or demand for any products once approved. Adverse events in our or others’

clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of REACT or our future product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates, all of which would have a negative impact on our business and operations.

We are conducting our first Phase 3 clinical trial and may be unable to successfully complete it or any future clinical trials.

The conduct of a Phase 3 clinical trial is a complicated process. Although members of our management team have conducted Phase 3 clinical trials in the past while employed at other companies, we as a company are currently conducting our first Phase 3 trial, and as a result may require more time and incur greater costs than we anticipate. Failure to include the correct treatment regimen, complete, or delays in, our Phase 3 clinical trial could prevent us from or delay us in commencing future clinical trials for REACT, obtaining regulatory approval of and commercializing REACT, which would adversely impact our financial performance. In addition, some of our competitors are currently conducting clinical trials for product candidates that treat the same indications as REACT, and patients who are otherwise eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors which may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of our product candidates, or approved products for the conditions for which we are developing our product candidates.

Clinical trials may be subject to delays as a result of patient enrollment taking longer than anticipated or greater than anticipated subject withdrawal. We may not be able to initiate or continue clinical trials for REACT or our future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size and demographics of the patient population required for analysis of the clinical trial's primary endpoints and the process for identifying patients;
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining subjects, diversion of health care resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- the proximity of subjects to clinical trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies and other competing product candidates' clinical trials;

[Table of Contents](#)

- our ability to obtain and maintain clinical trial subject informed consents; and
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion.

For example, we are initially developing REACT for the treatment of CKD due to diabetes or congenital anomalies of kidney and urinary tract. In the United States, CKD is estimated to affect over 38 million adults. We may encounter difficulties enrolling subjects in our clinical trials of REACT due, in part, to the stringent inclusion criteria for subjects, the novelty of the treatment modality and the fact that it involves a physically invasive procedure. In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as REACT, and this competition may reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which may reduce the number of patients who are available for our clinical trials in such clinical trial site.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our future clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of REACT or any of our future product candidates. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

Furthermore, due to the follow-up period of at least 24 months and the requirement for on-site visits, subjects may drop out of our clinical trials at a higher rate than we anticipate or may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as REACT and any future product candidates. Even if we are able to enroll a sufficient number of subjects for our clinical trials, we may have difficulty maintaining enrollment of such subjects in our clinical trials.

The design or execution of our ongoing and future clinical trials may not support marketing approval.

The design or execution of a clinical trial can determine whether its results will support marketing approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. Additionally, in some instances, there can be significant variability in safety or efficacy results between different trials with the same product candidate due to numerous factors, including differences in trial protocols, size and type of the patient populations, variable adherence by investigators and subject to protocol requirements and the rate of dropout among clinical trial subjects. We do not know whether any clinical trials we conduct will demonstrate consistent or adequate efficacy and safety to obtain marketing approval to market REACT or any of our future product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for REACT or any of our future product candidates. REACT may not be approved even if it achieves its primary endpoints in our Phase 3 clinical trials or registrational trials. The FDA or comparable foreign regulatory authorities may disagree with our trial designs and our interpretation of data from nonclinical studies or clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 or registrational clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of REACT or any of our future product candidates, if approved.

[Table of Contents](#)

We have obtained RMAT Designation from the FDA for REACT, but this may not lead to a faster development or regulatory review process, and such designation does not increase the likelihood that any of our product candidates will receive marketing approval in the United States and the FDA may withdraw such designation.

We intend to evaluate regulatory strategies that could enable us to take advantage of expedited development pathways for REACT, including the RMAT designation that we have already received, although we cannot be certain that REACT will qualify for any additional expedited development pathways or that regulatory authorities will grant, or allow us to maintain, the relevant designations.

RMAT designation is intended to expedite the development and review of product candidates that are designed to treat serious or life-threatening diseases and unmet need when “preliminary clinical evidence indicates that a product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.” The designation of REACT with expedited designation provides potential benefits that include: more frequent meetings with FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient cell therapy program, beginning as early as Phase 1; organizational commitment involving senior managers; and eligibility for rolling review and priority review if supported by clinical data at the time of the submission of the BLA.

Cell and gene therapies, therapeutic tissue engineered products, human cell and tissue products, and combination products using any such therapies or products that are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition are eligible for designation by the FDA as RMATs. The RMAT designation is intended to facilitate efficient development and expedite review of regenerative medicine therapies by offering eligibility for priority review or accelerated approval, as well as early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval.

We applied for RMAT designation for REACT, which was granted by the FDA on October 28, 2021. As contemplated by the RMAT designation and as directed by the FDA, we requested a comprehensive, multidisciplinary Type B meeting with the FDA to review the status of preclinical and clinical development and manufacturing of REACT, and to discuss the planned clinical program intended to support approval of the product candidate. The FDA provided detailed written responses to our questions included in the meeting request, and the Type B meeting was held in March 2022. As a result of that meeting, we will continue to advance the USA clinical development program with the benefit of enhanced clarity as to the FDA’s expectations and requirements for a registrational program, including the design of the trials needed for approval, manufacturing assays, and comparability studies. The FDA’s input is more fully set forth under the heading “Phase 3 Clinical Development (REGEN-006 and REGEN-016)” in the section titled “*Business of ProKidney.*”

Even though we obtained RMAT designation in October 2021, such a designation does not change the standards for product approval, and there is no assurance that this designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by RMAT designation. Thus, even though RMAT designation was granted for REACT, we may not experience a faster development process, review or marketing approval compared to conventional FDA procedures. The FDA may withdraw RMAT designation if it believes that the product no longer meets the qualifying criteria. It is also possible that the FDA could provide further input on our trial design, in which case our timelines to completion of the clinical development of REACT could be delayed. Our business may be harmed if we are unable to avail ourselves of these or any other expedited development and regulatory pathways.

[Table of Contents](#)

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we must focus on development programs and product candidates that we identify for specific indications. As such, we are only focused on the development of REACT for the treatment of CKD. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for these product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We have conducted and may in the future continue to conduct additional clinical trials for REACT outside the United States, and the FDA and similar foreign regulatory authorities may not accept data from such trials conducted in locations outside of their jurisdiction.

We have conducted additional clinical trials for REACT in the Asia-Pacific region, European Union, and Latin America, and may in the future continue to conduct clinical trials outside the United States, including in South America, Australia, New Zealand, or other foreign jurisdictions. The acceptance of data from clinical trials conducted outside the United States by the FDA may be subject to certain conditions or may be rejected. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless: (i) the data are applicable to the United States population and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign clinical trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from clinical trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in REACT not receiving approval or clearance for commercialization in the applicable jurisdiction.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the pharmacological properties that we desire or attractive pharmacokinetics;
- our inability to design and develop a suitable manufacturing process; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

[Table of Contents](#)

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our share price.

Due to our limited resources and access to capital, we must make decisions on the allocation of resources to certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business.

We have limited financial and human resources and intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. In addition, we may seek to accelerate our development timelines, including by initiating certain clinical trials of REACT or our future product candidates before earlier-stage studies have been completed. This approach may cause us to commit significant resources to prepare for and conduct later-stage trials for one or more product candidates that subsequently fail earlier-stage clinical testing. Therefore, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities or expend resources on product candidates that are not viable.

There can be no assurance that we will ever be able to identify additional therapeutic opportunities for REACT or our future product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed or never achieved.

From time to time, we may estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of clinical trials and the submission of regulatory filings, including IND submissions. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize REACT or any of our future product candidates.

Risks Related to the Manufacturing of REACT and Our Future Product Candidates

Cell therapies are complex and difficult to manufacture, and we could experience manufacturing problems that result in delays in the development or commercialization of REACT, our lead product candidate, or otherwise harm our business.

The manufacture of cell therapy products is technically complex and necessitates substantial expertise and capital investment. Production difficulties caused by unforeseen events may delay the availability of material for our clinical trials. Further, we are not aware of any other cell therapy that has been manufactured for a market of the anticipated size for REACT. If REACT is approved for commercial sale, as to which no assurance can be given, we may be unable to meet market demand for the product in a timely manner due to the complex processes that are involved in its manufacturing.

Additionally, all entities involved in the preparation of therapeutics for clinical trials or commercial sale are subject to extensive cGMP, state and federal regulations, as well as foreign requirements when applicable.

[Table of Contents](#)

Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP regulations. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of REACT that may not be detectable in final product testing. We must supply all necessary documentation in support of a BLA or MAA on a timely basis. Our facilities and quality systems, including those of any third parties we contract with to manufacture any critical component of the final product, must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of REACT or any of our other potential products. In addition, the FDA and other regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of REACT or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted at such facilities, and they could put a hold on one or more of our clinical trials if our facilities, or those of our contracted third parties, do not pass such audits or inspections. If such facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted. Any failure to adhere to or document compliance with such regulatory requirements could lead to a delay or interruption in the availability of REACT for clinical trials or enforcement action from the FDA, EMA or foreign regulatory authorities. If we or our suppliers were to fail to comply with the requirements of the FDA, EMA or other regulatory authority, it could result in regulatory actions or sanctions being imposed on us, including the issuance of FDA Form 483 notices of inspectional observations, warning letters or untitled letters, clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of REACT. Our potential future dependence upon others for the manufacture of REACT may also adversely affect our future profit margins and our ability to commercialize REACT or any future product candidates that receive regulatory approval on a timely and competitive basis.

Biological products are inherently difficult to manufacture. REACT is manufactured using technically complex processes requiring specialized equipment and facilities, highly specific raw materials, autologous cells collected from patients, and reagents, and the process involves various production constraints. Even though we aim to have backup supplies of raw materials and reagents whenever possible, we cannot be certain they will be sufficient if our primary sources are unavailable. A shortage of a critical raw material or reagent, or a technical issue during manufacturing may lead to delays in clinical development or commercialization plans. Any changes in the manufacturing of components of the raw materials we use could result in unanticipated or unfavorable effects in our manufacturing processes, resulting in delays.

Delays or failures in the manufacture of cell therapies can result in a patient being unable to receive their cell therapy or a requirement to re-manufacture which itself then causes delays in manufacture for other patients. Any delay or failure or inability to manufacture on a timely basis can adversely affect a patient's outcomes and delay the timelines for our clinical trials. Such delays or failure or inability to manufacture can result from:

- a failure in the manufacturing process itself, for example by an error in manufacturing equipment or reagent failure, failure in any step of the manufacturing process, failure to maintain a cGMP environment or failure in quality systems applicable to manufacture, sterility failures, or contamination during process;
- product loss or failure due to logistical issues associated with the collection of a patient's autologous cells or other samples, shipping that material to analytical laboratories, and shipping the final cell therapy back to the location using cold chain distribution where it will be administered to the patient, manufacturing issues associated with the differences in patient starting materials, inconsistency in cell growth and variability in product characteristics;
- a lack of reliability or reproducibility in the manufacturing process itself, leading to variability in end manufacture of the cell therapy, which may lead to regulatory authorities placing a hold on a clinical

[Table of Contents](#)

trial or requesting further information on the process, which could in turn result in delays to the clinical trials;

- product loss or failure due to logistical issues including issues associated with the differences between patients' autologous cells or characteristics, interruptions to process, contamination, failure to supply patient apheresis material within required timescales (for example, as a result of an import or export hold-up) or supplier error;
- inability to have enough manufacturing slots to manufacture cell therapies for patients as and when those patients require manufacture;
- inability to procure starting materials or to manufacture starting materials;
- interruptions in our supply chain, which may require us to find an alternative manufacturer or supplier for one or more components that we need in the manufacture of REACT, which would in turn require such manufacturer or supplier to be qualified through a BLA and/or MAA supplement, could lead the regulatory agencies to require additional studies if a new manufacturer is relied upon for commercial production, and may involve substantial costs and delays related to switching manufacturers;
- loss of or close-down of any manufacturing facility used in the manufacture of our cell therapies, or the inability to find alternative manufacturing capability in a timely fashion;
- loss or contamination of patient starting material, requiring the starting material to be obtained again from the patient or the manufacturing process to be re-started; and
- a requirement to modify or make changes to any manufacturing process, which may also require comparability testing that delays our ability to make the required modifications or perform any required comparability testing in a timely fashion, require further regulatory approval or require successful tech transfer to CMOs to continue manufacturing.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of REACT, cause us to incur higher costs and prevent us from commercializing REACT successfully, if approved.

Our current costs of manufacturing REACT for use in our ongoing Phase 2 RMCL-002 study are approximately \$100,000 per patient. We anticipate that these costs will be lower for our Phase 3 trials and that the costs will continue to decrease by up to 50% from the costs of manufacturing REACT for our Phase 2 RMCL-002 study as we manufacture REACT at commercial scale with implementation of automation, bioprocess developments, formulation improvements and streamlining of the supply chain. We expect to utilize automation in all aspects of manufacturing ranging from tissue processing, cell expansion and renal cell selection to formulation and filling of the final product. We will also extend automation to other manufacturing activities, including warehouse operations and supply chain. In addition, we intend to improve bioprocess development to further reduce manufacturing costs of the commercial REACT product, assuming receipt of necessary regulatory approvals. Culture media represents the highest cost in REACT processing, and we are exploring reduced culture media usage via bioprocess and automation improvements. Further, our final commercial REACT product is planned to be a cryopreserved formulation, which is projected to reduce manufacturing costs compared to our fresh REACT formulation. We expect to leverage bulk purchasing to actively negotiate pricing of materials to further drive cost reductions. However, there can be no assurance that the manufacturing costs for our Phase 3 trials when we manufacture REACT at commercial scale will actually be lower than for our ongoing Phase 2 RMCL-002 study. A number of factors may contribute to an inability to achieve these cost reductions, including any failures to achieve the automation efficiencies that we anticipate, cost overruns or inefficiencies in the supply chain, and any failure to improve the formulation or bioprocessing of REACT in a manner that results in lower costs.

We have our own manufacturing capabilities, which may result in increased costs being incurred by us.

Our manufacturing facility for REACT is within our Winston-Salem facility in North Carolina, and this facility currently manufactures SRCs for use in our clinical trials. Regulatory authorities, in particular the FDA, might not continue to approve our ability to manufacture SRCs or other cell therapies at the Winston-Salem facility.

Our ability to successfully manufacture our own cell therapies at the Winston-Salem facility within a reasonable period of time and within currently projected costs is dependent on a number of factors, including:

- our ability to recruit the required employees at a suitable level and experience and within required timescales and to maintain employment of such required employees;
- our ability to obtain regulatory approval for the facility and for the manufacture of cell therapies at the facility and to satisfy regulatory authorities on an ongoing basis;
- our ability to manufacture cell therapies reliably and reproducibly and to timescales sufficient to support required patient administration;
- our ability to manufacture cell therapies in compliance with the applicable regulatory requirements, including requirements applicable in both the United States and the European Union, including cGMP, enforced by the FDA and state regulatory authorities;
- our ability to develop internal quality controls and processes sufficient to enable manufacture and supply of cell therapies at our Winston-Salem facility;
- our ability to establish comparability with currently used manufacturing processes and for such comparability data to be accepted by the appropriate regulatory authorities; and
- our ability to fund ongoing development, including equipment requirements necessary for successful manufacture of cell therapies at our facility.

Any delay or failure in manufacture at our facility could result in delays to the supply of cell therapies for our clinical trials. Should we become unable to produce cell therapies for use in our clinical trials or be unable to produce cell therapies at the required level, then we will be unable to support such clinical trials until alternative manufacturing capability is secured.

Our autologous cell therapy products are patient-specific, and we need to ensure that the correct product is administered to the correct patient.

Administration of autologous cell therapies is patient-specific and personalized medicine. The process requires careful handling of patient-specific products and fail-safe tracking to ensure that the tracking process is without error and that patient samples are tracked from patient collection, through manufacturing and re-administration to the same patient. While such mechanisms are in place, should the tracking process fail, whether at our own facility, a third-party facility or at any point in the manufacturing and supply process, a patient could receive another patient's SRCs, resulting in significant toxicity and potentially patient fatality. We will need to invest in enhanced systems, such as bar coding, to further ensure fail-safe tracking. There is always a risk of a failure in any such system. Inability to develop or adopt an acceptable fail-safe tracking methodology and handling regime may delay or prevent us from receiving regulatory approval and/or result in significant toxicity and potentially patient fatality if a patient receives another patient's SRCs. This risk may be increased where autologous cell therapies are used in clinical trials that we do not control or sponsor and, should an error be made in the administration of our autologous cell therapies in such clinical trials, this could affect the steps required in our own clinical trials and manufacturing process requiring the addition of further tracking mechanisms to ensure fail-safe tracking. The tracking systems required to further ensure safe patient administration may also require enhanced procedures and administration to satisfy other regulatory requirements, for example, data protection requirements in Europe. The need to ensure tracking systems are adequate and to

comply with these additional regulatory requirements may result in delay to the start of clinical trials or the need to obtain additional regulatory licenses or consents prior to starting such trials.

Delays in obtaining regulatory approval of the manufacturing process and facility to produce REACT or disruptions in the manufacturing process may delay or disrupt our commercialization efforts. Very few cGMP cell therapy manufacturing facilities in the United States have received approval from the FDA for the manufacture of an approved cell therapy product.

Before we can begin to commercially manufacture REACT or any of our future product candidates, we must obtain regulatory approval from the FDA for our manufacturing processes and for the facility in which manufacturing is performed. A manufacturing authorization must also be obtained from the appropriate EU regulatory authorities prior to commercialization in the European Union. Very few cGMP cell therapy manufacturing facilities in the United States have received approval from the FDA for the manufacture of an approved cell therapy product and, therefore, the timeframe required for us to obtain regulatory approval for our product candidates is uncertain. In addition, we must pass a pre-approval inspection of the manufacturing facility, including any facilities that produce any component of REACT, by the FDA and other relevant regulatory authorities before REACT or any of our future cell therapy product candidates can obtain marketing approval. In response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities while local, national and international conditions warrant. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain therapeutic manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized or deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. However, on December 29, 2021, the FDA announced that due to the rapid spread of the COVID-19 omicron variant, certain inspections, such as domestic and foreign preapproval, surveillance, and for-cause inspections that are not deemed mission-critical, would be postponed through January 19, 2022, and that the agency would reassess plans to resume foreign inspections. Should the FDA determine that an inspection is necessary for approval of a new drug application (“NDA”) and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

In order to obtain approval, we will need to ensure that all of our processes, quality systems, methods, equipment, policies and procedures are compliant with cGMP and other applicable regulations, and perform extensive audits of vendors, contract laboratories, and suppliers. If any of our vendors, contract laboratories, or suppliers is found to be out of compliance with cGMP or other applicable regulations relating to REACT, we may experience delays or disruptions in manufacturing while we work with such third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern, among

[Table of Contents](#)

other things, quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP regulations, we will be obligated to spend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we may be subject to regulatory enforcement actions or other legal sanctions and may not be permitted to sell any products that we may develop.

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

We do not have experience as a company managing a complex supply chain or satisfying manufacturing-related regulatory requirements.

The FDA, the EMA and other foreign regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable lot release tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a product lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in a cell therapy product that could lead to lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing processes could restrict our ability to meet market demand for our products.

Managing an autologous ex vivo cell therapy supply chain is highly complex. We must identify, engage, and coordinate with treatment centers where patients' cellular source material must be collected, prepared and transported to the manufacturing facility and the cryopreserved therapeutic product must be returned to the treatment center for administration to the patient using controlled temperature shipping containers.

Once collected from the patient, the cellular source material must be prepared and stored according to specified procedures. While we intend to standardize the processes at treatment centers, if there is a deviation of the processes, the cellular source material from a patient could be adversely impacted and potentially result in manufacturing failures. The patient's cellular materials must be transported to the manufacturing facility using a shipping container that maintains the material at a sufficiently cold temperature and must typically be delivered and processed within four days of collection. While we intend to use reputable couriers and agents for the transport of such materials, if the shipping container is opened or damaged such that the appropriate storage/shipping temperature is not maintained, the cellular source material may be adversely impacted and it may not be feasible to manufacture a cell therapy product for the patient. Similarly, if a shipment is delayed due to adverse weather, misrouting, being held up at a customs point, COVID-19 impacts or other events, the cellular source material may not be delivered within a time window that will allow for its use for the successful manufacture of a cell therapy product.

Similarly, the patient's autologous cell therapy product must be returned to the clinical site for administration to the patient using a specialized shipping container that maintains the material at a very low temperature. While we intend to use reputable couriers and agents for the transport of our products, if the shipping container is opened or damaged such that the very low temperature is not maintained, the cell therapy product may be adversely impacted and it may not be feasible to administer it to the patient or, if administered, it could cause harm to the patient. Similarly, if a shipment is delayed due to adverse weather, misrouting, being held up at a customs point, COVID-19 impacts or other events, and is not delivered to the clinical site within the time period that the very low temperature is maintained, the cell therapy product may be adversely affected and be unable to be administered or, if administered, could cause harm to the patient.

We may be delayed or unable to identify, engage, successfully coordinate with or qualify treatment centers in the regions we are targeting as part of our commercial launch strategy, which could delay or prevent patients

[Table of Contents](#)

from receiving cell therapy treatments, if approved. For example, due to COVID-19-related travel restrictions, some in-person visits to qualify certain potential treatment centers were postponed or required to take place remotely. If our treatment centers fail to perform satisfactorily, we may suffer reputational, operational, and business harm.

Any of the above events, should they happen, could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

We depend on third-party suppliers for materials that are necessary for the conduct of clinical trials of REACT, our lead product candidate, and the loss of these third-party suppliers or their inability to supply us with sufficient quantities of adequate materials, or to do so at acceptable quality levels and on a timely basis, could harm our business.

Manufacturing REACT, our lead product candidate, requires many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of REACT. Some of these suppliers may not have the capacity to support clinical trials and commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays or interruption in receiving key materials and equipment to support clinical or commercial manufacturing. Any significant delay or interruption in the supply of components or sub-assemblies, or our inability to obtain substitute components, sub-assemblies or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and harm our business.

For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. The supply of the reagents and other specialty materials and equipment that are necessary to produce REACT could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier could result in delay, and we may not be able to find other acceptable suppliers on acceptable terms, or at all. Switching suppliers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If we change suppliers for commercial production, applicable regulatory agencies may require us to conduct additional studies or trials. If key suppliers are lost, or if the supply of the materials is diminished or discontinued, we may not be able to develop, manufacture and market REACT in a timely and competitive manner, or at all. An inability to continue to source products from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for REACT, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials or equipment on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or equipment or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and/or commercialization plans. If such a change occurs for product candidate that is already in clinical development, the change may require us to perform both *ex vivo* comparability studies and to collect additional data from subjects prior to undertaking more advanced clinical trials. These factors could cause the delay of nonclinical studies or clinical trials, regulatory submissions, required approvals or commercialization of REACT

or future product candidates that we develop, cause us to incur higher costs and prevent us from commercializing our product candidates successfully.

Any microbial contamination in the manufacturing process for our cell-based product, shortages of raw materials or failure of any of our key suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules.

Given the nature of cell product manufacturing, there is a risk of microbial contamination. Any microbial contamination could adversely affect our ability to produce, release or administer our cell therapies on schedule and could, therefore, harm our results of operations and cause reputational damage.

Some of the raw materials required in our manufacturing processes are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of REACT could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

REACT requires cryopreservation with specific storage, handling and administration at the clinical sites.

REACT requires cryopreservation and must be stored at very low temperatures in specialized freezers or specialized shipping containers until immediately prior to use. For administration, the cryopreserved product container must be carefully removed from storage, rapidly thawed under controlled temperature conditions in an area proximal to the patient's bedside and immediately administered to the patient. The handling, thawing and administration of the cryopreserved cell therapy product must be performed according to specific instructions, typically using specific disposables, and some steps must be completed within specific time periods. Failure to correctly handle the product, follow the instructions for thawing and administration and or failure to administer the product within the specified period post-thaw could negatively impact the efficacy and or safety of the product.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through clinical trials to marketing approval and commercialization, various aspects of the development program, such as manufacturing methods and the product's formulation, may be altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. These changes carry the risk that they will not achieve their intended objectives. Any of these changes could cause REACT or any of our future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of our ongoing or planned clinical trials, require us to perform bridging clinical trials or repeat one or more clinical trials, increase clinical trial costs, delay any potential approval of REACT or any of our future product candidates and jeopardize our ability to commercialize REACT or any of our future product candidates and generate revenue.

In addition, there are risks associated with process development and large-scale manufacturing for clinical trials or commercial distribution including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMP, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that we will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. Additionally, the manufacturing processes for biological products is more complex and expensive than with small-molecule

products, and additional manufacturing suppliers may be needed to manufacture clinical trial supplies for these development programs. If we are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our current operations are concentrated in a number of locations, including a single manufacturing facility in North Carolina. We or the third parties upon whom we depend may be adversely affected by earthquakes, wildfires or other natural disasters, as well as epidemics, pandemics and other incidents, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of REACT or any of our future product candidates or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event prevented us from using all or a significant portion of our manufacturing facilities, or otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place, including use of contract manufacturers and inherent risks associated therewith with respect to technology transfer and quality issues, may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to the Commercialization of REACT and Our Future Product Candidates

Even if REACT or a future product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if REACT or any other product candidates we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, such as Medicare and Medicaid programs and managed care organizations, and others in the medical community. In addition, the availability of coverage by third-party payors may be affected by existing and future health care reform measures designed to reduce the cost of health care. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages of our current or future product candidates compared to alternative treatments;
- product labeling or product insert requirements of the FDA, EMA or other foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning or REMS;

Table of Contents

- the clinical indications for which our current or future product candidates are approved;
- availability of alternative treatments already approved or commercially launched in the future;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies, including where there may be a perception that our therapies, if approved, involve an increased risk of adverse events;
- the recommendations with respect to our product candidates in guidelines published by various scientific organizations applicable to us and our product candidates;
- the strength of marketing and distribution support;
- any restrictions on the use of our products together with other medications;
- our ability to hire and retain a sales force in the United States;
- the ability to obtain sufficient third-party coverage and adequate reimbursement for our products, including necessary reimbursement codes;
- the prevalence and severity of any side effects;
- the ability to obtain Current Procedural Terminology (“CPT”) Codes and Resource-Based Relative Value Scale for appropriate provider reimbursement;
- the ability to obtain designated International Classification of Diseases (“ICD-10”) codes from the WHO for disease designation;
- willingness of provider proceduralists to perform invasive kidney procedures that may cause increased medical liability from procedural-related or cell based adverse events; and
- the ability to provide advanced procedural training for delivery of product candidates.

Sales of cell-based products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians’ organizations, hospitals, other health care providers, government agencies or private insurers will determine that our products are safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable. If government and other third-party payors do not provide coverage and adequate reimbursement levels for any products we commercialize, market acceptance and commercial success would be reduced. REACT is percutaneously injected into the kidney and requires additional proceduralist technical training with possible ongoing maintenance of certification. Facilities where REACT is delivered may require additional cell-based licensing by state, federal or laboratory certification agencies and require equipment with appropriate technology and inventories.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell any products for which we obtain regulatory approval, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If REACT or any of our future product candidates ultimately receives regulatory approval, we expect to establish a

[Table of Contents](#)

marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, including product administration and product delivery, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop and for which we receive regulatory approval ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

The affected populations for REACT or any of our future product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for REACT or our future product candidates.

Our projections of the number of people who have the diseases we are seeking to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with REACT or any of our future product candidates, are estimates based on our knowledge and understanding of these diseases. These estimates may prove to be incorrect, and new studies, medications, or medical practices may further reduce the estimated incidence or prevalence of this disease. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with REACT or any of our future product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain approval for REACT or any of our future product candidates, the FDA or other regulators may limit their approved indications to more narrow uses or subpopulations within the populations for which we are targeting development of REACT or any of our future product candidates.

The total addressable market opportunity for REACT or any of our future product candidates will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if

approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources. Accordingly, the incidence and prevalence estimates included in this prospectus should be viewed with caution. Further, the data and statistical information used in this prospectus, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

Obtaining and maintaining regulatory approval of REACT or any of our future product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of REACT or future product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of REACT or any of our future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, similar foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval and licensure procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining similar foreign regulatory approvals and compliance with similar foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of REACT or any of our future product candidates will be harmed.

Off-label use or misuse of our products may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, and/or subject us to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product.

If we have any product candidate approved, our product labeling, advertising, and promotion will be subject to regulatory requirements and continuing regulatory review. In the United States, the FDA and the FTC strictly regulate the promotional claims that may be made about pharmaceutical products to ensure that any claims about such products are consistent with regulatory approvals, not misleading or false, and adequately substantiated by clinical data. The promotion of a medicine or biologic product in a manner that is false, misleading, unsubstantiated, or for unapproved (or off-label) uses may result in enforcement letters, inquiries and investigations and civil and criminal sanctions by the FDA, FTC, and other regulatory authorities. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly

promoted off-label uses may be subject to significant sanctions and may result in false claims litigation under federal and state statutes, which can lead to consent decrees, civil monetary penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid and other federal and state health care programs. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required that companies enter into consent decrees and/or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. Any off-label use of REACT or any of our future product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation.

Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities and stakeholders.

REACT and our future product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated, and our operating results will suffer if we fail to compete effectively.

Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, REACT or any of our future product candidates may face competition from biosimilar products. In the United States, REACT is expected to be regulated by the FDA as a biological product, and we intend to seek approval for REACT pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009 (the “BPCIA”) created an abbreviated pathway for FDA approval of biosimilar and interchangeable biological products based on a previously licensed reference product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for REACT.

We believe that any of our current or future product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for generic follow-on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing, including whether a future competitor seeks an interchangeability designation for a biosimilar of one of our products. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient-provider relationship and a patient’s specific medical needs, health care providers are not restricted from prescribing biosimilar products in an off-label manner. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own nonclinical studies and clinical trials. In such a situation, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

[Table of Contents](#)

If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

Competitor companies or hospitals may be able to take advantage of EU rules permitting sales of unlicensed medicines for individual patients to sell competing products without a marketing authorization.

The EU medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a health care professional and for use by an individual patient under his direct personal responsibility. This may in certain countries also apply to products manufactured in a country outside the European Union and imported to treat specific patients or small groups of patients. In addition, designated advanced therapy medicinal products (“ATMPs”) do not need a marketing authorization if they are prepared on a non-routine basis and are used within the same EU member state in a hospital in accordance with a medical prescription for an individual patient.

These exemptions could allow our competitors to make sales in the EU without having obtained a marketing authorization and without undergoing the expense of clinical trials, especially if those competitors have cell processing facilities in the relevant EU member state. Similarly, certain hospitals may be able to compete with us on the basis of these rules. Because any such sales would be made without a marketing authorization, there would be no need for the competitor company or hospital to refer to the clinical data in our marketing authorization dossiers, and so any data exclusivity protection that we may obtain for our products would not prevent such competing sales.

Coverage and reimbursement may be limited or unavailable in certain market segments for REACT or our future product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

In the United States and in other countries, patients who are prescribed treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory marketing approval will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities such as Medicare, Medicaid, TRICARE, and the Veterans Administration, managed care providers, private health insurers, and other organizations. Coverage and adequate reimbursement from governmental health care programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Even if any of our products obtains regulatory approval, patients are unlikely to use such products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, any of our products, if approved, or assure that coverage and reimbursement will be available for any product that we may develop. REACT, due to the novel cell therapy and new indication for CKD, may require formulation of CPT codes with resource-based relative value unit appropriation and ICD-10 designation. Each are obtained through different processes and may lead to reimbursement delays of unknown lengths of times.

Government authorities and other third-party payors decide which treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor’s determination that use of a product is:

- a covered benefit under its health plan;

Table of Contents

- safe, effective and medically necessary;
- appropriate for the specific patient;
- supported by peer-reviewed medical journals;
- included in clinical practice guidelines;
- cost-effective; and
- neither experimental nor investigational.

Our ability to commercialize successfully any of our products for which we obtain regulatory approval will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health care programs and private health insurers. Moreover, a payor's decision to provide coverage for a biopharmaceutical product does not imply that an adequate reimbursement rate will be approved. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize REACT or any of our future product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for REACT or any of our future product candidates, if approved.

Changes to current laws and state and federal health care reform measures that may be adopted in the future may result in additional reductions in Medicare and other health care funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of REACT or our future product candidates.

We face an inherent risk of product liability as a result of testing REACT or any of our future product candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if REACT or any of our future product candidates causes or is perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of REACT or any of our future product candidates. Even a successful defense of these claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;

[Table of Contents](#)

- injury to our reputation;
- withdrawal of clinical trial subjects and inability to continue clinical trials;
- initiation of investigations by regulators;
- significant costs to defend the related litigation;
- reduced resources of our management to pursue our business strategy;
- substantial monetary awards to trial subjects;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any products that we may develop; and
- decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We will need to obtain additional insurance for clinical trials as REACT continues clinical development and as additional product candidates enter the clinic. However, we may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

If we or any contract manufacturers and suppliers we engage, now or in the future, fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could substantially harm our business.

We and any CMOs and suppliers we engage, now or in the future, are subject to numerous federal, state and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous materials, including chemicals and biological materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the

event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could substantially harm our business.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct, supervise and monitor a certain portion of our research and nonclinical testing and clinical trials for REACT, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize REACT, or such approval or commercialization may be delayed, and our business may be substantially harmed.

We depend, or may depend in the future, upon third parties to conduct certain aspects of our nonclinical studies and clinical trials, and to monitor and manage data, under agreements with universities, medical institutions, CROs, strategic collaborators and others. We expect to have to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs. We expect to continue to rely on third parties, including clinical CROs, medical institutions and clinical investigators, to conduct those clinical trials. If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms, if at all. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, the performance of our CROs and other third parties conducting our trials may also be interrupted by the ongoing COVID-19 pandemic, including due to travel restrictions, quarantine policies, heightened exposure of CRO or clinical site or other vendor staff who are health care providers to COVID-19 or prioritization of resources toward the pandemic.

Any third parties conducting aspects of our nonclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our nonclinical studies and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the nonclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, or if due to federal or state orders or absenteeism due to the COVID-19 pandemic they are unable to meet their contractual and regulatory obligations, our product development timelines, including clinical development timelines, may be extended, delayed or terminated, and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize REACT. As a result, our financial results and the commercial prospects for REACT would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We will rely especially heavily on third parties over the course of our clinical trials and will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical trial protocol. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of

trial sponsors, clinical investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional nonclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with biologic product produced under cGMP, and likely cGTP regulations and will require a large number of test subjects. Our failure or any failure by our contracted third parties, including CROs, to comply with these regulations or to recruit a sufficient number of subjects may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or health care privacy and security laws.

We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval for REACT or any of our future product candidates.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of REACT or any of our future product candidates or commercialization of REACT or any of our future product candidates, producing additional losses and depriving us of potential revenue.

We rely on third parties for materials, including tissue samples, required for our research and development activities, and if we are unable to reach agreements with these third parties our research and development activities would be delayed.

We rely on third parties, primarily hospitals, health clinics and academic institutions, for the provision of tissue samples and other materials required in our research and development activities. Obtaining these materials requires various approvals as well as reaching a commercial agreement on acceptable terms with the hospital or other provider of the materials. While we currently have agreements in place with the institutions from which we receive our tissue samples, we do not have any exclusive arrangements with such sources and there is no guarantee that we will be able to maintain or renew such agreements on commercially reasonable terms, if at all. If we were unable to maintain or renew such agreements we would be forced to seek new arrangements with new hospitals, clinics or health institutions. If so, we may not be able to reach agreements with alternative partners or do so on terms acceptable to us. If we are unable to enter into such agreements, our research and development activities will be delayed and our ability to implement a key part of our development strategy will be compromised.

We may in the future seek to enter into collaborations with third parties for the development and commercialization of REACT and/or our future product candidates, and our future collaborations will be important to our business. If we are unable to enter into collaborations, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to consider partnerships in indications and geographies where we believe partners can add significant commercial and/or development capabilities. Further, we have limited capabilities for product

[Table of Contents](#)

development and do not yet have any capability for commercialization. Accordingly, we have entered into and may in the future enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology.

Any future collaborations we enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of REACT or our future product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to REACT or one or more of our future product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not provide us with timely and accurate information regarding development progress and activity under any future license agreement, which could adversely impact our ability to report progress to our investors and otherwise plan development of REACT or our future product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

[Table of Contents](#)

If any future collaborations we enter into do not result in the successful discovery, development and commercialization of product candidates or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of our collaborators.

Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators for REACT and future product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully establish a collaboration for REACT or any of our future product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into future collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop REACT or future product candidates, bring them to market and generate revenue from sales of such products or continue to develop our technology, and our business may be materially and adversely affected. Even if we are successful in our efforts to establish new strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to REACT or our future product candidates could delay their development and commercialization and reduce their competitiveness even if it reaches the market.

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with customers, health care providers, physicians, prescribers, purchasers, third-party payors, charitable organizations and patients will be subject to applicable anti-kickback, fraud and abuse and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, upon commercialization of REACT or any of our future product candidates, if approved, we will be subject to additional health care statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct our business. Health care providers, including physicians, in the United States and elsewhere play a primary role in the recommendation and prescription of biopharmaceutical products. Arrangements with third-party payors and customers can expose biopharmaceutical manufacturers to broadly applicable fraud and abuse and other health care laws and regulations, including, without limitation, the federal Anti-Kickback Statute (the "AKS") and the FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biopharmaceutical products. In

[Table of Contents](#)

particular, the research of REACT or any of our future product candidates, as well as the promotion, sales and marketing of health care items and services, as well as certain business arrangements in the health care industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

The health care laws that may affect us include: the federal fraud and abuse laws, including the AKS; false claims and civil monetary penalties laws, including the FCA and Civil Monetary Penalties Law; federal data privacy and security laws, including HIPAA, as amended by HITECH; and the federal Physician Payments Sunshine Act related to ownership and investment interests and payments and/or other transfers of value made to or held by physicians (including doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals and, beginning in 2022, information regarding payments and transfers of value provided to other health care professionals, such as physician assistants and nurse practitioners among others, during the previous year. In addition, many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. Moreover, several states require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require manufacturers to report information related to payments and other transfers of value to physicians and other health care providers or marketing expenditures. Additionally, some state and local laws require the registration of biopharmaceutical sales representatives in the jurisdiction.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable health care laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from other aspects of its business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded health care programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other health care providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded health care programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory oversight and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with REACT or any of our future product candidates.

If REACT or any of our future product candidates is approved, activities such as the manufacturing, labeling, packaging, storage, advertising, promotion, sampling, and record keeping for the products will be

[Table of Contents](#)

subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and cGTP regulations. Biopharmaceutical manufacturers and any CMOs responsible for any product manufacturing processes are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP and cGTP regulations and any applicable foreign equivalents. As such, we and any CMOs we may employ in the future will be subject to continual review and inspections to assess compliance with cGMP and cGTP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

The FDA or a comparable foreign regulatory authority may also impose requirements for costly post-marketing nonclinical studies or clinical trials (often called Phase 4 trials) and post-marketing surveillance to monitor the safety or efficacy of the product. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, production problems or issues with the facility where the product is manufactured or processed, such as product contamination or significant noncompliance with applicable cGMP regulations, a regulator may impose restrictions on that product, the manufacturing facility or us. If we or our third-party providers fail to comply fully with applicable regulations, then we may be required to initiate a recall or withdrawal of our products.

Later discovery of previously unknown problems with REACT or any of our future product candidates, including adverse events of unanticipated severity or frequency, or with our manufacturing processes, or failure to comply with regulatory requirements, may result in the following, among other things:

- restrictions on the manufacturing of the product, the approved manufacturers or the manufacturing process;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- withdrawal of the product from the market;
- product recalls;
- warning or untitled letters from the FDA or comparable notice of violations from foreign regulatory authorities;
- refusal of the FDA or other applicable regulatory authority to approve pending applications or supplements to approved applications;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- suspension of any of our ongoing clinical trials;
- product seizure or detention or refusal to permit the import or export of products; and
- consent decrees, injunctions or the imposition of civil or criminal penalties.

In addition, regulatory authorities' policies (such as those of the FDA or EMA) may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of REACT or any of our future product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are otherwise not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

[Table of Contents](#)

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of REACT or any of our future product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Changes in health care policies, laws and regulations, including legislative measures aimed at reducing health care costs, may impact our ability to obtain approval for, or commercialize REACT or any of our future product candidates, if approved.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the health care system made in an effort to contain costs, improve quality and expand access to care. In the United States, there have been and continue to be a number of health care-related legislative initiatives, as well as executive, judicial and Congressional challenges to existing health care laws that have significantly affected, and could continue to significantly affect, the health care industry. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, together with subsequent amendments and regulations (collectively, the "ACA"), is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to health care, including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. In addition, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to medicines pricing, reduce the cost of prescription medicines under government payor programs and review the relationship between pricing and manufacturer patient programs. We expect that additional U.S. federal health care reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for health care products and services, which could result in reduced demand for REACT or any of our future product candidates or additional pricing pressures.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

[Table of Contents](#)

Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities.

Separately, the FDA has announced its commitment to achieving timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals; however, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. In response to the COVID-19 pandemic and the subsequent waves of infection due to variants of SARS-CoV-2, the FDA postponed most routine inspections of foreign and domestic manufacturing facilities but continued to conduct mission-critical according to a risk-based prioritization system. During this period, the FDA issued a guidance document describing the FDA's plans to conduct voluntary remote interactive assessments of certain drug manufacturing facilities and clinical research sites in situations where an in-person inspection would not be prioritized or deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. After a significant decline in COVID-19 cases across the United States in the beginning of 2022, the FDA resumed domestic surveillance inspections on February 7, 2022 and is conducting inspections of foreign manufacturing facilities for which the foreign country has provided clearance and is within the CDC's Level 1 or 2 COVID-19 travel recommendation. Despite the resumption of normal inspection activities, the FDA continues to employ remote assessments as a tool for evaluating regulatory compliance of foreign and domestic facilities. However, if another rapid rise in COVID-19 cases occurs, the FDA may decide to postpone foreign and domestic inspections again. In such a situation, should the FDA require an inspection for approval of an NDA or BLA, but one cannot be completed during the review cycle due to travel restrictions, and the agency decides a remote interactive evaluation would be inadequate, the FDA has previously stated its general intent to issue a complete response letter or defer action on such applications until an inspection can be completed. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

EU medicine marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

We intend to seek approval to market REACT in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for REACT, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of medicines and cell based therapeutics is subject to governmental control and other market regulations which could put pressure on the pricing and usage of REACT. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of REACT will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for REACT and may be affected by existing and future health care reform measures. Additionally, the international regulatory landscape related to reimbursement is uncertain, and likely will continue to evolve before we are able to commercialize REACT.

Much like the federal AKS prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to

physicians is governed by the national anti-bribery laws of EU Member States, and in respect of the United Kingdom (which is no longer a member of the European Union), the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including the European Economic Area (the "EEA"), the proposed pricing for a medicine must be approved before it may be lawfully marketed. The requirements governing medicine pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. In addition, these regulations are evolving and subject to change, possibly before we are able to commercialize REACT. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about subjects and health care providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. Recently, California passed the California Consumer Privacy Act of 2018 (the "CCPA"), which went into effect in January 2020 and provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health

information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. The CCPA may lead to similar laws in other U.S. states or at a national level, which could increase our potential liability and adversely affect our business.

In addition to our operations in the United States, which may be subject to health care and other laws relating to the privacy and security of health information and other personal information, we are conducting, and we may conduct in the future, clinical trials in EEA and may become subject to additional European data privacy laws, regulations and guidelines. The General Data Protection Regulation, (EU) 2016/679 (“GDPR”) became effective on May 25, 2018, and deals with the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals in the EEA. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals’ requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to €10,000,000 or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to €20,000,000 or up to 4% of our total worldwide annual turnover, whichever is greater, for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers.

Further, national laws of member states of the European Union are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. The United Kingdom’s decision to leave the European Union, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the European Union.

We are conducting clinical trials in the EEA, and the GDPR increases our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we are required to have in place additional mechanisms and safeguards to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is a rigorous and time-intensive process that increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. We expect that we will continue to face uncertainty as to whether our efforts to comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or biopharmaceutical partners. We may also experience hesitation, reluctance, or refusal by European or multi-national vendors or biopharmaceutical partners to continue to use our products due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such vendors or biopharmaceutical partners may also view any alternative approaches to compliance as being too costly, too

burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the forgoing could materially harm our business, prospects, financial condition and results of operations.

Legal, political and economic uncertainty relating to our international operations could negatively impact or restrict our operations.

Following the result of a referendum in 2016, Brexit took effect on January 31, 2020. Pursuant to the formal withdrawal arrangements agreed to by the United Kingdom and the European Union, as of January 1, 2021, the United Kingdom is no longer subject to the transition period during which EU rules continued to apply (the “Transition Period”). Negotiations between the United Kingdom and the European Union are expected to continue in relation to the customs and trading relationship between the United Kingdom and the European Union following the expiry of the Transition Period.

Since a significant proportion of the regulatory framework in the United Kingdom is applicable to our business, and REACT, our lead product candidate, is derived from EU directives and regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of REACT in the United Kingdom or the European Union. For example, as a result of the uncertainty surrounding Brexit, the EMA relocated to Amsterdam from London. Following the Transition Period, the United Kingdom will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorizations from the EMA, and unless a specific agreement is entered into, a separate process for authorization of cell-based products will be required in the United Kingdom, the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing REACT in the United Kingdom or the European Union and limit our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of REACT into the European Union, or we may incur expenses in establishing a manufacturing facility in the European Union in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom or the European Union for REACT, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the European Union.

Further, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. individual or business entity from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the biopharmaceutical industry, because in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals and health care providers in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information products classified for national security purposes, as well as certain products, technology and technical data relating to those products. As we expand our

[Table of Contents](#)

operations throughout the world, we will be required to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, the "Trade Laws") prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Our executive officers, directors, security holders and their respective affiliates may have competitive pecuniary interests that conflict with our interests.

We have not adopted a policy that expressly prohibits our directors, executive officers, security holders or affiliates from having a direct or indirect pecuniary or financial interest in any investment to be acquired or disposed of by us or in any transaction to which we are a party or have an interest. Nor do we have a policy that expressly prohibits any such persons from engaging for their own account in business activities of the types conducted by us. Accordingly, such persons or entities may have a conflict between their interests and ours.

Our Charter provides that we renounce, to the maximum extent permitted by law, our interest in any corporate opportunity offered to any director who is not also an employee of the Company or about which any such director acquires knowledge unless such opportunity is expressly offered to such person solely in his or her capacity as a director of the Company and such opportunity is one we are legally and contractually permitted to undertake and would otherwise be reasonable for us to pursue. In addition, our Charter contains provisions to exculpate and indemnify, to the maximum extent permitted by law, such persons in respect of any liability, obligation or duty to our company that may arise as a consequence of such persons becoming aware of any business opportunity or failing to present such business opportunity.

The personal and financial interests of our directors and officers may result in a conflict of interest and may result in a breach of their fiduciary duties to us as a matter of Cayman Islands law and we or our shareholders might have a claim against such individuals for infringing on our shareholders' rights. See the section titled "Description of ProKidney Securities—Certain Differences in Corporate Law—Shareholders' Suits" for further information on the ability to bring such claims. However, we might not ultimately be successful in any claim we may make against them for such reason.

[Table of Contents](#)

Because we are incorporated under the laws of the Cayman Islands, you may face difficulties in protecting your interests, and your ability to protect your rights through the U.S. federal courts may be limited.

We are an exempted company incorporated under the laws of the Cayman Islands. As a result, it may be difficult for investors to effect service of process within the United States upon our directors or executive officers, or enforce judgments obtained in the United States courts against our directors or officers.

Our corporate affairs will be governed by our Charter, the Cayman Islands Companies Act and the common law of the Cayman Islands. We will also be subject to the federal securities laws of the United States. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, the decisions of whose courts are of persuasive authority, but are not binding on a court in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are different from what they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a different body of corporate and securities laws as compared to the United States, and certain states, such as Delaware, may have more fully developed and judicially interpreted bodies of corporate law. In addition, Cayman Islands companies may not have standing to initiate a shareholder derivative action in a Federal court of the United States.

We have been advised by our Cayman Islands legal counsel that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against us judgments of courts of the United States predicated upon the civil liability provisions of the federal securities laws of the United States or any state; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against us predicated upon the civil liability provisions of the federal securities laws of the United States or any state, so far as the liabilities imposed by those provisions are penal in nature. In those circumstances, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the United States, the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere.

As a result of all of the above, public shareholders may have more difficulty in protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would as public shareholders of a United States company.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our business will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and REACT, our lead product candidate, its respective components, synthetic intermediates, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing REACT is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a

court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patenting process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied. In addition, we may not pursue, obtain, or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

The strength of patents in the biotechnology and biopharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover REACT or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our technology, including REACT, or prevent others from designing around the claims in our patents. If the breadth or strength of protection provided by the patent applications we hold with respect to REACT is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, REACT. Further, if we encounter delays in our clinical trials, the period of time during which we could market REACT under patent protection would be reduced.

We cannot be certain that we were the first to file any patent application related to our technology, including REACT, and, if we were not, we may be precluded from obtaining patent protection for our technology, including REACT.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the United States Patent and Trademark Office (the "USPTO") to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, for United States applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor's disclosure.

We may be required to disclaim part or all of the term of certain patents. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect REACT, or would be found by a court to be infringed by a competitor's technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to REACT, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in REACT or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that may issue that cover our products.

[Table of Contents](#)

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy-Smith America Invents Act (the “America Invents Act”) after March 2013, the United States moved from a “first-to-invent” to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. In addition, the courts have yet to address many of these provisions and the applicability of the America Invents Act and new regulations on specific patents discussed herein, for which issues have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the compositions of REACT but that are not covered by the claims of our patents or those of our licensors;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications invented or developed using U.S. government funding, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors’ patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors’, as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover REACT;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;

[Table of Contents](#)

- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights;
- if any of our owned or in-licensed patents or applications were made with U.S. government funds, it is possible that the U.S. government may assert certain march-in rights to force us or our licensor to grant a license to third-parties to allow them to practice the claimed invention; or
- the patents of others may have an adverse effect on our business.

We may enter into license or other collaboration agreements in the future that may impose certain obligations on us. If we fail to comply with our obligations under such future agreements with third parties, we could lose license rights that may be important to our future business.

In connection with our efforts to expand our pipeline of product candidates, we may enter into certain licenses or other collaboration agreements in the future pertaining to the in-license of rights to additional candidates. Such agreements may impose various diligence, milestone payment, royalty, insurance or other obligations on us. If we fail to comply with these obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licenses or agreements.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which REACT, our lead product candidate, or any other product candidate's technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we may license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In addition, we may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, or any other intellectual property that may be related to our in-licensed intellectual

[Table of Contents](#)

property. For example, we cannot be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be negatively impacted, and our business and competitive position would be harmed.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third-party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If one or more third parties obtain or are otherwise able to replicate these techniques, an important feature and differentiator of our clinical development strategy will become available to potential competitors. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We also plan to adopt policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

Third-party claims of intellectual property infringement may be costly and time consuming to defend and could prevent or delay our product discovery, development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell REACT, our lead product candidate, and use our proprietary technologies without infringing the proprietary rights of third

parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post-grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that REACT and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing REACT. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that REACT may give rise to claims of infringement of the patent rights of others.

The Purple Book Continuity Act, enacted in December 2020 under Title II § 325, directs the FDA for the first time to publicly list certain patent information in the “Purple Book,” a database of approved biological products. Specifically, a reference product sponsor (“RPS”) is required to provide to FDA the list of patents and corresponding expiry dates (referred to here as the “initial list”), not later than 30 days after the RPS has provided the initial list to a 351(k) applicant under section 351(l)(3)(A) or (l)(7) of the Public Health Service Act. Accordingly, the RPS must only provide information on its patents to the FDA for listing in the Purple Book after it engages in the patent dance with a follow-on developer or biosimilar. As such, it is not always clear to industry participants, including us, which patents cover various types of medicines, products or their methods of use or manufacture, especially in the earlier stages of product discovery and development. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidate, technologies or methods.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management’s attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes on or violates the third-party’s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner’s attorneys’ fees;
- a court prohibiting us from developing, manufacturing, marketing or selling REACT, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do;
- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products and any license that is available may be non-exclusive, which could result in our competitors gaining access to the same intellectual property; and
- redesigning REACT or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations,

financial condition and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents of which we are currently unaware with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment that encompass the composition, use or manufacture of REACT. There may be currently pending patent applications of which we are currently unaware which may later result in issued patents that REACT or their use or manufacture may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patent were held by a court of competent jurisdiction to cover REACT, intermediates used in the manufacture of REACT or our materials generally, aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize REACT may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize REACT. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of REACT. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize REACT, which could harm our business significantly.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and biopharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse

effect on the price of our securities. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that may be relevant to or necessary for the commercialization of REACT in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market REACT. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We may not be successful in obtaining or maintaining necessary intellectual property rights to develop any future product candidates on acceptable terms.

REACT, our current product candidate, may require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing our compounds and pre-existing biopharmaceutical compounds. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize REACT. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, or challenging the patent rights of others, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our current or future licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and

time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question or for other reasons. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

We may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-examination, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the European Patent Office (the "EPO") or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by REACT or our proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference or derivation proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on our owned and in-licensed issued patents and patent applications are or will be due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In certain circumstances, even inadvertent noncompliance events may permanently and irrevocably jeopardize patent rights. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Certain patents covering REACT could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensors initiate legal proceedings against a third-party to enforce a patent covering REACT, the defendant could counterclaim that the patent covering REACT, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover REACT. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on REACT. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Our earliest patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could have a similar material adverse effect on our business, results of operations, financial condition and prospects.

Changes in patent law in the United States, changes in the administration's interpretation of the law, or changes in the law in other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On March 16, 2013, under the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to

file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO on or after March 16, 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We have limited foreign intellectual property rights and may not be able to protect and enforce our intellectual property rights throughout the world.

Although we have multiple patents in countries outside of the United States, we do not have intellectual property rights in all potential markets outside the United States where CKD is prevalent. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do

not favor the enforcement of, and may require a compulsory license to, patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Patent terms may be inadequate to protect our competitive position on REACT or our future product candidates for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-United States legislation for extending the term of patents covering REACT or our future product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest claimed U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering REACT or any of our future product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, also known as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five additional years beyond the expiration date as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended. However, we may not be granted the full extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process. Also, we may not be granted any extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish REACT, if approved for marketing, from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors

may infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. Any of the foregoing events may have a material adverse effect on our business. Moreover, any name we propose to use with REACT in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Risks Related to Managing Our Business and Operations

We expect to expand our clinical development and research and regulatory capabilities, our manufacturing and administrative capacities, and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could adversely affect our operations.

As of July 31, 2022, we had approximately 77 full-time employees. As our clinical development and commercialization plans and strategies develop, and as we transition into operating as a public company, we will need to expand our managerial, clinical, regulatory, manufacturing, sales, marketing, financial, development and legal capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our development and commercialization efforts effectively, including the clinical and FDA review process for REACT and any other product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our ability to continue to develop and, if approved, commercialize REACT will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of REACT or any of our future product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize REACT or any other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to continue developing REACT or identify and develop new product candidates will be impaired, which could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including Tim Bertram, our Chief Executive Officer; Deepak Jain, our Chief Operating Officer; James Coulston, our Chief Financial Officer; and Joseph Stavas, our SVP Clinical Development. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations globally from several locations, including the United States and the Cayman Islands. Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we intend to provide equity awards that vest over time, some of which may be in the form of unregistered shares and may dilute the voting and economic rights of our shareholders. The value to employees of such equity awards that vest over time may be significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our key employees are at-will employees, which means that any of our employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior scientific and medical personnel.

Our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state health care laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government health care programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of REACT or any of our future product candidates could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and study subjects, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyberattack. The number and complexity of these threats continue to increase over time. If a material breach of, or accidental or intentional loss of data from, our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed, and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state privacy and health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and

protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to civil or criminal penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including GDPR, may also apply to health-related and other personal information obtained outside of the United States. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU (which also includes the EEA) data protection rules. Further, the Brexit has created more uncertainty with regard to data protection regulation in the United Kingdom. The United Kingdom retained the GDPR in UK law, which sits alongside the amended version of the Data Protection Act 2018. The European Union adopted an adequacy decision so that data can be transferred from the European Union to the United Kingdom. Additionally, there are no new requirements for transfer from the United Kingdom to the European Union. However, going forward, the European Union's and United Kingdom's data protection rules could diverge, and data transfers may not be possible and/or new arrangements may need to be put in place. In particular, it is unclear to what extent the United Kingdom regime will begin diverging from the GDPR and how data transfers to and from the United Kingdom will be regulated.

In addition, California recently enacted the CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA became effective on January 1, 2020, but the California Privacy Rights Act was recently enacted to strengthen elements of the CCPA effective January 1, 2023. In addition, there are a number of other states that have considered similar privacy proposals, with states like Virginia and Colorado enacting their own privacy laws (also scheduled to come into effect in January 1, 2023 and July 1, 2023, respectively). These privacy laws may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Changes in tax law or policy could increase our effective tax rate and tax liability or the taxes payable by holders of our ordinary shares, each of which could have a material adverse effect on our business, financial condition and results of operations.

We could be adversely affected by changes in applicable tax laws, regulations, or administrative interpretations thereof. For example, the U.S. federal tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"), enacted in December 2017, resulted in fundamental changes to the Internal Revenue Code of 1986, as amended (the "Code") including, among many other things, a reduction to the federal corporate income tax rate, a partial limitation on the deductibility of business interest expense, a limitation on the deductibility of certain director and officer compensation expense, limitations on net operating loss carrybacks and carryovers and changes relating to the scope and timing of U.S. taxation on earnings from international business operations. Subsequent legislation, the Coronavirus Aid, Relief, and Economic Security Act (the

“CARES Act”) enacted on March 27, 2020, relaxed certain of the limitations imposed by the Tax Act for certain taxable years, including the limitation on the use and carryback of net operating losses and the limitation on the deductibility of business interest expense. The exact impact of the Tax Act and the CARES Act for future years is difficult to quantify, but these changes could materially affect our investors, the companies in which our clients invest, or us. Legislative proposals in the U.S., if adopted, would increase the corporate income tax rate and capital gains tax rate. In addition, other changes could be enacted in the future to limit further the deductibility of interest, subject carried interests to more onerous taxation or effect other changes that could have a material adverse effect on our business, results of operations and financial condition. Such changes could also include increases in state taxes and other changes to state tax laws to replenish state and local government finances depleted by costs attributable to the COVID-19 pandemic and the reduction in tax revenues due to the accompanying economic downturn.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are or may become subject to taxation in more than one tax jurisdiction. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of newly enacted tax legislation, changes in the mix of our profitability from jurisdiction to jurisdiction, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

We may be a passive foreign investment company, or “PFIC,” which could result in adverse U.S. federal income tax consequences to U.S. investors.

ProKidney believes that it is likely classified as a PFIC for U.S. federal income tax purposes. If we are a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U.S. Holder of our Class A ordinary shares, such U.S. Holder may be subject to adverse U.S. federal income tax consequences and may be subject to additional reporting requirements. There can be no assurances with respect to our status as a PFIC for our current taxable year or any subsequent taxable year. Our actual PFIC status for any taxable year, moreover, will not be determinable until after the end of such taxable year. If we determine we are a PFIC for any taxable year (of which there can be no assurance), we will endeavor to provide to a U.S. Holder such information as the IRS may require, including a PFIC Annual Information Statement, upon request, in order to enable a U.S. Holder to make and maintain a “qualified electing fund” election. There can be no assurance, however, that ProKidney will timely provide such information. For more information, please see the section entitled “*Certain Material U.S. and Non-Income Tax Considerations—U.S. Holders—PFIC Considerations.*” We urge U.S. investors to consult their own tax advisors regarding the possible application of the PFIC rules.

Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could adversely affect our financial condition and results of operations.

We will be subject, directly or indirectly, to income taxes in various jurisdictions, and our tax liabilities will be subject to the allocation of expenses in differing jurisdictions. Our future effective tax rates could be subject to volatility or adversely affected by a number of factors, including:

- changes in the valuation of our deferred tax assets and liabilities;
- expected timing and amount of the release of any tax valuation allowances;
- tax effects of share-based compensation;

[Table of Contents](#)

- costs related to intercompany restructurings;
- changes in tax laws, regulations or interpretations thereof; or
- lower-than-anticipated future earnings in jurisdictions where we have lower statutory tax rates and higher-than-anticipated future earnings in jurisdictions where we have higher statutory tax rates.

In addition, we may be subject to audits of our income, sales and other transaction taxes by taxing authorities. Outcomes from these audits could have an adverse effect on our financial condition and results of operations.

Our principal shareholders have significant influence over us, including over decisions that require the approval of shareholders, and their interests may conflict with the interests of holders of ProKidney Corp. Class A ordinary shares.

The Voting Agreement provides, with respect to the election, appointment or removal of any director of the Company, that, until the third anniversary of the Closing, CEC will vote all of its voting shares in the capital of the Company in a manner proportionate to the manner in which all other ProKidney Class B ordinary shares not held by CEC are voted. As a result, Tolerantia effectively controls approximately 64.7% (accounting for approximately 23.9% held by CEC) of the combined voting power of ProKidney Corp. with respect to the election, appointment or removal of any director. Additionally, Pablo Legorreta, as Chairperson of the Board, is affiliated with and majority owns and controls Tolerantia. As a result, Tolerantia and its affiliates have significant influence over the management and affairs of the Company, and, acting together, effectively control the election, appointment or removal of any director and have indirect control over the approval of significant corporate transactions, including any merger, consolidation or sale of all or substantially all of our assets and the issuance or redemption of equity interests in certain circumstances, to the extent such matters require approval of the Board.

In addition, Tolerantia and CEC together control approximately 64.7% of the combined voting power of the Company. The interests of these shareholders may not always coincide with, and in some cases may conflict with, our interests and the interests of our other shareholders, including the holders of ProKidney Class A ordinary shares. For instance, these shareholders could attempt to delay or prevent a change in control, even if such change in control would benefit our other shareholders, which could deprive our shareholders of an opportunity to receive a premium for their ProKidney Class A ordinary shares. This concentration of ownership may also affect the prevailing market price of our ProKidney Class A ordinary shares due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in your best interests.

Further, because these shareholders hold their economic interest in our business through ProKidney LP, rather than through ProKidney Corp., their interests may further conflict with the interests of holders of ProKidney Class A ordinary shares. For example, such holders may have different tax positions from ProKidney Corp., which could influence their decisions regarding whether and when ProKidney Corp. should dispose of assets or incur new or refinance existing indebtedness, and whether and when ProKidney Corp. should undergo certain changes of control within the meaning of the Tax Receivable Agreement or terminate the Tax Receivable Agreement. In addition, the structuring of future transactions may take into consideration these tax or other considerations even where no similar benefit would accrue to ProKidney Corp. These holders' significant ownership in ProKidney Corp. and resulting ability, acting together, to effectively control us may discourage someone from making a significant equity investment in ProKidney Corp., or could discourage transactions involving a change in control, including transactions in which a holder of ProKidney Class A ordinary shares might otherwise receive a premium for their shares over the then-current market price.

Because we are a “controlled company” within the meaning of the Nasdaq rules, our shareholders may not have certain corporate governance protections that are available to shareholders of companies that are not controlled companies.

So long as more than 50% of the voting power for the election of directors is held by an individual, a group or another company, we will qualify as a “controlled company” within the meaning of the Nasdaq corporate governance standards. Pursuant to the terms of the Voting Agreement, Tolerantia effectively controls a majority of the voting power of all outstanding ProKidney Corp. ordinary shares with respect to the election, appointment or removal of any director. As a result, we are a “controlled company” within the meaning of the Nasdaq corporate governance standards and are not subject to the requirements that would otherwise require us to have: (i) a majority of our board of directors consist of independent directors, (ii) subject to the exception pursuant to Nasdaq Listing Rule 5605(b)(2), our board of directors have a compensation committee that is composed of at least two members, each of whom is an independent director, with a written charter addressing the committee’s purpose and responsibilities and (iii) director nominees must be selected, or recommended for the board’s selection, either by independent directors constituting a majority of the board’s independent directors in a vote in which only independent directors participate, or by a nominating and corporate governance committee comprised solely of independent directors with a written charter addressing the committee’s purpose and responsibilities. Pursuant to the requirements under the Business Combination Agreement, a majority of the directors of the Board are “independent” directors for the purposes of the Nasdaq Listing Rules, but for at least some period following the Business Combination, we may utilize the other exemptions described above.

Tolerantia may have its interest in the Company diluted due to future equity issuances or its own actions in selling shares of the Company, in each case, which could result in a loss of the “controlled company” exemption under the Nasdaq listing rules. We would then be required to comply with those provisions of the Nasdaq listing requirements.

Antitakeover provisions contained in our Charter, as well as provisions of Cayman Islands law, could impair a takeover attempt.

Our Charter contains provisions that may discourage unsolicited takeover proposals that shareholders may consider to be in their best interests. These provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. These provisions will include, among other things:

- no cumulative voting in the election of directors, which limits the ability of minority shareholders to elect director candidates;
- a classified board of directors with three-year staggered terms, which could delay the ability of shareholders to change the membership of a majority of the Board;
- the requirement that directors may only be removed from the Board by special resolution;
- the right of the Board to elect a director to fill a vacancy of the Board created by the expansion of the Board or the resignation, death, or removal of a director in certain circumstances, which prevents shareholders from being able to fill vacancies on the Board;
- a prohibition on shareholders calling an extraordinary general meeting and the requirement that a meeting of shareholders may only be called by members of the Board, which may delay the ability of our shareholders to force consideration of a proposal or to take action, including the removal of directors; and
- the right of the Board to issue and set the voting and other rights of preference shares, which could adversely affect the voting power and other rights of the holders of ordinary shares.

The JOBS Act permits “emerging growth companies” like us to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies.

We currently qualify as an “emerging growth company” as defined in Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, we take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including: (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 of SOX; (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements; and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. As a result, our shareholders may not have access to certain information they deem important. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year: (a) following July 2, 2026, the fifth (5th) anniversary of our IPO; (b) in which we have total annual gross revenue of at least \$1.07 billion; or (c) in which we are deemed to be a large accelerated filer, which means the market value of our Class A ordinary shares that is held by non-affiliates equals or exceeds \$700 million as of the last business day of our prior second fiscal quarter, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Additionally, we are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our ordinary shares that is held by non-affiliates exceeds \$250 million as of the last business day of the prior fiscal quarter, or (ii) our annual revenues equaled or exceeded \$100 million during such completed fiscal year, and the market value of our ordinary shares that is held by non-affiliates equals or exceeds \$700 million as of the last business day of the prior second fiscal quarter.

We cannot predict if investors will find our Class A ordinary shares less attractive because we rely on these exemptions. If some investors find our Class A ordinary shares less attractive as a result, there may be a less active trading market for our Class A ordinary shares, and our share price may be more volatile.

Our internal controls over financial reporting may not be effective and our independent registered public accounting firm may not be able to certify as to their effectiveness, which could have a significant and adverse effect on our business and reputation.

As a public company, we are required to comply with the SEC’s rules implementing Sections 302 and 404 of SOX, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. To comply with the requirements of being a public company, we will be required to provide attestation on internal

controls commencing with the annual report for fiscal year ended December 31, 2022, and we may need to undertake various actions, such as implementing additional internal controls and procedures and hiring additional accounting or internal audit staff. The standards required for a public company under Section 404 of SOX are significantly more stringent than those that were previously required of us as a privately held company. Further, as an emerging growth company, our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 until the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event that it is not satisfied with the level at which our controls are documented, designed or operating.

Testing and maintaining these controls can divert our management's attention from other matters that are important to the operation of our business. If we identify material weaknesses in our internal control over financial reporting or are unable to comply with the requirements of Section 404 or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting when we no longer qualify as an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our ordinary shares could be negatively affected, and we could become subject to investigations by the SEC or other regulatory authorities, which could require additional financial and management resources.

Risks Related to our Organizational Structure

We are a limited partner of ProKidney LP but may, in certain circumstances, lose the benefit of limited liability.

We are a limited partner of ProKidney LP, a limited partnership registered under the laws of Ireland.

Under the Irish LP Act, limited partners of Irish limited partnerships will not be liable for the debts or obligations of the partnership beyond the amount of capital they have contributed. However, the Irish LP Act also provides that such limited liability may be lost if (i) a limited partner (such as ProKidney Corp.) takes part in the management of the business of the partnership, (ii) there is a failure to register ProKidney LP as a limited partnership or any change to the registration details of ProKidney LP, including changes to the name of ProKidney LP, the general nature of the business of ProKidney LP, the principal place of business of ProKidney LP, the partners or the name of any partner of ProKidney LP, the term of character of ProKidney LP, the sum contributed by any limited partner or the liability of any partner by reason of his becoming a limited instead of a general partner or a general instead of a limited partner; and (iii) a limited partner withdraws some or a part of his, her or its capital, in which circumstance he, she or it will be liable for the debts and obligations of the firm up to the amount so withdrawn.

We are a holding company, and our only material asset is our interest in ProKidney LP, and we are accordingly dependent upon distributions made by our subsidiaries to pay taxes, make payments under the Tax Receivable Agreement and pay dividends.

We are a holding company with no material assets other than our ownership of Post-Combination ProKidney Common Units. As a result, we have no independent means of generating revenue or cash flow. Our ability to pay taxes, make payments under the Tax Receivable Agreement and pay dividends, if any, will depend on the financial results and cash flows of ProKidney LP and its subsidiaries and the distributions we receive from ProKidney LP. Deterioration in the financial condition, earnings or cash flow of ProKidney LP and its subsidiaries, for any reason, could limit or impair our ability to pay such distributions. Additionally, to the extent that we need funds and ProKidney LP and/or any of its subsidiaries are restricted from making such distributions under applicable law or regulation or under the terms of any financing arrangements, or ProKidney LP is otherwise unable to provide such funds, it could materially adversely affect our liquidity and financial condition.

Subject to the potential risk of being treated as a publicly traded partnership discussed below, ProKidney LP will continue to be treated as a partnership for U.S. federal income tax purposes and, as such, generally will not be subject to any entity-level U.S. federal income tax. Instead, the taxable income of ProKidney LP will be allocated to holders of Post-Combination ProKidney Common Units, including ProKidney Corp. Accordingly, we may be required to pay income taxes on our allocable share of any net taxable income of ProKidney LP (e.g., U.S. federal income and branch profits tax to the extent such net taxable income is effectively connected to the conduct of a trade or business in the United States). Under the terms of the Second Amended and Restated ProKidney Limited Partnership Agreement, ProKidney LP is obligated to make tax distributions to holders of Post-Combination ProKidney Common Units (including ProKidney Corp.) calculated at certain assumed tax rates. In addition to tax expenses, we will also incur expenses related to our operations, including payment obligations under the Tax Receivable Agreement (and the cost of administering such payment obligations), which could be significant and some of which may be reimbursed by ProKidney LP (excluding payment obligations under the Tax Receivable Agreement). We intend to cause ProKidney LP to make distributions to holders of Post-Combination ProKidney Common Units pro rata, in amounts sufficient to cover all applicable income taxes (calculated at assumed tax rates), relevant operating expenses, payments required to be made by us under the Tax Receivable Agreement and dividends, if any, declared by us. However, as discussed below, ProKidney LP's ability to make such distributions may be subject to various limitations and restrictions including, but not limited to, restrictions on distributions that would either violate any contract or agreement to which ProKidney LP is then a party, including debt agreements, or any applicable law, or that would have the effect of rendering ProKidney LP insolvent. If our cash resources are insufficient to meet our obligations under the Tax Receivable Agreement and to fund our obligations, we may be required to incur additional indebtedness to provide the liquidity needed to make such payments, which could materially adversely affect its liquidity and financial condition and subject us to various restrictions imposed by any such lenders. To the extent that we are unable to make payments under the Tax Receivable Agreement for any reason, such payments will be deferred and will accrue interest until paid; *provided, however*, that nonpayment for a specified period may constitute a material breach of a material obligation under the Tax Receivable Agreement and therefore accelerate payments due under the Tax Receivable Agreement, which could be substantial.

Additionally, although ProKidney LP generally will not be subject to any entity-level U.S. federal income tax, it may be liable under federal tax legislation for adjustments to its tax return, absent an election to the contrary. In the event ProKidney LP's calculations of taxable income are incorrect, its members, including ProKidney Corp., in later years may be subject to material liabilities pursuant to this federal legislation and its related guidance.

We anticipate that the distributions we will receive from ProKidney LP may, in certain periods, exceed our actual tax liabilities and obligations to make payments under the Tax Receivable Agreement. The Board, in its sole discretion, may make any determination from time to time with respect to the use of any such excess cash so accumulated, which may include, among other uses, to pay dividends on ProKidney Class A ordinary shares. We will have no obligation to distribute such cash (or other available cash other than any declared dividend) to our shareholders.

Dividends on ProKidney Class A ordinary shares, if any, will be paid at the discretion of the Board, which will consider, among other things, our business, operating results, financial condition, current and expected cash needs, plans for expansion and any legal or contractual limitations on our ability to pay such dividends. Financing arrangements may include restrictive covenants that restrict our ability to pay dividends or make other distributions to our shareholders. Under the Irish LP Act, a limited partner of ProKidney LP may lose its limited liability where such limited partner withdraws some or a part of his, her or its contribution to ProKidney LP, in which circumstance he, she or it will be liable for debts and obligations of ProKidney up to the amount so withdrawn.

ProKidney's subsidiaries are generally subject to similar legal limitations on their ability to make distributions to ProKidney. If ProKidney does not have sufficient funds to make distributions, our ability to declare and pay cash dividends may also be restricted or impaired.

In certain circumstances, ProKidney LP will be required to make distributions to us and the other holders of Post-Combination ProKidney Common Units, and the distributions that ProKidney LP will be required to make may be substantial.

ProKidney LP will generally be required from time to time to make pro rata distributions in cash to us and the other holders of Post-Combination ProKidney Common Units at certain assumed tax rates in amounts that are intended to be sufficient to cover the taxes on our and the other holders of Post-Combination ProKidney Common Units respective allocable shares of the taxable income of ProKidney LP. As a result of (i) potential differences in the amount of net taxable income allocable to us and the other holders of Post-Combination ProKidney Common Units, (ii) the lower tax rate applicable to corporations than individuals, (iii) our status as a non-U.S. person and (iv) the use of an assumed tax rate (the highest effective marginal combined U.S. federal, state and local income tax rate prescribed for an individual or corporate resident of New York, New York) in calculating ProKidney LP's distribution obligations, we may receive tax distributions significantly in excess of our tax liabilities and obligations to make payments under the Tax Receivable Agreement. We will determine in its sole discretion the appropriate uses for any excess cash so accumulated, which may include, among other uses, dividends, the payment of obligations under the Tax Receivable Agreement and the payment of other expenses. We will have no obligation to distribute such excess cash (or other available cash other than any declared dividend) to the holders of ProKidney Class A ordinary shares. No adjustments to the redemption or exchange ratio of Post-Combination ProKidney Common Units for ProKidney Class A ordinary shares will be made as a result of either (i) any cash dividend by us or (ii) any cash that we retain and do not distribute to our shareholders. To the extent that we do not distribute such excess cash as dividends on ProKidney Class A ordinary shares and instead, for example, holds such cash balances or lends them to ProKidney LP, holders of Post-Combination ProKidney Common Units would benefit from any value attributable to such cash balances as a result of their ownership of ProKidney Class A ordinary shares following a redemption or exchange of their ProKidney Common Units.

Under the Tax Receivable Agreement, we are required to pay 85% of certain tax savings recognized by ProKidney Corp. as a result of the increases in tax basis of ProKidney assets attributable to the exchanges of ProKidney Common Units for ProKidney Class A ordinary shares and certain other tax benefits, and those payments may be substantial.

The Closing ProKidney Unitholders may exchange their Post-Combination ProKidney Common Units for ProKidney Class A ordinary shares or, subject to certain restrictions, cash, pursuant to the Exchange Agreement, subject to certain conditions and transfer restrictions as set forth therein and in the Second Amended and Restated ProKidney Limited Partnership Agreement. These exchanges are expected to result in increases in our allocable share of the tax basis of the tangible and intangible assets of ProKidney LP. These increases in tax basis may increase (for tax purposes) depreciation and amortization deductions and therefore reduce the amount of income or franchise tax that we would otherwise be required to pay in the future had such exchanges never occurred.

In connection with the Business Combination, we entered into the Tax Receivable Agreement, which generally provides for the payment by it of 85% of certain tax savings, if any, that we recognize as a result of these increases in tax basis and certain other tax attributes of ProKidney LP and tax benefits related to entering into the Tax Receivable Agreement. These payments are the obligation of ProKidney Corp. and not of ProKidney LP. The actual increase in our allocable share of ProKidney's tax basis in its assets, as well as the amount and timing of any payments under the Tax Receivable Agreement, will vary depending upon a number of factors, including the timing of exchanges, the market price of the Class A ordinary share at the time of the exchange, the extent to which such exchanges are taxable and the amount and timing of the recognition of our income. Many of the factors that will determine the amount of payments that we will make under the Tax Receivable Agreement are outside of our control and such payments, if any, could be substantial and could have a material adverse effect on our financial condition. Even assuming, among other things, that there are no material changes in relevant tax law, that ProKidney LP's enterprise value is equal to the enterprise value that was agreed to in the

Business Combination at the time all Post-Combination ProKidney Common Units are exchanged, and that there are significant future redemptions or exchanges of Post-Combination ProKidney Common Units, payments under the Tax Receivable Agreement are not expected to be material because ProKidney LP does not currently (i) plan to migrate business operations to the United States, or (ii) otherwise anticipate tax benefits outside of the United States from redemptions or exchanges of Post-Combination ProKidney Common Units that would trigger obligations under the Tax Receivable Agreement based upon the intended operations of ProKidney LP outside the United States. In addition, because ProKidney LP does not currently have business operations in the United States and does not expect to generate significant operating revenues in the near future, if at all, payments under the Tax Receivable Agreement in the near future, if any, are not expected to be material. If, contrary to current intended business operations and strategy, the business operations are migrated to the United States, the business operations outside of the United States change, or there are material changes in relevant tax law, then payments under the Tax Receivable Agreement could be material. Any payments made by us under the Tax Receivable Agreement will generally reduce the amount of overall cash flow that might have otherwise been available to us. To the extent that we are unable to make timely payments under the Tax Receivable Agreement for any reason, the unpaid amounts will be deferred and will accrue interest until paid. Furthermore, our future obligation to make payments under the Tax Receivable Agreement could make it a less attractive target for an acquisition, particularly in the case of an acquirer that cannot use some or all of the tax benefits that may be deemed realized under the Tax Receivable Agreement.

In certain cases, payments under the Tax Receivable Agreement may exceed the actual tax benefits we realize or may be accelerated.

Payments under the Tax Receivable Agreement will be based on the tax reporting positions that we determine, and the IRS or any other taxing authorities may challenge all or any part of the tax basis increases, as well as other tax positions that we take, and a court may sustain such a challenge. In the event any tax benefits initially claimed by us are disallowed, the current Closing ProKidney Unitholders will not be required to reimburse us for any excess payments that may previously have been made under the Tax Receivable Agreement, for example, due to adjustments resulting from examinations by taxing authorities. Rather, excess payments made to such holders will be netted against any future cash payments otherwise required to be made by us, if any, after the determination of such excess. However, a challenge to any tax benefits initially claimed by us may not arise for a number of years following the initial time of such payment or, even if challenged early, such excess cash payment may be greater than the amount of future cash payments that we might otherwise be required to make under the terms of the Tax Receivable Agreement and, as a result, there might not be future cash payments from which to net against. As a result, in certain circumstances we could make payments under the Tax Receivable Agreement in excess of our actual income or franchise tax savings, which could materially impair our financial condition.

Moreover, the Tax Receivable Agreement provides that, in the event that (i) we exercise our early termination rights under the Tax Receivable Agreement, (ii) the Tax Receivable Agreement is rejected by operation of law in a bankruptcy case, (iii) certain changes of control of ProKidney Corp. occur (as described in the Tax Receivable Agreement) or (iv) we are more than three months late in making a payment due under the Tax Receivable Agreement (unless we in good faith determine that we have insufficient funds to make such payment) or otherwise materially breach any of our material obligations under the Tax Receivable Agreement, our obligations under the Tax Receivable Agreement will accelerate, and we will be required to make an immediate lump-sum cash payment to the Closing ProKidney Unitholders equal to the present value of all forecasted future payments that would have otherwise been made under the Tax Receivable Agreement, which lump-sum payment would be based on certain assumptions, including those relating to our future taxable income. The lump-sum payment to the Closing ProKidney Unitholders could be substantial and could exceed the actual tax benefits that we realize subsequent to such payment because such payment would be calculated assuming, among other things, that we would be able to use the assumed potential tax benefits in future years, and that tax rates applicable to us would be the same as they were in the year of the termination.

[Table of Contents](#)

There may be a material negative effect on our liquidity if the payments under the Tax Receivable Agreement exceed the actual income or franchise tax savings that we realize. Furthermore, our obligations to make payments under the Tax Receivable Agreement could also have the effect of delaying, deferring or preventing certain mergers, asset sales, other forms of business combinations or other changes of control. We may need to incur additional indebtedness to finance payments under the Tax Receivable Agreement to the extent our cash resources are insufficient to meet our obligations under the Tax Receivable Agreement as a result of timing discrepancies or otherwise. Such indebtedness may have a material adverse effect on our financial condition.

Finally, because we are a holding company with no operations of our own, our ability to make payments under the Tax Receivable Agreement depends on the ability of ProKidney LP to make distributions to us. To the extent that we are unable to make payments under the Tax Receivable Agreement for any reason, such payments will be deferred and will accrue interest until paid, which could negatively impact our results of operations and could also affect our liquidity in periods in which such payments are made.

If ProKidney LP were to become a publicly traded partnership taxable as a corporation for U.S. federal income tax purposes, we and ProKidney LP might be subject to potentially significant tax inefficiencies, and we would not be able to recover payments previously made by us under the Tax Receivable Agreement even if the corresponding tax benefits were subsequently determined to have been unavailable due to such status.

We intend to operate such that ProKidney LP does not become a publicly traded partnership taxable as a corporation for U.S. federal income tax purposes. A “publicly traded partnership” is a partnership the interests of which are traded on an established securities market or are readily tradable on a secondary market or the substantial equivalent thereof. Under certain circumstances, exchanges of Post-Combination ProKidney Common Units pursuant to the Exchange Agreement or other transfers of Post-Combination ProKidney Common Units could cause ProKidney LP to be treated as a publicly traded partnership. Applicable Treasury Regulations provide for certain safe harbors from treatment as a publicly traded partnership, and we intend to operate such that exchanges or other transfers of Post-Combination ProKidney Common Units qualify for one or more such safe harbors. For example, the Exchange Agreement and the Second Amended and Restated ProKidney Limited Partnership Agreement, which were entered into in connection with the consummation of the Business Combination, provide for limitations on the ability of ProKidney Unitholders to transfer their Post-Combination ProKidney Common Units and provide us with the right to cause the imposition of limitations and restrictions (in addition to those already in place) on the ability of ProKidney Unitholders to exchange their Post-Combination ProKidney Common Units, including pursuant to the Exchange Agreement, to the extent we believe it is necessary to ensure that ProKidney LP will continue to be treated as a partnership for U.S. federal income tax purposes.

If ProKidney LP were to become a publicly traded partnership taxable as a corporation for U.S. federal income tax purposes, significant tax inefficiencies might result for us and ProKidney LP. For example, we may not be able to realize tax benefits covered under the Tax Receivable Agreement, and we would not be able to recover any payments previously made by us under the Tax Receivable Agreement, even if the corresponding tax benefits (including any claimed increase in the tax basis of ProKidney’s assets) were subsequently determined to have been unavailable.

We are a Cayman Islands exempted company. The rights of our shareholders may be different from the rights of shareholders governed by the laws of U.S. jurisdictions.

We are a Cayman Islands exempted company. Our corporate affairs will continue to be governed by our Charter and by the laws of the Cayman Islands. The rights of shareholders and the responsibilities of members of the Board may be different from the rights of shareholders and responsibilities of directors in companies governed by the laws of U.S. jurisdictions. In the performance of its duties, the board of directors of a solvent Cayman Islands exempted company is required to consider that company’s best interests, which may differ from the interests of one or more of its individual shareholders.

USE OF PROCEEDS

All of the Class A ordinary shares offered by the Selling Securityholders pursuant to this prospectus will be sold by the Selling Securityholders for their respective accounts. We will not receive any of the proceeds from these sales.

The Selling Securityholders will pay any underwriting discounts and commissions and expenses incurred by the Selling Securityholders for brokerage, accounting, tax or legal services or any other expenses incurred by the Selling Securityholders in disposing of the securities. We will bear the costs, fees and expenses incurred in effecting the registration of the securities covered by this prospectus, including all registration and filing fees, Nasdaq listing fees and fees and expenses of our counsel and our independent registered public accounting firm.

MARKET PRICE, TICKER SYMBOL AND DIVIDEND INFORMATION

Market Price and Ticker Symbol

Our Class A ordinary shares are currently listed on Nasdaq under the symbol “PROK.”

The closing price of the Class A ordinary shares on August 5, 2022, was \$7.40.

Holders

As of July 31, 2022, there were 61 holders of record of our Class A ordinary shares and 3 holders of record of our Class B ordinary shares.

Such numbers do not include beneficial owners holding our securities through nominee names. There is no public market for our Class B ordinary shares.

Dividend Policy

We have not paid any cash dividends on our Class A ordinary shares or Class B ordinary shares to date. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of the Board at such time.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

In this section, unless the context otherwise requires, the “combined company” or “ProKidney” refer to ProKidney Corp. (formerly Social Capital Suvretta Holdings Corp. III) and its subsidiaries after the Closing, “SCS” refers to SCS prior to the Closing, and “Legacy ProKidney” refers to ProKidney LP and its subsidiaries prior to the Closing.

The following unaudited pro forma condensed combined financial information for the three months ended March 31, 2022 and for the year ended December 31, 2021 combines the historical statement of operations of SCS and the historical consolidated statement of operations of Legacy ProKidney, giving effect to the Business Combination as if it had occurred on January 1, 2021. The unaudited pro forma condensed combined balance sheet as of March 31, 2022 combines the historical balance sheet of SCS and Legacy ProKidney, giving effect to the Business Combination as if it had occurred on March 31, 2022, and the unaudited pro forma condensed combined balance sheet as of December 31, 2021 combines the historical balance sheet of SCS and Legacy ProKidney, giving effect to the Business Combination as if it had occurred on December 31, 2021.

The following unaudited pro forma condensed combined financial information presents the combination of the financial information of SCS and Legacy ProKidney, adjusted to give effect to the Business Combination and other events contemplated by the Business Combination Agreement. The following unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11 of Regulation S-X as amended by the final rule, Release 33-10786 “Amendments to Financial Disclosures about Acquired and Disposed Businesses.”

The unaudited pro forma condensed combined financial information has been prepared to illustrate the effect of the Business Combination and has been prepared for informational purposes only. The unaudited pro forma condensed combined statement of operations is not necessarily indicative of what the actual results of operations would have been had the Business Combination taken place on the date indicated, nor is it indicative of the future consolidated results of operations of the combined company. The pro forma adjustments were based on the information available as of the date of these unaudited pro forma condensed combined financial statements and are subject to change as additional information becomes available and analyses are performed. Actual results may differ materially from the assumptions within the accompanying unaudited pro forma condensed combined financial information.

On July 11, 2022, SCS and Legacy ProKidney consummated the Business Combination pursuant to the Business Combination Agreement. The historical financial information has been adjusted to give pro forma effect to the following events that are related and/or directly attributable to the Business Combination. The unaudited pro forma condensed combined financial information The following pro forma condensed combined financial statements presented herein reflect the actual redemption of 22,829,769 Class A ordinary shares in conjunction with the shareholder vote on the Business Combination contemplated by the Business Combination Agreement at the extraordinary general meeting held on July 11, 2022.

The following summarizes the pro forma share ownership of the combined company’s Class A ordinary shares after giving effect to the Business Combination.

	New ProKidney Ordinary Shares	Ownership
Public Shareholders	2,170,231	0.9%
Sponsor	6,890,000	2.9%
Third Party PIPE Investors	36,840,000	15.2%
Sponsor Related PIPE Investors	15,640,000	6.5%
ProKidney Unitholders (including the ProKidney Related PIPE Investors)	<u>180,000,000</u>	<u>74.5%</u>
Total Shares Outstanding	241,540,231	100.00%

[Table of Contents](#)

The unaudited pro forma condensed combined financial information is based on and should be read in conjunction with:

- the accompanying notes to the unaudited pro forma condensed combined financial information;
- the historical unaudited condensed financial statements of SCS as of and for the three months ended March 31, 2022, the historical audited condensed financial statements for SCS as of December 31, 2021 and for the period from February 25, 2021 (date of inception) through December 31, 2021, and the related notes, in each case, included elsewhere in this prospectus;
- the historical unaudited consolidated financial statements of Legacy ProKidney as of and for the three months ended March 31, 2022, the historical audited consolidated financial statements of Legacy ProKidney as of and for the year ended December 31, 2021, and the related notes, in each case, included elsewhere in this prospectus; and
- other information relating to SCS and Legacy ProKidney contained in this prospectus, including the Business Combination Agreement and the description of certain terms thereof set forth under “*Summary of the Prospectus—Recent Developments—Business Combination Agreement*,” as well as the disclosures contained in “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*.”

UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEETS MARCH 31, 2022
(in thousands, except share and per share amounts)

	SCS Historical	ProKidney Historical	Transaction Accounting Adjustments (Note 3)	Note	Proforma Combined
Current assets					
Cash and cash equivalents	\$ 52	\$ 29,802	\$ 531,461	(a)	\$561,315
Prepaid assets	543	592	—		1,135
Prepaid clinical	—	4,855	—		4,855
Other current assets	—	—	—		—
Total current assets	<u>595</u>	<u>35,249</u>	<u>531,461</u>		<u>567,305</u>
Investments held in Trust Account	250,034	—	(250,034)	(b)	—
Fixed assets, net	—	11,103	—		11,103
Right of use assets, net	—	1,673	—		1,673
Deferred offering costs	—	5,108	(5,108)	(c)	—
Intangible assets, net	—	374	—		374
Other long term assets	124	—	—		124
Total assets	<u>\$ 250,753</u>	<u>\$ 53,507</u>	<u>\$ 276,319</u>		<u>\$580,579</u>
Current liabilities					
Accounts payable	\$ 27	\$ 2,509	\$ (34)		\$ 2,502
Lease liabilities	—	328	—		328
Accrued expenses and other	5,342	8,117	—		13,459
Related party notes payable	—	20,000	(20,000)	(d)	—
Income taxes payable	—	958	—		958
Advances from related party	44	—	(44)	(e)	—
Total current liabilities	<u>5,413</u>	<u>31,912</u>	<u>(20,078)</u>		<u>17,247</u>
Long term liabilities					
Deferred underwriting fee payable	7,700	—	(7,700)	(f)	—
Lease liabilities, net of current portion	—	1,428	—		1,428
Tax Receivable Agreement liability	—	—	—	(g)	—
Temporary equity:					
Class A ordinary shares subject to possible redemption	250,000	—	(250,000)	(h)	—
Redeemable noncontrolling interest	—	—	422,491	(i)	422,491
ProKidney Corp.:					
ProKidney Corp. Class A ordinary shares	—	—	58	(j),(h),(o)	58
ProKidney Corp. Class B ordinary shares	—	—	18	(k)	18
SCS:					
SCS Preference shares, \$0.0001 par value	—	—	—		—
SCS Class A ordinary shares, \$0.0001 par value	—	—	—		—
SCS Class B ordinary shares, \$0.0001 par value	1	—	(1)	(o)	—
ProKidney:					
ProKidney - Class A Units	—	186,500	(186,500)	(k)	—
ProKidney - Class B Units	—	62,663	(62,663)	(k)	—
Additional paid-in capital	—	—	131,531	(k),(l)	131,531
Accumulated deficit	(12,361)	(228,996)	249,163	(k)	7,806
Total equity	<u>(12,360)</u>	<u>20,167</u>	<u>131,606</u>		<u>139,413</u>
Total liabilities, redeemable noncontrolling interest and equity	<u>\$ 250,753</u>	<u>\$ 53,507</u>	<u>\$ 276,319</u>		<u>\$580,579</u>

UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEETS DECEMBER 31, 2021
(in thousands, except share and per share amounts)

	SCS Historical	ProKidney Historical	Transaction Accounting Adjustments (Note 3)	Note	Proforma Combined
Current assets					
Cash and cash equivalents	\$ 440	\$ 20,558	\$ 551,493	(a)	\$572,491
Prepaid assets	505	588	—		1,093
Prepaid clinical	—	6,100	—		6,100
Other current assets	—	25	—		25
Total current assets	<u>945</u>	<u>27,271</u>	<u>551,493</u>		<u>579,709</u>
Investments held in Trust Account	250,008	—	(250,008)	(b)	—
Fixed assets, net	—	11,358	—		11,358
Right of Use assets, net	—	1,241	—		1,241
Intangible assets, net	—	428	—		428
Other long term assets	248	—	—		248
Total assets	<u>\$ 251,201</u>	<u>\$ 40,298</u>	<u>\$ 301,485</u>		<u>\$592,984</u>
Current liabilities					
Accounts payable	\$ 1,870	\$ 2,834	\$ —		\$ 4,704
Lease liabilities	—	267	—		267
Accrued expenses and other	—	9,213	—		9,213
Advances from related party	10	—	(10)	(c)	—
Total current liabilities	<u>1,880</u>	<u>12,314</u>	<u>(10)</u>		<u>14,184</u>
Long term liabilities					
Deferred underwriting fee payable	7,700	—	(7,700)	(d)	—
Lease liabilities, net of current portion	—	1,067	—		1,067
Tax Receivable Agreement liability	—	—	—	(m)	—
Temporary equity:					
Class A ordinary shares subject to possible redemption	250,008	—	(250,008)	(e)	—
Redeemable noncontrolling interest	—	—	430,480	(f)	430,480
New ProKidney:					
New ProKidney Class A ordinary shares	—	—	58	(g),(e),(l)	58
New ProKidney Class B ordinary shares	—	—	18	(h)	18
SCS:					
SCS Preference shares, \$0.0001 par value	—	—	—		—
SCS Class A ordinary shares, \$0.0001 par value	—	—	—		—
SCS Class B ordinary shares, \$0.0001 par value	1	—	— (1)	(l)	—
ProKidney:					
ProKidney - Class A Units	—	186,500	(186,500)	(h)	—
ProKidney - Class B Units	—	1,927	(1,927)	(h)	—
Additional paid-in capital	—	—	128,648	(h),(i)	128,648
Accumulated deficit	(8,388)	(161,510)	188,427	(h)	18,529
Total equity	<u>(8,387)</u>	<u>26,917</u>	<u>128,723</u>		<u>147,253</u>
Total liabilities, redeemable noncontrolling interest and equity	<u>\$ 251,201</u>	<u>\$ 40,298</u>	<u>\$ 301,485</u>		<u>\$592,984</u>

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED MARCH 31, 2022
(in thousands, except share and per share amounts)

	<u>SCS Historical</u>	<u>ProKidney Historical</u>	<u>Transaction Accounting Adjustments (Note 3)</u>	<u>Note</u>	<u>Proforma Combined</u>
Operating expenses					
Research and development	\$ —	\$ 28,490	\$ —		\$ 28,490
Operation and formation costs	4,006	—	—		4,006
General and administrative	—	37,972	—		37,972
Total operating expenses	<u>4,006</u>	<u>66,462</u>	<u>—</u>		<u>70,468</u>
Operating loss	(4,006)	(66,462)	—		(70,468)
Other income					
Interest expense	—	(14)	—		(14)
Interest income	25	—	(8)	(aa)	17
Total other income	25	(14)	(8)		3
Net loss before income taxes	(3,981)	(66,476)	(8)		(70,465)
Income tax expense	—	1,010	—	(bb)	1,010
Net loss	<u>(3,981)</u>	<u>(67,486)</u>	<u>(8)</u>		<u>(71,475)</u>
Net loss attributable to noncontrolling interest	—	—	(53,264)	(cc)	(53,264)
Net loss available to Class A ordinary shares	<u>\$ (3,981)</u>	<u>\$ (67,486)</u>	<u>\$ 53,256</u>		<u>\$ (18,211)</u>
Weighted average Class A ordinary shares, basic and diluted					<u>61,540,231</u>
Net loss per share attributable to Class A ordinary shares, basic and diluted					\$ (0.30) (dd)

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENTS OF OPERATIONS
FOR THE YEAR ENDED DECEMBER 31, 2021
(in thousands, except share and per share amounts)

	<u>SCS Historical</u>	<u>ProKidney Historical</u>	<u>Transaction Accounting Adjustments (Note 3)</u>	<u>Note</u>	<u>Proforma Combined</u>
Operating expenses					
Research and development	\$ —	\$ 46,255	\$ —		\$ 46,255
Operation and formation costs	2,333		—		2,333
General and administrative	—	8,855	—		8,855
Total operating expenses	<u>2,333</u>	<u>55,110</u>	<u>—</u>		<u>57,443</u>
Operating loss	(2,333)	(55,110)	—		(57,443)
Other income					
Interest income	8	2	(8)	(aa)	2
Total other income	8	2	(8)		2
Net loss before income taxes	(2,325)	(55,108)	(8)		(57,441)
Income tax expense	—	38	—	(bb)	38
Net loss	<u>(2,325)</u>	<u>(55,146)</u>	<u>(8)</u>		<u>(57,479)</u>
Net loss attributable to noncontrolling interest	—	—	(42,834)	(cc)	(42,834)
Net loss available to Class A ordinary shares	<u>\$ (2,325)</u>	<u>\$ (55,146)</u>	<u>\$ 42,826</u>		<u>\$ (14,645)</u>
Weighted average Class A ordinary shares, basic and diluted					<u>61,540,231</u>
Net loss per share attributable to Class A ordinary shares, basic and diluted					\$ (0.24) (dd)

NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of Transaction

On July 11, 2022, SCS and Legacy ProKidney consummated the Business Combination contemplated by the Business Combination Agreement.

Following the Closing, the combined company was organized in an umbrella partnership-C corporation (or “Up-C”) structure, and the combined company’s direct assets consisted of Post-Combination ProKidney Common Units and all of the issued and outstanding equity interests of GP, which replaced Legacy GP as the general partner of Legacy ProKidney upon the Closing, and substantially all of the operating assets and business of the combined company is held indirectly through Legacy ProKidney, as described further below. ProKidney is domiciled in the Cayman Islands.

Pursuant to the Business Combination Agreement, the following transactions occurred:

- prior to the Closing: (i) Legacy ProKidney amended and restated the ProKidney Limited Partnership Agreement to be in the form of the Second Amended and Restated ProKidney Limited Partnership Agreement, which became effective upon the completion of the Business Combination; (ii) GP amended and restated its constitution, which became effective upon the completion of the Business Combination; (iii) SCS obtained the requisite approvals to amend and restate its amended and restated the memorandum and articles of association then in effect to be in the form of the Charter, which became effective upon the completion of the Business Combination; (iv) (A) each issued and outstanding Legacy ProKidney Class B Unit that was not vested pursuant to the terms of the applicable award agreement with the PMEL Existing Holder as of such time was recapitalized into one PMEL RCU, which would, when vested in accordance with the applicable award agreement, automatically convert into a Post-Combination ProKidney Common Unit (and the associated Legacy ProKidney Class B PMEL RSR would vest) and (B) all other issued and outstanding Legacy ProKidney Class A Units and ProKidney Class B Units were recapitalized into an aggregate number of Post-Combination ProKidney Common Units equal to (x) 175,000,000 minus (y) the number of PMEL RCUs issued pursuant to the foregoing clause (A); (v) Legacy ProKidney completed a restructuring of PMEL; and (vi) Legacy ProKidney issued 5,000,000 Post-Combination ProKidney Common Units pursuant to certain Subscription Agreements in connection with the election by certain holders to purchase Post-Combination ProKidney Common Units in lieu of SCS Class A ordinary shares; and
- at the Closing: (i) Legacy ProKidney issued to SCS a number of Post-Combination ProKidney Common Units equal to the number of fully diluted outstanding SCS ordinary shares as of immediately prior to the Closing (but after giving effect to all redemptions of SCS Class A ordinary shares and the purchase of SCS Class A ordinary shares and/or Post-Combination ProKidney Common Units pursuant to the PIPE Investment), in exchange for (a) (x) ProKidney Class B ordinary shares, which shares have no economic rights but entitle the holders thereof to vote on all matters on which shareholders of the combined company are entitled to vote generally, and (y) ProKidney Class B PMEL RSRs, which shall convert into ProKidney Class B ordinary shares upon the vesting of the associated PMEL RCUs (as described above), (b) an amount in cash equal to the aggregate proceeds obtained by SCS in the PIPE Investment and (c) an amount in cash equal to the aggregate proceeds available for release to SCS from the Trust Account (after giving effect to all redemptions of SCS Class A ordinary shares and after payment of any deferred underwriting commissions being held in the Trust Account and payment of certain transaction expenses); (ii) Legacy GP resigned as the general partner of Legacy ProKidney and GP was admitted as the general partner of Legacy ProKidney; (iii) Legacy ProKidney distributed to the Closing ProKidney Unitholders the ProKidney Class B ordinary shares and ProKidney Class B PMEL RSRs received pursuant to clause (i)(a) (x) and (y) above; and (iv) the Earnout Participants received the Earnout Rights, which Earnout Rights will vest in three equal tranches upon the achievement of certain ProKidney share price milestones or certain change of control events. When

[Table of Contents](#)

vested, the Earnout RCUs will automatically convert into Post-Combination ProKidney Common Units and the associated Earnout RSRs will automatically convert into ProKidney Class B ordinary shares, respectively.

Pursuant to the Exchange Agreement as described elsewhere in this prospectus, each Post-Combination ProKidney Common Unit, together with one Class B ordinary share, is generally exchangeable for one Class A ordinary share, subject to certain procedures and restrictions.

Basis of Presentation and Accounting Policies

The unaudited pro forma condensed combined financial information has been adjusted to include transaction accounting adjustments related to the Business Combination in accordance with GAAP.

We determined that the Business Combination qualified as a common control transaction and, therefore, was accounted for akin to a reverse recapitalization, with no goodwill or other intangible assets recorded, in accordance with GAAP. Legacy ProKidney is considered the accounting acquirer primarily based on the evaluation of the following facts and circumstances:

Under the guidance in ASC 805 for transactions between entities under common control, the assets, liabilities, and noncontrolling interests of Legacy ProKidney and SCS were recognized at their carrying amounts on the date of the Business Combination. Under this method of accounting, SCS was treated as the “acquired” company for financial reporting purposes. Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of Legacy ProKidney issuing shares for the net assets of SCS, accompanied by a recapitalization. The net assets of SCS were stated at their historical value within the pro formas with no goodwill or other intangible assets recorded.

- The individual controlling Legacy ProKidney prior to the Business Combination also controls the combined company as a result of the Voting Agreement, which provides Tolerantia with the majority of the votes related to the appointment and removal of the majority of the Board;
- The Legacy ProKidney unitholders prior to the Closing comprise a majority of the voting power of the combined company following the Closing;
- Senior management of Legacy ProKidney prior to the Closing comprise the senior management of the combined company following the Closing; and
- The operations of Legacy ProKidney prior to the Closing comprise the ongoing operations of the combined company following the Closing.

Upon completion of the Business Combination, GP became the sole general partner of Legacy ProKidney. Giving effect to the redemption of 22,829,769 Class A ordinary shares, ProKidney has the sole voting interest in Legacy ProKidney through its ownership of GP. As a result, ProKidney consolidated the financial results of Legacy ProKidney and reports a non-controlling interest related to the Post-Combination ProKidney Units held by Legacy ProKidney’s investors prior to the Closing on ProKidney’s consolidated balance sheet. The computation of the non-controlling interest following the Closing, based upon the various redemption scenarios shown, is as follows:

	<u>Units</u>	<u>Percentage</u>
Interest in ProKidney LP held by the Issuer	61,540,231	25.5%
Noncontrolling interest in the Issuer	180,000,000	74.5%
Total	241,540,231	100.0%

Proposed Accounting Treatment of the Earnout Rights

As discussed in this Note 1, the Earnout Participants received 17,500,000 Earnout Rights upon Closing. Upon satisfaction, during the five-year period after the Closing, of certain volume weighted average price

(“VWAP”) thresholds, or a change in control with a per share price exceeding the VWAP thresholds within a five-year period immediately following the Closing, the Earnout Rights will automatically vest and convert into Post-Combination ProKidney Common Units and ProKidney Class B ordinary shares. As the Business Combination was accounted for as a reverse recapitalization, the issuance of the Earnout Rights to the Legacy ProKidney unitholders was accounted for as an equity transaction. Since the Earnout Rights were payable to the Legacy ProKidney unitholders (i.e., the accounting acquirer in the business combination), the accounting for the Earnout Rights arrangement did not fall under Accounting Standards Codification (“ASC”) Topic 805, Business Combinations nor Topic 718, Stock Compensation.

The accounting for the Earnout Rights was also evaluated under ASC Topic 480, Distinguishing Liabilities from Equity, to determine if the arrangement should be classified as a liability. As part of that preliminary analysis, it was determined that the Earnout Rights did not meet the criteria to be accounted for as a liability. Additionally, the Earnout Rights were evaluated under ASC Topic 815, Derivatives. As part of that preliminary analysis, it was determined that the Earnout Rights met the definition of a derivative; however, they meet the scope exception criteria as they were clearly and closely related to the entity’s own shares, and met the criteria for equity treatment. Therefore, an adjustment to recognize the Earnout Rights would have no net impact on any financial statement line item as it would simultaneously increase and decrease additional paid-in capital. Thus, no adjustment has been applied to the unaudited pro forma combined financial information related to the Earnout Rights.

2. Adjustments to Unaudited Pro Forma Condensed Combined Financial Information

The unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11 of Regulation S-X. The adjustments in the unaudited pro forma condensed combined financial information have been identified and presented to provide relevant information necessary for an illustrative understanding of the combined company upon consummation of the Business Combination in accordance with GAAP.

The unaudited pro forma condensed combined financial information has been presented for illustrative purposes only and is not necessarily indicative of the operating results and financial position that would have been achieved had the Business Combination occurred on the dates indicated. The unaudited pro forma condensed combined financial information does not purport to project the future operating results or financial position of ProKidney following the completion of the Business Combination. The unaudited pro forma adjustments represent management’s estimates based on information available as of the date of this unaudited pro forma condensed combined financial information and are subject to change as additional information becomes available and analyses are performed. SCS and Legacy ProKidney did not have any historical relationship prior to the transactions. Accordingly, no pro forma adjustments were required to eliminate activities between the companies.

The unaudited pro forma condensed combined financial statements give effect to the redemption of 22,829,769 Class A ordinary shares.

3. Transaction Adjustments

Adjustments to Unaudited Pro Forma Condensed Combined Balance Sheet as of March 31, 2022

(a) Represents pro forma adjustments to cash and cash equivalents to reflect the following:

<u>(in thousands)</u>	<u>Note</u>	
SCS cash held in Trust Account	(1)	\$ 250,034
Payment of deferred underwriting fees	(2)	(7,700)
PIPE Financing	(3)	574,800
Payment to redeeming Public Stockholders	(4)	(228,329)
Payment of other transaction costs	(5)	(37,300)
Repayment of related party notes payable	(6)	(20,000)
Repayment of related party advance	(7)	(44)
Excess cash to balance sheet from Business Combination		<u>\$ 531,461</u>

- (1) Reflects the liquidation and reclassification of investments held in the Trust Account to cash and cash equivalents.
- (2) Reflects the payment of \$7.7 million of underwriters' fees deferred by SCS and which were paid at the Closing.
- (3) Reflects the gross proceeds of \$574.8 million from the issuance and sale of 57.5 million ProKidney Class A ordinary shares at \$10.00 per share pursuant to the Subscription Agreements entered into with PIPE Investors in connection with the PIPE Investment.
- (4) Represents the payments made to the holders of SCS Class A ordinary shares in connection with the redemption of 22,829,769 SCS Class A ordinary shares.
- (5) Represents transaction costs of \$37.3 million incurred by Legacy ProKidney prior to, or concurrent with, the Closing that were cash settled upon Closing in accordance with the Business Combination Agreement. Of that amount, approximately \$17.5 million related to investment transaction fees; \$11.9 million related to equity financing fees associated with the PIPE Investment, and the remaining \$7.9 million related to direct and incremental costs such as legal, tax, accounting, third-party advisory and other miscellaneous fees. This amount excluded the \$7.7 million of deferred underwriting fees related to the SCS initial public offering as described in note (2) above, any amounts relating to the ProKidney Promissory Notes, which were repaid at the Closing, and other SCS transaction costs.
- (6) Represents repayment of amounts drawn on ProKidney Promissory Notes.
- (7) Repayment of related party advance.
- (b) Reflects the liquidation and reclassification of investments held in the Trust Account to cash and cash equivalents.
- (c) Represents reclassification of Legacy ProKidney deferred offering costs incurred through March 31, 2022 to additional paid in capital as an offset to the proceeds from the transaction.
- (d) Reflects repayment of amounts drawn on the ProKidney Promissory Notes.
- (e) Repayment of related party advance.
- (f) Reflects the payment of \$7.7 million of underwriters' fees deferred by SCS for which payment is due upon the Closing.
- (g) Upon the completion of the Business Combination, the combined company became a party to the Tax Receivable Agreement. Under the terms of the Tax Receivable Agreement, the combined company is required to pay to certain parties to the agreement 85% of the tax savings that it is deemed to realize in certain circumstances as a result of certain tax attributes that exist following the Transaction and that are created thereafter, including as a result of payments made under the Tax Receivable Agreement. The combined company does not expect to record net deferred tax assets related to the tax basis adjustments associated with the exchange of Paired Interests as those deferred tax assets are not more

[Table of Contents](#)

likely than not expected to be realized in accordance with ASC 740—Income Taxes. Accordingly, the combined company has not recorded a liability related to the Tax Receivable Agreement as of December 31, 2021, as the liability is not considered to be probable in accordance with ASC 450—Contingencies.

- (h) Reflects the reclassification of SCS Class A ordinary shares, giving effect to the redemption of 22,829,769 SCS Class A ordinary shares.
- (i) As discussed in Note 1 to these unaudited pro forma condensed consolidated financial statements, the combined company will consolidate ProKidney, but does not own 100% of the economic interest in ProKidney. The noncontrolling interest reflecting actual redemptions is 74.5%.
- (j) Reflects the gross proceeds of \$574.8 million, net of an adjustment for the associated par value, from the issuance and sale of 57.5 million ProKidney Class A ordinary shares at \$10.00 per share pursuant to the Subscription Agreements entered into with PIPE Investors in connection with the PIPE Investment.
- (k) Represents the recapitalization of the Legacy ProKidney Class A and Class B Units upon issuance of ProKidney Class B ordinary shares and Class B PMEL RSRs to Closing ProKidney Unitholders.
- (l) Represents pro forma adjustments to additional paid in capital to reflect the following:

<u>(in thousands)</u>	<u>Note</u>	
PIPE Financing	(j)	\$ 574,743
Reclassification of ordinary shares subject to redemption to permanent equity	(h)	21,705
Issuance of Class B ordinary shares to existing ProKidney owners	(k)	(18)
Transaction related fees	(m)	(37,300)
Issuance of Earnout Shares	(n)	—
Reclassification of ProKidney deferred offering costs to equity upon close	(c)	(5,108)
Noncontrolling interest	(i)	(422,491)
Adjusted additional paid in capital		<u>\$ 131,531</u>

- (m) Represents transaction costs of \$37.3 million incurred by Legacy ProKidney prior to, or concurrent with, the Closing that were cash settled upon Closing in accordance with the Business Combination Agreement. Of that amount, approximately \$17.5 million related to investment transaction fees; \$11.9 million related to equity financing fees associated with the PIPE financing and the remaining \$7.9 million related to direct and incremental costs such as legal, tax, accounting, third-party advisory and other miscellaneous fees. This amount excluded the \$7.7 million of deferred underwriting fees related to the SCS initial public offering as described in note (2) above, any amounts relating to the ProKidney Promissory Notes, which were repaid at the Closing, and other SCS transaction costs.
- (n) Represents the issuance of 17,500,000 Earnout Rights to Earnout Participants upon Closing. As discussed in Note 2 to the unaudited condensed consolidated financial statements, the adjustment to recognize the Earnout Rights would have no net impact on any financial statement line item as it would simultaneously increase and decrease additional paid-in capital.
- (o) Represents the exchange of SCS Class A ordinary shares, SCS Class B ordinary shares and related director restricted stock units held by the Sponsor and an independent director of SCS for ProKidney Class A ordinary shares.

Adjustments to Unaudited Pro Forma Condensed Combined Statement of Operations for the Three Months Ended March 31, 2022

- (aa) Represents the adjustment to eliminate interest income related to the investment held in Trust Account.
- (bb) Does not reflect a pro forma adjustment to income tax expense as Legacy ProKidney has historically been in a net loss position. Legacy ProKidney files as a partnership for federal and state income tax

[Table of Contents](#)

purposes. As such, each partner is responsible for reporting income or loss to the extent required by federal and state income tax regulations, based upon their respective share of Legacy ProKidney income and expenses. ProKidney-US is a limited liability company and has elected to be treated as a C corporation, therefore, a provision for federal and state taxes has been recorded. Income tax expense of the combined company may differ from historical results due to the change in structure of ProKidney.

- (cc) Represents the adjustment for the net loss attributable to noncontrolling interest. The noncontrolling interest, giving effect to redemptions, is 74.5%.
- (dd) Represents the loss per share calculated using the historical weighted average shares outstanding, and the issuance of additional shares in connection with the Business Combination, assuming the shares were outstanding since January 1, 2021. As the Business Combination and related equity transactions are being reflected as if they had occurred at the beginning of the period presented, the calculation of weighted average shares outstanding for basic and diluted net income per share assumes that the shares issuable relating to the Business Combination were outstanding for the entirety of the period presented.

Adjustments to Unaudited Pro Forma Condensed Combined Balance Sheet as of December 31, 2021

- (a) Represents pro forma adjustments to cash and cash equivalents to reflect the following:

<u>(in thousands)</u>	<u>Note</u>	
SCS cash held in Trust Account	(1)	\$ 250,008
Payment of deferred underwriting fees	(2)	(7,700)
PIPE Financing	(3)	574,800
Payment to redeeming Public Shareholders	(4)	(228,305)
Payment of other transaction costs	(5)	(37,300)
Repayment of related party advance	(6)	(10)
Excess cash to balance sheet from Business Combination		<u>\$ 551,493</u>

- (1) Reflects the liquidation and reclassification of investments held in the Trust Account to cash and cash equivalents.
- (2) Reflects the payment of \$7.7 million of underwriters' fees deferred by SCS and which were paid at the Closing.
- (3) Reflects the gross proceeds of \$574.8 million from the issuance and sale of 57.5 million ProKidney Class A ordinary shares at \$10.00 per share pursuant to the Subscription Agreements entered into with PIPE Investors in connection with the PIPE Investment.
- (4) Represents the payments made to the holders of SCS Class A ordinary shares in connection with the redemption of 22,829,769 SCS Class A ordinary shares.
- (5) Represents transaction costs of \$37.3 million incurred by Legacy ProKidney prior to, or concurrent with, the Closing that were cash settled upon Closing in accordance with the Business Combination Agreement. Of that amount, approximately \$17.5 million related to investment transaction fees; \$11.9 million related to equity financing fees associated with the PIPE financing and the remaining \$7.9 million related to direct and incremental costs such as legal, tax, accounting, third-party advisory and other miscellaneous fees. This amount excludes the \$7.7 million of deferred underwriting fees related to the SCS initial public offering as described in note (2) above, any amounts relating to the ProKidney Promissory Notes, which were repaid at the Closing, and other SCS transaction costs.
- (6) Repayment of related party advance.
 - (b) Reflects the liquidation and reclassification of investments held in the Trust Account to cash and cash equivalents.
 - (c) Repayment of related party advance.

[Table of Contents](#)

- (d) Reflects the payment of \$7.7 million of underwriters' fees deferred by SCS and which were paid at the Closing.
- (e) Reflects the reclassification of SCS Class A ordinary shares, giving effect to the redemption of 22,829,769 SCS Class A ordinary shares.
- (f) As discussed in Note 1 to these unaudited pro forma condensed consolidated financial statements, the combined company will consolidate ProKidney but does not own 100% of the economic interest in Legacy ProKidney. The noncontrolling interest reflecting actual redemptions is 74.5%.
- (g) Reflects the gross proceeds of \$574.8 million, net of an adjustment for the associated par value, from the issuance and sale of 57.5 million ProKidney Class A ordinary shares at \$10.00 per share pursuant to the Subscription Agreements entered into with PIPE Investors in connection with the PIPE Investment.
- (h) Represents the recapitalization of the Legacy ProKidney Class A and Class B Units upon issuance of ProKidney Class B ordinary shares and Class B PMEL RSRs to Closing ProKidney Unitholders.
- (i) Represents pro forma adjustments to additional paid in capital to reflect the following:

<u>(in thousands)</u>	<u>Note</u>	
PIPE Financing	(g)	\$ 574,743
Reclassification of ordinary shares subject to redemption to permanent equity	(e)	21,703
Issuance of Class B ordinary shares to existing ProKidney owners	(h)	(18)
Transaction related fees	(j)	(37,300)
Issuance of Earnout Shares	(k)	—
Noncontrolling interest	(f)	(430,480)
Adjusted additional paid in capital		<u>\$ 128,648</u>

- (j) Represents transaction costs of \$37.3 million incurred by Legacy ProKidney prior to, or concurrent with, the Closing that were cash settled upon Closing in accordance with the Business Combination Agreement. Of that amount, approximately \$17.5 million related to investment transaction fees; \$11.9 million related to equity financing fees associated with the PIPE financing and the remaining \$7.9 million related to direct and incremental costs such as legal, tax, accounting, third-party advisory and other miscellaneous fees. This amount excluded the \$7.7 million of deferred underwriting fees related to the SCS initial public offering as described in note (2) above, any amounts relating to the ProKidney Promissory Notes, which were repaid at the Closing, and other SCS transaction costs.
- (k) Represents the issuance of 17,500,000 Earnout Rights to Earnout Participants upon Closing. As discussed in Note 2 to the unaudited condensed consolidated financial statements, the adjustment to recognize the Earnout Rights would have no net impact on any financial statement line item as it would simultaneously increase and decrease additional paid-in capital.
- (l) Represents the exchange of SCS Class A ordinary shares, SCS Class B ordinary shares and related director restricted stock units held by the Sponsor and an independent director of SCS for ProKidney Class A ordinary shares.
- (m) Upon the completion of the Business Combination, the combined company became a party to the Tax Receivable Agreement. Under the terms of the Tax Receivable Agreement, the combined company is required to pay to certain parties to the agreement 85% of the tax savings that it is deemed to realize in certain circumstances as a result of certain tax attributes that exist following the Transaction and that are created thereafter, including as a result of payments made under the Tax Receivable Agreement. The combined company does not expect to record net deferred tax assets related to the tax basis adjustments associated with the exchange of Paired Interests as those deferred tax assets are not more likely than not expected to be realized in accordance with ASC 740—Income Taxes. Accordingly, the combined company has not recorded a liability related to the Tax Receivable Agreement as of December 31, 2021, as the liability is not considered to be probable in accordance with ASC 450—Contingencies.

[Table of Contents](#)

Adjustments to Unaudited Pro Forma Condensed Combined Statement of Operations for the Year Ended December 31, 2021

- (aa) Represents the adjustment to eliminate interest income related to the investment held in Trust Account.
- (bb) Does not reflect a pro forma adjustment to income tax expense as Legacy ProKidney has historically been in a net loss position. Legacy ProKidney files as a partnership for federal and state income tax purposes. As such, each partner is responsible for reporting income or loss to the extent required by federal and state income tax regulations, based upon their respective share of Legacy ProKidney income and expenses. ProKidney-US is a limited liability company and has elected to be treated as a C corporation, therefore, a provision for federal and state taxes has been recorded. Income tax expense of the combined company may differ from historical results due to the change in structure of ProKidney.
- (cc) Represents the adjustment for the net loss attributable to noncontrolling interest. The noncontrolling interest, giving effect to actual redemptions, is 74.5%.
- (dd) Represents the loss per share calculated using the historical weighted average shares outstanding, and the issuance of additional shares in connection with the Business Combination, assuming the shares were outstanding since January 1, 2021. As the Business Combination and related equity transactions are being reflected as if they had occurred at the beginning of the period presented, the calculation of weighted average shares outstanding for basic and diluted net income per share assumes that the shares issuable relating to the Business Combination were outstanding for the entirety of the period presented.

BUSINESS OF PROKIDNEY

The following discussion reflects the business of ProKidney and its subsidiaries. In this section, unless context suggests otherwise, “we,” “us” and “our” generally refer to ProKidney LP and its subsidiaries prior to the Business Combination, and to ProKidney Corp. and its subsidiaries following the Business Combination.

Overview

We are a clinical-stage biotechnology company with a transformative proprietary cell therapy platform capable of treating multiple chronic kidney diseases using a patient’s own cells isolated from the patient intended for treatment. Our approach seeks to redefine the treatment of chronic kidney disease (“CKD”), shifting the emphasis away from management of kidney failure, to the restoration or improvement of kidney function to stop or delay progression of CKD. Our lead product candidate, which we refer to as REACT, is designed to stabilize or improve kidney function in a CKD patient’s diseased kidneys. REACT is a product that includes SRCs prepared from a patient’s own, autologous, renal cells. SRCs are formulated into a product for reinjection into the patient’s kidney using a minimally invasive outpatient procedure that can be repeated if necessary. Because REACT is a personalized treatment composed of cells prepared from a patient’s kidney, there is no need for treatment with immunosuppressive therapies, which are required during a patient’s lifetime when a patient receives a kidney transplant from another, allogeneic donor.

We are currently conducting a Phase 3 development program and multiple Phase 2 clinical trials for REACT in subjects with moderate to severe diabetic kidney disease. We are also conducting a Phase 1 clinical trial for REACT in subjects with congenital anomalies of the kidney and urinary tract (“CAKUT”). REACT has been well tolerated by subjects with moderate to severe diabetic kidney disease in Phase 1 and 2 clinical testing to date. It has also been shown to stabilize renal function in subjects based on measurements of iohexol renal clearance and urinary albumin-to-creatinine ratio (“UACR”). REACT has received Regenerative Medicine Advanced Therapy (“RMAT”) designation from the FDA.

Our patented technology includes multiple breakthroughs in the manufacturing and medical delivery of cellular therapy products. While it has long been held that the body contains cells with regenerative power, our technology is able to prepare key progenitor cells, SRCs, from expanded patient kidney cells for reinjection into patients and restore their lost kidney function due to chronic diseases. Our process begins when a small biopsy of a patient’s diseased kidney is sent to our cGMP manufacturing facility. We are able to process cells taken from the biopsy and select those with a regenerative capacity. The selected cells, SRCs, are formulated into a personalized product for reinjection into the damaged kidney. To date, clinical studies suggest that REACT can positively impact renal function by stabilizing eGFR or attenuating the rate of eGFR decline in patients with type 2 diabetic CKD. Other improvements observed with REACT treatment include stabilization in UACR, increased kidney cortical thickness, and improved hemoglobin levels, suggestive of a reduced risk of anemia.

We are initially pursuing the development of REACT for use in moderate to severe CKD patients in the United States with diabetes as the primary cause and may include hypertension as potential label expansion indication. We estimate that approximately 38-39 million adults, representing approximately 15% of the U.S. adult population, currently suffer from CKD, of which approximately 17-18 million patients have stage 3 or 4 CKD, and approximately 13.4 million patients have stage 3 or 4 CKD that is caused by diabetes (approximately 8.3 million) or hypertension (approximately 5.1 million). With respect to those patients with CKD caused primarily by diabetes, we estimate that approximately 4-5 million patients would be eligible to be treated with REACT.

Our Pipeline

We are leveraging our cell therapy technology to develop product candidates designed to stop or delay renal failure in CKD from diabetes and CAKUT. The following table summarizes our current pipeline:

Multiple Potential Therapeutic Targets for Treatment of CKD

Lead Platform Programs (Clinical Development)		Preclinical	IND	Phase 1	Phase 2	Phase 3	Registration (BLA/MAA)
REACT/CKD	Diabetes Type II – Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m ² , N = 81)	Phase 2		RMCL-002 → 002 OLE		Fully Enrolled; Following Pz	
	Diabetes Type II – Prevent/Delay CKD 1/4 (20-50 ml/min/1.73m ² , N = 1,200)	Phase 3		REGEN-006/014 → 018		Enrolling in US	
	Diabetes Type II – Delay CKD 4/5 (14-20 ml/min/1.73m ² , N = 10)	Phase 2		REGEN-003		Fully Enrolled; Following Pz	
	Diabetes Repeat Dose Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m ² , N = 30)	Phase 2 (injecting both kidneys w/ redox trigger)		REGEN-007		Enrolling	
REACT/CAKUT	Congenital Anomalies – Prevent/Delay N=15	Phase 1		REGEN-004		Enrolling	

* Plan to launch an additional phase 3 trial REGEN-016 in the first quarter of 2023.

Biopsy tissue of a patient’s diseased kidney is obtained, and from that sample we prepare and select for SRCs, progenitor cells, by enzymatically dissociating tissue, expanding the dissociated cells and separating the expanded cells via density gradient centrifugation. Clinical studies suggest that REACT can positively impact renal function by stabilizing eGFR or attenuating the rate of eGFR decline in type 2 diabetic CKD patients. We have developed a cryopreserved version of REACT that allows for long-term product preservation to be used in our Phase 3 trials of REACT (called REGEN-006 and REGEN-016), and our Phase 2 trial of REACT (called REGEN-007), treating diabetes patients with CKD. In addition to the cryopreserved formulation of REACT, we are using a gelatin-based hydrogel formulation in our ongoing Phase 2 trials (called RMCL-002 and REGEN-003) and Phase 1 trial (called REGEN-004). We have two preclinical programs (called REACT/Gen and REACT/Universal) where we plan to use genetically modified bioactive renal cell populations to provide regenerative effects to a diseased kidney. The preclinical programs aim to effectively obtain “universal donor” immune-privileged renal cell populations, where gene editing is used to generate “allogeneic” renal cell populations, to be administered to patients without immunosuppression.

Our Team and Corporate History

We have an experienced internal research and development team focused on utilizing our deep understanding of kidney disease pathways to discover and develop novel cell-based therapies with a multi-modal mechanism targeting various pathways. Since our founding, we have expanded our team to incorporate additional expertise as needed to pursue our goal of becoming a fully integrated biopharmaceutical company. We have assembled key management team members with expertise in kidney disease, cell therapy, development, regulatory affairs, medical affairs, operations, quality, and manufacturing. Our Chief Executive Officer, Tim Bertram, has more than 38 years of pharmaceutical development expertise and has led innovations in cellular therapeutics for over 18 years. Our Chief Operating Officer, Deepak Jain, Ph.D., has over 36 years of experience in the development of biologics, tissue engineered and cell therapy products. Our technology is being developed based on work that has been conducted for the past 20 years at different institutions.

ProKidney Bermuda was formed in December 2018 as a Bermuda limited liability company and was founded by a group of investors in the pharmaceutical industry. ProKidney Bermuda was initially capitalized with \$75 million.

In January 2019, ProKidney Bermuda acquired all of the equity interests in ProKidney-KY and ProKidney-US. ProKidney-KY was duly incorporated under the Cayman Islands Companies Act on

[Table of Contents](#)

December 21, 2015 as an exempted company. In 2020, ProKidney-KY's name was changed from RegenMed (Cayman) Ltd. to ProKidney, and ProKidney US' name was changed from Twin City Bio LLC to ProKidney, LLC. ProKidney-US is a Delaware limited liability company formed on December 18, 2015. On August 5, 2021, ProKidney LP was organized as a limited partnership under the Irish LP Act, and, as applicable, the Partnership Act 1890, of Ireland, with ProKidney Bermuda becoming a wholly owned subsidiary of ProKidney LP. References to "ProKidney" or the "Company" generally refer to ProKidney LP after this reorganization and to ProKidney Corp. following the Closing.

ProKidney Bermuda acquired the equity interests in ProKidney-KY to develop its renal advanced cell therapy, which has the potential to stabilize or improve renal function in patients with chronic kidney disease or delay or eliminate the need for dialysis and organ transplantation. ProKidney acquired ProKidney-US to provide contractual development and manufacturing services to ProKidney-KY, which is ProKidney-US's only customer.

Our Strategy

Our goal is to become a fully integrated biopharmaceutical company pioneering treatments for CKD. Key components of our business strategy include the following:

- **Obtain regulatory approval for and successfully commercialize REACT, initially as a treatment for patients with chronic kidney disease caused by diabetes.** We intend to continue to pursue the clinical development of REACT through a world-wide Phase 3 clinical development program that has been reviewed by both the EMA and the FDA. We activated the first site for our first Phase 3 clinical trial, REGEN-006, in the fourth quarter of 2021 with the first Informed Consent Form signed and the first subject randomized into the trial in the first quarter of 2022. Our second Phase 3 trial, REGEN-016, is planned to randomize, or "launch," in the first quarter of 2023 outside the United States. A long term follow up trial, REGEN-008, is expected to launch in late 2023, for subjects who received REACT as part of our trials REGEN-006, REGEN-007 and REGEN-016.
- **Expand the clinical development of REACT for the treatment of additional indications, including CKD caused by Congenital Anomalies of the Kidney and Urinary Tract and hypertension.** CAKUT is the cause of more than 50% of pediatric cases of renal failure, with long-term complications of CKD which may progress into adulthood. We are currently enrolling patients in REGEN-004, a Phase 1 clinical trial that is designed to assess the ability of REACT to prevent, stop, or delay the negative effects of CAKUT. We aim to complete the enrollment and obtain additional interim data by the end of 2022. Results from interim data may not be indicative of results from future data as patient enrollment continues and more patient data becomes available and will be viewed with caution until the final data are available. Hypertension related CKD is the second most common cause of CKD in adults. Future trials may address CKD in this population.
- **Discover and develop additional product candidates for the treatment of kidney diseases utilizing our cell therapy approach.** Our team has extensive experience in discovery research, deep expertise in kidney disease and a strong record of publication in high-impact peer reviewed journals. The team is focused on understanding additional disease pathways associated with kidney disease, identifying key targets for intervention and generating product candidates against these targets. We may also in-license from or collaborate with third parties to develop product candidates that, based on our understanding of kidney diseases and pathways, we believe are promising therapeutics.
- **Maintain and continually refine our sophisticated internal expertise in manufacturing our products.** We have developed and built a cGMP manufacturing facility in which we manufacture REACT for clinical trials, which we intend to continue to develop for purposes of the eventual commercial manufacturing process, assuming receipt of necessary regulatory approvals. Our current cGMP manufacturing facility is capable of manufacturing product for our Phase 3 clinical trials and could serve as our commercial launch facility. We anticipate construction of automated manufacturing facilities to meet demand for REACT upon commercialization.

Kidney Disease Overview

CKD is highly prevalent in the United States and European Union. Based on available U.S. data from the 2018 National Health and Nutritional Examination Survey, we expect the aggregate CKD population in the United States to reach approximately 74.4 million in 2020, approximately 82.2 million in 2030 and approximately 90.9 million in 2040. The estimated aggregate CKD population in the European Union can reach approximately 93% of the expected CKD population in the United States. We believe that the prevalence in the United States is approximately 15% of the adult population. The most common causes of CKD among adults are diabetes, hypertension, and glomerular disease, and in the pediatric population, CAKUT. In the United States, it is believed that approximately 18 million patients per year suffer stage 3 or 4 from CKD.

Our Approach: Working to Restore Kidney Function through Autologous Cell Therapy

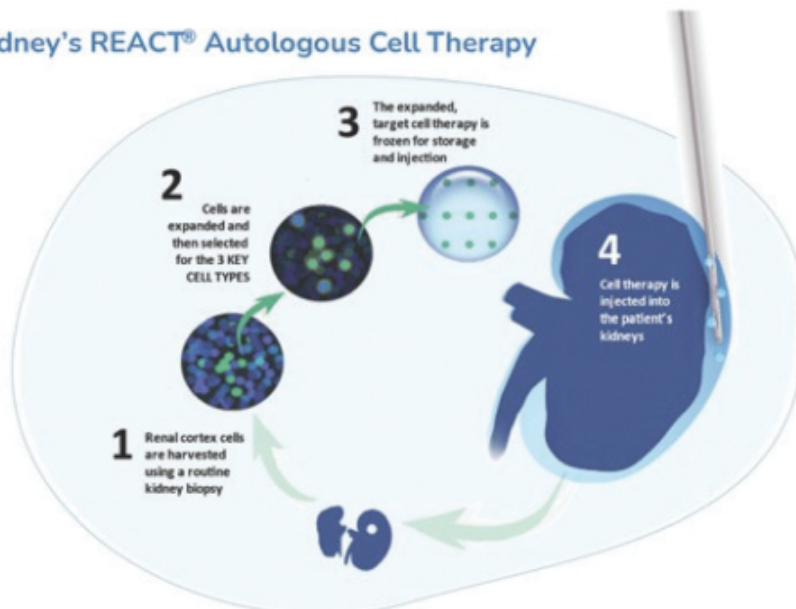
Autologous cell therapy refers to the prevention or treatment of human disease by the administration of a person's own cells that have been selected, multiplied and formulated for delivery outside the body. We believe that our technology has the potential to restore kidney function by using a patient's own SRCs to restore natural healing processes. By contrast, organ transplantation from other donors, or allogeneic transplants, can be associated with surgical complications, organ rejection and failure. Further, organ transplantation patients live with the adverse effects of immunosuppressive therapies and ongoing therapeutic maintenance that are required in order to reduce the risk of rejection of transplanted organs.

Our kidney restoration process begins when a small biopsy of the diseased kidney is sent to our laboratory. We are able to identify the patient's own healthy progenitor cells and formulate them into a personalized product that can be re-injected into the damaged kidney for repair and restoration of function. Due to one severe bleed that occurred during an early REACT injection procedure, we changed to a noncutting needle design for the REACT procedure, and there have been no injection-related serious adverse events since then. Based on preclinical studies, when the manufactured REACT product candidate is injected into the diseased kidney, the progenitor cells it comprises rapidly distribute throughout the kidney and integrate into the damaged nephrons and interstitium. To date, clinical studies suggest that treatment with REACT in patients with type 2 diabetes and CKD can positively impact renal function by stabilizing eGFR or attenuating the rate of eGFR decline. Other improvements observed with REACT treatment include stabilization and/or reduction in UACR, increased kidney cortical thickness, and improved hemoglobin levels, suggestive of a reduced risk of anemia.

REACT, an autologous homologous cell admixture, is made from expanded autologous SRCs, obtained from each individual subject's kidney biopsy. To manufacture REACT, biopsy tissue from each enrolled subject will be sent to ProKidney, in whose facilities renal cells will be expanded and SRCs selected. SRCs are then formulated into the cryopreserved or gelatin-based hydrogel product at a concentration of 100×10^6 cells/mL, and shipped to the clinical site.

ProKidney's REACT[®] Autologous Cell Therapy

ProKidney



Our Product Candidates

REACT is currently in a Phase 3 development program, as well as ongoing Phase 2 clinical trials, for the treatment of moderate to severe diabetic kidney disease and a Phase 1 clinical trial for REACT in patients with CAKUT. These trials are being or will be conducted at over 150 clinical sites throughout the United States, Europe, Asia and Latin America. REACT has been well tolerated in clinical trials to date involving patients with moderate to severe diabetic kidney disease. For example, in the RMCL-002 Phase 2 clinical trial, the interim analysis as of September 2021 demonstrates there is a statistically significant improvement in a measurement of kidney function, referred to as eGFR, between treatment arms in the trial, measured at six months after the second injection of REACT (p-value=0.032), nine months after the second injection of REACT (p-value=0.018), and 12 months after the second injection of REACT (p-value=0.019). The procedure appeared to be well tolerated, consistent with renal biopsy. Adverse events reported are generally associated with co-morbidities of Type 2 diabetes. The ongoing clinical development program utilizes a newly developed percutaneous injection method into the kidney that is conducted using conscious sedation in an outpatient same-day procedure. We cannot assure you that the improvements in eGFR that we have observed as of September 2021 in our RMCL-002 Phase 2 clinical trial will be observed in any future clinical trials. Likewise, promising results in interim analyses or other preliminary analyses may not ensure that the clinical trial as a whole will be successful.

Background and Unmet Need

Chronic Kidney Disease (CKD)

CKD is characterized by progressive nephropathy that, without therapeutic intervention, will worsen until the subject reaches end stage renal disease ("ESRD"). CKD patients suffer from reduced kidney function, demonstrated by decreased eGFR, or evidence of kidney damage, such as increased excretion of urinary albumin as shown in physician office laboratory testing. The global prevalence of CKD is estimated at 10% with ranges of 8-16% in various high populations. CKD is associated with considerable morbidity, such as diabetes mellitus, and is often accompanied by adverse outcomes due to underlying disease states and/or risk factors such as renovascular disease, hypertension and diabetes, causing an increased risk of mortality. 97% of patients with moderate to severe CKD have asymptomatic Stage 3 disease, but even this stage of CKD is associated with a

two- to four-fold rise in cardiovascular disease risk, along with a significant increase in all-cause mortality. Only a small proportion of CKD patients progress to ESRD (i.e., Stage 5 disease), but the increasing life expectancy of humans has led to growing numbers of patients with chronic diseases and end-stage organ failure. Even with costly treatments, subjects with ESRD experience substantial morbidity and mortality. To survive, ESRD subjects require renal replacement therapy through peritoneal dialysis, hemodialysis or kidney transplantation. Preventing or delaying the onset of adverse outcomes of CKD via early intervention is the primary strategy for CKD management. Nevertheless, early treatments have been less than optimal, resulting in a significant unmet medical need for improved interventional strategies to manage CKD and delay the regression to ESRD.

The major causes of CKD in adults are diabetes and hypertension. Nearly half of all CKD cases arise from diabetes, with or without hypertension. The incidence of CKD continues to increase, primarily due to the increased worldwide incidence of type 2 diabetes and metabolic syndrome. Staging and grading of kidney function are most often quantified by estimated glomerular filtration rate, which is defined as the volume of plasma from which a given substance is completely cleared by glomerular filtration per unit time. KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease provided guidelines intended to aid general practitioners and nephrologists in the evaluation, classification, and management of CKD in both adults and children. As set forth below, Figure 1 categorizes the risk of ESRD from “low” to “very high” based on both eGFR measurements, ranging from >90 mL/min/1.73m² to <30 mL/min/1.73m², and albuminuria classifications ranging from <30 mg/g to >300 mg/g. When the kidneys cease to function entirely, which constitutes ESRD, renal replacement therapy in the form of dialysis or transplantation is generally required.

Summary of Classification Estimates for CKD

CURRENT CHRONIC KIDNEY DISEASE (CKD) NOMENCLATURE USED BY KDIGO

CKD is defined as abnormalities of kidney structure or function, present for >3 months, with implications for health. CKD is classified based on Cause, GFR category (G1–G5), and Albuminuria category (A1–A3), abbreviated as CGA.

Prognosis of CKD by GFR and albuminuria category

Prognosis of CKD by GFR and albuminuria categories: KDIGO 2012				Persistent albuminuria categories		
				Description and range		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/mmol	30–300 mg/g 3–30 mg/mmol	>300 mg/g >30 mg/mmol
GFR categories (mL/min per 1.73 m ²) Description and range	G1	Normal or high	≥90			
	G2	Mildly decreased	60–89			
	G3a	Mildly to moderately decreased	45–59			
	G3b	Moderately to severely decreased	30–44			
	G4	Severely decreased	15–29			
	G5	Kidney failure	<15			

Green, low risk (if no other markers of kidney disease, no CKD); yellow, moderately increased risk; orange, high risk; red, very high risk.

All-cause mortality rates were shown to increase as GFR declined; mortality rates were highest at Stages 4-5 of CKD. Populations defined as having an eGFR <60 mL/min/1.73m² consistently exhibited a higher mortality rate than comparator groups where there was no evidence of CKD.

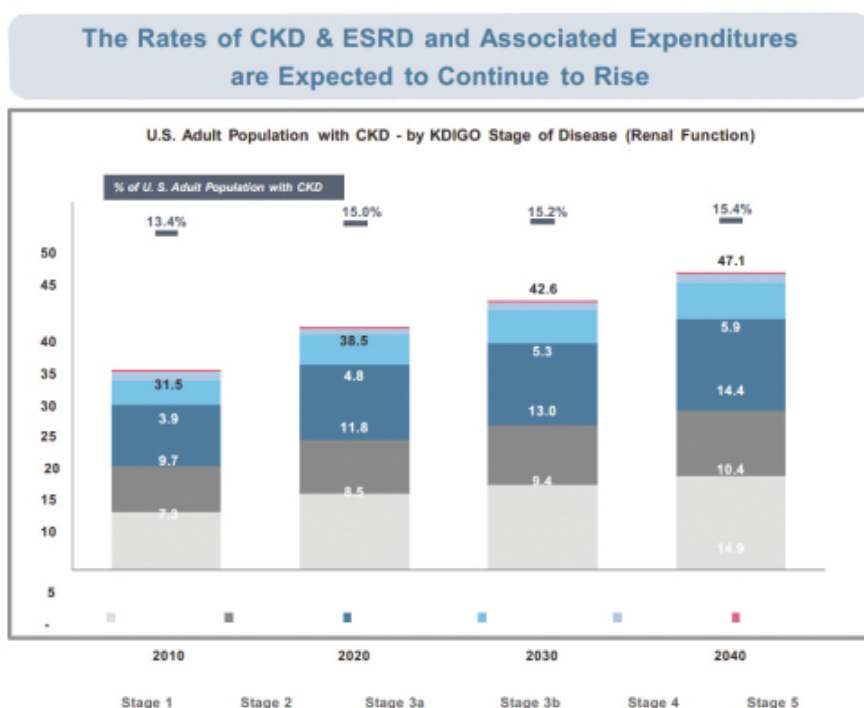
Treatment of patients with CKD is focused on slowing progression and preparing for kidney failure or replacement. For many patients, CKD occurs as part of a complex comorbidity cluster, especially with cardiovascular disease and type 2 diabetes.

Table of Contents

Increased risk of cardiovascular disease can be a complication of CKD or an independent comorbidity associated with type 2 diabetes. The goals in the treatment of CKD are to lower cardiovascular risk and prevent or slow the progression of kidney failure via administration of angiotensin converting enzyme inhibitors and/or angiotensin receptor blockers to decrease proteinuria and control hypertension, insulin and anti-diabetic agents for glycemic control (e.g., reduced serum hemoglobin A1c), and statin therapy to counter dyslipidemia.

When a patient reaches ESRD, renal replacement therapy in the form of kidney dialysis or transplantation is generally required. The vast majority of Stage 5 CKD patients in the United States and certain other developed countries receive hemodialysis. Dialysis replaces about 5-15% of kidney function, depending on the intensity and frequency of use; dialysis also helps to restore fluid and electrolyte balance when kidneys fail. However, the life expectancy of an ESRD patient initiating hemodialysis is < 10 years. Additionally, hemodialysis has been associated with multiple, serious complications as well as interference with quality of life, due to the need for frequent dialysis and vascular access maintenance. Although kidney transplantation remains the most effective form of therapy for CKD currently, there is a chronic shortage of organs. If a patient can secure a kidney for transplantation, long-term immunosuppressive therapy is required to prevent rejection. Use of these regimens results in a higher incidence of infection and, over the long term, some types of cancer. And while xenotransplantation might be a promising alternative approach to bridge the gap between the supply and demand of human organs, tissues, and cells, immunological barriers are also limiting factors in clinical xenotransplantation.

While patients continue to lose kidney function on existing therapies, the cost of CKD treatment is high and the rates of CKD and ESRD along with the associated expenditures are expected to continue to rise. As a large source of healthcare expenditure in the United States, the Medicare spend on beneficiaries with CKD is \$80 billion. Medicare spend on beneficiaries with ESRD can reach \$50 billion, with \$93,000 Medicare annual cost per patient for dialysis. Additionally, the estimated ESRD cost per patient with commercial insurance, assuming a five-year dialysis period, is up to \$2 million.



* Based on ProKidney management estimates and analysis

We estimate that there are approximately 4 to 5 million REACT eligible patients. Assuming that we obtain requisite regulatory approvals and that the REACT market penetration rate is 1% in the United States alone, the expected size of the overall market in the United States for REACT could reach up to \$16 billion based on the average cost of recently launched novel targeted therapies. Taken together, there is a critical medical and market need for improved therapies for CKD which could stop or dramatically slow the progression of disease and significantly delay the need for renal transplantation.

Congenital Anomalies of the Kidney and Urinary Tract (CAKUT)

CAKUT is a group of abnormalities affecting the kidneys or other structures of the urinary tract. CAKUT results from abnormal development of the urinary tract system and is present at birth (i.e., it is congenital), although the abnormality may not become apparent until later in life. CAKUT is the most common kind of congenital birth defect, affecting roughly 1 in 500 babies born.

Individuals with CAKUT have one or more kidney or urinary tract abnormalities. The parts of the urinary tract that may be affected include the bladder, the tubes that carry urine from each kidney to the bladder (the ureters), and the tube that carries urine from the bladder out of the body (the urethra). For paired structures, like the kidneys and ureters, one or both may be affected.

There are various types of CAKUT. Many different developmental abnormalities are classified as CAKUT, including underdevelopment or absence of a kidney and nephrons, a kidney formed of fluid-filled sacs called cysts, buildup of urine in the kidneys, an extra ureter leading to the kidney, a blockage in a ureter where it joins the kidney, an abnormally wide ureter, backflow of urine from the bladder into the ureter, and an abnormal membrane in the prostatic urethra that blocks the flow of urine out of the bladder.

The causes of CAKUT are complex, and much remains to be uncovered about the genetic and environmental regulators of kidney and outflow tract development. It is likely that a combination of genetic and environmental factors contribute to the formation of kidney and urinary tract abnormalities. The genetic factors involved in most cases of CAKUT are unknown. Syndromic CAKUT is caused by changes in the genes associated with the particular syndrome. Variations in these same genes can also underlie some cases of isolated CAKUT. In addition, environmental factors may influence development of CAKUT. The risk of CAKUT is higher in babies whose mothers had diabetes, took certain medications that are harmful to the kidneys, such as some anti-seizure medicines, or lacked certain vitamins and minerals, such as folate and iron, during pregnancy.

Most cases of CAKUT are diagnosed from antenatal ultrasound imaging, and the remaining cases of CAKUT are usually only diagnosed after an infant or child develops a urinary tract infection, prompting ultrasound and/or other imaging studies to examine the kidneys and outflow tracts.

CAKUT is often one of several features of a condition that affects multiple body systems, and it varies in severity. The abnormalities can result in recurrent urinary tract infections or a buildup of urine in the urinary tract, which may damage the kidneys or other structures. Severe CAKUT can lead to life-threatening kidney failure and ESRD. Children with severe CAKUT may require dialysis and transplantation as infants, and they may experience long-term effects on their ability to lead independent lives as adults.

There is currently a need for greater understanding of the pathogenesis of CAKUT, as well as an unmet need for means for providing proper treatment of those affected by this condition.

Clinical Development

Our completed clinical trials and currently ongoing clinical trials of REACT are summarized below; the name of the product candidate tested in the trials was changed from Neo-Kidney Augment (“NKA”) to REACT after completion of some of the trials.

The summary below also includes interim results which are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. In particular, we have announced interim results from our ongoing RMCL-002 Phase 2 clinical trial and REGEN-004 Phase 1 clinical trial and plan to evaluate interim results from our ongoing REGEN-006 Phase 3 clinical trial in early 2025 and REGEN-016 Phase 3 clinical trial in mid-2025. Interim results from clinical trials that we may complete are not necessarily indicative of results from future data and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available.

Diabetic Kidney Disease (DKD)

Phase 1 Clinical Development (TNG-CL010 and TNG-CL011)

TNG-CL010 was an open-label safety and delivery optimization study of REACT (formerly known as NKA) in subjects with CKD conducted in Sweden. TNG-CL010 commenced in April 2013 and terminated in December 2014. TNG-CL011 was also an open-label safety and delivery optimization study of REACT in subjects with type 2 diabetes and CKD conducted in the United States. TNG-CL011 commenced with first subject enrolled in February 2014 and terminated in December 2014.

The primary objective of these trials was to assess the safety and delivery of REACT injected into one kidney. Six subjects from Sweden (TNG-CL010) and one from the United States with Diabetes Type 2 CKD, ranging in age from 53-70 years, eGFR levels between 19-34 (average 25 +/- 2, Cystatin C) and iohexol clearance of 15-39, average 26 +/- 3, were enrolled. One subject with Type 2 DKD was enrolled in TNG-CL011.

The results from the Phase 1 trials indicated that REACT was well tolerated when administered to the kidney, with no adverse events from the autologous SRC. When the decline of renal function pre- and post- injection were compared, the subjects receiving REACT in this Phase 1 trial had an imputed delay in dialysis of approximately 1.5 years beyond the standard of care because of slowing in the rate of reduction in eGFR from pre-injection baseline. Cortical thickness increased in the injected kidney from an average of 14 mm at time of injection to approximately 16 mm after one year. Renal function was stabilized following the REACT injection by iohexol clearance and based on the subjects' ACRs. Subjects with a baseline anemia (n = 3 of 7) showed improved hemoglobin levels after REACT injection, and the remaining subjects maintained normal levels during the study. Antihypertensive medication was reduced in three of six subjects during the first six months following injection with REACT.

Phase 2 Clinical Development (RMCL-001, RMCL-002, REGEN-003, and REGEN-007) RMCL-001:

RMCL-001 was a Phase 2, open-label safety and efficacy study of REACT in subjects with type 2 diabetes and CKD. The study commenced in May 2016 and was ended in May 2017.

The primary objective of this study was to assess the safety and efficacy of a second REACT injection using a minimally invasive percutaneous procedure that was done under conscious sedation as a same-day outpatient procedure. A single subject with an eGFR of 14ml/min/1.73m² was enrolled from the Phase 1 study (TNG-CL011) described above. The second dose of REACT was manufactured from cryopreserved renal cells obtained from the Phase 1 renal biopsy. The subject was administered a dose of 3x10⁶ cells/g-KWest. The subject's eGFR increased to approximately 20 ml/min/1.73m² for a period of eight months, after which the subject experienced a precipitous drop in renal function and began hemodialysis. The study was terminated by the sponsor of the clinical trial after this subject went onto dialysis and resources diverted to study RMCL-002.

RMCL-002:

RMCL-002 is an ongoing Phase 2, prospective, randomized, double-arm, deferred treatment, open-label, repeat dose, safety and efficacy study of REACT in subjects with type 2 diabetes and CKD. The first subject was enrolled in this study in February 2017, and subjects are now undergoing follow-up.

The primary objective of this study is to assess the safety and efficacy of up to two REACT injections given six months (up to four weeks after target date) apart in Type 2 Diabetic Disease patients with eGFRs between 20 and 50 ml/min/1.73m², with both doses delivered into the biopsied kidney using an outpatient, minimally invasive, percutaneous approach under conscious sedation in less than 90 minutes. Patients will receive two doses of REACT of 3x10⁶ cells/g-KWest.

Patients were randomized (1:1) to the active treatment group and the deferred treatment group (i.e., the control group) following renal biopsy. Subjects in the active treatment group receive their first REACT injection as soon as the REACT product is manufactured and shipped to the clinical site. After six months (up to four weeks after target date), a second injection is given, as appropriate. In contrast, subjects in the deferred treatment group will undergo a 12-month period of observation after renal biopsy. The deferred treatment group allows assessment of the rate of change in kidney function and co-morbidities in a nonexposed group compared to the active treated arm. During this time, they will receive contemporaneous, standard-of-care therapy for CKD while undergoing follow-up evaluations every three months, similar to subjects in the active treatment group. After 12 months, subjects from the deferred treatment group will receive a series of up to two REACT injections given six months (+/- four weeks of the target date) apart, as appropriate. Consequently, the study design includes a randomized control group receiving standard-of-care treatment for the first 12 months and a randomized, active treatment group receiving up to two REACT injections and follow-up evaluations during the same period of time. In addition, each subject's baseline rate of renal decline, based on adequate historical and clinical data obtained 18 months prior to REACT injection, will serve as a comparator for monitoring the rate of progression of renal insufficiency over time.

The aggregate number of subjects enrolled for the Phase 2 clinical trial was 83. Upon withdrawal and/or replacement of 2 subjects, 81 subjects were enrolled as of December 2020, of which 39 subjects were enrolled into the active treatment group and 42 subjects were enrolled into the deferred treatment group. As of March 31, 2022, 39 subjects enrolled in the active group received their first injection, and 34 have received their second. No further injections will occur in the active group. 33 subjects in the deferred group have crossed over into the active group, with 33 subjects having received their first injection and 21 having received their second injection as of March 31, 2022.

The rate of progression of renal function for the active treatment group, assessed via pre-randomized serial measurements of eGFR over 24 months after the last REACT injection, will be compared against that of the deferred treatment group. In addition, each subject's baseline rate of eGFR decline, derived from historical and clinical data, will be compared against the individual subject's rate of eGFR decline through 24 months following the final REACT injection. The rate of progression of renal function of subjects, if any, who received a single REACT injection may be compared against that of subjects who received two REACT injections. Patients will be followed through 24 months after their last REACT injection in part 1 of the trial. An open label extension portion of the study (part 2) was added in February 2021 to follow all subjects for an additional 3 years. Visits will be conducted at 3-month intervals to give a total of 5 years (part 1 + part 2) of follow-up after the last REACT injection.

Subjects in this trial will complete the Kidney Disease Quality of Life ("KDQOL") survey, which is a subjective kidney-specific measure of health-related quality of life, and the EQ-5D-5L survey, which is a health-related quality of life questionnaire. Scores from the active treatment group will be compared against scores from the deferred treatment group. Subjects from the deferred treatment group will comprise the control group for the analysis of KDQOL scores. In addition, each subject's baseline score will be compared against his or her

[Table of Contents](#)

KDQOL scores obtained over the 24-month period after the last REACT injection. KDQOL scores from subjects who received a single REACT injection may be compared against scores from subjects who received two injections.

Results as of the September 2021 interim analysis demonstrate that renal function has stabilized or improved in the subjects who have received a full course (2 injections) of REACT and has steadily declined in the deferred treatment group. The overall mean total slope for the active treatment group is a positive (+5.0 ml/min/1.73m²/year), whereas the overall mean total slope for the deferred treatment group is a decline (-3.9 ml/min/1.73m²/year). This shows an effect difference of +8.9 ml/min/1.73m²/year in annualized change in renal function between the active treatment group and the deferred treatment group. Each slope is calculated using a simple linear regression between the average eGFR measurements on the first injection day and three, six, nine and 12 months following the last injection day, where the averages are assumed to be equally spaced.

The interim analysis as of September 2021 demonstrates there is a statistically significant difference in the average eGFR between treatment arms (subjects who received a full course of REACT compared to the standard of care) at six months post 2nd injection (p-value=0.032), nine months post 2nd injection (p-value=0.018) and 12 months post 2nd injection (p-value=0.019). The outpatient kidney biopsy and REACT injections procedures are minimally invasive and well tolerated and complications are commensurate with standard of care and published cohort trials and meta-analysis studies. Other adverse events reported are commonly associated with the co-morbidities of Type 2 diabetes and similar to those seen in other small molecule CKD trials.

We aim to have all deferred subjects dosed in 2022, obtain additional interim data and complete all active subjects follow-up in November 2023, complete all deferred subjects follow-up in 2024, and expect the clinical study report to be available in early 2025. Results from interim data may not be indicative of results from future data.

REGEN-003:

REGEN-003 is a Phase 2, prospective open-label, single-arm, safety and tolerability study of REACT in subjects with type 2 diabetes and CKD. This study commenced in March 2018 with first subject enrolled.

The primary objective of this study is to assess the safety and efficacy of up to two REACT injections given six months (up to four weeks after target date) apart in Type 2 Diabetic Kidney Disease patients with eGFRs between 14 and 20 ml/min/1.73m² and delivered into the biopsied kidney using a minimally invasive percutaneous approach that can be delivered under conscious sedation in less than 90 minutes. Subjects have an eGFR of between 14—20 ml/min/1.73m². Subjects receive up to two doses of REACT of 3x10⁶ cells/ g-KWest.

This study has completed enrollment and dosing has commenced for all 10 subjects, with nine subjects having received both doses.

We completed the enrollment of 10 subjects in February 2020. As of March 31, 2022, seven subjects had initiated dialysis, one of which died due to complications related to COVID. An additional subject died due to cardiovascular complications. For the seven subjects that initiated dialysis (baseline average eGFR of 17.5 ml/min/1.73m²), the time between the first REACT injection and the initiation of dialysis averaged 76 weeks, ranging from 34 weeks to 121 weeks. Of the 10 subjects, two responding and receiving a second dose of REACT had a positive annualized eGFR slope of +1.1 ml/min/1.73m²/year, while the other eight subjects are continuing to progress with an average decline in annualized eGFR of -3.9 ml/min/1.73m²/year.

We aim to continue to follow-up until late 2022 and expect the clinical study report to be available in 2023.

REGEN-007:

REGEN-007 is an ongoing Phase 2, prospective, randomized, open-label, repeat dose, double-arm, controlled safety and efficacy study of REACT in subjects with type 1 or 2 diabetes and CKD.

The primary objective of this study is to assess the safety and efficacy of up to two REACT injections given three months apart (up to 60 days after target date) in Type 1 and 2 Diabetic Kidney Disease with eGFRs between 20 and 50 mL/min/1.73m²) and delivered into biopsied and non-biopsied contralateral kidneys using a minimally invasive percutaneous approach, as compared to a single REACT injection followed by monitoring and a potential second injection delivered into the non-biopsied contralateral kidney using a minimally invasive percutaneous approach triggered by a 20% decrease in eGFR and/or a 30% increase in UACR, that is delivered within 60 days of trigger being met. In previous Phase 2 studies, we injected the same kidney twice to demonstrate the safety and efficacy of REACT using a minimally invasive injection procedure. Based on an observed favorable safety profile in previous studies, we are proceeding with the injection of REACT into both kidneys in REGEN-007, which we expect will result in increased therapeutic effect as compared to injecting a single kidney, as the systemic effects of Type-2 diabetes mellitus impact both kidneys. By injecting both kidneys, patients have maximal exposure to REACT cells, with the potential to impact a greater proportion of renal mass. Further, the number of glomeruli (the filtering units of the kidney) that are amenable to regenerative therapy is effectively doubled when injecting both kidneys, thereby allowing both kidneys to initiate healing and repair to improve function. The main goal of REGEN-007 is to evaluate whether REACT injections in both kidneys as opposed to two injections in the same kidney will: (a) increase the improvement of kidney function over and above the mean eGFR improvement observed in REGEN-002, or (b) increase the number of patients in which kidney function stabilizes or improves as compared to the number of patients in which this was observed in REGEN-002, or both.

Subjects will receive up to two doses of REACT of 3x10⁶ cells/ g-KWest. The study will enroll subjects between the ages of 30 and 80 with an eGFR >20 and ≤50 mL/min/1.73m². Subjects will be randomized (1:1) before renal biopsy into two cohorts. Cohort 1 will receive the two REACT injections three months apart. Cohort 2 will receive the first REACT injection, and a trigger, as described below, must be met to qualify for the second REACT injection > 3 months after the first dose. This will allow a comparison of the effects of a specified amount of time between dosing, as compared to a biologic trigger between dosing.

Each of the subjects in cohort 1 will receive the first REACT injection as soon as the REACT product is manufactured and shipped to the clinical site. After three months, subjects will receive a second injection, as appropriate. Subjects in cohort 2 will also receive one REACT injection as soon as the REACT product is manufactured and shipped to the clinical site. For cohort 2, a second REACT injection will only be administered if a subject meets one or more clinical surrogate marker criteria. The second REACT injection will be administered to subjects in cohort 2 no less than three months after the first injection, within 30 days (up to four weeks after target date) of meeting the re-dose trigger. The re-dose triggers include (1) a 30-day sustained decline in eGFR by at least 20% from baseline and (2) an increase in the baseline UACR of at least 30% greater than 30mg/gram, measured thirty days after the baseline measurement is taken. For all subjects who receive a second injection, the second injection will be administered in the non-biopsied contralateral kidney.

During this time, subjects in cohort 2 will receive contemporaneous, standard-of-care therapy for CKD while undergoing follow-up evaluations at one, 14 (up to 7 days after target date) and 28 days (up to 7 days after target date) following the first injection, and then at three months (up to 10 days after target date) following the first injection, similar to subjects in cohort 1. All subjects will continue with long-term follow-up visits at three-month intervals for a period of 24 months following the last injection. In addition, each subject's baseline rate of renal decline, based on adequate historical, clinical data obtained 24 months prior to the first REACT injection, will serve as a comparator for monitoring the rate of progression of renal insufficiency over time. The primary efficacy endpoint of REGEN-007 is improvement in the rate of renal function decline as indicated by the change from pre-injection baseline value in total (acute + chronic) slope of eGFR over 24 months. The primary safety endpoint is treatment-emergent adverse events through 24 months following the last REACT injection. REGEN-007 is an unblinded study in which cohort 1 patients will receive the same treatment regimen as the patients in our Phase 3 program that are randomized to the active arms. Therefore, REGEN-007 may provide some insights regarding the magnitude of clinical benefit that could be observed in our Phase 3 program.

[Table of Contents](#)

We commenced enrollment for REGEN-007 in the third quarter of 2021 and has expanded target enrollment from 30 to up to 50 subjects, as a result of strong investigator interest. As of June 1, 2022, 24 subjects were enrolled with 12 subjects randomized to cohort 1 and 12 subjects randomized to cohort 2. As of that date, four subjects in cohort 1 had received their first dose of REACT™, two of whom received a second dose into the contralateral kidney, and five subjects in cohort 2 received their first dose of REACT.

We anticipate initial evaluation data from this study from a limited number of patients in the first half of 2023, with topline data expected in 2025.

Phase 3 Clinical Development (REGEN-006 and REGEN-016):

We applied for RMAT designation for REACT, which was granted by the FDA on October 28, 2021. As contemplated by the RMAT designation and as directed by the FDA, we requested a comprehensive, multidisciplinary Type B meeting with the FDA to review the status of preclinical and clinical development and manufacturing of REACT, and to discuss the planned clinical program intended to support approval of the product candidate. The FDA provided detailed written responses to our questions included in the meeting request, and the Type B meeting was held in March 2022. As a result of that meeting, we made some modifications to the Phase 3 trial designs, including the following:

- increased the planned sample size from 500 to 600 subjects in both REGEN-006 and REGEN-016;
- removed the increase in UACR of at least 30% and of at least 30 mg/g, using the random urine microalbumin/urine creatinine ratio sustained for 90 days, from the primary composite endpoint for both REGEN-006 and REGEN-016; and
- added a sham control arm and single blind component to the design of REGEN-016.

We will continue to advance the USA clinical development program with the benefit of enhanced clarity as to the FDA's expectations and requirements for a registrational program, including the design of the trials needed for approval, manufacturing assays, and comparability studies, as set forth below.

REGEN-006:

REGEN-006 is a Phase 3, randomized, single-blinded, bi-lateral kidney dose, sham control arm, controlled efficacy study of REACT in subjects with type 2 diabetes and CKD Stages 3a-4 with moderate to severe albuminuria. Albuminuria refers to the presence of an excess of the protein albumin in urine, which is a sign of kidney disease.

The primary objective of this study is to assess the efficacy of up to two REACT injections given three months apart and delivered into biopsied and non-biopsied contralateral kidneys using a minimally invasive percutaneous approach. The total planned enrollment is 600 subjects. Subjects in the treatment group will receive two doses of REACT of 3×10^6 cells/ g-KWest. The study will enroll subjects between the ages of 30 and 80 years of age with an eGFR ≥ 20 and ≤ 50 mL/min/1.73m².

The primary composite endpoint is the time from first injection to the earliest of:

- at least 40% reduction in eGFR, using the 2009 CKD-EPI serum creatinine equation, sustained for 30 days;
- eGFR < 15 mL/min/1.73m² using the 2009 CKD-EPI serum creatinine equation, sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
- renal or cardiovascular death.

Subjects will be randomized (1:1) to the treatment group and the "masked" sham control group prior to renal biopsy.

[Table of Contents](#)

Each of the subjects in the treatment group will receive the first REACT injection 12 weeks following renal biopsy. After three months, a second injection will be given, as appropriate, into the contralateral kidney. In contrast, subjects in the control group will receive two sham injections, the first of which will be administered 12 weeks following sham biopsy, and the second of which will be administered three months after the first sham injection. During this time, subjects in the control (sham) group will receive contemporaneous, standard-of-care therapy for CKD while undergoing follow-up evaluations at one, 14 and 28 days (+7 days) following the first injection, and then at three months (+10 days) following the first injection, similar to subjects in the treatment group. All subjects will continue in the study until they experience a qualifying event under the primary composite endpoint or reach the end of the study.

Subjects will complete the KDQOL and EQ-5D-5L surveys. Scores from the treatment group will be compared against scores from the control group. In addition, each subject's baseline score will be compared against his or her KDQOL scores obtained over the 24-month period after the last REACT injection. Additionally, KDQOL scores from subjects who received a single REACT injection may be compared against scores from subjects who received two injections.

This study began enrollment in the first quarter of 2022. As of March 31, 2022, 20 subjects had signed informed consent forms, and two were awaiting treatment assignment.

We aim to evaluate interim data for REGEN-006 in early 2025. Results from interim data may not be indicative of results from future data.

REGEN-016:

REGEN-016 is a planned Phase 3, randomized, single-blinded, sham control arm, bi-lateral kidney dose, controlled efficacy study of REACT in subjects with type 2 diabetes and CKD Stages 3a-4 with moderate to severe albuminuria.

The primary objective of this study is to assess the efficacy of up to two REACT injections given three months apart and delivered into biopsied and non-biopsied contralateral kidneys using a minimally invasive percutaneous approach. The total planned enrollment is 600 subjects. Subjects in the treatment group will receive two doses of REACT of 3×10^6 cells/ g-KWest. The study will enroll subjects between the ages of 30 and 80 years of age with an eGFR ≥ 20 and ≤ 50 mL/min/1.73m².

Subjects will be randomized (1:1) to the treatment group and the "masked" sham control group prior to renal biopsy.

Each of the subjects in the treatment group will receive the first REACT injection 12 weeks following renal biopsy. After three months, a second injection will be given, as appropriate, into the contralateral kidney. In contrast, subjects in the control group will receive two sham injections, the first of which will be administered 12 weeks following sham biopsy, and the second of which will be administered three months after the first sham injection. During this time, subjects in the control group will receive contemporaneous, standard-of-care therapy for CKD while undergoing follow-up evaluations at the same time intervals as subjects in the treatment group. All subjects will continue in the study until they experience a qualifying event under the primary composite endpoint or reach the end of the study.

The primary composite endpoint is the time from first injection to the earliest of:

- at least 40% reduction in eGFR, using the 2009 CKD-EPI serum creatinine equation, sustained for 30 days;
- eGFR < 15 mL/min/1.73m² using the 2009 CKD-EPI serum creatinine equation, sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
- renal or cardiovascular death.

[Table of Contents](#)

Subjects will complete the KDQOL and EQ-5D-5L surveys. Scores from the treatment group will be compared against scores from the control group. In addition, each subject's baseline score will be compared against his or her KDQOL scores obtained over the 24-month period after the last REACT injection. Additionally, KDQOL scores from subjects who received a single REACT injection may be compared against scores from subjects who received two injections.

Enrollment for this study is planned to begin in the first quarter of 2023.

We aim to evaluate data for REGEN-016 in mid-2025, with the potential for conditional FDA approval anticipated in 2026.

Congenital Anomalies of the Kidney and Urinary Tract (CAKUT)

Phase 1 (REGEN-004):

REGEN-004 is a Phase 1, prospective, open-label, single-arm, safety, tolerability, and early efficacy study of REACT in subjects with CKD from CAKUT.

The primary objective of this study is to assess the safety and efficacy of up to two REACT injections given six months (up to four weeks after target date) apart and delivered into the biopsied kidney using a minimally invasive percutaneous approach that can be delivered under conscious sedation in less than 90 minutes in patients with Chronic Kidney Disease with eGFRs between 14 and 50 ml/min/1.73m² due to Congenital Anomalies of the Kidneys and Urinary Tract. The planned enrollment is 15 subjects. Subjects will receive two doses of REACT of 3x10⁶ cells/ g-KWest.

As of March 31, 2021, five subjects were enrolled, all had received their first injection, and four subjects had received both injections.

Early interim results as of August 2021 demonstrated that in three of the five subjects currently enrolled, renal function had improved to an annualized eGFR slope of 3.38 ml/min/1.73m²/year compared to their pre-dose slope of negative -4.19 ml/min/1.73m²/year. No adverse events have been associated with REACT. The minimally invasive percutaneous procedure has a well-tolerated safety profile consistent with renal biopsy. No adverse events have been reported to date.

We aim to complete the enrollment by the end of 2022 and obtain additional interim data in mid-2022. Results from interim data may not be indicative of results from future data.

Planned Studies

Phase 2 (REGEN-017)

REGEN-017 is a planned Phase 2 study of REACT in subjects with diabetes and CKD who were previously enrolled in the sham control arm of either REGEN-006 or REGEN-016. Subjects will be enrolled in REGEN-017, either when a Phase 3 event is triggered or following completion of study visits in Phase 3 protocols.

Each of the subjects will receive the first REACT injection 12 weeks following renal biopsy. After three months, a second injection will be given, as appropriate, into the contralateral kidney. Subjects will continue for follow-up observation visits for a duration of 12 months following their second REACT injection before continuing into REGEN-008.

Phase 4 Clinical Development (REGEN-008)

REGEN-008 is a Phase 4, prospective, open-label, observational extension study of REACT in subjects with diabetes and CKD who were previously enrolled and treated with cryopreserved REACT in the REGEN-006,

[Table of Contents](#)

REGEN-007, REGEN-016 and REGEN-017 studies. The total planned enrollment is approximately 600 subjects with no control arm.

The primary objective of this study is to evaluate the long term safety of up to two REACT injections given three months apart and delivered percutaneously into biopsied and non-biopsied contralateral kidneys on renal function in participants with diabetes and CKD.

Subjects who had participated in REGEN-006, REGEN-007, and REGEN-016 with exposure to REACT will continue for long-term follow-up observation visits every three months (+ 10 days) alternating between clinic and telephone visits after enrollment for a duration of five years following their completion in the previous studies. Visits will include physical examinations, laboratory draws, documentation of vitals and assessment of any concomitant medical changes. Once a year, subjects will also be asked to complete KDQOL and EQ-5D-5L surveys.

We aim to continue REGEN-008 long-term follow-up to 2030.

Phase 4 Clinical Development (REGEN-009)

REGEN-009 will be a prospective, open-label, observational extension study of REACT in subjects with CAKUT who were previously enrolled and treated with REACT in the REGEN-004, REGEN-005 and REGEN-011 studies. We plan to launch the REGEN-009 in late 2022.

The primary objective of this study is to assess the long-term safety and efficacy (including durability) of REACT on renal function in subjects with CAKUT.

Subjects who participate in a CAKUT trial will continue for long-term follow-up observation visits every three months after enrollment for a duration of five years following their completion in the previous studies. Visits will include physical examinations, laboratory draws, documentation of vitals, and assessment of any concomitant medical changes. Once a year, subjects will also be asked to complete KDQOL and EQ-5D-5L surveys.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid technological advancement, significant competition, and an emphasis on intellectual property. We face potential competition from many different sources, including major and specialty pharmaceutical and biotechnology companies, including developers of tubular and glomerular cell drug modulators, e.g., SGLT2 inhibitors, antifibrosis medications, e.g., Mineralocorticoid Receptor Antagonists—MRAs, induced pluripotent cells, other autologous mesenchymal stem cells and mechanical renal assist devices such as implantable and wearable renal dialysis machines, and advances in peritoneal dialysis and home dialysis. Cell-based clinical trials by other companies are underway globally with umbilical, adipose and bone marrow derived mesenchymal stem cells for CKD. Early-phase human induced pluripotent stem cell therapies for kidney diseases are ongoing in Japan.

Any product candidates that we successfully develop and commercialize will compete with current therapies and new therapies that may become available in the future. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety profile, dosing, cost, effectiveness of promotional support and intellectual property protection. With respect specifically to REACT, we expect the key competitive factors affecting its success, if approved, will include the intended patient population, the relative convenience of dosing and administration, and efficacy.

Many other companies working on medications for controlling chronic kidney disease, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and

[Table of Contents](#)

development, pre-clinical testing, clinical trials, manufacturing, and marketing than we do. We believe that our principal competitors include developers of SGLT2 inhibitors, including canagliflozin (marketed as Invokana[®] by companies including Janssen Pharmaceuticals, Inc.), dapagliflozin (marketed under the brand names Farxiga[®] and Forxiga[®] by companies including AstraZeneca plc and Bristol-Myers Squibb Company), empagliflozin (marketed as Jardiance[®] by companies including Boehringer Ingelheim and Eli Lilly and Company) and finerenone (marketed as Kerendia[®] by companies including Bayer AG), and MRAs, which are small-molecule therapies recently approved to lower risks of CKD progression. Future collaborations and merger and acquisitions may result in further resource concentration among a smaller number of competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. These competitors may also vie for a similar pool of qualified scientific and management talent, sites and patient populations for clinical trials, as well as for technologies complementary to, or necessary for, our programs.

Supply and Manufacturing

With support from high level manufacturing and regulatory expertise, our internal manufacturing capabilities have enabled us to progress rapidly through our clinical trials. We believe that our current manufacturing capacities enable us to provide sufficient quantities of clinical trial material to supply the clinical trials. As we continue to develop our product candidates, we may need to expand our manufacturing capacities. The manufacturing facilities located in Winston Salem, North Carolina and the quality systems are fully compliant with cGMP and meet EU and FDA regulations. It usually takes approximately 12 weeks to produce the clinical REACT products. As of the date hereof, our manufacturing team, facilities, and bioprocess capacity have produced over 200 cell therapies. During our clinical trials, we have had a greater-than-95% success rate in creating a REACT product from a patient's biopsy material.

Our facility design and quality systems have been audited by European Qualified Persons (QP) and certified as compliant with EU cGMP requirements for phase 2/3 manufacturing. Our bioprocesses have been reviewed by the FDA and EMA and validation activities are ongoing in anticipation of being commercial-ready for the potential launch of REACT. We plan to build additional manufacturing capacity to meet the expanding demand.

Our commercial strategy focuses on process automation to scale up to meet the projected market for REACT, if we obtain the necessary regulatory approvals. We are collaborating with engineering companies such as DEKA Research & Development Corp. to develop automated manufacturing processes for the potential commercial production of REACT, including a REACT launch facility after we complete the Phase 3 patient enrollment and dosing in 2026, and two commercial manufacturing facilities after we launch REACT.

Our current costs of manufacturing REACT for use in our ongoing Phase 2 RMCL-002 study are approximately \$100,000 per patient. We anticipate that these costs will be lower for our Phase 3 trials and that the costs will continue to decrease by up to 50% from the costs of manufacturing REACT for our Phase 2 RMCL-002 study as we manufacture REACT at commercial scale with implementation of automation, bioprocess developments, formulation improvements, and streamlining of the supply chain. We expect to utilize automation in all aspects of manufacturing ranging from tissue processing, cell expansion and renal cell selection to formulation and filling of the final product. We will also extend automation to other manufacturing activities, including warehouse operations and supply chain. In addition, we intend to improve bioprocess development to further reduce manufacturing costs of the commercial REACT product, assuming receipt of necessary regulatory approvals. Culture media represents the highest cost in REACT processing, and we are exploring reduced culture media usage via bioprocess and automation improvements. Further, our final commercial REACT product is

[Table of Contents](#)

planned to be a cryopreserved formulation, which is projected to reduce manufacturing costs compared to our fresh REACT formulation. We expect to leverage bulk purchasing to actively negotiate pricing of materials to further drive cost reductions. However, there can be no assurance that the manufacturing costs for our Phase 3 trials when we manufacture REACT at commercial scale will actually be lower than for our ongoing Phase 2 RMCL-002 study. A number of factors may contribute to an inability to achieve these cost reductions, including any failures to achieve the automation efficiencies that we anticipate, cost overruns or inefficiencies in the supply chain and any failure to improve the formulation or bioprocessing of REACT in a manner that results in lower costs.

Key Agreements

Master Services Agreement, dated February 15, 2021, by and between George Clinical PTY Limited and ProKidney-KY

ProKidney-KY entered into a Master Services Agreement dated February 15, 2021 (the “George Clinical MSA”) with George Clinical PTY Limited (“George Clinical”), upon which George Clinical agreed to provide ProKidney-KY with certain clinical research services pursuant to work orders, including the setup and management of an Endpoint Adjudication Committee for ProKidney-KY’s protocol REGEN-006 and verification process for ProKidney-KY’s protocol REGEN-007, as well as a Data Safety Monitoring Board and a Steering Board Committee for ProKidney-KY’s development programs.

ProKidney-KY and George Clinical agreed to indemnify each other against certain third-party claims. The George Clinical MSA will continue until February 15, 2026, unless terminated earlier by either party. ProKidney-KY may terminate the George Clinical MSA upon 30 days’ prior written notice to George Clinical for any reason. Either party may terminate the George Clinical MSA (i) for material breach by the other party if, upon 30 days’ prior written notice by the non-breaching party, the breach has not been cured, or (ii) upon the insolvency or declaration of bankruptcy of the other party. ProKidney-KY may terminate any work order immediately if (i) the relevant study is terminated, or (ii) George Clinical breaches a material term of the George Clinical MSA or does not perform the services to ProKidney-KY’s reasonable satisfaction and does not remedy the breach or perform satisfactorily within 30 days of receiving a notice from ProKidney-KY specifying the nature of the breach or non-performance. George Clinical may terminate any work order upon written notice if it believes on reasonable grounds that continued performance of the services poses an unacceptable risk to patient safety or may violate regulatory or scientific standards.

Research, Development, Engineering Services and License Memorandum and Agreement, dated January 16, 2022, by and between ProKidney-KY and DEKA Products Limited Partnership

ProKidney-KY entered into a Research, Development, Engineering Services and License Memorandum and Agreement dated January 16, 2022 (the “RDELA”) with DEKA Products Limited Partnership and its general partner DEKA Research & Development Corp. (collectively, “DEKA”) under which DEKA will work with ProKidney-KY to develop certain technology to enhance the Company’s manufacturing and delivery capabilities for REACT. Under the RDELA, ProKidney-KY pays DEKA for its work on these research and development projects on a cost-plus model. DEKA owns the resulting IP and grants ProKidney-KY an exclusive, royalty-free, world-wide license to the resulting IP for purposes related to the provisions of cell therapy for the treatment of renal insufficiency.

Under the terms of the RDELA, ProKidney-KY agrees to indemnify DEKA for claims arising out of the use of the technology licensed to ProKidney-KY (including losses related to IP infringement claims and personal injury or products liability claims) and DEKA agrees to indemnify ProKidney-KY for claims arising out of the use of the technologies developed and licensed to third parties.

The term of the RDELA extends through the commercial life of any licensed technology developed thereunder subject to termination for breach and for ProKidney-KY’s convenience.

[Table of Contents](#)

The initial payment for DEKA's work under the RDELA was made through the issuance of 2,750,000 Class B-1 Units of ProKidney Management Equity LLC. All subsequent payments have been and will be made by ProKidney- KY in cash.

Master Services Agreement, dated April 20, 2020, by and between IQVIA RDS Inc. and ProKidney-KY

ProKidney-KY entered into a Master Services Agreement dated April 20, 2020 (the "IQVIA MSA") with IQVIA RDS, Inc. ("IQVIA"), under which IQVIA agreed to provide services for individual studies or projects of ProKidney-KY pursuant to work orders covering strategic planning, expert consultation, clinical trial services, statistical programming and analysis, data processing, data management, regulatory services, project management, pharmacovigilance, central laboratory services, clinical pharmacology services, electrocardiogram services and other services.

ProKidney-KY and IQVIA agreed to indemnify each other against certain third-party claims. The IQVIA MSA has an initial term of five years, or until terminated by either party, and will automatically renew each year for one-year periods, unless either party notifies the other party in writing at least 90 days prior to the renewal date that the notifying party wishes to terminate the IQVIA MSA. ProKidney-KY may terminate the IQVIA MSA without cause upon 60 days' prior written notice to IQVIA. Either party may terminate the IQVIA MSA, or any work order thereunder, (i) for material breach by the other party if, upon 30 days' prior written notice by the non-breaching party, the breach has not been cured, or (ii) upon the insolvency or declaration of bankruptcy of the other party. IQVIA may suspend services under if IQVIA reasonably determines that IQVIA's performance under the IQVIA MSA, or a work order thereunder, would constitute a potential or actual violation of regulatory, scientific, or ethical standards.

Master Agreement for Clinical Trials Services, dated April 2, 2020, by and between ProKidney-KY and Frenova, LLC

ProKidney-KY entered into a Master Agreement for Clinical Trials Services, dated April 2, 2020 (the "Frenova MSA") with Frenova, LLC d/b/a Frenova Renal Research ("Frenova"), under which Frenova agreed to provide ProKidney-KY with certain services related to the implementation and management of clinical development programs pursuant to statements of work ("SOWs") encompassing such services for ProKidney-KY's protocols RMCL-002, REGEN-006 and REGEN-007.

The Frenova MSA has an initial term of five years, or until terminated by either party, and will automatically renew each year for one-year periods, unless either party notifies the other party in writing at least 60 days prior to the renewal date that the notifying party wishes to terminate the Frenova MSA. ProKidney-KY may terminate the Frenova MSA or any SOW thereunder upon 60 days' prior written notice to Frenova for any reason. Frenova may terminate the Frenova MSA for material breach under the Frenova MSA by ProKidney-KY if, upon 60 days' prior written notice, the breach has not been cured. Additionally, Frenova may terminate any SOW upon 30 days' prior written notice if (i) ProKidney-KY cancels or materially delays the requested services; (ii) unanticipated material changes to the project assumptions cannot be addressed to both parties' satisfaction; (iii) changes to the study protocol cause enrollment targets to become commercially unreasonable; or (iv) ProKidney-KY is unable to make timely payments to Frenova resulting in Frenova lacking funds to process payments to the trial sites. Either party may terminate the Frenova MSA or any SOW thereunder (i) upon the insolvency or declaration of bankruptcy of the other party, (ii) if the other party is excluded, suspended, sanctioned or otherwise restricted from participating in federal health care programs, or (iii) the performance of the service would constitute a potential or actual violation of legal, regulatory, scientific, or ethical standards. ProKidney-KY and Frenova also agreed to indemnify each other against certain third-party claims.

Master Services Agreement, dated May 1, 2019, by and between PPD Development, LP and ProKidney-KY

ProKidney-KY entered into a Master Services Agreement dated May 1, 2019 (the "PPD MSA") with PPD Development, L.P. ("PPD"), under which PPD agreed to perform clinical development services in connection

[Table of Contents](#)

with ProKidney-KY's clinical research programs, and ProKidney-KY agreed to pay PPD in accordance with rates for such services, as set forth in the project addenda.

The PPD MSA has an initial term of five years and may be extended by mutual written agreement of the parties. ProKidney-KY may terminate any project addendum under the PPD MSA without cause upon 30 days' prior written notice. Either party may terminate any project addendum under the PPD MSA upon the other party's breach of the PPD MSA or project addendum upon 30 days' prior written notice, provided that the breach is not cured within such 30-day period. Either party may terminate the PPD MSA or any project addendum thereunder upon the occurrence of certain insolvency events. ProKidney-KY and PPD also agreed to indemnify each other against certain third-party claims.

Master Services Agreement, dated August 14, 2015, by and between CTI Clinical Trial Services Inc. and RegenMedTX, LLC

RegenMedTX, LLC ("RegenMedTX"), a subsidiary of ProKidney-KY, entered into a Master Services Agreement dated August 14, 2015 (the "CTI MSA") with CTI Clinical Trial Services, Inc. & CTI Clinical Consulting Services, Inc. ("CTI"), under which CTI agreed to provide RegenMedTX with certain clinical research or design and development services in connection with ProKidney-KY's clinical trials pursuant to work orders.

RegenMedTX will own all materials, documents and information obtained by, developed by or provided to CTI by or on behalf of RegenMedTX as a part of CTI's services or any work order thereunder. The CTI MSA will continue unless terminated by the parties. Either party may terminate the CTI MSA or a work order for any reason upon 90 days' prior written notice to the other party or for material breach by the other party upon 30 days' written notice, provided that the material breach has not been cured within the 30-day period. RegenMedTX may immediately terminate the CTI MSA, or a work order thereunder, if (i) the FDA withdraws authorization and approval to conduct a study or (ii) RegenMedTX reasonably determines that for medical, clinical or patient safety reasons, a study should terminate immediately.

Laboratory Service Agreements with LabCorp

Laboratory Service Agreement, dated August 16, 2016, by and among Covance Central Laboratory Services LP, Covance Central Laboratory Services SA`RL and ProKidney-KY

In August 2016, ProKidney-KY entered into a Laboratory Service Agreement with Covance Central Laboratory Services LP and Covance Central Laboratory Services SA`RL (now known as Labcorp, as described further below) (the "2016 LSA"), under which Labcorp agreed to perform certain services for ProKidney-KY's protocol RMCL-002.

The initial term of the 2016 LSA was 42 months, subject to automatic renewal for successive one-year periods unless a party provides the other party with written notice of its intention to not renew at least 60 days prior to the commencement of a renewal term. Either party may terminate the 2016 LSA upon written notice to the other party, effective immediately, if (i) the other party commits a material breach of any term of the 2016 LSA and fails to remedy such breach within a 30-day period, (ii) the other party repeatedly breaches any term of the 2016 LSA, (iii) anyone commences bankruptcy proceedings against the other party, which proceedings are not dismissed within 60 days, (iv) a court of competent jurisdiction appoints a custodian for the other party or substantially all of its assets, (v) the other party fails to pay its debts as they fall due, or (vi) any event occurs or proceeding is initiated having a similar effect to the events mentioned above. ProKidney-KY may terminate the 2016 LSA for any reason upon 90 days' prior written notice to Labcorp. ProKidney-KY granted Labcorp an unrestricted, royalty-free license to aggregate and use any system data produced by or for Labcorp as part of the services with other system data owned or licensed by Labcorp provided Labcorp does not identify such data as belonging to ProKidney-KY.

[Table of Contents](#)

Laboratory Service Agreement, dated August 1, 2017, by and among Covance Central Laboratory Services LP, Covance Central Laboratory Services SA` RL and ProKidney-KY

In August 2017, ProKidney-KY entered into a Laboratory Service Agreement with Labcorp (the “2017 LSA”). Under the terms of the 2017 LSA, Labcorp agreed to perform certain services for ProKidney’s protocol REGEN-003. The 2017 LSA has substantially similar terms and termination provisions to the 2016 LSA.

Laboratory Service Agreement, dated June 21, 2019, by and among Covance Central Laboratory Services LP, Covance Central Laboratory Services SA` RL and ProKidney-KY

In June 2019, ProKidney-KY entered into a Laboratory Service Agreement with Labcorp (the “2019 LSA”). Under the terms of the 2019 LSA, Labcorp agreed to perform certain services for ProKidney-KY’s protocol REGEN-004. The 2019 LSA has an initial term of 50 months and will renew automatically for successive one- year periods unless a party provides the other party with written notice of its intention to not renew at least 60 days prior to the commencement of a renewal term. The parties may terminate the 2019 LSA under terms that are substantially similar to the termination provisions of the 2016 LSA and 2017 LSA.

Laboratory Service Agreement, dated September 16, 2021, by and among Labcorp Central Laboratory Services LP, Labcorp Central Laboratory Services SA` RL and ProKidney-KY

ProKidney-KY and Labcorp Central Laboratory Services LP (formerly known as Covance Central Laboratory Services LP) and Labcorp Central Laboratory Services SA` RL (formerly known as Covance Central Laboratory Services SA` RL) (Collectively, “Labcorp”) entered into a Laboratory Service Agreement dated September 16, 2021 (the “Labcorp LSA”), under which Labcorp agreed to perform certain services for ProKidney-KY’s protocol REGEN-006.

The term of the Labcorp LSA will continue until the conclusion of the REGEN-006 study. Either party may terminate the Labcorp LSA under terms that are substantially similar to the termination provisions of the 2016 LSA, the 2017 LSA and the 2019 LSA, as well as pursuant to certain insolvency events. ProKidney-KY and Labcorp also agreed to indemnify each other against certain third-party claims. ProKidney-KY granted Labcorp an unrestricted, royalty-free license to aggregate and use any system data produced by or for Labcorp as part of the services with other system data owned or licensed by Labcorp provided Labcorp does not identify such data as belonging to ProKidney-KY.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, and product candidates that are important to the development and implementation of our business. For example, we have or are pursuing patents covering the composition of matter for each of our product candidates and we generally pursue patent protection covering methods-of-use for each clinical trial. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Additionally, we expect to benefit, where appropriate, from statutory frameworks in the United States, Europe and other countries that provide a period of clinical data exclusivity to compensate for the time required for regulatory approval of our products.

We continually assess and refine our intellectual property strategy as we develop new technologies and product candidates. We plan to file additional patent applications based on our intellectual property strategies where appropriate, including where we seek to adapt to competition or to improve business opportunities. Further, we plan to file patent applications, as we consider appropriate under the circumstances, to protect new technologies that we develop.

[Table of Contents](#)

To cover our proprietary technologies, proprietary cell-based REACT product and related methods, such as methods of use, we have filed patent applications representing 15 patent families. As of July 31, 2022, our patent estate, which is solely owned, included 286 total issued patents or pending patent applications with nine issued U.S. patents, nine pending U.S. non-provisional patent applications, five pending U.S. provisional patent applications, two pending Patent Cooperation Treaty (PCT) applications, 168 issued foreign patents and 93 pending foreign patent applications in various foreign jurisdictions.

Specifically, our patent family with claims directed to cells formulated in REACT, implantable constructs, and methods of using the same to, for example, improve kidney function or treat kidney disease, includes 30 issued patents and 10 pending patent applications. Patents in this family have been issued in nine jurisdictions, including the United States (three issued patents), Europe (two issued patents, each separately validated in seven countries), China, Japan, and South Korea. Issued patents and any further patents that may be issued from this family's 10 pending applications are expected to expire in 2029 absent any patent term adjustments or extensions.

We also own two patent families directed to our REACT formulations and methods of preparing the formulations. Across these families, we have 13 issued patents in multiple jurisdictions, including the United States, China, Japan, South Korea, and Canada. We also have 13 patent applications that are pending in multiple jurisdictions, including the United States, Europe, China, Japan, Hong Kong, South Korea, Canada, Mexico, and Australia. Patents across these two patent families, including any patents that may be issued from the pending applications, are expected to expire between 2031 and 2038, depending upon their respective filing dates and absent any patent term adjustments or extensions.

Additionally, we own two patent families with claims directed to quality control methods for ensuring that renal cells for formulation in REACT, prepared by our proprietary methods, have phenotypic and functional profiles indicative of therapeutic activity. Within the first patent family, we have 58 issued patents in various jurisdictions, including the United States (two issued patents), Europe (two issued patents, one of which has been validated in 21 countries and the other has been validated in 20 countries), China, Japan (two issued patents), South Korea (two issued patents), Hong Kong, Australia (two issued patents), and New Zealand (two issued patents) and are expected to expire in 2033 absent any patent term adjustments or extensions. We also have nine patent applications that are pending in multiple jurisdictions, including the United States, Europe, Australia, China, and South Korea, and are expected to expire in 2033 absent any patent term adjustments or extensions. Our second patent family includes a PCT stage application. Any patents that issue from a national or regional stage application filed from this PCT application are expected to expire in 2041 absent any patent term adjustments or extensions.

We further own three patent families directed to methods of improving kidney function and/or in treating kidney disease, e.g., diabetic kidney disease or kidney disease resulting from a congenital anomaly. Across these families, we have three issued patents, including one U.S. patent and 28 pending patent applications filed in 15 jurisdictions, including the United States, Europe, Hong Kong, China, Korea, Japan, Australia, Brazil, Mexico, Israel, Canada, and Mexico. Our issued U.S. patent is expected to expire in 2037 absent any patent term adjustments or extensions. Patents across all three patent families, if issued, are expected to expire between 2036 and 2042, depending upon their respective filing dates and absent any patent term adjustments or extensions.

In addition, we plan to file additional applications on aspects of our innovations that may have patent terms that extend beyond these dates.

The term of individual patents depends upon the laws of the countries in which they are obtained. In the countries in which we currently file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application, which serves as a priority application. However, the term of a U.S. patent may be extended to compensate for the time required to obtain regulatory approval to sell a medicine (a patent term extension) or by delays encountered during patent prosecution that are caused by the USPTO (referred to as

patent term adjustment). For example, the Hatch-Waxman Act permits a patent term extension for FDA-approved medicines of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the medicine is under regulatory review and diligence during the review process. Patent term extensions cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent covering an approved medicine or its method of use may be extended. A similar kind of patent extension, referred to as a Supplementary Protection Certificate, is available in Europe. Legal frameworks are also available in certain other jurisdictions to extend the term of a patent. We currently intend to seek patent term extensions on any of our issued patents in any jurisdiction where we have a qualifying patent and the extension is available; however there is no guarantee that the applicable regulatory authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. Further, even if our patent is extended, the patent, including the extended portion of the patent, may be held invalid or unenforceable by a court of final jurisdiction in the United States or a foreign country.

As with other biotechnology and pharmaceutical companies, our ability to obtain and maintain a proprietary position on our product candidates and technologies will depend on our success in obtaining effective patent claims on these pending patents and enforcing those claims if granted. However, our pending patent applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Furthermore, our competitors may be able to independently develop and commercialize products with similar mechanisms of action and duplicate our methods of treatments or strategies without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a therapeutic product we may develop, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our clinical candidates. The area of patent and other intellectual property rights in pharmaceuticals is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our clinical candidates.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to obtain and maintain our proprietary position for our product candidates and technology will depend on our success in enforcing the claims that have been granted or may grant. However, any of our patents, including patents that we may rely on to protect our market for approved therapeutics, may be held invalid or unenforceable by a court of final jurisdiction. Alternatively, we may decide that it is in our interest to settle a litigation in a manner that affects the term or enforceability of our patent. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights. Accordingly, we cannot predict the breadth or enforceability of claims that have been or may be granted in our patents or in third-party patents.

Trade secrets

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees, and consultants, and invention assignment agreements with our employees. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Government regulation

In the United States, biological products, including cell-based regenerative therapy products, are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the “FD&C Act”), the Public Health Service Act (the “PHS Act”) and other federal, state, local and foreign statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the research, development, clinical trial, testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products. Each clinical trial protocol for a cell- based therapy product must be reviewed by the FDA. FDA approval must be obtained before the marketing of any biological product. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals.

Ethical, social and legal concerns about gene or cell-based therapies, genetic testing and genetic research could result in additional laws and regulations restricting or prohibiting the processes we may use. Federal and state legislatures, agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive laws and regulations or interpretations of existing laws or regulations, or claims that our product candidates are unsafe or pose a hazard, could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of our product candidates under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

U.S. biological products development process

The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to GLP, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an IND which must become effective before human clinical trials may begin;
- approval of the protocol and related documentation by an IRB, or ethics committee at each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to applicable IND regulations, good clinical practices, or GCPs and other clinical-trial related regulation, to evaluate the safety and efficacy of the investigational biological product for each proposed indication;
- submission to the FDA of a BLA for marketing approval that includes sufficient evidence of establishing the safety, purity, and potency of the proposed biological product for each proposed indication, including from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the biological product’s identity, strength, quality and purity and, if applicable, compliance with the FDA’s cGTPs for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites to assure compliance with GLP and GCP and the integrity of the clinical data submitted in support of the BLA;
- review of the product candidate by an FDA advisory committee, where appropriate or if applicable;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies); and
- FDA review and approval, or licensure, of the BLA.

[Table of Contents](#)

Preclinical Studies

Before testing any biological product candidate, including a cell-based regenerative therapy product, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of a product candidate's biological characteristics, chemistry, toxicity, stability and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin.

The conduct of the preclinical tests must comply with federal regulations and requirements including GLP. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after an IND for an investigational drug candidate is submitted to the FDA and human clinical trials have been initiated.

Human clinical trials in support of a BLA

All clinical trials must be conducted under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Study subjects must sign an informed consent form before participating in a clinical trial. There are also requirements governing the reporting of on-going clinical trials and clinical trial results to public registries.

An IND is an exemption from the FD&C Act that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. Such authorization must be secured prior to interstate shipment and administration of any biologic product candidate that is not the subject of an approved BLA. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, must be submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Following commencement of a clinical trial, the FDA may also place a clinical hold or partial clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When a foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study complies with certain

regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval or licensing. In particular, such studies must be conducted in accordance with GCP, including review and approval by an IEC and informed consent from subjects and must meet other clinical trial requirements, such as sufficient patient population size and statistical powering. The FDA must be able to validate the data through an onsite inspection, if deemed necessary by the FDA.

An IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a DSMB. This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study.

Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific timeframes to the National Institutes of Health for public dissemination on the ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The National Institutes of Health's (NIH) Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both NIH and FDA have recently begun enforcing those requirements against non-compliant clinical trial sponsors.

Clinical trials typically are conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some product candidates for severe or life-threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2.* The product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide, if appropriate, an adequate basis for approval and product labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the NIH and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of such information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all.

Human cell-based products administered directly into kidney tissue are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the study period, the number of patients the FDA will require to be enrolled in the studies in order to establish the safety, purity and potency of human cell-based therapy products, or that the data generated in these studies will be acceptable to the FDA to support marketing approval.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. review and approval processes

After the completion of clinical trials of a biological product candidate, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity, potency and efficacy of the investigational product for its proposed indication or indications to the satisfaction of the FDA. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each BLA must be accompanied by a significant user fee (for example, for fiscal year 2022, this application fee exceeds \$3.1 million). The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for registered biologic product manufacturers, currently more than \$300,000 per program. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins

[Table of Contents](#)

an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure, potent and effective for its proposed indication or indications and whether the product is being manufactured in accordance with cGMP to ensure the continued safety, purity and potency of such product.

Under the performance goals and policies implemented by the FDA under PDUFA, for original BLAs, the FDA targets ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended due to FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving a BLA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. For a cell-based therapy product, the FDA also will not approve the product if the manufacturer is not in compliance with the cGTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products (“HCT/ Ps”), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the cGTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through appropriate screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP, cGTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

Additionally, the FDA may refer any BLA, including applications for novel biologic candidates which present difficult questions of safety or efficacy, to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval. The FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The FDA also may require submission of a REMS if it determines that a REMS is necessary to ensure that the benefits of the medicine outweigh its risks and to assure the safe use of the medicine or biological product. The REMS could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Under the Pediatric Research Equity Act (“PREA”), a BLA or supplement to a BLA for a novel product (e.g., new active ingredient, new indication, etc.) must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. The PREA requires a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to submit an initial Pediatric Study Plan

(“PSP”), within sixty days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from pre-clinical studies, early phase clinical trials or other clinical development programs.

The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product’s continued safety, purity and potency. The approval process is lengthy and often difficult, and the FDA may refuse to approve a BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. On the basis of the FDA’s evaluation of the BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue either an approval letter or a Complete Response Letter (“CRL”). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may choose to either resubmit the BLA addressing all of the deficiencies identified in the letter, or withdraw the application. If and when those deficiencies have been addressed to the FDA’s satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If a product receives regulatory approval from the FDA, the approval is limited to the conditions of use (e.g., patient population, indication) described in the application. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product’s safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, RMAT and Priority Review Designations

The FDA has various programs, including Fast Track designation, RMAT designation and priority review, that are intended to expedite or simplify the process for the development or FDA review of medicines and biologics that are intended for the treatment of serious or life-threatening diseases or conditions. These programs do not change the standards for approval but may help expedite the development or approval process.

To be eligible for fast-track designation, the FDA must determine, based on the request of a sponsor, that a new medicine or biological product is intended to treat a serious or life-threatening condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be

potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA or BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging from the clinical trial process.

As part of the 21st Century Cures Act (the “Cures Act”), enacted in December 2016, Congress amended the FD&C Act to facilitate an efficient development program for, and expedite review of regenerative medicine advanced therapies, or RMATs, which include cell and gene therapies, therapeutic tissue engineered products, human cell and tissue products, and combination products using any such therapies or products. REACT has received RMAT designation from the FDA. RMAT designation does not include HCT/Ps regulated solely under section 361 of the PHS Act and 21 Code of Federal Regulations Part 1271. This program is intended to facilitate efficient development and expedite review of regenerative medicine therapies that are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition. A sponsor may request that FDA designate a medicine as a RMAT concurrently with or at any time after submission of an IND. The FDA has 60 calendar days to determine whether the medicine meets the criteria, including whether there is preliminary clinical evidence indicating that the medicine has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence from clinical trials, patient registries, or other sources of real-world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

Finally, the FDA may designate a product for priority review if it is a medicine or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed medicine represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA’s goal for taking action on a marketing application from ten months to six months for an original BLA or for a New Molecular Entity NDA from the date of filing.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, RMAT therapy designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Accelerated approval pathway

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the

product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a medicine or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality (“*IMM*”), and that is reasonably likely to predict an effect on *IMM* or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a medicine receiving accelerated approval perform post- marketing clinical trials to verify and describe the predicted effect on *IMM* or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs and biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a medicine, such as an effect on *IMM*. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a medicine.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a medicine, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of medicines for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor’s agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the medicine’s clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the medicine. All promotional materials for product candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

Post-approval requirements

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with promotion and advertising requirements.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. We must comply with applicable requirements in the cGMP and cGTP regulations, including quality control and quality assurance and maintenance of records and documentation. Entities involved in the manufacture and distribution of approved biologics and HCT/Ps are required to register their establishments with the FDA and certain state agencies, as well as applicable foreign counterparts, and are

subject to periodic unannounced inspections by such governmental authorities for compliance with cGMP, cGTP and other laws. Accordingly, we must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Future inspections by governmental authorities may identify compliance issues at our facilities that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMP or cGTP, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including voluntary recall and regulatory sanctions as described below.

Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the internet, as well as the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"). Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or a BLA supplement, which may require the applicant to develop additional data or conduct additional pre-clinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Once an approval or clearance of a medicine is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information, imposition of post-market or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;

[Table of Contents](#)

- refusal of the FDA to approve pending NDAs/BLAs or supplements to approved NDAs/BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of medicine and medicine samples at the federal level, and sets minimum standards for the registration and regulation of pharmaceutical distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Furthermore, the Drug Supply Chain Security Act (“DSCSA”) was enacted with the aim of building an electronic system to identify and trace certain prescription medicines distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

U.S. patent term restoration and marketing exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our patents, if and as applicable, to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

A biological product may also obtain pediatric market exclusivity in the United States. Pediatric exclusivity is a type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a Written Request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA’s request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a Written Request does not require the sponsor to undertake the described studies.

Reference product exclusivity for biological products

In March 2010, the ACA was enacted in the United States and included the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, the FDA has approved a number of biosimilars, and numerous biosimilars have been approved in Europe. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilars.

A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. The FDA approved the first interchangeable biosimilars, including an interchangeable monoclonal antibody biosimilar, in 2021.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. If pediatric studies are performed and accepted by the FDA as responsive to a Written Request, the 12-year exclusivity period will be extended for an additional six months. In addition, the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a supplement for the reference product for a subsequent application filed by the same sponsor or manufacturer of the reference product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

The BPCIA is complex and is still being interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty.

Additional regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Furthermore, some countries have enacted or are considering enacting legal restrictions on the import or export of human genetic materials, cells or tissues. For example, in China, the Ministry of Science and Technology (“MOST”) and the former Ministry of Health in June 1998 jointly established the Interim Measures for the Administration of Human Genetic Resources in China. In July 2015, the MOST issued the Service Guide for the Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, which provides that foreign entities that collect and use patients’ human genetic resources in clinical trials shall be required to file for an advance approval with the Human Genetic Resources Administration Office (“HGRAO”) through its online system.

In October 2017, the MOST issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources, which simplified the approval process for collecting and using human genetic resources for the purpose of seeking marketing authorization of medicines in China.

In May 2019, the State Council of China issued the Regulation on the Administration of Human Genetic Resources (the “HGR Regulation”), which stipulates the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities. Pursuant to this new rule, a new filing system (as opposed to the advance approval approach originally in place) is put in place for international clinical trials using Chinese patients’ biospecimens at clinical study sites without involving the export of such biospecimens outside of China. A notification filing that specifies the type, quantity and usage of the biospecimens, among others, with the HGRAO is required before conducting such clinical trials. The collection, use, and outbound transfer of Chinese patients’ biospecimens in international collaboration for basic scientific research involving export are still subject to the advance approval of the HGRAO.

In October 2020, the Standing Committee of the National People’s Congress promulgated the China Biosecurity Law, which became effective on April 15, 2021. The China Biosecurity Law reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative fines significantly in cases in which foreign entities are alleged to have collected, preserved or exported Chinese human genetic resources.

U.S. Foreign Corrupt Practices Act

The FCPA, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

Government regulation outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy,

[Table of Contents](#)

labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products as well as authorization and approval of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

European Union clinical trials regulation

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a Clinical Trial Application (“CTA”) must be submitted for each clinical trial to each country’s National Competent Authority (“NCA”) and at least one IEC, much like the FDA and an IRB, respectively. Once the CTA is approved in accordance with a country’s requirements, the corresponding clinical trial may proceed. Under the current regime (the EU Clinical Trials Directive 2001/20/EC and corresponding national laws) all suspected unexpected serious adverse reactions to the investigated medicine that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

Under the Clinical Trials Regulation (EU) No 536/2014, which came into effect on January 31, 2022, there is a centralized application procedure where one EU Member State’s competent authority takes the lead in reviewing part I of the application, which contains scientific and medicinal product documentation, and the other national authorities only have limited involvement. Part II, which contains the national and patient-level documentation, is assessed individually by each EU Member State. Any substantial changes to the trial protocol or other information submitted with the CTA must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with good manufacturing practices. Other national and EU-wide regulatory requirements may also apply.

Medicinal product review and approval in the EEA

In the EEA (comprised of the EU Member States plus Norway, Iceland and Liechtenstein), medicinal products, including ATMPs, are subject to extensive pre- and post-market regulation by regulatory authorities at both the EEA and national levels. Regulated in accordance with Regulation (EC) No 1394/2007 (the “ATMP Regulation”), ATMPs comprise gene therapy products, somatic cell therapy products and tissue engineered products. The CAT (as defined below) designated REACT as a tissue engineered product. Gene therapy products deliver genes into the body that lead to a therapeutic, prophylactic or diagnostic effect. We anticipate that REACT will be regulated as an ATMP in the EEA.

To obtain regulatory approval of an ATMP under EEA regulatory systems, we must submit a marketing authorization application (“MAA”) under the centralized procedure administered by the EMA. The application used to submit the BLA in the United States is similar to the required application process in the European Union, with the exception of, among other things, certain specific requirements set out in the ATMP Regulation, for example certain additional product characteristic information that must be included in the MAA. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid across all of the EEA. As provided for in the ATMP Regulation, the scientific evaluation of MAAs for ATMPs is primarily performed by a specialized scientific committee called the Committee for Advanced Therapies (the “CAT”). The CAT prepares a draft opinion on the quality, safety and efficacy of the ATMP which is the subject

of the MAA, which is sent for final approval to the Committee for Medicinal Products for Human Use (the “CHMP”). The CHMP recommendation is then sent to the European Commission, which adopts a decision binding in all EEA Member States. The maximum timeframe for the evaluation of a MAA for an ATMP is 210 days from receipt of a valid MAA, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CAT and/or CHMP. Clock stops may extend the timeframe of evaluation of a MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, which makes and issues the final decision to grant a marketing authorization within 67 days of receipt of the EMA’s recommendation. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

Now that the United Kingdom (which comprises Great Britain and Northern Ireland) has left the European Union, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Ireland Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January, 1 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency (the “MHRA”), the United Kingdom medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required.

Data and marketing exclusivity

The EEA also provides opportunities for market exclusivity. Upon receiving marketing authorization in the EEA, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator’s preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization during a period of eight years from the date on which the reference product was first authorized in the EEA. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator’s data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if an innovative medicinal product gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on a MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials. There is, however, no guarantee that a product will be considered by the European Union’s regulatory authorities to be an innovative medicinal product, and products may therefore not qualify for data exclusivity.

Post-approval controls

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include the following:

- The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that

system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (“PSURs”).

- All new MAAs must include a risk management plan (“RMP”), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.
- All advertising and promotional activities for the product must be consistent with the approved Summary of Product Characteristics (“SmPC”), and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each EU Member State and can differ from one country to another.

Failure to comply with European Union and EU Member State laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products (both before and after grant of the marketing authorization), manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. Such penalties could include delays or refusal to authorize the conduct of clinical trials or to grant the marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Brexit and the Regulatory Framework in the United Kingdom

In June 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as “Brexit”). Thereafter, in March 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom formally left the European Union on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical law remained applicable to the United Kingdom. This transition period ended on December 31, 2020. Since the regulatory framework in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom as United Kingdom legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the United Kingdom in the long-term. The MHRA, the United Kingdom medicines and medical devices regulator, has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now that the transition period is over, which will be updated as the United Kingdom’s regulatory position on medicinal products evolves over time. On June 28, 2021, the European Commission issued a decision that the United Kingdom ensures an adequate level of protection for personal data transferred under the GDPR from the European Union to the United Kingdom.

Other health care laws and compliance requirements

If our product candidates are approved in the United States, we will have to comply with various U.S. federal and state laws, rules and regulations pertaining to health care fraud and abuse, including anti-kickback laws and false claims laws, rules and regulations. Violations of the fraud and abuse laws are punishable by

criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, including Medicare and Medicaid. These laws include:

- the AKS, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal health care program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the AKS or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA or federal civil money penalties statute;
- the federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal health care programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the Civil Monetary Penalties Law (beneficiary inducement law), which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular supplier of items or services reimbursable by a federal or state governmental program;
- HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, health care benefits, items or services relating to health care matters; similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of medicines, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the U.S. Department of Health and Human Services (“DHHS”) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, certified nurse midwives and teaching hospitals, as well as ownership and investment interests held by the providers described above and their immediate family; and
- the FCPA and other anti-corruption laws and regulations pertaining to our financial relationships and interactions with foreign government officials, which prohibit U.S. companies and their employees, officers, and representatives from paying, offering to pay, promising, or authorizing the payment of

[Table of Contents](#)

anything of value to any foreign government official (including, potentially, healthcare professionals in countries in which we operate or may sell our products), government staff member, political party, or political candidate to obtain or retain business or to otherwise seek favorable treatment.

In November 2020, the DHHS finalized significant changes to the regulations implementing the AKS, as well as the civil monetary penalty rules regarding beneficiary inducements, with the goal of offering the healthcare industry more flexibility and reducing the regulatory burden associated with those fraud and abuse laws, particularly with respect to value-based arrangements among industry participants.

Additionally, we are subject to state and foreign equivalents of each of the health care laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the AKS and FCA, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Health Care Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines, imprisonment and/or exclusion or suspension from federal and state health care programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the FCA as well as under the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing health care fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable health care laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other health care providers are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state health care programs (such as Medicare and Medicaid), and imprisonment, any of which could adversely affect our ability to operate our business and our financial results. The approval and commercialization of any of our product candidates outside the United States will also subject us to foreign equivalents of the health care laws mentioned above, among other foreign laws.

If any of the physicians or other health care providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded health care programs, which may also adversely affect our business.

The risk of our being found in violation of these laws is increased by the fact that many of these laws have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could

cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust system to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that a health care company may violate one or more of the requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial cost.

Data Privacy and Security

There are federal, state and foreign laws governing the privacy and security of health information and personal information, many of which differ from each other in significant ways and apply simultaneously, thus complicating compliance efforts.

HIPAA, as amended by HITECH, and its implementing regulations, strengthens and expands requirements relating to the privacy, security, and transmission of individually identifiable health information; and requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information.

HITECH strengthened and expanded HIPAA and increased penalties for violations. Under HITECH, regulated entities are subject to enforcement by the federal government and by state Attorneys General, who were given authority to enforce HIPAA under HITECH. Some state laws impose privacy protections more stringent than HIPAA and data security requirements applicable to information beyond health care information (for example, the CCPA). These state laws create an additional level of enforcement and may require additional reporting in the event of breach. Most of the health care providers in the United States with whom we collaborate to develop and test our products must comply with HIPAA and applicable state law. We may not be directly subject to these laws, however, we must structure our activities in compliance with these laws to ensure that we can access and use health information to support our research, development and other activities. Our failure to comply with these privacy and security laws or a breach of health information or personal data could prompt enforcement against our health care provider partners, create third party liability for our company and/or cause significant financial or reputational harm to our company.

We may also be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EEA, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

Health care reform

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in

[Table of Contents](#)

December 2016, the Cures Act was signed into law. The Cures Act, among other things, was intended to modernize the regulation of pharmaceuticals and devices and to spur innovation, but its ultimate implementation is uncertain. Legislative proposals continue to be discussed in the U.S. Congress as potentially leading to a future “Cures 2.0” bill that is expected to have bipartisan support. In addition, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA’s user fee programs and included additional medicine and biological product provisions. The next legislative reauthorization must be completed in 2022, which has the potential to make further changes to FDA authorities or policies pertaining to biopharmaceutical products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, the containment of healthcare costs has become a priority of federal and state governments and the prices of therapeutics have been a focus in this effort. The U.S. government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic and biosimilar products for branded prescription medicines and biologics, respectively. In recent years, the U.S. Congress has considered reductions in Medicare reimbursement levels for medicines and biologics administered by physicians. CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some medicines and biologics. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products we may market in the future. While Medicare regulations apply only to pharmaceutical benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

The ACA, as amended by the Health Care and Education Affordability Reconciliation Act, was enacted in 2010 and substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly impacted the pharmaceutical industry. The ACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical manufacturers, and impose additional health policy reforms. With regard to biopharmaceutical products, the ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for therapeutics that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription medicines, created a new Medicare Part D coverage gap discount program, and expanded the 340B drug discount program. As another example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive healthcare provisions and amendments to existing laws, including a requirement that all manufacturers of medicines and biological products covered under Medicare Part B report the product’s average sales price, to the DHHS beginning on January 1, 2022, subject to enforcement via civil money penalties.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA since its enactment, and it is possible that there will be additional challenges and amendments to the ACA in the future.

Other legislative changes have been proposed and adopted since passage of the ACA that affect health care expenditures. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030 unless additional Congressional action is taken. However, due to COVID-19 pandemic relief legislation and subsequent legislation, the 2% Medicare sequester reductions were suspended from May 1, 2020 through

June 30, 2021 (a 1% sequester applied from April 1, 2022 through June 30, 2022), and the sequester was extended in order to offset the added expense of the 2020 suspension. Further legislative and regulatory changes under the ACA remain possible, although the new administration under President Biden has signaled that it plans to build on the ACA and expand the number of people who are eligible for health insurance subsidies under it. President Biden indicated that he intends to use executive orders to undo changes to the ACA made by the former administration and would advocate for legislation to build on the ACA. It is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate medicine prices, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the United States.

In recent years, there has been heightened governmental scrutiny over the manner in which biopharmaceutical manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to medicine pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of medicines under Medicare, and reform government program reimbursement methodologies for pharmaceutical products. Congress and the executive branch have each indicated that it will continue to seek new legislative and/or administrative measures to control the costs of medicines, making this area subject to ongoing uncertainty.

At the state level in the United States, legislatures have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional federal, state, and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Coverage and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any cell-based regenerative therapies for which we may obtain regulatory approval. In the United States and markets in other countries, sales of any cell-based therapies for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from payors. Payors include government authorities, managed care providers, private health insurers and other organizations. Patients who are prescribed treatments for their conditions and providers who prescribe such treatments generally rely on these third-party payors to reimburse all or part of the treatment and other associated health care costs. The process for determining whether a payor will provide coverage for a medicine, device or biologic product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a payor not to cover our cell-based therapies could reduce physician utilization of our products, if they are approved, and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate

[Table of Contents](#)

reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development and manufacturing costs. Further, due to the COVID-19 pandemic, millions of individuals have lost or may lose employer-based insurance coverage, which may adversely affect our ability to commercialize our products in certain jurisdictions.

In addition, coverage and reimbursement for products can differ significantly from payor to payor. One payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Additionally, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

Payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and reimbursement for any product, we may need to conduct expensive evidence generation studies in order to demonstrate the medical necessity and cost-effectiveness of such a product, in addition to the costs required to obtain regulatory approvals. If payors do not consider a product to be cost-effective compared to current standards of care, they may not cover the product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to cover its costs or make a profit.

Outside of the United States, the pricing of pharmaceutical products is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed with the government authority. Furthermore, some countries may require the completion of additional studies that compare the effectiveness and/or cost-effectiveness of a particular therapy to current standards of care as part of so-called health technology assessments in order to obtain reimbursement or pricing approval. Additionally, there may be a need for activities to secure reimbursement for procedures associated with products administered in a hospital setting under the diagnosis-related group system, whereby a billing code may not exist or may be currently insufficient to cover the cost of the procedure. In other instances, countries may monitor and control product volumes and issue guidance to physicians to limit prescriptions in the form of treatment policies. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage health care expenditures.

Human Capital Resources

As of July 31, 2022, ProKidney had 77 full-time employees. This included 26 in research and development, 41 in manufacturing, operations, quality control and quality assurance, and 10 in general and administrative functions. We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages. We consider our relations with our employees to be good.

Facilities

Our headquarters are located in Winston-Salem, North Carolina, where we lease approximately 38,400 square feet of office, manufacturing and research space, under a lease that expires on September 30, 2026. We have leased approximately 2,700 square feet of additional office space in Winston-Salem, which we plan to use as our new principal executive offices. This lease commenced in April 2022 and is expected to expire in April 2027. There is an additional office located in Raleigh, North Carolina where we lease approximately 2,200 square feet, under a lease that expires February 28, 2025. There was an amendment to the original lease for the

[Table of Contents](#)

Raleigh office. The amended lease is for approximately 5,700 square feet that will expire on January 31, 2027. Further, there has been an additional amendment to the original lease for the Raleigh office, which increases the total space to approximately 7,900 square feet and will expire on July 31, 2027. We believe our facilities are adequate for our current needs and that suitable additional substitute space would be available if needed.

Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of the financial condition and results of operations should be read together with the financial statements and the related notes to those statements included elsewhere in this prospectus. The discussion and analysis should also be read together with the pro forma financial information as of and for the three months ended March 31, 2022 and as of and for the year ended December 31, 2021 included in this prospectus. See "Unaudited Pro Forma Condensed Financial Information." Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. In this section, unless the context otherwise requires, references to "we," "us," "our," the "Company" and "ProKidney" refer to ProKidney LP and its subsidiaries prior to the Closing and to ProKidney Corp. and its subsidiaries after the Closing, and "SCS" refers to SCS prior to the Closing.

Overview

We are a clinical-stage biotechnology business with a transformative proprietary cell therapy platform capable of treating multiple chronic kidney diseases using a patient's own cells isolated from the patient intended for treatment. Our approach seeks to redefine the treatment of CKD, shifting the emphasis away from management of kidney failure, to the restoration or improvement of kidney function to stop or delay progression of CKD. Our lead product candidate, which we refer to as REACT, is designed to stabilize or improve kidney function in a CKD patient's diseased kidneys. REACT is a product that includes SRCs prepared from a patient's own, autologous, renal cells. SRCs are formulated into a product for reinjection into the patient's kidney using a minimally invasive outpatient procedure that can be repeated if necessary. Because REACT is a personalized treatment composed of cells prepared from a patient's kidney, there is no need for treatment with immunosuppressive therapies, which are required during a patient's lifetime when a patient receives a kidney transplant from another, allogeneic donor.

We are currently conducting a Phase 3 development program and multiple Phase 2 clinical trials for REACT in subjects with moderate to severe diabetic kidney disease. We are also conducting a Phase 1 clinical trial for REACT in subjects with CAKUT. REACT has been well tolerated by subjects with moderate to severe diabetic kidney disease in Phase 1 and 2 clinical testing to date. It has also been shown to stabilize renal function in subjects based on measurements of iohexol renal clearance and UACR. REACT has received RMAT designation from the FDA.

ProKidney Bermuda was incorporated under the laws of Bermuda in December 2018, and it was initially capitalized with \$75.0 million to finance the purchase of ProKidney-KY and ProKidney-US, and to fund the clinical development of REACT. In December 2014, Tengion, whose assets were purchased in March 2015 by RegenMedTX, LLC, a predecessor to ProKidney, commenced a Chapter 7 Case by filing a voluntary petition for relief under the provisions of chapter 7 of title 11 of the United States Code, 11 U.S.C. §§ 101 et seq. in the Bankruptcy Court. As a result of the filing of the Chapter 7 Case, a Chapter 7 trustee was appointed by the Bankruptcy Court to assume control of Tengion.

On August 5, 2021, ProKidney LP was formed as a limited partnership under the laws of Ireland, with ProKidney Bermuda becoming a wholly owned subsidiary of ProKidney LP. Since inception, ProKidney and its subsidiaries have devoted substantially all of their resources to raising capital, organizing and staffing, business and scientific planning, conducting discovery and research activities, acquiring or discovering product candidates, establishing and protecting their intellectual property portfolio, developing and progressing REACT and preparing for clinical trials, establishing arrangements with third parties for the manufacture of component

[Table of Contents](#)

materials, and providing general and administrative support for these operations. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

On July 11, 2022, SCS and ProKidney LP completed the Business Combination, and SCS's corporate name was changed to "ProKidney Corp."

The combined company was organized in an umbrella partnership-C corporation (a so called "Up-C" structure). ProKidney Corp. is a holding company, and our direct assets consist of Post-Combination ProKidney Common Units and all of the issued and outstanding equity interests of GP, which became the general partner of ProKidney LP upon the Closing. ProKidney Corp. controls GP, with the rights of management specified in the Second Amended and Restated ProKidney Limited Partnership Agreement.

From inception through March 31, 2022, ProKidney and its subsidiaries funded their operations primarily through capital contributions and promissory notes issued to certain ProKidney unitholders and have received aggregate net proceeds from these transactions of \$186.5 million and \$35.0 million, respectively. The \$35.0 million received under the promissory notes was repaid at the Closing.

We incurred significant operating losses since inception, including net losses of \$67.5 million and \$11.6 million for the three months ended March 31, 2022 and 2021, respectively, and \$55.1 million and \$26.7 million for the years ended December 31, 2021 and 2020, respectively. As of March 31, 2022 and December 31, 2021, we had an accumulated deficit of \$229.0 million and \$161.5 million, respectively. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, particularly if and as we continue to invest in our research and development activities, expand our product pipeline, hire additional personnel, invest in and grow our business, maintain, expand and protect our intellectual property portfolio, and seek regulatory approvals for and commercialize any approved product candidates. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, audit, accounting, regulatory, tax-related, director and officer insurance, investor relations and other expenses that we did not incur as a private company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the public or private sale of equity, government or private party grants, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. If we are unable to obtain additional funding, we could be forced to delay, reduce or eliminate some, or all, of our research and development programs, product portfolio expansion or any commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. If we raise funds through strategic collaborations or other similar arrangements with third parties, we may have to relinquish valuable rights to our platform technology, future revenue streams, research programs or product candidates or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our units. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic or other events. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability.

As of March 31, 2022, we had cash and cash equivalents of \$29.8 million. Additionally, we have remaining availability of \$65.0 million under the ProKidney Promissory Notes. We expect that, having completed the Business Combination and accounting for \$574.8 million received in the PIPE Investment, our cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through 2024. We have based this estimate on assumptions that may prove to be wrong and we could exhaust our capital resources sooner than we expect.

The Business Combination

The Business Combination will be accounted for as a common control transaction in accordance with GAAP. Under the guidance in ASC 805, SCS will be treated as the “acquired” company for financial reporting purposes. Accordingly, the Business Combination will be reflected as the equivalent of ProKidney issuing shares for the net assets of SCS, accompanied by a recapitalization whereby no goodwill or other intangible assets are recorded. Operations following the Business Combination are those of ProKidney Corp. The Business Combination will have a significant impact on our future reported financial position and results as a consequence of the reverse capitalization.

The Business Combination resulted in gross proceeds of approximately \$596,537,000. This amount reflects a contribution of \$21,737,000 of cash held in SCS’s trust account, net of redemptions, and a \$574,800,000 concurrent private placement of Class A ordinary shares of the combined company, priced at \$10.00 per share (the “PIPE Placement”). At the Closing, these proceeds were used to repay the outstanding balance of \$35,000,000 under the Company’s two promissory note agreements with certain holders of its Class A Units (the “Promissory Notes”) and related accrued interest. Additionally, the proceeds were used to pay those expenses previously incurred by SCS related to the business combination of approximately \$21,029,000 as well as advisory and placement fees of approximately \$29,389,000 incurred in connection with the PIPE Placement.

Business Impact of the COVID-19 Pandemic

The global COVID-19 pandemic continues to rapidly evolve, and we will continue to monitor the COVID-19 situation closely. To date, our financial condition and operations have not been significantly impacted by the COVID-19 pandemic. However, we cannot, at this time, predict the specific extent, duration or full impact that the COVID-19 pandemic will have on our financial condition and operations, including our ongoing and planned clinical trials. The extent of the impact of the COVID-19 on our business, operations and clinical development timelines and plans remains uncertain and will depend on certain developments, including the duration and spread of the outbreak and its impact on our clinical trial enrollment, trial sites, contract research organizations (“CROs”), and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel as some of our employees are working remotely. We will continue to actively monitor the rapidly evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. The development of our product candidates could be disrupted and materially adversely affected in the future by the COVID-19 pandemic. Our planned clinical trials also could be delayed due to government orders and site policies on account of the pandemic, and some patients may be unwilling or unable to travel to study sites, enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize REACT or any future product candidates. Furthermore, COVID-19 could affect our employees or the employees of research sites and service providers on whom we rely, including CROs, as well as those of companies with which we do business, including our suppliers, thereby disrupting our business operations. Quarantines and travel restrictions imposed by governments in the jurisdictions in which we and the companies with which we do business operate could materially impact the ability of employees to access clinical sites, laboratories, manufacturing sites and offices. These and other events resulting from the COVID-19 pandemic could disrupt, delay, or otherwise adversely impact our business.

Financial Operations Overview

Revenue

We have not generated any revenue since inception, and we do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts for REACT or any other product

[Table of Contents](#)

candidates are successful and result in marketing approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such agreements.

Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with our research and development activities, including the development of REACT.

Research and development costs include:

- external research and development expenses incurred under agreements with CROs and other scientific development services;
- costs of other outside consultants, including their fees and related travel expenses;
- costs related to compliance with quality and regulatory requirements;
- costs of laboratory supplies and acquiring and developing clinical trial materials;
- payments made under third-party licensing agreements;
- personnel-related expenses, including salaries, bonuses, benefits and share-based compensation expenses, for individuals involved in research and development activities; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, insurance and other internal operating costs.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated balance sheets as prepaid clinical or as a component of total accrued expenses and other. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized, even when there is no alternative future use for the research and development. The capitalized amounts are recorded as prepaid clinical and are expensed as the related goods are delivered or the services are performed.

Research and development activities are central to our business model. We expect that our research and development expenses will increase significantly for the foreseeable future as REACT moves into later stages of clinical development.

The successful development of REACT and any product candidates we may develop in the future is highly uncertain. Therefore, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development and commercialization of any of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of REACT or potential future product candidates, if approved. This is due to the numerous risks and uncertainties associated with developing product candidates, many of which are outside of our control, including the uncertainty of:

- the timing and progress of non-clinical and clinical development activities;
- the number and scope of non-clinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- establishing an appropriate safety profile;
- the number of sites and patients including clinical trials;

Table of Contents

- the countries in which the clinical trials are conducted;
- per patient trial costs;
- successful patient enrollment in, and the initiation of, clinical trials, as well as drop out or discontinuation rates, particularly in light of the current COVID-19 pandemic environment;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration (“FDA”) and comparable foreign regulatory authorities;
- the number of trials required for regulatory approval;
- the timing, receipt and terms of any regulatory approvals from applicable regulatory authorities;
- our ability to establish new licensing or collaboration arrangements;
- the performance of our future collaborators, if any;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- significant and changing government regulation and regulatory guidance;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work, particularly in light of the current COVID-19 pandemic environment;
- obtaining, maintaining, defending and enforcing patient claims or other intellectual property rights;
- the potential benefits of REACT over other therapies;
- launching commercial sales of REACT, if approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of REACT, should it obtain regulatory approval.

Any changes in the outcome of any of these variables could mean a significant change in the costs and timing associated with the development of our product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never obtain regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits and equity-based compensation expenses for individuals involved in our executive, finance, corporate and administrative functions, as well as expenses for outside professional services, including legal, audit, accounting and tax-related services and other consulting fees, facility-related expenses, which include depreciation costs and other allocated expenses for rent and maintenance of facilities, insurance costs, recruiting costs, travel expenses and other general administrative expenses.

We expect that our general and administrative expenses will increase significantly for the foreseeable future as our business expands and we hire additional personnel to support our operations. We also anticipate increased expenses associated with being a public company, including costs for legal, audit, accounting, investor and public relations, tax-related services, director and officer insurance, and regulatory costs related to compliance with the rules and regulations of the SEC as well as listing standards applicable to companies listed on a national securities exchange.

[Table of Contents](#)

Other Income (Expense)

Other income consists of interest income earned on cash and cash equivalents held in financial institutions. We expect our interest income to increase following the completion of this merger as we invest the net proceeds from this merger pending their use in our operations.

Income Tax (Expense) Benefit

Income tax expense reflects federal and state taxes on income earned by our subsidiary that is organized as a C corporation for U.S. income tax purposes.

Results of Operations

Comparison of Three Months Ended March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,		
	2022	2021	Change
Operating expenses:			
Research and development	\$ 28,490	\$ 9,859	\$ 18,631
General and administrative	37,972	1,744	36,228
Total operating expense	66,462	11,603	54,859
Loss from operations	(66,462)	(11,603)	(54,859)
Interest expense	(14)	—	(14)
Net loss before taxes	(66,476)	(11,603)	(54,873)
Income tax expense (benefit)	1,010	6	1,004
Net loss	<u>\$(67,486)</u>	<u>\$(11,609)</u>	<u>\$(55,877)</u>

Research and development expenses

The increase in research and development expenses of approximately \$18.6 million was primarily driven by a \$14.1 million increase in cost related to equity-based payments for services rendered by a third-party in prior periods, as the cost of those payments was adjusted to the fair value of the awards issued upon their grant date in the three months ended March 31, 2022. Additionally, equity-based compensation costs increased approximately \$3.3 million for the three months ended March 31, 2022, due to additional awards granted to employees during the period. Further, cash based compensation costs increased by \$0.8 million, driven primarily by the hiring of additional personnel.

General and administrative expenses

The increase in general and administrative expenses of approximately \$36.2 million was primarily driven by a \$30.0 million increase in equity-based compensation for Class B-1 Units sold at less than their fair value to employees and other service providers of the Company. Additionally, there was a \$5.1 million increase in equity-based compensation expense which was driven by a modification to the existing awards as well as the grant of additional awards during the three months ended March 31, 2022.

Income tax expense

The increase in income tax expense of approximately \$1.0 million was driven primarily by the impact of a provision of the Tax Act which became effective for tax years beginning after December 31, 2021. This

[Table of Contents](#)

provision requires specified research and development expenses to be capitalized and amortized ratably over a five-year period and is the primary driver of the income tax expense recognized during the three months ended March 31, 2022.

Comparison of Years Ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,		Change
	2021	2020	
Operating expenses:			
Research and development	\$ 46,255	\$ 21,042	\$ 25,213
General and administrative	8,855	5,982	2,873
Total operating expense	55,110	27,024	28,086
Loss from operations	(55,110)	(27,024)	(28,086)
Other income			
Interest income	2	43	(41)
Net loss before taxes	(55,108)	(26,981)	(28,127)
Income tax expense (benefit)	38	(232)	270
Net loss	<u>\$(55,146)</u>	<u>\$(26,749)</u>	<u>\$(28,397)</u>

Research and development expenses

Research and development expenses increased primarily due to the startup costs incurred in 2021 in connection with the launch of our Phase 3 clinical study REGEN-006 in 2022. As a Phase 3 trial, REGEN-006 is planned to be much larger in scope than the clinical trials ongoing in 2020. In addition to the impact of spending on REGEN-006, we also began enrollment in our Phase 2 study REGEN-007 in the latter part of 2021.

General and administrative expenses

The increase in general and administrative expenses of approximately \$2.9 million was primarily driven by services performed in anticipation of a going-public transaction and our reorganization pursuant to our organization as an Irish limited partnership.

Liquidity and Capital Resources

Sources of liquidity

Since inception, we have not recognized any revenue and have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. From inception through March 31, 2022, we have funded our operations primarily through capital contributions and the ProKidney Promissory Notes and have received aggregate net proceeds from these transactions of \$186.5 million and \$20.0 million, respectively. The \$20.0 million received under the promissory notes was repaid at the Closing.

We expect that the net proceeds from the Business Combination, together with our cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through 2024. We

[Table of Contents](#)

have based this estimate on assumptions that may prove to be wrong and we could exhaust our capital resources sooner than we expect.

We expect our expenses to increase substantially if, and as, we:

- initiate and continue research and clinical development of our product candidates, including in particular our clinical trials for REACT;
- incur third-party manufacturing costs to support our non-clinical studies and clinical trials of our product candidate and, if approved, its commercialization;
- seek to identify and develop additional product candidates;
- make investment in developing internal manufacturing capabilities; and
- seek regulatory and marketing approvals for our product candidates.

In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, audit, accounting, investor and public relations, regulatory, tax-related, director and officer insurance premiums and other expenses that we did not incur as a private company. Developing pharmaceutical products, including conducting clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any product candidates or generate revenue from the sale of any product candidate for which we may obtain marketing approval. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product that we do not expect to be commercially available for at least several years, if ever.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the public or private sale of equity, government or private party grants, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our unitholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain additional funding, we could be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or any commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. If we raise funds through strategic collaborations or other similar arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs or product candidates or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our units. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic or otherwise. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses, and there is no assurance that we will ever be profitable or generate positive cash flow from operating activities.

[Table of Contents](#)

Cash Flows

Cash Flows for the Three Months Ended March 31, 2022 and 2021

The following table provides information regarding our cash flows for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net cash used in operating activities	<u>\$(15,459)</u>	<u>\$(7,256)</u>
Net cash used in investing activities	(839)	(1,389)
Net cash provided by financing activities	<u>25,542</u>	<u>19,993</u>
Net change in cash and cash equivalents	<u>\$ 9,244</u>	<u>\$ 11,348</u>

Cash Flows for the Years Ended December 31, 2021 and 2020

The following table provides information regarding our cash flows for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	<u>\$(50,299)</u>	<u>\$(25,181)</u>
Net cash used in investing activities	(5,191)	(5,456)
Net cash provided by financing activities	<u>71,470</u>	<u>19,989</u>
Net change in cash and cash equivalents	<u>\$ 15,980</u>	<u>\$(10,648)</u>

Operating Activities

Net cash used in operating activities was approximately \$15.5 million for the three months ended March 31, 2022, reflecting a net loss of approximately \$67.5 million and uses driven by changes in working capital of approximately \$1.4 million. Such uses were partially offset by non-cash charges of \$53.4 million. The non-cash charges primarily consisted of equity-based compensation expense of \$52.7 million and depreciation and amortization expense of \$0.7 million. The changes in working capital primarily relate to the timing of payments made to our vendors for services performed.

Net cash used in operating activities was approximately \$7.3 million for the three months ended March 31, 2021, reflecting a net loss of \$11.6 million, partially offset by non-cash charges of \$0.5 million and a net change of \$3.8 million in our net working capital. The non-cash charges primarily consisted of depreciation and amortization of \$0.4 million and equity-based compensation expense of \$0.2 million.

The approximately \$8.2 million increase in cash used in operating activities for the three months ended March 31, 2022 compared to the three months ended March 31, 2021 was primarily driven by the increased use of cash related to the timing of payments to our vendors and the net loss incurred during the period, after adjusting for the non-cash charges.

Net cash used in operating activities was approximately \$50.3 million for the year ended December 31, 2021, reflecting a net loss of approximately \$55.1 million, partially offset by non-cash charges of \$2.7 million, and changes in working capital of \$2.2 million. The non-cash charges primarily consisted of depreciation and amortization expense of \$2.0 million and equity-based compensation expense of \$0.7 million. The changes in working capital primarily relate to the timing of payments made to our vendors for services performed.

[Table of Contents](#)

Net cash used in operating activities was approximately \$25.2 million for the year ended December 31, 2020, reflecting a net loss of \$26.7 million, partially offset by non-cash charges of \$1.7 million and a net change of \$0.1 million in our net operating assets. The non-cash charges primarily consisted of depreciation and amortization of \$1.0 million and equity-based compensation expense of \$0.7 million.

The approximately \$25.1 million increase in cash used in operating activities for the year ended December 31, 2021 compared to the year ended December 31, 2020 was primarily due to a \$28.4 million increase in our net loss which was driven by increased spending related to the planned launch of our Phase 3 clinical study, REGEN-006. The impact of the increased net loss was offset by higher non-cash charges for depreciation, amortization and equity compensation as well as changes in net working capital.

Investing Activities

Net cash used in investing activities were approximately \$0.8 million and \$1.4 million for the three months ended March 31, 2022 and 2021, respectively, which was due to purchases of equipment and facility expansion.

Net cash used in investing activities were approximately \$5.2 million and \$5.5 million for the years ended December 31, 2021 and 2020, respectively, which was due to purchases of equipment and facility expansion.

Financing Activities

Net cash provided by financing activities was \$25.5 million and \$20.0 million for the three months ended March 31, 2022 and 2021, respectively, which was due to the borrowing of funds under the ProKidney Promissory Notes and sales of our Class B-1 Units in the 2022 period and due to proceeds received from the issuance of our Class A Units in the 2021 period.

Net cash provided by financing activities was \$71.5 million and \$20.0 million for the years ended December 31, 2021 and 2020, respectively, which was due to proceeds received from the issuance of our Class A Units.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements. Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our audited consolidated financial statements included in this prospectus.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the JOBS Act. The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies, allowing them to delay the adoption of those standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our consolidated financial statements may not be comparable to the financial statements of companies that are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make our ordinary shares less attractive to investors.

DESCRIPTION OF PROKIDNEY SECURITIES

The following summary of the material terms of our securities is not intended to be a complete summary of the rights and preferences of such securities and is qualified by reference to our Charter, which is incorporated by reference as an exhibit to the registration statement of which this prospectus is a part. We urge you to read our Charter described herein in its entirety for a complete description of the rights and preferences of our securities. Unless the context requires otherwise, all references to “we,” “us,” “our,” the “Company” and “ProKidney” in this section refer solely to ProKidney Corp. and not to our subsidiaries.

Authorized and Outstanding Shares

We are authorized to issue 1,005,000,000 shares, consisting of (x) 500,000,000 Class A ordinary shares, par value \$0.0001 per share, (y) 500,000,000 Class B ordinary shares, par value \$0.0001 per share and (z) 5,000,000 preference shares, par value \$0.0001 per share.

Class A Ordinary Shares

Voting Rights

Each holder of Class A ordinary shares is entitled to one vote for each Class A ordinary shares held of record by such holder on all matters on which shareholders generally are entitled to vote. The holders of the Class A ordinary shares do not have cumulative voting rights in the appointment of directors. Generally, all matters to be voted on by shareholders must be approved by a resolution passed by the holders of not less than a simple majority of ordinary shares entitled to vote in person or represented by proxy, with Class A shareholders and Class B shareholders voting together as a single class. Notwithstanding the foregoing, the holders of the outstanding Class A ordinary shares are entitled to vote separately upon any amendment to the Charter (including by merger, consolidation, reorganization or similar event) that would alter or change the powers, preferences or special rights of such Class A ordinary shares in a manner that has an adverse effect upon such rights.

Dividend Rights

Subject to preferences that may be applicable to any outstanding preference shares, the holders of Class A ordinary shares are entitled to receive ratably such dividends, if any, as may be declared from time to time by the Board out of funds legally available therefor. All dividends are subject to certain restrictions under Cayman Islands law, namely that we may only pay dividends out of profits or share premium account, and provided always that, in no circumstances may a dividend be paid if this would result in us being unable to pay our debts as they fall due in the ordinary course of business.

Rights upon Liquidation, Dissolution and Winding-Up

In the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs, the holders of our Class A ordinary shares are entitled to share ratably in all assets remaining after payment of our debts and other liabilities, subject to prior distribution rights of preference shares or any class or series of shares having a preference over our Class A ordinary shares, then outstanding, if any.

Preemptive or Other Rights

The holders of our Class A ordinary shares have no preemptive or conversion rights or other subscription rights (other than in connection with certain issuances of common units under the Second Amended and Restated ProKidney Limited Partnership Agreement). There are no redemption or sinking fund provisions applicable to our Class A ordinary shares. The rights, preferences and privileges of holders of our Class A ordinary shares will be subject to those of the holders of any preference shares we may issue in the future.

Class B Ordinary Shares

Voting Rights

Each holder of our Class B ordinary shares is entitled to one vote for each Class B ordinary share held of record by such holder on all matters on which shareholders generally are entitled to vote. The holders of our Class B ordinary shares do not have cumulative voting rights in the election of directors. Generally, all matters to be voted on by shareholders must be approved by a majority of the votes entitled to be cast by all shareholders present in person or represented by proxy, with Class A shareholders and Class B shareholders voting together as a single class. Notwithstanding the foregoing, the holders of our outstanding Class B ordinary shares are entitled to vote separately upon any amendment to the Charter (including by merger, consolidation, reorganization or similar event) that would alter or change the powers, preferences or special rights of such Class B ordinary shares in a manner that has an adverse effect upon such rights.

Dividend Rights

The holders of our Class B ordinary shares will not participate in any dividends declared by our board of directors.

Rights upon Liquidation, Dissolution and Winding-Up

In the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs, the holders of our Class B ordinary shares are entitled to a ratable amount equal to the capital paid up on such Class B ordinary shares of all assets remaining after payment of our debts and other liabilities, subject to prior distribution rights of preference shares or any class or series of shares having a preference over our Class B ordinary shares, then outstanding, if any. Our Class B ordinary shares shall not carry any other right to participate in our profits or assets.

Preemptive or Other Rights

The holders of our Class B ordinary shares do not have preemptive, subscription, redemption or conversion rights. There will be no redemption or sinking fund provisions applicable to our Class B ordinary shares.

Issuance and Forfeiture of Class B Ordinary Shares

In the event that any of our outstanding Class B ordinary shares cease to be held directly or indirectly by a holder of an equal amount of Post-Combination ProKidney Common Units, such share will automatically be transferred to us for no consideration and thereupon will be retired. We will not issue additional Class B ordinary shares other than in connection with the valid issuance or transfer of Post-Combination ProKidney Common Units in accordance with our governing documents.

Preference Shares

Our Charter provides that the Board has the authority, without further action by the holders of our ordinary shares, to establish one or more series of preference shares where issue of such series of preference shares is considered by the Board not to have an adverse effect upon rights attached to our Class A ordinary shares and Class B ordinary shares. Preference shares may be issued from time to time in one or more series of any number of shares, provided that the aggregate number of shares issued shall not exceed the total number of preference shares authorized, and with such powers, including voting powers, if any, and the designations, preferences and relative, participating, optional or other special rights, if any, and any qualifications, limitations or restrictions thereof, all as shall be stated and expressed in the resolution or resolutions providing for the designation and issue of such preference shares from time to time adopted by the Board pursuant to authority so to do which is

[Table of Contents](#)

expressly vested in the Board. The powers, including voting powers, if any, preferences and relative, participating, optional and other special rights of each series of preference shares, and the qualifications, limitations or restrictions thereof, if any, may differ from those of any and all other series at any time outstanding.

The issuance of preference shares may have the effect of delaying, deferring or preventing a change in control of ProKidney without further action by the shareholders. Additionally, the issuance of preference shares may adversely affect the holders of our ordinary shares by restricting dividends on our Class A ordinary shares, diluting the voting power of our Class A ordinary shares and Class B ordinary shares or subordinating the liquidation rights of our Class A ordinary shares and Class B ordinary shares. As a result of these or other factors, the issuance of preference shares could have an adverse impact on the market price of our Class A ordinary shares. At present, we have no plans to issue any preference shares.

Register of Members

Under Cayman Islands law, the Company must keep a register of members and there will be entered therein:

- the names and addresses of the members, a statement of the shares held by each member, and of the amount paid or agreed to be considered as paid, on the shares of each member and the voting rights of shares;
- the date on which the name of any person was entered on the register as a member; and
- the date on which any person ceased to be a member.

Under Cayman Islands law, the register of members of our company is prima facie evidence of the matters set out therein (i.e., the register of members will raise a presumption of fact on the matters referred to above unless rebutted) and a member registered in the register of members will be deemed as a matter of Cayman Islands law to have legal title to the shares as set against its name in the register of members. Upon the closing of this offering, the register of members will be immediately updated to reflect the issue of shares by us. Once our register of members has been updated, the shareholders recorded in the register of members will be deemed to have legal title to the shares set against their name. However, there are certain limited circumstances where an application may be made to a Cayman Islands court for a determination on whether the register of members reflects the correct legal position. Further, the Cayman Islands court has the power to order that the register of members maintained by a company should be rectified where it considers that the register of members does not reflect the correct legal position. If an application for an order for rectification of the register of members were made in respect of our ordinary shares, then the validity of such shares may be subject to re-examination by a Cayman Islands court.

Earnout Rights

The Earnout Participants received an additional aggregate amount of 17,500,000 Earnout RCUs and 17,500,000 Earnout RSRs which will convert, in the case of Earnout RCUs, into Post-Combination ProKidney Common Units and, in the case of Earnout RSRs, into our Class B ordinary shares to vest in three equal tranches upon our ordinary shares satisfying certain VWAP thresholds of \$15.00, \$20.00, \$25.00, respectively, for any 20 trading days within any 30 consecutive trading day period commencing on or after the Closing and ending on or prior to the fifth anniversary of the Closing; *provided* that (i) if one or all of the VWAP thresholds has not been achieved prior to the end of the five-year period following the Closing and (ii) we consummate a transaction that results in a change of control with a per share price exceeding the VWAP thresholds, then the applicable share price trigger that has not been satisfied will be deemed to have been satisfied, and, at the closing of such transaction, we shall issue the applicable portion of the Class B ordinary shares issuable upon the vesting of the Earnout Rights as if such share price trigger has been achieved.

[Table of Contents](#)

Earnout RCUs

We issued to the Earnout Participants the Earnout RCUs, denoted as Series 1 RCUs, Series 2 RCUs and Series 3 RCUs, in each case, equal to the earnout series amount for such Earnout Participant. Upon the achievement of certain of our share price milestones, the Earnout RCUs held by such participant will be converted into Post-Combination ProKidney Common Units. Any Earnout RCUs that have not vested by the fifth anniversary of the Closing will be forfeited and cancelled for no consideration.

Earnout RSRs

We issued to Earnout Participants the Earnout RSRs, denoted as Class B Series 1 RSRs, Class B Series 2 RSRs and Class B Series 3 RSRs, in each case, equal to the earnout series amount for such Earnout Participant. Upon the achievement of certain of our share price milestones, such Earnout RSRs held by such Earnout Participant will be converted into our Class B ordinary shares. Any such Earnout RSRs that have not vested by the fifth anniversary of the Closing will be forfeited and cancelled for no consideration.

PMEL Post-Combination Issuance

In connection with the Business Combination, PMEL Post-Combination Unitholders received an additional aggregate amount of each of PMEL RCUs and PMEL RSRs equal to the amount of such unitholder's pro rata interest in the unvested Legacy ProKidney Class B Units held by PMEL prior to the Closing, which will convert, in the case of PMEL RCUs, into Post-Combination ProKidney Common Units and, in the case of PMEL RSRs, into our Class B ordinary shares when vested in accordance with the terms of the applicable award agreement.

PMEL RCUs

At the Closing, we issued to PMEL Post-Combination Unitholders a number of PMEL RCUs equal to the amount of such unitholder's pro rata interest in the unvested Legacy ProKidney Class B Units held by PMEL prior to the Closing. Upon the vesting of a PMEL RCU in accordance with the terms of the applicable award agreement, if any, such RCUs held by such PMEL Post-Combination Unitholder will be converted into Post-Combination ProKidney Common Units.

PMEL RSRs

At the Closing, we issued to PMEL Post-Combination Unitholders a number of PMEL RSRs equal to the amount of such unitholder's pro rata interest in the unvested Legacy Class B Units held by PMEL prior to the Closing. Upon the vesting of a PMEL RCU in accordance with the terms of the applicable award agreement, if any, such PMEL RSRs held by such PMEL Post-Combination Unitholder will be converted into our Class B ordinary shares.

Dividends

The payment of any cash dividends is within the discretion of the Board.

The Second Amended and Restated ProKidney Limited Partnership Agreement provides that pro rata cash distributions be made to holders of Post-Combination ProKidney Common Units at certain assumed tax rates, which we refer to as "tax distributions."

Any financing arrangements that we enter into in the future may include restrictive covenants that limit our ability to pay dividends. All dividends are subject to certain restrictions under Cayman Islands law, namely that we may only pay dividends out of profits or share premium account, and provided always that, in no circumstances may a dividend be paid if this would result in the Company being unable to pay its debts as they fall due in the ordinary course of business.

[Table of Contents](#)

Our subsidiaries are generally subject to similar legal limitations on their ability to make distributions to ProKidney.

Registration Rights

At the Closing, we entered into the Amended and Restated Registration Rights Agreement with the Sponsor and certain Holders. Under the Amended and Restated Registration Rights Agreement, Class A ordinary shares held by the Holders party thereto (as well as their permitted transferees) and by parties to the Exchange Agreement are entitled to registration rights. The Amended and Restated Registration Rights Agreement provides for us to, within 30 days after the Closing Date, submit or file with the SEC a shelf registration statement registering the resale of our ordinary shares held by the Holders and use our commercially reasonable efforts to have such registration statement declared effective as soon as practicable after the submission or filing thereof, but in no event later than (a) 90 days following the submission or filing deadline, if the SEC notifies us that it will “review” the Registration Statement and (b) the 10th business day after the date we are notified (orally or in writing, whichever is earlier) by the SEC that the registration statement will not be “reviewed” or will not be subject to further review. In addition, the Holders have certain “piggy-back” registration rights.

Lock-Up Restrictions

At the closing of the Business Combination, we, the Sponsor and certain Closing ProKidney Unitholders entered into the Lock-Up Agreement. The Lock-Up Agreement contains certain restrictions on transfer with respect to the Sponsor and the ProKidney Unitholders party thereto. Such restrictions begin at the Closing and end on the earlier of (i) the date that is 180 days after the Closing and (ii)(a) for 33% of the Lock-Up Shares (other than the Earnout Shares and the Private Placement Shares)(as each such term is defined in the Lock-Up Agreement), the date on which the last reported sale price of our Class A ordinary share equals or exceeds \$12.50 per share for any 20 trading days within any 30-trading day period commencing at least 30 days after the Closing and (b) for an additional 50% of the Lock-Up Shares (other than the Earnout Shares and the Private Placement Shares), the date on which the last reported sale price of our Class A ordinary share equals or exceeds \$15.00 per share for any 20 trading days within any 30-trading day period commencing at least 30 days after the Closing. Notwithstanding the above, (i) the lock-up period for any Earnout Shares will expire not earlier than 180 days after such Earnout Shares are issued; (ii) 50% of the Lock-Up Shares held by certain Closing ProKidney Unitholders and their affiliates will remain locked up until the earlier of four years following the Closing and the date that we receive notice of any regulatory market authorization, including full or conditional authorization, to market REACT (but, in any event, not earlier than 180 days following the Closing or (in the case of Earnout Shares) the date of issuance); and (iii) the lock-up period for the Private Placement Shares will expire 30 days after the Closing. The restrictions on transfer set forth in the Lock-Up Agreement are subject to customary exceptions.

Transfer Agent

The transfer agent for our ordinary shares is Continental Stock Transfer & Trust Company.

Stock Exchange Listing

Our Class A ordinary shares is listed for trading on Nasdaq under the symbol “PROK.”

Certain Anti-Takeover Provisions of the Charter

Our Charter contains provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by the Board. These provisions could also make it difficult for shareholders to take certain actions, including appointing directors who are not nominated by the members of the Board or taking other corporate actions, including effecting changes in our management. For instance, our

Charter does not provide for cumulative voting in the appointment of directors and does provide for a classified board of directors with three-year staggered terms, which could delay the ability of shareholders to change the membership of a majority of the Board. The Board is empowered to appoint a director to fill a vacancy created by the expansion of the Board or the resignation, death, or removal of a director in certain circumstances; and our advance notice provisions in our Charter requires that shareholders must comply with certain procedures in order to nominate candidates to the Board or to propose matters to be acted upon at a shareholders' meeting.

Our authorized but unissued ordinary shares and preference shares are available for future issuances without shareholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved ordinary shares and preference shares could render more difficult or discourage an attempt to obtain control of ProKidney by means of a proxy contest, tender offer, merger or otherwise.

Certain Differences in Corporate Law

Cayman Islands companies are governed by the Cayman Islands Companies Act. The Cayman Islands Companies Act is modeled on English Law but does not follow recent English Law statutory enactments, and differs from laws applicable to United States corporations and their shareholders. Set forth below is a summary of the material differences between the provisions of the Cayman Islands Companies Act applicable to us and the laws applicable to companies incorporated in the United States and their shareholders.

Mergers and Similar Arrangements

In certain circumstances, the Cayman Islands Companies Act allows for mergers or consolidations between two Cayman Islands companies, or between a Cayman Islands exempted company and a company incorporated in another jurisdiction (*provided* that is facilitated by the laws of that other jurisdiction).

Where the merger or consolidation is between two Cayman Islands companies, the directors of each company must approve a written plan of merger or consolidation containing certain prescribed information. That plan or merger or consolidation must then be authorized by either (a) a special resolution (usually a majority of 66 2/3% in value of the voting shares voted at a shareholder meeting) of the shareholders of each company; or (b) such other authorization, if any, as may be specified in such constituent company's memorandum and articles of association. No shareholder resolution is required for a merger between a parent company (i.e., a company that owns at least 90% of the issued shares of each class in a subsidiary company) and its subsidiary company. The consent of each holder of a fixed or floating security interest of a constituent company must be obtained, unless the court waives such requirement. If the Cayman Islands Registrar of Companies is satisfied that the requirements of the Cayman Islands Companies Act (which includes certain other formalities) have been complied with, the Registrar of Companies will register the plan of merger or consolidation.

Where the merger or consolidation involves a foreign company, the procedure is similar, save that with respect to the foreign company, the directors of the Cayman Islands exempted company are required to make a declaration to the effect that, having made due enquiry, they are of the opinion that the requirements set out below have been met: (i) that the merger or consolidation is permitted or not prohibited by the constitutional documents of the foreign company and by the laws of the jurisdiction in which the foreign company is incorporated, and that those laws and any requirements of those constitutional documents have been or will be complied with; (ii) that no petition or other similar proceeding has been filed and remains outstanding or order made or resolution adopted to wind up or liquidate the foreign company in any jurisdictions; (iii) that no receiver, trustee, administrator or other similar person has been appointed in any jurisdiction and is acting in respect of the foreign company, its affairs or its property or any part thereof; and (iv) that no scheme, order, compromise or other similar arrangement has been entered into or made in any jurisdiction whereby the rights of creditors of the foreign company are and continue to be suspended or restricted.

[Table of Contents](#)

Where the surviving company is the Cayman Islands exempted company, the directors of the Cayman Islands exempted company are further required to make a declaration to the effect that, having made due enquiry, they are of the opinion that the requirements set out below have been met: (i) that the foreign company is able to pay its debts as they fall due and that the merger or consolidation is bona fide and not intended to defraud unsecured creditors of the foreign company; (ii) that in respect of the transfer of any security interest granted by the foreign company to the surviving or consolidated company (a) consent or approval to the transfer has been obtained, released or waived; (b) the transfer is permitted by and has been approved in accordance with the constitutional documents of the foreign company; and (c) the laws of the jurisdiction of the foreign company with respect to the transfer have been or will be complied with; (iii) that the foreign company will, upon the merger or consolidation becoming effective, cease to be incorporated, registered or exist under the laws of the relevant foreign jurisdiction; and (iv) that there is no other reason why it would be against the public interest to permit the merger or consolidation.

Where the above procedures are adopted, the Cayman Islands Companies Act provides for a right of dissenting shareholders to be paid a payment of the fair value of their shares upon their dissenting to the merger or consolidation if they follow a prescribed procedure. In essence, that procedure is as follows: (a) the shareholder must give their written objection to the merger or consolidation to the constituent company before the vote on the merger or consolidation, including a statement that the shareholder proposes to demand payment for their shares if the merger or consolidation is authorized by the vote; (b) within 20 days following the date on which the merger or consolidation is approved by the shareholders, the constituent company must give written notice to each shareholder who made a written objection; (c) a shareholder must within 20 days following receipt of such notice from the constituent company, give the constituent company a written notice of their intention to dissent including, among other details, a demand for payment of the fair value of their shares; (d) within seven days following the date of the expiration of the period set out in paragraph (b) above or seven days following the date on which the plan of merger or consolidation is filed, whichever is later, the constituent company, the surviving company or the consolidated company must make a written offer to each dissenting shareholder to purchase their shares at a price that the company determines is the fair value and if the company and the shareholder agree the price within 30 days following the date on which the offer was made, the company must pay the shareholder such amount; and (e) if the company and the shareholder fail to agree a price within such 30 day period, within 20 days following the date on which such 30 day period expires, the company (and any dissenting shareholder) must file a petition with the Cayman Islands Grand Court to determine the fair value and such petition must be accompanied by a list of the names and addresses of the dissenting shareholders with whom agreements as to the fair value of their shares have not been reached by the company. At the hearing of that petition, the court has the power to determine the fair value of the shares together with a fair rate of interest, if any, to be paid by the company upon the amount determined to be the fair value. Any dissenting shareholder whose name appears on the list filed by the company may participate fully in all proceedings until the determination of fair value is reached. These rights of a dissenting shareholder are not available in certain circumstances, for example, to dissenters holding shares of any class in respect of which an open market exists on a recognized stock exchange or recognized interdealer quotation system at the relevant date and the consideration paid for such shares meets certain requirements under the Cayman Islands Companies Act or where the consideration for such shares to be contributed are shares of any company listed on a national securities exchange or shares of the surviving or consolidated company.

Moreover, Cayman Islands law has separate statutory provisions that facilitate the reconstruction or amalgamation of companies in certain circumstances, schemes of arrangement will generally be more suited for complex mergers or other transactions involving widely held companies, commonly referred to in the Cayman Islands as a "scheme of arrangement" which may be tantamount to a merger. In the event that a merger was sought pursuant to a scheme of arrangement (the procedures for which are more rigorous and take longer to complete than the procedures typically required to consummate a merger in the United States), the arrangement in question must be approved by a majority in number of each class of shareholders and creditors with whom the arrangement is to be made and who must in addition represent three-fourths in value of each such class of shareholders or creditors, as the case may be, that are present and voting either in person or by proxy at a

[Table of Contents](#)

meeting, or meeting summoned for that purpose. The convening of the meetings and subsequently the terms of the arrangement must be sanctioned by the Grand Court of the Cayman Islands. While a dissenting shareholder would have the right to express to the court the view that the transaction should not be approved, the court can be expected to approve the arrangement if it satisfies itself that:

- we are not proposing to act illegally or beyond the scope of our corporate authority and the statutory provisions as to majority vote have been complied with;
- the shareholders have been fairly represented at the meeting in question;
- the arrangement is such as a businessman would reasonably approve; and
- the arrangement is not one that would more properly be sanctioned under some other provision of the Cayman Islands Companies Act or that would amount to a “fraud on the minority.”

If a scheme of arrangement or takeover offer (as described below) is approved, any dissenting shareholder would have no rights comparable to appraisal rights (providing rights to receive payment in cash for the judicially determined value of the shares), which would otherwise ordinarily be available to dissenting shareholders of United States corporations.

Squeeze-out Provisions

When a takeover offer is made and accepted by holders of 90% of the shares to whom the offer relates within four months, the offeror may, within a two-month period, require the holders of the remaining shares to transfer such shares on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands, but this is unlikely to succeed unless there is evidence of fraud, bad faith, collusion or inequitable treatment of the shareholders.

Further, transactions similar to a merger, reconstruction and/or an amalgamation may in some circumstances be achieved through means other than these statutory provisions, such as a share capital exchange, asset acquisition or control, or through contractual arrangements of an operating business.

Shareholders' Suits

Our Cayman Islands counsel is not aware of any reported class action having been brought in a Cayman Islands court. Derivative actions have been brought in the Cayman Islands courts, and the Cayman Islands courts have confirmed the availability for such actions. In most cases, we will be the proper plaintiff in any claim based on a breach of duty owed to us, and a claim against (for example) our officers or directors usually may not be brought by a shareholder. However, based both on Cayman Islands authorities and on English authorities, which would in all likelihood be of persuasive authority and be applied by a court in the Cayman Islands, exceptions to the foregoing principle apply in circumstances in which:

- a company is acting, or proposing to act, illegally or beyond the scope of its authority;
- the act complained of, although not beyond the scope of the authority, could be effected if duly authorized by more than the number of votes which have actually been obtained; or
- those who control the company are perpetrating a “fraud on the minority.”

A shareholder may have a direct right of action against us where the individual rights of that shareholder have been infringed or are about to be infringed.

Enforcement of Civil Liabilities

The Cayman Islands has a different body of corporate and securities laws as compared to the United States and provides less protection to investors. Additionally, Cayman Islands companies may not have standing to sue before the Federal courts of the United States.

[Table of Contents](#)

We have been advised by our Cayman Islands legal counsel that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against us judgments of courts of the United States predicated upon the civil liability provisions of the federal securities laws of the United States or any state; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against us predicated upon the civil liability provisions of the federal securities laws of the United States or any state, so far as the liabilities imposed by those provisions are penal in nature. In those circumstances, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the United States, the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, and or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere.

Special Considerations for Exempted Companies

We are an exempted company with limited liability (meaning our public shareholders have no liability, as members of the company, for liabilities of the company over and above the amount paid for their shares) under the Cayman Islands Companies Act. The Cayman Islands Companies Act distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except for the exemptions and privileges listed below:

- annual reporting requirements are minimal and consist mainly of a statement that the company has conducted its operations mainly outside of the Cayman Islands and has complied with the provisions of the Cayman Islands Companies Act;
- an exempted company's register of members is not open to inspection;
- an exempted company does not have to hold an annual shareholder meeting;
- an exempted company may issue negotiable or bearer shares or shares with no par value;
- an exempted company may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 30 years in the first instance);
- an exempted company may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- an exempted company may register as a limited duration company; and
- an exempted company may register as a segregated portfolio company.

Anti-Money Laundering, Counter-Terrorist Financing, Prevention of Proliferation Financing and Financial Sanctions Compliance – Cayman Islands

In order to comply with legislation or regulations aimed at the prevention of money laundering, terrorist financing, proliferation financing and compliance with financial sanctions, we are required to adopt and maintain certain procedures, and may require purchasers to provide evidence to verify their identity and source of funds. Where permitted, and subject to certain conditions, we may also delegate the maintenance of our anti-money laundering, terrorist financing, prevention of proliferation financing and financial sanctions compliance procedures (including the acquisition of due diligence information) to a suitable person.

Table of Contents

We reserve the right to request such information as is necessary to verify the identity of a purchaser. In some cases the directors may be satisfied that no further information is required since an exemption applies under the Anti-Money Laundering Regulations (as amended) of the Cayman Islands (the "Regulations"). Depending on the circumstances of each application, a detailed verification of identity might not be required where:

- a) the purchaser is a relevant financial business required to comply with the Regulations or is a majority-owned subsidiary of such a business; or
- b) assessed as having a low degree of risk of money laundering and terrorist financing in accordance with the Regulations (each a "Low Risk Country") or is a majority-owned subsidiary of such subscriber; or
- c) the purchaser is a central or local government organization, statutory body or agency of government in the Cayman Islands or a Low Risk Country; or
- d) the purchaser is a company that is listed on a recognized stock exchange and subject to disclosure requirements which impose requirements to ensure adequate transparency of beneficial ownership, or is a majority-owned subsidiary of such a company; or
- e) the purchaser is a pension fund for a professional association, trade union or is acting on behalf of employees of an entity referred to in sub-paragraphs (a) to (d); or
- f) the application is made through a nominee or the applicant is relying on an introduction from an introducer, which nominee or introducer, as applicable, falls within one of sub-paragraphs (a) to (e). In this situation the company may rely on a written assurance from the nominee or the introducer (as applicable) which confirms (i) that the requisite identification and verification procedures on the applicant for business and (for introducers only) its beneficial owners have been carried out; (ii) the nature and intended purpose of the business relationship; (iii) that the nominee or the introducer has identified the source of funds of the applicant for business; (iv) (for introducers only) that the introducer is supervised or monitored by an overseas regulatory authority and has measures in place to comply with customer due diligence and record keeping requirements; and (v) that the nominee or introducer shall make available on request and without delay copies of any identification and verification data or information and relevant documents.

For the purposes of these exceptions, recognition of a financial institution, regulatory authority or jurisdiction will be determined in accordance with the Regulations by reference to the Equivalent Jurisdiction definition.

In the event of delay or failure on the part of the subscriber in producing any information required for verification purposes, we may refuse to accept the application, in which case any funds received will be returned without interest to the account from which they were originally debited.

We also reserve the right to refuse to make any payment to a shareholder if our directors or officers suspect or are advised that the payment to such shareholder might result in a breach of applicable anti-money laundering, counter-terrorist financing, prevention of proliferation financing and financial sanctions or other laws or regulations by any person in any relevant jurisdiction, or if such refusal is considered necessary or appropriate to ensure our compliance with any such laws or regulations in any applicable jurisdiction.

If any person resident in the Cayman Islands knows or suspects, or has reasonable grounds for knowing or suspecting, that another person is engaged in criminal conduct, is involved with terrorism or terrorist property or proliferation financing or is the target of a financial sanction and the information for that knowledge or suspicion came to their attention in the course of business in the regulated sector or other trade, profession, business or employment, the person will be required to report such knowledge or suspicion to (i) the Financial Reporting Authority of the Cayman Islands, pursuant to the Proceeds of Crime Act (as amended) of the Cayman Islands if the disclosure relates to criminal conduct, money laundering or proliferation financing or is the target of a financial sanction or (ii) a police officer of the rank of constable or higher, or the Financial Reporting Authority,

[Table of Contents](#)

pursuant to the Terrorism Act (as amended) of the Cayman Islands, if the disclosure relates to involvement with terrorism or terrorist financing and property. Such a report will not be treated as a breach of confidence or of any restriction upon the disclosure of information imposed by any enactment or otherwise.

Data Protection – Cayman Islands

We have certain duties under the Data Protection Act (as amended) of the Cayman Islands (the “DPA”) based on internationally accepted principles of data privacy.

Privacy Notice

Introduction

This privacy notice puts our shareholders on notice that through your investment in the Company you will provide us with certain personal information which constitutes personal data within the meaning of the DPA (“personal data”). In the following discussion, the “company” refers to us and our affiliates and/or delegates, except where the context requires otherwise.

Investor Data

We will collect, use, disclose, retain and secure personal data to the extent reasonably required only and within the parameters that could be reasonably expected during the normal course of business. We will only process, disclose, transfer or retain personal data to the extent legitimately required to conduct our activities of on an ongoing basis or to comply with legal and regulatory obligations to which we are subject. We will only transfer personal data in accordance with the requirements of the DPA, and will apply appropriate technical and organizational information security measures designed to protect against unauthorized or unlawful processing of the personal data and against the accidental loss, destruction or damage to the personal data.

In our use of this personal data, we will be characterized as a “data controller” for the purposes of the DPA, while our affiliates and service providers who may receive this personal data from us in the conduct of our activities may either act as our “data processors” for the purposes of the DPA or may process personal information for their own lawful purposes in connection with services provided to us.

We may also obtain personal data from other public sources. Personal data includes, without limitation, the following information relating to a shareholder and/or any individuals connected with a shareholder as an investor: name, residential address, email address, contact details, corporate contact information, signature, nationality, place of birth, date of birth, tax identification, credit history, correspondence records, passport number, bank account details, source of funds details and details relating to the shareholder’s investment activity.

Who this Affects

If you are a natural person, this will affect you directly. If you are a corporate investor (including, for these purposes, legal arrangements such as trusts or exempted limited partnerships) that provides us with personal data on individuals connected to you for any reason in relation your investment in the company, this will be relevant for those individuals and you should transmit the content of this Privacy Notice to such individuals or otherwise advise them of its content.

How the Company May Use a Shareholder’s Personal Data

The company, as the data controller, may collect, store and use personal data for lawful purposes, including, in particular:

- where this is necessary for the performance of our rights and obligations under any purchase agreements;

[Table of Contents](#)

- where this is necessary for compliance with a legal and regulatory obligation to which we are subject (such as compliance with anti-money laundering, counter-terrorist financing, prevention of proliferation financing, financial sanctions and FATCA/CRS requirements); and/or
- where this is necessary for the purposes of our legitimate interests and such interests are not overridden by your interests, fundamental rights or freedoms.

Should we wish to use personal data for other specific purposes (including, if applicable, any purpose that requires your consent), we will contact you.

Why We May Transfer Your Personal Data

In certain circumstances we may be legally obliged to share personal data and other information with respect to your shareholding with the relevant regulatory authorities such as the Cayman Islands Monetary Authority or the Tax Information Authority. They, in turn, may exchange this information with foreign authorities, including tax authorities.

We anticipate disclosing personal data to persons who provide services to us and their respective affiliates (which may include certain entities located outside the United States, the Cayman Islands or the European Economic Area), who will process your personal data on our behalf.

The Data Protection Measures We Take

Any transfer of personal data by us or our duly authorized affiliates and/or delegates outside of the Cayman Islands shall be in accordance with the requirements of the DPA.

We and our duly authorized affiliates and/or delegates shall apply appropriate technical and organizational information security measures designed to protect against unauthorized or unlawful processing of personal data, and against accidental loss or destruction of, or damage to, personal data.

We shall notify you of any personal data breach that is reasonably likely to result in a risk to your interests, fundamental rights or freedoms or those data subjects to whom the relevant personal data relates.

Rights of Individual Data Subjects

Individual data subjects have certain data protection rights, including the right to:

- be informed about the purposes for which your personal data are processed;
- access your personal data;
- stop direct marketing;
- restrict the processing of your personal data;
- have incomplete or inaccurate personal data corrected;
- ask us to stop processing your personal data;
- be informed of a personal data breach (unless the breach is unlikely to be prejudicial to you);
- complain to the Data Protection Ombudsman; and
- require us to delete your personal data in some limited circumstances.

SECURITIES ACT RESTRICTIONS ON RESALE OF SECURITIES

Rule 144

Pursuant to Rule 144 under the Securities Act (“Rule 144”), a person who has beneficially owned restricted Class A ordinary shares of ProKidney for at least six months would be entitled to sell their securities; *provided* that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least three months before the sale and have filed all required reports under Section 13 or 15(d) of the Exchange Act during the 12 months (or such shorter period as we were required to file reports) preceding the sale.

Persons who have beneficially owned restricted ordinary shares for at least six months but who are our affiliates at the time of, or at any time during the three months preceding a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of:

- 1% of the total number of ordinary shares then outstanding; or
- the average weekly reported trading volume of ordinary shares during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales by our affiliates under Rule 144 are also limited by manner of sale provisions and notice requirements and by the availability of current public information about us.

Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies

Rule 144 is not available for the resale of securities initially issued by shell companies (other than business- combination related shell companies) or issuers that have been at any time previously a shell company. However, Rule 144 also includes an important exception to this prohibition if the following conditions are met:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and material required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials) other than Form 8-K reports; and
- at least one year has elapsed from the time that the issuer filed current Form 10 type information with the SEC reflecting its status as an entity that is not a shell company.

Following the Closing, we are no longer a shell company, and so, once the conditions listed above are satisfied, Rule 144 will become available for the resale of the above-noted restricted securities.

BENEFICIAL OWNERSHIP OF SECURITIES

The following table sets forth information known to the Company regarding the beneficial ownership of the Company's ordinary shares as of July 31, 2022 by:

- each person known to the Company to be the beneficial owner of more than 5% of the outstanding Company ordinary shares;
- each of Company's executive officers and directors; and
- all executive officers and directors of the Company as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security, including options and warrants that are currently exercisable or exercisable within 60 days. Except as described in the footnotes below and subject to applicable community property laws and similar laws, we believe that each person listed below has sole voting and investment power with respect to such shares.

The beneficial ownership of the Company ordinary shares is based on 61,540,231 Class A ordinary shares and 170,723,961 Class B ordinary shares issued and outstanding as of July 31, 2022.

Unless otherwise indicated, we believe that all persons named in the table below have sole voting and investment power with respect to all ordinary shares beneficially owned by them.

Name and Address of Beneficial Owner(1)	Class A Ordinary Shares	Class B Ordinary Shares	% of Total Voting Power
<i>Directors and Named Executive Officers</i>			
Tim Bertram, Ph.D.(2)	—	2,696,468	1.2%
Pablo Legorreta(3)(11)	—	94,677,968	40.8%
William F. Doyle(4)	—	1,350,469	*
Jennifer Fox	—	—	—
José Ignacio Jiménez Santos	—	—	—
Alan M. Lotvin(5)	—	1,350,469	*
John M. Maraganore, Ph.D.(6)	—	450,156	*
Brian J.G. Pereira, M.D(7)	—	1,350,469	*
Uma Sinha, Ph.D.	30,000	—	*
Deepak Jain, Ph.D.(8)	—	937,836	*
Joseph Stavas, M.D., MPH(9)	—	735,391	*
<i>All Directors and Executive Officers as a Group (14 persons)</i>	30,000	103,453,062	44.6%
<i>Greater-than-Five Percent Holders:</i>			
Tolerantia, LLC(3)(11)	—	94,677,968	40.8%
Control Empresarial de Capitales, S.A. de C.V. (formerly Inversora Carso, S.A. de C.V.)(10)(11)	—	63,118,645	27.2%
Chamath Palihapitiya(12)	13,273,000	—	5.5%
SC PIPE Holdings LLC(12)	9,500,000	—	3.9%
Banco Invex, S.A., Institución de Banca Múltiple, Invex Grupo Financiero, as Trustee of Trust I14165(14)	5,000,000	—	2.2%
IHCI Investments LP(15)	5,000,000	—	2.2%
Jupiter CAN LP(16)	5,000,000	—	2.2%
Morgan Stanley Investment Management Inc.(17)	10,000,000	—	4.3%
Averill Master Fund, Ltd.(18)	3,140,000	—	1.4%

* Indicated beneficial ownership of less than 1%.

Table of Contents

- (1) Unless otherwise noted, the business address of each of the following entities or individuals is c/o ProKidney Corp., 2000 Frontis Plaza Blvd., Ste 250, Winston-Salem, North Carolina, 27103.
- (2) Represents 2,696,468 Class B ordinary shares issued as consideration in the Business Combination and does not include 2,248,469 Class B ordinary shares issuable upon the vesting of PMEL RCUs.
- (3) Represents 94,677,968 Class B ordinary shares held by Tolerantia, LLC (“Tolerantia”), a Delaware limited liability company, which is an affiliate controlled and majority-owned by Mr. Pablo Legorreta. Mr. Legorreta controls the voting and disposition of the shares held by Tolerantia. Mr. Legorreta disclaims beneficial ownership of the shares held by Tolerantia except to the extent of his indirect pecuniary interest therein. The business address of Tolerantia is 110, East 59th Street, Suite 3300, New York, New York, 10022.
- (4) Represents 1,350,469 Class B ordinary shares issued as consideration in the Business Combination and does not include 163,857 Class B ordinary shares issuable upon the vesting of PMEL RCUs.
- (5) Represents 1,350,469 Class B ordinary shares issued as consideration in the Business Combination and does not include 163,857 Class B ordinary shares issuable upon the vesting of PMEL RCUs.
- (6) Represents 450,156 Class B ordinary shares issued as consideration in the Business Combination and does not include 163,857 Class B ordinary shares issuable upon the vesting of PMEL RCUs.
- (7) Represents 1,350,469 Class B ordinary shares issued as consideration in the Business Combination and does not include 163,857 Class B ordinary shares issuable upon the vesting of PMEL RCUs.
- (8) Represents 937,836 Class B ordinary shares issued as consideration in the Business Combination and does not include 630,103 Class B ordinary shares issuable upon the vesting of PMEL RCUs.
- (9) Represents 735,391 Class B ordinary shares issued as consideration in the Business Combination and does not include 315,650 Class B ordinary shares issuable upon the vesting of PMEL RCUs.
- (10) Information in the table and footnote is based upon information provided to us by the direct shareholder, Control Empresarial de Capitales S.A. de C.V., acting as successor of Inversora Carso S.A. de C.V. by virtue of a merger (“CEC”). Represents 63,118,645 Class B ordinary shares held by CEC. Members of the Slim family, directly or indirectly, own all of the issued and outstanding voting equity securities of CEC. Therefore, the Slim family may be deemed to beneficially own indirectly the Class B ordinary shares held by CEC. CEC is a sociedad anónima de capital variable organized under the laws of the United Mexican States (“Mexico”). The Slim family has an address of Paseo de las Palmas 736, Colonia Lomas de Chapultepec, 11000 Ciudad de Mexico, Mexico and Control Empresarial has an address of Paseo de las Palmas 781, Piso 3, Colonia Lomas de Chapultepec, Seccion III, Miguel Hidalgo, Ciudad de Mexico, Mexico, 11000.
- (11) The Voting Agreement provides that from the Closing until the third anniversary of the Closing, CEC shall vote all ordinary shares beneficially held by it in a manner proportionate to the manner in which all other Class B ordinary shares not held by CEC, including the Class B ordinary shares beneficially held by Tolerantia, are voted, with respect to the election, appointment, or removal of any director to the Board. As a result, Tolerantia may be deemed to share beneficial ownership of CEC’s ordinary shares.
- (12) The business address of each of Chamath Palihapitiya and SC PIPE Holdings LLC is c/o SC Master Holdings, LLC 506 Santa Cruz Avenue, Suite 300.
- (13) Consists of 9,500,000 Class A ordinary shares held of record by SC PIPE Holdings LLC and 3,773,000 Class A ordinary shares held of record by SC Master Holdings, LLC. Mr. Palihapitiya may be deemed to beneficially own (within the meaning of Rule 13d-3 under the Exchange Act) securities held by SC PIPE Holdings LLC and/or SC Master Holdings, LLC by virtue of his control over such entities.
- (14) Consists of 5,000,000 Class A ordinary shares held of record by Banco Invex, S.A., Institución de Banca Múltiple, Invex Grupo Financiero, acting solely and exclusively in its capacity as trustee of the trustee of Trust I14165 (the “Trust”), whose record holders are the Trust Beneficiaries (as defined below), issued in connection with, and, upon the closing of, the PIPE Placement. Each of (i) Bertha Paula Michel Gonzalez, (ii) Maria Magdalena Michel Gonzalez and (iii) Maximino Jose Michel Gonzalez (collectively, the “Trust Beneficiaries”), has voting and dispositive power over, one-third of the total number of Class A ordinary shares held by the Trust. The address of the Trust is Boulevard Manuel Avila Camacho No. 40, Piso 7, Lomas De Chapultepec, Ciudad De México 11000. The address of each of the Trust Beneficiaries is Bosque De Radiatas 6-602, Bosques De Las Lomas, Cuajimalpa 05120, Mexico.

Table of Contents

- (15) Consists of 5,000,000 Class A ordinary shares held of record by IHCI Investments LP issued in connection with, and, upon the closing of, the PIPE Placement. The address of IHCI Investments LP is 1188 Union, Montreal QC H3B 0E5, Canada.
- (16) Consists of 5,000,000 Class A ordinary shares held of record by Jupiter CAN LP issued in connection with, and, upon the closing of, the PIPE Placement. The address of Jupiter CAN LP is 5930 Royal Lane, Suite E, #117, Dallas TX 75230-3896.
- (17) Morgan Stanley Investment Management Inc. is the adviser or sub-adviser, as the case may be, of each of (i) Brighthouse Funds Trust I: Morgan Stanley Discovery Portfolio, holding 497,653 Class A ordinary shares, (ii) ERAFP Actions Mid Cap USA I holding 12,443 Class A ordinary shares, (iii) Growth Trust holding 245,905 Class A ordinary shares, (iv) Inception Trust holding 166,790 Class A ordinary shares, (v) Johnson & Johnson Pension and Savings Master Trust (JJ9L) holding 15,421 Class A ordinary shares, (vi) Johnson & Johnson Pension and Savings Master Trust (JJ9LDB) holding 136,426 Class A ordinary shares, (vii) Kinstead Global Equity Pool holding 16,039 Class A ordinary shares, (viii) Lawrencium Atoll Investments Ltd. holding 34,707 Class A ordinary shares, (ix) Master Trust for Defined Contribution Plans of American Airlines, Inc. and Affiliates holding 109,253 Class A ordinary shares, (x) Morgan Stanley Funds (UK)—Global Insight Fund holding 7,231 Class A ordinary shares, (xi) Morgan Stanley Insight Fund holding 1,421,688 Class A ordinary shares, (xii) Morgan Stanley Institutional Fund Trust—Discovery Portfolio holding 800,384 Class A ordinary shares, (xiii) Morgan Stanley Institutional Fund, Inc.—Inception Portfolio holding 332,167 Class A ordinary shares, (xiv) Morgan Stanley Institutional Fund, Inc.—Counterpoint Global Portfolio holding 3,802 Class A ordinary shares, (xv) Morgan Stanley Institutional Fund, Inc.—Global Endurance Portfolio holding 19,748 Class A ordinary shares, (xvi) Morgan Stanley Institutional Fund, Inc.—Global Insight Portfolio holding 67,622 Class A ordinary shares, (xvii) Morgan Stanley Institutional Fund, Inc.—Growth Portfolio holding 3,865,953 Class A ordinary shares, (xviii) Morgan Stanley Investment Funds—Counterpoint Global Fund holding 1,657 Class A ordinary shares, (xix) Morgan Stanley Investment Funds—Global Endurance Fund holding 34,186 Class A ordinary shares, (xx) Morgan Stanley Investment Funds—Global Insight Fund holding 293,852 Class A ordinary shares, (xxi) Morgan Stanley Investment Funds—US Growth Fund holding 1,549,102 Class A ordinary shares, (xxii) Morgan Stanley Investment Funds—US Insight Fund holding 46,844 Class A ordinary shares, (xxiii) Morgan Stanley Variable Insurance Fund, Inc.—Discovery Portfolio holding 79,084 Class A ordinary shares, (xxiv) Morgan Stanley Variable Insurance Fund, Inc.—Growth Portfolio holding 242,043 Class A ordinary shares (collectively, the “MS Accounts”) and holds voting and dispositive power with respect to shares of record held by each of the MS Accounts. Each of the MS accounts received their respective Class A ordinary shares in connection with the issuance of, and, upon the closing of, the PIPE Placement. The address of Morgan Stanley Investment Management Inc., acting as adviser or sub-adviser, as the case may be, of each of the MS Accounts is 522 Fifth Avenue, New York, NY 10036.
- (18) Consists of 3,140,000 Class A ordinary shares held of record by Averill Master Fund, Ltd. issued in connection with, and, upon the closing of, the PIPE Placement. The address of Averill Master Fund, Ltd. is 540 Madison Avenue, 7th Floor, New York, NY 10022.

SELLING SECURITYHOLDERS

This prospectus relates to the possible resale by the Selling Securityholders of up to 232,530,000 Class A ordinary shares. The Selling Securityholders may from time to time offer and sell any or all of the Class A ordinary shares set forth below pursuant to this prospectus and any accompanying prospectus supplement. When we refer to the “Selling Securityholders” in this prospectus, we mean the persons listed in the table below, and the pledgees, donees, transferees, assignees, successors, designees and others who later come to hold any of the Selling Securityholders’ interest in the Class A ordinary shares other than through a public sale. We cannot advise you as to whether the Selling Securityholders will in fact sell any or all of such Class A ordinary shares. In addition, the Selling Securityholders may sell, transfer or otherwise dispose of, at any time and from time to time, Class A ordinary shares in transactions exempt from the registration requirements of the Securities Act after the date of this prospectus. For purposes of this table, we have assumed that the Selling Securityholders will have sold all of the securities covered by this prospectus upon the completion of the offering.

The following table is prepared based on information provided to us by the Selling Securityholders. It sets forth the name and address of the Selling Securityholders, the aggregate number of Class A ordinary shares and Class B ordinary shares or restricted stock rights underlying Class B ordinary shares (issuable upon the vesting of the restricted stock rights), which Class B ordinary shares are exchangeable, pursuant to the Exchange Agreement, to for Class A ordinary Shares that the Selling Securityholders may offer pursuant to this prospectus, and the beneficial ownership of the Selling Securityholders both before and after the offering. We have based the percentage ownership prior to this offering on a total of 232,314,192 shares outstanding, which includes 61,540,231 Class A ordinary shares and 170,723,961 Class B ordinary shares outstanding, in each case as of July 31, 2022.

We have determined beneficial ownership in accordance with the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Unless otherwise indicated below, to our knowledge, the persons and entities named in the tables have sole voting and sole investment power with respect to all securities that they beneficially own, subject to community property laws where applicable.

Selling Securityholder information for each additional Selling Securityholder, if any, will be set forth by prospectus supplement to the extent required prior to the time of any offer or sale of such Selling Securityholder’s shares pursuant to this prospectus. Any prospectus supplement may add, update, substitute, or change the information contained in this prospectus, including the identity of each Selling Securityholder and the number of shares registered on its behalf. A Selling Securityholder may sell or otherwise transfer all, some or none of such shares in this offering. See “*Plan of Distribution.*”

Name of Selling Securityholder	Class A Ordinary Shares	Class B Ordinary Shares (or Securities Convertible into Class B Ordinary Shares)	Percentage Voting Power	Number of Ordinary Shares Offered	Number of Ordinary Shares Beneficially Owned After the Offered Shares are Sold	Percentage Voting Power
Anna-Maria and Stephen Kellen Foundation, Inc.(1)	1,000,000		*	1,000,000	—	— %
Averill Master Fund, Ltd.(2)	3,140,000		1.4%	3,140,000	—	— %
Banco Invex, S.A., Institución de Banca Múltiple, Invex Grupo Financiero, as Trustee of Trust I14165(3)	5,000,000		2.2%	5,000,000	—	— %
Brighthouse Funds Trust I: Morgan Stanley Discover y Portfolio(4)	497,653		*	497,653	—	— %
Brown University(5)	1,000,000		*	1,000,000	—	— %
Carlos X. Del Rio(6)	27,500		*	27,500	—	— %
Control Empresarial de Capitales, S.A. de C.V. (formerly Inversora Carso, S.A. de C.V.)(7)		63,118,645	27.2%	63,118,645	—	— %

[Table of Contents](#)

Name of Selling Securityholder	Class A Ordinary Shares	Class B Ordinary Shares (or Securities Convertible into Class B Ordinary Shares)	Percentage Voting Power	Number of Ordinary Shares Offered	Number of Ordinary Shares Beneficially Owned After the Offered Shares are Sold	Percentage Voting Power
CP WY REMAINDER INTEREST TRUST U/A/D DATED DECEMBER 22, 2021(8)	3,000,000		1.3%	3,000,000	—	— %
David Spiegel(9)	10,000		*	10,000	—	— %
Denise and Michael Kellen Foundation, Inc.(10)	100,000		*	100,000	—	— %
DJG Associated, LLC(11)	600,000		*	600,000	—	— %
Donald P. Spencer and Vickie Riccardo JTWROS(12)	50,000		*	50,000	—	— %
ERAFP Actions Mid Cap USA I(4)	12,443		*	12,443	—	— %
Fourteen Plus Twelve Partners, LLC(13)	200,000		*	200,000	—	— %
George W. Siguler Family Trust (14)	125,000		*	125,000	—	— %
Growth Trust(4)	245,905		*	245,905	—	— %
Hill Family Alternative Investments LLC(15)	500,000		*	500,000	—	— %
Hottinger AG(16)	100,000		*	100,000	—	— %
IHCI Investments LP(17)	5,000,000		2.2%	5,000,000	—	— %
Inception Trust(4)	166,790		*	166,790	—	— %
Johnson & Johnson Pension and Savings Master Trust (JJ9L)(4)	15,421		*	15,421	—	— %
Johnson & Johnson Pension and Savings Master Trust (JJ9LDB)(4)	136,426		*	136,426	—	— %
Juan Maria Pedro David Michel(18)	800,000		*	800,000	—	— %
Jupiter CAN(19)	5,000,000		2.2%	5,000,000	—	— %
Kinstead Global Equity Pool(4)	16,039		*	16,039	—	— %
KJB Associated LLC(20)	200,000		*	200,000	—	— %
Lawrencium Atoll Investments Ltd.(4)	34,707		*	34,707	—	— %
Leman Management Nominees Limited(21)	2,000,000		*	2,000,000	—	— %
Luis Felipe Mancera de Arrigunaga(22)	80,000		*	80,000	—	— %
Marina Kellen French Foundation(23)	100,000		*	100,000	—	— %
Master Trust for Defined Contribution Plans of American Airlines, Inc. and Affiliates(4)	109,253		*	109,253	—	— %
Max Pierre David Michel(24)	800,000		*	800,000	—	— %
MGG Strategic SICAF SIF, for and on behalf of its compartment, MGG Strategic(25)	1,000,000		*	1,000,000	—	— %
Mikel Andoni Arriola Peñalosa (26)	15,000		*	15,000	—	— %
Monique Berthe Michele Madeleine David Michel(27)	800,000		*	800,000	—	— %
Morgan Stanley Funds (UK)—Global Insight Fund(4)	7,231		*	7,231	—	— %
Morgan Stanley Insight Fund(4)	1,421,688		*	1,421,688	—	— %
Morgan Stanley Institutional Fund Trust—Discovery Portfolio(4)	800,384		*	800,384	—	— %
Morgan Stanley Institutional Fund, Inc.—Counterpoint Global Portfolio(4)	3,802		*	3,802	—	— %
Morgan Stanley Institutional Fund, Inc.—Global Endurance Portfolio(4)	19,748		*	19,748	—	— %
Morgan Stanley Institutional Fund, Inc.—Global Insight Portfolio(4)	67,622		*	67,622	—	— %
Morgan Stanley Institutional Fund, Inc.—Growth Portfolio(4)	3,865,953		1.7%	3,865,953	—	— %
Morgan Stanley Institutional Fund, Inc.—Inception Portfolio(4)	332,167		*	332,167	—	— %
Morgan Stanley Investment Funds—Counterpoint Global Fund(4)	1,657		*	1,657	—	— %
Morgan Stanley Investment Funds—Global Endurance Fund(4)	34,186		*	34,186	—	— %
Morgan Stanley Investment Funds—Global Insight Fund(4)	293,852		*	293,852	—	— %
Morgan Stanley Investment Funds—US Growth Fund(4)	1,549,102		*	1,549,102	—	— %

Table of Contents

Name of Selling Securityholder	Class A Ordinary Shares	Class B Ordinary Shares (or Securities Convertible into Class B Ordinary Shares)	Percentage Voting Power	Number of Ordinary Shares Offered	Number of Ordinary Shares Beneficially Owned After the Offered Shares are Sold	Percentage Voting Power
Morgan Stanley Investment Funds—US Insight Fund(4)	46,844		*	46,844	—	— %
Morgan Stanley Variable Insurance Fund, Inc.—Discovery Portfolio(4)	79,084		*	79,084	—	— %
Morgan Stanley Variable Insurance Fund, Inc.—Growth Portfolio(4)	242,043		*	242,043	—	— %
Nogra Group SICAF-SIF, for and on behalf of its compartment, Nogra Group SICAF—SIF—GG Strategic (the Investor)(28)	1,200,000		*	1,200,000	—	— %
Pamela Mallon Siguler Family Trust(29)	125,000		*	125,000	—	— %
Paul Mower(30)	7,500		*	7,500	—	— %
ProKidney Management Equity LLC(31)		22,203,387	5.6%	22,203,387	—	— %
iPrime Participations LLC(32)	300,000		*	300,000	—	— %
Regina Mancera Bustamante(33)	100,000		*	100,000	—	— %
Ricardo José Garza Bustamante(34)	50,000		*	50,000	—	— %
SC PIPE Holdings LLC(35)	9,500,000		4.1%	9,500,000	—	— %
Stephen M. Kellen 2004 Trust FBO Annabelle Garrett(36)	75,000		*	75,000	—	— %
Stephen M. Kellen 2004 Trust FBO Andrew Gundlach(37)	75,000		*	75,000	—	— %
Stephen M. Kellen 2004 Trust FBO Caroline L. Kellen(38)	75,000		*	75,000	—	— %
Stephen M. Kellen 2004 Trust FBO Christopher N. Kellen(39)	75,000		*	75,000	—	— %
Sukumar Nagendran(40)	10,000		*	10,000	—	— %
Tensleep Group LLC(41)	10,000		*	10,000	—	— %
Tolerantia, LLC(42)		94,677,968	40.8%	94,677,968	—	— %
WECMA Family, LLC(43)	250,000		*	250,000	—	— %
Uma Sinha, Ph.D.(44)	30,000		*	30,000	—	— %

** Less than 1%.

- (1) Consists of 1,000,000 Class A ordinary shares. The address of Anna-Maria and Stephen Kellen Foundation, Inc. is 1345 Avenue of the Americas, 47th Floor, New York, NY 10105.
- (2) Consists of 3,140,000 Class A ordinary shares. The address of Averill Master Fund, Ltd. is 540 Madison Avenue, 7th Floor, New York, NY 10022.
- (3) Consists of 5,000,000 Class A ordinary shares held of record by Banco Inxev, S.A., Institución de Banca Múltiple, Inxev Grupo Financiero, acting solely and exclusively in its capacity as trustee of the trustee of Trust I14165 (the "Trust"), whose record holders are the Trust Beneficiaries (as defined below). Each of (i) Bertha Paula Michel Gonzalez, (ii) María Magdalena Michel Gonzalez and (iii) Maximino Jose Michel Gonzalez (collectively, the "Trust Beneficiaries"), has voting and dispositive power over, one-third of the total number of Class A ordinary shares held by the Trust. The address of the Trust is Boulevard Manuel Avila Camacho No. 40, Piso 7, Lomas De Chapultepec, Ciudad De México 11000. The address of each of the Trust Beneficiaries is Bosque De Radiatas 6-602, Bosques De Las Lomas, Cuajimalpa 05120, Mexico.
- (4) Morgan Stanley Investment Management Inc. is the adviser or sub-adviser, as the case may be, of each of (i) Brighthouse Funds Trust I: Morgan Stanley Discovery Portfolio, holding 497,653 Class A ordinary shares, (ii) ERAFP Actions Mid Cap USA I holding 12,443 Class A ordinary shares, (iii) Growth Trust holding 245,905 Class A ordinary shares, (iv) Inception Trust holding, 166,790 Class A ordinary shares, (v) Johnson & Johnson Pension and Savings Master Trust (JJ9L) holding 15,421 Class A ordinary shares, (vi) Johnson & Johnson Pension and Savings Master Trust (JJ9LDB) holding 136,426 Class A ordinary shares, (vii) Kinstead Global Equity Pool holding 16,039 Class A ordinary shares, (viii) Lawrencium Atoll Investments Ltd. holding 34,707 Class A ordinary shares, (ix) Master Trust for Defined Contribution Plans of American Airlines, Inc. and Affiliates holding 109,253 Class A ordinary shares, (x) Morgan Stanley Funds (UK)—Global Insight Fund holding 7,231 Class A ordinary shares, (xi) Morgan Stanley Insight Fund holding 1,421,688 Class A ordinary shares, (xii) Morgan Stanley Institutional Fund Trust—Discovery Portfolio holding 800,384 Class A ordinary shares, (xiii) Morgan Stanley Institutional Fund, Inc.—Inception Portfolio holding 332,167 Class A ordinary shares, (xiv) Morgan Stanley Institutional Fund, Inc.—Counterpoint Global Portfolio holding 3,802 Class A ordinary shares, (xv) Morgan Stanley Institutional Fund, Inc.—Global Endurance Portfolio holding 19,748 Class A ordinary shares, (xvi) Morgan Stanley Institutional Fund, Inc.—Global Insight Portfolio holding 67,622 Class A ordinary shares, (xvii) Morgan Stanley Institutional Fund,

Table of Contents

- Inc.—Growth Portfolio holding 3,865,953 Class A ordinary shares, (xviii) Morgan Stanley Investment Funds—Counterpoint Global Fund holding 1,657 Class A ordinary shares, (xiv) Morgan Stanley Investment Funds—Global Endurance Fund holding 34,186 Class A ordinary shares, (xx) Morgan Stanley Investment Funds—Global Insight Fund holding 293,852 Class A ordinary shares, (xxi) Morgan Stanley Investment Funds—US Growth Fund holding 1,549,102 Class A ordinary shares, (xxii) Morgan Stanley Investment Funds—US Insight Fund holding 46,844 Class A ordinary shares, (xxiii) Morgan Stanley Variable Insurance Fund, Inc.—Discovery Portfolio holding 79,084 Class A ordinary shares, (xxiv) Morgan Stanley Variable Insurance Fund, Inc.—Growth Portfolio holding 242,043 Class A ordinary shares (collectively, the “MS Accounts”) and holds voting and dispositive power with respect to shares of record held by each of the MS Accounts. The address of Morgan Stanley Investment Management Inc., acting as adviser or sub-adviser, as the case may be, of each of the MS Accounts is 522 Fifth Avenue, New York, NY 10036.
- (5) Consists of 1,000,000 Class A ordinary shares. The address of Brown University is 121 South Main Street, 9th floor, Providence RI, 02903.
- (6) Consists of 27,500 Class A ordinary shares. The address of Carlos X. Del Rio is Monte Everest 440, Col. Lomas de Chapultepec, Ciudad de México, 11000, Mexico.
- (7) Information in the table and footnote is based upon information provided to us by the direct shareholder, Control Empresarial de Capitales S.A. de C.V., acting as successor of Inversora Carso S.A. de C.V. by virtue of a merger (“CEC”). Consists of 63,118,645 Class B ordinary shares held by CEC, which may be exchanged, together with a corresponding number of Post-Combination ProKidney Common Units, pursuant to the Exchange Agreement, for 63,118,645 Class A ordinary shares. Members of the Slim family, directly or indirectly, own all of the issued and outstanding voting equity securities of CEC. Therefore, the Slim family may be deemed to beneficially own indirectly the Class B ordinary shares held by CEC. CEC is a sociedad anónima de capital variable organized under the laws of the United Mexican States (“Mexico”). The Slim family has an address of Paseo de las Palmas 736, Colonia Lomas de Chapultepec, 11000 Ciudad de Mexico, Mexico and Control Empresarial has an address of Paseo de las Palmas 781, Piso 3, Colonia Lomas de Chapultepec, Seccion III, Miguel Hidalgo, Ciudad de Mexico, Mexico, 11000.
- (8) Consists of 3,000,000 Class A ordinary shares. The address of CP WY REMAINDER INTEREST TRUST U/A/D DATED DECEMBER 22, 2021 is 506 Santa Cruz Avenue, Suite 300 Menlo Park, California 94025.
- (9) Consists of 10,000 Class A ordinary shares.
- (10) Consists of 100,000 Class A ordinary shares. The address of Denise and Michael Kellen Foundation, Inc. is 1345 Avenue of the Americas, 47th Floor, New York, NY 10105.
- (11) Consists of 600,000 Class A ordinary shares. The address of DJG Associated, LLC is 62 Vineyard Lane, Greenwich, CT 06831.
- (12) Consists of 50,000 Class A ordinary shares. The address of Donald P. Spencer and Vickie Riccardo JTWROS is 370 Palmetto Road, St. Augustine, FL 32080.
- (13) Consists of 200,000 Class A ordinary shares. The address of Fourteen Plus Twelve Partners, LLC is 62 Vineyard Lane, Greenwich, CT 06831.
- (14) Consists of 125,000 Class A ordinary shares. The address of George W. Siguler Family Trust is 893 Ponte Vedra Blvd, Ponte Vedra Beach, FL 32082.
- (15) Consists of 500,000 Class A ordinary shares. The address of Hill Family Alternative Investments LLC is 834 Fifth Avenue, 10B, New York, NY 10065.
- (16) Consists of 100,000 Class A ordinary shares. The address of Hottinger AG is 60 Rue du Stand, Geneva 1204, Switzerland.
- (17) Consists of 5,000,000 Class A ordinary shares. The address of IHCI Investments LP is 1188 Union, Montreal QC H3B 0E5, Canada.
- (18) Consists of 800,000 Class A ordinary shares. The address of Juan María Pedro David Michel is Bosque de Radiatas 6-602, Bosques de las Lomas, Cuajimalpa 05120, Mexico.
- (19) Consists of 5,000,000 Class A ordinary shares. The address of Jupiter CAN LP is 5930 Royal Lane, Suite E, #117, Dallas, TX 75230.
- (20) Consists of 200,000 Class A ordinary shares. The address of KJB Associated LLC is 860 United Nations Plz Apt #33D, New York, NY 10017.
- (21) Consists of 2,000,000 Class A ordinary shares. The address of Leman Management Nominees Limited is Wessex House 2nd Floor, 45 Reid Street, Hamilton HM 12, Bermuda.
- (22) Consists of 80,000 Class A ordinary shares. The address of Luis Felipe Mancera de Arrigunaga is Colina 52 Lomas de Bezarcas 11910, Mexico City, Mexico.
- (23) Consists of 100,000 Class A ordinary shares. The address of Marina Kellen French Foundation is 1345 Avenue of the Americas, 47th Floor, New York, NY 10105.
- (24) Consists of 800,000 Class A ordinary shares. The address of Max Pierre David Michel is Bosque de Radiatas 6-602-103, Bosques de las Lomas, Cuajimalpa 05120, Mexico.
- (25) Consists of 1,000,000 Class A ordinary shares. The address of MGG Strategic SICAF SIF, for and on behalf of its compartment, MGG Strategic is 18 Avenue de la Porte Neuve, Luxembourg 2227, Luxembourg.
- (26) Consists of 15,000 Class A ordinary shares. The address of Mikel Andoni Arriola Peñalosa is Av. Paseo de la Reforma 2693, 401-C, Lomas de Bezares, Miguel Hidalgo, Mexico City 11910, Mexico.
- (27) Consists of 800,000 Class A ordinary shares. The address of Monique Berthe Michele Madeleine David Michel is Bosque de Radiatas 6-602-103, Bosques de las Lomas, Cuajimalpa 05120, Mexico.
- (28) Consists of 1,200,000 Class A ordinary shares. The address of GG 1978 SICAF SIF, for and on behalf of its compartment, GG Strategic (the Investor) is 18 Avenue de la Porte Neuve, Luxembourg 2227, Luxembourg.
- (29) Consists of 125,000 Class A ordinary shares. The address of Pamela Mallon Siguler Family Trust is 893 Ponte Vedra Blvd, Ponte Vedra Beach, FL 32082.
- (30) Consists of 7,500 Class A ordinary shares. The address of Paul Mower is 614 Lakota Lane (PO Box 4112), Jackson, WY 83001.

Table of Contents

- (31) Consists of (i) 12,927,348 13,045,190 Class B ordinary shares, (ii) 117,842 Class B ordinary shares issuable upon the vesting of PMEL RCUs within 60 days of July 31, 2022 and (iii) 9,158,197 PMEL RCUs held by ProKidney Management Equity LLC on behalf of individual unitholders. Upon vesting of the PMEL RCUS, the aggregate of 22,203,387 Class B ordinary shares may be exchanged, together with a corresponding number of Post-Combination ProKidney Common Units, pursuant to the Exchange Agreement, for a total of 22,203,387 Class A ordinary shares.
- (32) Consists of 300,000 Class A ordinary shares. The address of Prime Participations LLC is 110 East 59th Street, 33rd Fl, New York, NY 10022.
- (33) Consists of 100,000 Class A ordinary shares. The address of Regina Mancera Bustamante is Bosque de Tulipanes 14, Col. Bosques de las Lomas, Cuajimalpa 05120, Mexico.
- (34) Consists of 50,000 Class A ordinary shares. The address of Ricardo José Garza Bustamante is Av de Los Poetas 100, RCA 901, Col. Cumbres de Santa Fe, Mexico City 05600, Mexico.
- (35) The business address of SC PIPE Holdings LLC is c/o SC Master Holdings, LLC 506 Santa Cruz Avenue, Suite 300.
- (36) Consists of 75,000 Class A ordinary shares. The address of Stephen M. Kellen 2004 Trust FBO Annabelle Garrett is 1345 Avenue of the Americas, 47th Floor, New York, NY 10105.
- (37) Consists of 75,000 Class A ordinary shares. The address of Stephen M. Kellen 2004 Trust FBO Andrew Gundlach is 1345 Avenue of the Americas, 47th Floor, New York, NY 10105.
- (38) Consists of 75,000 Class A ordinary shares. The address of Stephen M. Kellen 2004 Trust FBO Caroline L. Kellen is 1345 Avenue of the Americas, 47th Floor, New York, NY 10105.
- (39) Consists of 75,000 Class A ordinary shares. The address Stephen M. Kellen 2004 Trust FBO Christopher N. Kellen is 1345 Avenue of the Americas, 47th Floor, New York, NY 10105.
- (40) Consists of 10,000 Class A ordinary shares.
- (41) Consists of 10,000 Class A ordinary shares. The address of Tensleep Group LLC is 140 S. Cache St. (PO Box 4112), Jackson, WY 83001.
- (42) Consists of 94,677,968 Class B ordinary shares held by Tolerantia, which may be exchanged, together with a corresponding number of Post-Combination ProKidney Common Units, pursuant to the Exchange Agreement, for 94,677,968 Class A ordinary shares. Tolerantia is an affiliate controlled and majority-owned by Mr. Pablo Legorreta. Mr. Legorreta controls the voting and disposition of the shares held by Tolerantia. Mr. Legorreta disclaims beneficial ownership of the shares held by Tolerantia except to the extent of his indirect pecuniary interest therein. The business address of Tolerantia is 110, East 59th Street, Suite 3300, New York, New York, 10022.
- (43) Consists of 250,000 Class A ordinary shares. The address of WECMA Family, LLC is 893 Ponte Vedra Blvd, Ponte Vedra Beach, FL 32082.
- (44) Consists of 30,000 Class A ordinary shares. The address of Uma Sinha, Ph.D. is c/o ProKidney Corp., 2000 Frontis Plaza Blvd., Ste 250, Winston-Salem, North Carolina, 27103.

MANAGEMENT

ProKidney Executive Officers and Directors

The following table provides certain information concerning the persons who serve as directors and executive officers of ProKidney following the consummation of the Business Combination and their ages as of July 31, 2022 and positions following the Business Combination:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Executive Officers:		
Tim Bertram, Ph.D.	66	Chief Executive Officer and Director
James Coulston, CPA	46	Chief Financial Officer
Deepak Jain, Ph.D.	68	Chief Operating Officer
Darin J. Weber, Ph.D.	54	Senior Vice President of Regulatory Development
Todd C. Girolamo	57	Chief Legal Officer
Libbie P. McKenzie, M.D.	49	Chief Medical Officer
Non-Employee Directors:		
Pablo Legorreta	58	Chairman of the Board, Director
William F. Doyle	60	Director
Alan M. Lotvin, M.D.	60	Director
Brian J.G. Pereira, M.D.	63	Director
Uma Sinha, Ph.D.	65	Director
John M. Maraganore, Ph.D.	59	Director
José Ignacio Jimenez Santos	47	Director
Jennifer Fox	51	Director

Information about the Executive Officers and Directors

Executive Officers

James Coulston, CPA

Mr. Coulston has served as our Chief Financial Officer since the Closing, having served as ProKidney-US's Chief Financial Officer since January 2022. Prior to that, Mr. Coulston served as ProKidney-US's Senior Vice President, Finance from January 2021 to December 2021 and ProKidney-US's Vice President, Finance from February 2019 to December 2020. Before joining ProKidney, from August 2015 to January 2019, Mr. Coulston served as the Executive Director, Finance of Banner Life Sciences LLC, a privately held clinical-stage pharmaceutical company combining a proven history of formulation expertise with proprietary technologies to create specialty pharmaceuticals that solve real unmet clinical needs, where Mr. Coulston oversaw the financial, human resources, and IT activities. From 2007 to 2015, Mr. Coulston held finance roles of increasing responsibility at Targacept Inc. (Nasdaq: TRGT), a clinical-stage biopharmaceutical company developing novel NNR Therapeutics™ before it merged with and into Catalyst Biosciences, Inc. (Nasdaq: CBIO), a clinical-stage biopharmaceutical company focused on creating and developing novel medicines to address serious medical conditions, including Senior Director, Finance and Controller. Mr. Coulston earned his B.S. and master degree in Accounting from North Carolina State University and is a Certified Public Accountant in the state of North Carolina.

Deepak Jain, Ph.D.

Dr. Jain has served as our Chief Operating Officer since the Closing, having served as ProKidney-US's Chief Operating Officer since March 2016. Dr. Jain brings over 36 years of experience in the development of tissue-engineered and cell therapy products. Previously, Dr. Jain held management roles of increasing responsibility at Johnson & Johnson (NYSE: JNJ) and Merck (NYSE: MRK) and was involved in the

[Table of Contents](#)

development of four marketed products including Johnson & Johnson's erythropoietin-based drug Eprex (epoetin alfa). Dr. Jain has served as Chairman of the American Society for Testing and Materials Task Group on Preservation of Cells and Tissue Engineered Medical Product's with Cells, and has served as Chairman of the USP Tissue and Tissue-based Products Ad hoc Advisory Panel and was member of the USP Biologics and Biotechnology Cell, Gene and Tissue Therapy Expert Committee. Dr. Jain received his B. Tech and M. Tech in Chemical Engineering and his Ph.D. in Biochemical Engineering from the Indian Institute of Technology in Delhi, India.

Darin J. Weber, Ph.D.

Dr. Weber has served as our Senior Vice President of Regulatory Development since the Closing, having served as ProKidney-US's Senior Vice President of Regulatory Development since September 2020, where he is responsible for leading the development and implementation of ProKidney's regulatory strategy in all markets, worldwide, and interfacing with regulatory authorities. Dr. Weber has over 25 years of experience in cellular and tissue-based regenerative medicine products, with previous roles as Senior Vice President of Regulatory and Quality at Medeor Therapeutics, from February 2016 to December 2019; Executive Vice President of Global Regulatory Affairs and Quality Management at Mesoblast, from June 2011 to February 2016; Senior Consultant for Cell and Gene Therapies at Biologics Consulting Group from February 2004 to May 2011, and positions of increasing responsibility at the FDA's CBER, including as Chief of Cellular Therapies Branch in the Office of Cellular, Tissues and Gene Therapies, (now known as the Office of Tissues and Advanced Therapies) from September 1996 to January 2004. He is a long-serving member of United States Pharmacopeia (USP) expert committees for human tissues and advanced therapies. Dr. Weber received his B.S. in Molecular Biology from The Evergreen State College and a Ph.D. in Biochemistry and Biophysics from Oregon State University.

Todd C. Girolamo

Mr. Girolamo has served as our Chief Legal Officer since July 2022. Mr. Girolamo joined ProKidney as General Counsel in March 2022. Prior to that, he spent 11 years at Caladrius Biosciences, Inc. (Nasdaq: CLBS), where he served as Chief Legal Officer, Senior Vice President of Corporate Development and Corporate Secretary. He began his legal career at Cahill Gordon & Reindel in 1990 and later at Reid & Priest, practicing in the areas of securities law, intellectual property, employment law and general commercial litigation. After private practice, Mr. Girolamo spent 12 years on Wall Street in institutional equities as a series 24, 7 and 63 licensed principal at Oppenheimer & Co., CIBC World Markets, Leerink Swann (now SVB Securities LLC) and Summer Street Research Partners where he specialized in equity research, sales, and trading of biotechnology, pharmaceuticals and medical technology market sectors. Mr. Girolamo then served as an analyst and portfolio manager at Lion's Path Capital managing a long-short portfolio of biopharma and med-tech equities. Mr. Girolamo received an A.B. with honors from Harvard College, a J.D. from the University of Pennsylvania Law School and an MBA from Columbia Business School.

Libbie P. McKenzie, M.D.

Dr. McKenzie has served as our Chief Medical Officer since the Closing, having served as ProKidney-US's Chief Medical Officer since April 2022. Prior to that, she held roles of increasing responsibility at IQVIA / Quintiles since June 2007. Most recently, Dr. McKenzie served as Vice President, Medical, Global Head of Lifecycle Safety Project Leadership and Strategic Solutions from November 2019 to March 2022, and as Vice President, Medical, Global Head of Marketed Product Safety and Medical Information from March 2015 to November 2018, and as Executive Director, Medical, Global Head of Safety Aggregate Reporting and Analytics from January 2013 to March 2015, and as Executive Director, Medical, Global Head of Medical Safety from January 2009 to January 2013, and as Associate Medical Director from June 2007 to January 2009. Prior to joining IQVIA / Quintiles, Dr. McKenzie was Medical Director and Medical Safety Officer at Ashfield / Drug Safety Alliance from October 2005 to May 2007. Dr. McKenzie has expertise in clinical, pharmacovigilance and regulatory affairs, with over fifteen years of industry experience. In addition to her corporate roles, Dr. McKenzie

[Table of Contents](#)

was Dialysis Unit Medical Director at NaphCare in Raleigh, NC, from 2006 to 2020, making her intimately familiar with the challenges faced by patients undergoing dialysis. She holds a B.S. in Biology and Psychology from Duke University and an M.D. from Duke University School of Medicine. She completed a residency in internal medicine and a fellowship in nephrology at Duke University Medical Center. Dr. McKenzie is a Fellow of the American Society of Nephrology and an Associate of the American College of Physicians.

Directors

Tim Bertram, Ph.D.

Dr. Bertram has served on the Board, as our Chief Executive Officer, and as a director on the GP Board since the Closing. Dr. Bertram has served as Chief Executive Officer of ProKidney-US and ProKidney-KY since January 2019, and served on the Legacy GP Board from January 2022 until the Closing. Dr. Bertram has also served as a member of the board of directors of ProKidney-KY (the “ProKidney-KY Board”) since January 2022. Since February 2017, Dr. Bertram has served on the board of directors of NexImmune, Inc. (Nasdaq: NEXI), a clinical-stage biotechnology company developing a novel approach to immunotherapy designed to orchestrate a targeted immune response by directing the function of antigen-specific T cells. Dr. Bertram served as Chief Scientific Officer of Tengion Inc. from 2004 to 2014 after serving as President of Research and Development, where he brought four cell-based therapeutic products from discovery through Phase 2 clinical development. Dr. Bertram was also involved in the development and registration of eight medical products while serving as a senior executive at Pfizer Inc. (NYSE: PFE), SmithKline Beecham Pharmaceuticals, and The Procter & Gamble Company (NYSE: PG) from 1985 to 2004. He was a faculty member at the University of Illinois, and a visiting scientist at the National Institutes of Health. Tengion Inc. filed a voluntary Chapter 7 bankruptcy petition in December 2014. Dr. Bertram received his D.V.M. in Biology and Veterinary Medicine and his Ph.D. in Cellular Pathology from Iowa State University and was board certified in Veterinary Pathology in 1984. Dr. Bertram’s qualifications to serve on the Board include his leadership experience in the healthcare industry, as well as his knowledge of ProKidney’s business.

Pablo Legorreta

Mr. Legorreta has served as Chairman of the Board and a director on the GP Board since the Closing. Mr. Legorreta served on the Legacy GP Board from August 2021 until the Closing, as a director of the ProKidney-KY Board since January 2019, and as a manager of ProKidney Bermuda since January 2019. Mr. Legorreta is the founder and has served as Chief Executive Officer of Royalty Pharma plc (Nasdaq: RPRX), a rapidly growing biopharma company and one of the largest dedicated life sciences investors in the world, since September 1996. Mr. Legorreta has also served as the Chairman of the board of directors of Royalty Pharma plc since April 2020. Mr. Legorreta has over 25 years of experience building and managing Royalty Pharma plc. Additionally, Mr. Legorreta is a co-founder of Pharmakon Advisors, LP, a leading provider of debt capital to the life sciences industry, where he has served as a managing member, since April 2009. Mr. Legorreta has served as a director of Epizyme, Inc. (Nasdaq: EPZM), a fully integrated, commercial-stage biopharmaceutical company developing and delivering novel epigenetic therapies, since November 2019. Additionally, Mr. Legorreta is a co-founder of Pharmakon Advisors, LP, a leading provider of debt capital to the life sciences industry, where he has served as a managing member since April 2009. Mr. Legorreta has served on the Board of Governors of the New York Academy of Sciences since January 2015, the Board of Trustees of Rockefeller University since March 2017, and the Board of Trustees and Compensation, Research and Innovation and Development Committees of the Hospital for Special Surgery since January 2015. Mr. Legorreta has also served on the boards of Brown University; Pasteur Foundation (French: Institut Pasteur), a French non-profit private foundation dedicated to the study of biology, micro-organisms, diseases, and vaccines; Open Medical Institute, an international initiative for medical professionals, which through education and research, aims to improve healthcare on a global scale; and The Park Avenue Armory, a nonprofit cultural institution within the historic Seventh Regiment Armory. Mr. Legorreta is the founder and Chairman of Alianza Médica para la Salud, a non-profit organization dedicated to enhancing the quality of health care in Latin America by providing doctors

[Table of Contents](#)

and healthcare providers with continued education opportunities. Since its foundation in December 2010, AMSA has provided over 500 scholarships to Mexican and Latin American doctors and healthcare providers to study abroad. Mr. Legorreta is also a founding member of Mount Sinai's new Institute for Health Equity Research, which is created in May 2020 in part as a response to the health inequities made apparent by COVID-19. Mr. Legorreta received his B.A. degree in Industrial Engineering from Universidad Iberoamericana in Mexico City. We believe that Mr. Legorreta's experience in investing in pharmaceutical royalties and managing a growing life sciences investment company, as well as significant background in investment banking and debt financing provide him with the qualifications and skills to serve as the Chairman and a member of the Board.

William F. Doyle

Mr. Doyle has served on the Board and on the GP Board since the Closing. Mr. Doyle was a member of the Legacy GP Board from January 2022 until the Closing and has served on the ProKidney KY-Board since January 2022. Mr. Doyle is a recognized expert in medical devices commercialization with over 20 years' experience in the advanced technology and healthcare industries as an entrepreneur, executive, management consultant and investor. He has served as Executive Chairman of NovoCure Limited (Nasdaq: NVCR), a commercial-stage oncology company which is currently developing Tumor Treating Fields, a new therapy for solid tumor cancers ("NovoCure"), since May 2016 and a member of the board of directors of NovoCure since February, 2004. Mr. Doyle has been a managing director of WFD Ventures LLC, a private venture capital firm he co-founded, since June 2002. Prior to that, Mr. Doyle was a member of Johnson & Johnson's Medical Devices and Diagnostics Group Operating Committee and was the Vice President, Licensing and Acquisitions from 1994 to 1999. While at Johnson & Johnson, Mr. Doyle was also the Worldwide President of Biosense-Webster, Inc. and a member of the board of directors of Johnson & Johnson Development Corporation, Johnson & Johnson's venture capital subsidiary. Mr. Doyle has served as a member of the board of directors of Elanco Animal Health, Inc. (NYSE: ELAN), a global leader in animal health dedicated to innovating and delivering products and services to prevent and treat disease in farm animals and pets, creating value for farmers, pet owners, veterinarians, stakeholders, and society as a whole, since October 2020 and a member of the board of directors of Minerva Neurosciences, Inc. (Nasdaq: NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system disorders, since November 2017. Previously, Mr. Doyle served as a member of the board of directors of OptiNose, Inc. (Nasdaq: OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, from June 2004 to October 2020, and Zoetis, Inc. (NYSE: ZTS), a leading animal health company, dedicated to supporting its customers and their businesses, from February 2015 to March 2016. Mr. Doyle earned his B.S. in Materials Science and Engineering from Massachusetts Institute of Technology and his M.B.A. from Harvard Business School. We believe Mr. Doyle is qualified to serve on the Board due to his business and investment experience and his extensive knowledge of ProKidney and the healthcare industry.

Jennifer Fox

Jennifer Fox has served on the Board and on the GP Board since July 2022. Ms. Fox has served as the Chief Financial Officer of Nuvation Bio Inc. since October 2020. Prior to this role, Ms. Fox served as Managing Director, Co-Head of North America Healthcare Corporate and Investment Banking Group at Citigroup from June 2015 to October 2020. From February 2006 to June 2015, Ms. Fox served as Managing Director at Deutsche Bank, most recently also as Co-Head of Life Sciences Investment Banking Group. Prior to that, Ms. Fox served as Senior Managing Director Healthcare Investment Banking at Bear Stearns, Vice President Healthcare Investment Banking at Bank of America and Financial Analyst, Investment Banking Analyst, Associate, Vice President, Health Care Investment Banking at Prudential Vector Healthcare Group and Prudential Securities Incorporated. Ms. Fox received B.S. degrees in Finance and Marketing from Manhattan College. We believe that Ms. Fox is qualified to serve on the Board because she has over 25 years of experience in the healthcare investment banking industry and has been a lead advisor to life sciences companies on over 200 financing and strategic transactions.

[Table of Contents](#)

José Ignacio Jiménez Santos

Mr. Jiménez Santos has served on the Board and on the GP Board since the Closing and was a member of the Legacy GP Board from August 2021 until the Closing. Mr. Jiménez Santos has served as the Chief Executive Officer of Afore Inbursa since August 2015 and the Chief Investment Officer of Grupo Financiero Inbursa, SAB de C.V., a public company registered on the Mexican Stock Exchange, since August 2013. Mr. Jiménez Santos served on the board of directors of Procesar SA de C.V., a private company that provides data processing services, from May 2019 to May 2022. Mr. Jiménez Santos also serves on the board of directors of Glycosyn, a private biotechnology company developing products based on unique bioactive sugars found in human milk. Mr. Jiménez Santos received his bachelor's degree in economics and finance from the Instituto Tecnológico Autonomo de México. We believe that Mr. Jiménez Santos' combined experience in finance, international investments and the biotechnology industry provide him with the qualifications and skills to serve as a member of the Board.

Alan M. Lotvin, M.D.

Dr. Lotvin has served on the Board and on the GP Board since the Closing. Dr. Lotvin was a member of the Legacy GP Board from January 2022 until the Closing and has served on the ProKidney KY-Board since January 2022. Dr. Lotvin has served as the Executive Vice President at CVS Health Corp (NYSE: CVS), a leading health solutions company, since November 2012, and the President of CVS Caremark since March 2020. Prior to that, Dr. Lotvin served as the Executive Vice President—Transformation at CVS Health Corporation from June 2018 to February 2020 and the Executive Vice President—Specialty Pharmacy at CVS Caremark from November 2012 to May 2018. Dr. Lotvin has extensive experience in the pharmacy benefit management (“PBM”) and specialty pharmacy industries. Before joining CVS Health Corp, Dr. Lotvin was the President and Chief Executive Officer of ICORE Healthcare, a Magellan Health Services company, and prior to that, Dr. Lotvin held senior positions in the PBM industry. Dr. Lotvin earned his B.S. in Biochemistry from Stony Brook University, his M.D. in Medicine from SUNY Downstate Health Sciences University, and his M.A. in Medical Informatics from Columbia University Graduate School of Arts and Sciences. We believe Dr. Lotvin is qualified to serve on the Board due to his extensive knowledge of ProKidney and the healthcare industry.

John M. Maraganore, Ph.D.

Dr. Maraganore has served on the Board and on the GP Board since the Closing. Dr. Maraganore was a member of Legacy GP Board from May 2022 until the Closing and has been a member of the ProKidney KY-Board since May 2022. Dr. Maraganore is the owner of JMM Consulting, LLC and is a venture partner at ARCH Venture Partners, a venture advisor at Atlas Venture, an executive advisor at RTW Investments and a senior advisor at Blackstone Life Sciences, each of which are investment funds. Previously, Dr. Maraganore served as the founding chief executive officer and as a director of Alnylam Pharmaceuticals, Inc. (“Alnylam”) (Nasdaq: ALNY), a publicly traded biopharmaceutical company, from 2002 until the end of 2021. From 2002 to 2007, Dr. Maraganore also served as president of Alnylam. From 1997 to 2002, Dr. Maraganore served in a number of leadership roles including as senior vice president, strategic product development with Millennium Pharmaceuticals, Inc., a biopharmaceutical company (now Takeda Oncology) (“Millennium”). Before Millennium, he served as director of molecular biology and director of market and business development at Biogen. Prior to Biogen, Dr. Maraganore was a scientist at ZymoGenetics, Inc., a biotechnology company, and The Upjohn Company, a pharmaceutical manufacturing company. Dr. Maraganore currently serves on the board of directors of publicly traded biotechnology companies Agios Pharmaceuticals, Inc. (Nasdaq: AGIO), Beam Therapeutics Inc. (Nasdaq: BEAM) and Kymera Therapeutics, Inc. (Nasdaq: KYMR), and on the board of directors of private biotechnology companies, including Hemab Therapeutics ApS, TranSend Therapeutics, Inc., Versanis Bio, Inc. and Aerium Therapeutics, Inc. Dr. Maraganore was formerly a director of bluebird bio, Inc. (Nasdaq: BLUE). In addition, he was formerly a venture partner at Third Rock Ventures, L.P., and was formerly chairman of the board of directors of Regulus Therapeutics, Inc. (Nasdaq: RGLS), a publicly traded biotechnology company. Dr. Maraganore serves as a strategic advisor and investor to Brii Biosciences, a private

[Table of Contents](#)

biotechnology company, and also serves in an advisory role with Pictet & Cie, an investment firm. He also serves as a strategic advisor for a number of private and public biotechnology companies. He is the former Chair and current member of the Executive Committee, the Emerging Companies Section Governing Board and the Health Section Governing Board of the Biotechnology Innovation Organization (BIO), where he serves as Chair Emeritus. Dr. Maraganore holds an M.S. and a Ph.D. in Biochemistry and Molecular Biology from the University of Chicago and a B.S. in Biological Sciences also from the University of Chicago. We believe that Dr. Maraganore is qualified to serve on the Board because he has over 35 years of experience in the biotechnology industry, bringing to the Board critical scientific, research and development, international and general management expertise.

Brian J. G. Pereira, M.D.

Dr. Pereira has served on the Board and on the GP Board since the Closing and was a member of the Legacy GP Board from January 2022 until the Closing. Dr. Pereira has served as the Chief Executive Officer at Visterra Inc., a clinical-stage biotechnology company committed to developing innovative antibody-based therapies for the treatment of patients with kidney diseases and other hard-to-treat diseases and a subsidiary of Otsuka America Inc., a global healthcare company listed on Tokyo Stock Exchange, since July 2013. Dr. Pereira has also served on the board of directors of Visterra Inc. since July, 2013. Dr. Pereira is a nationally recognized expert on kidney disease and nephrology, is the former Editor of the widely read textbook “Chronic Kidney Disease, Dialysis and Transplantation,” and has over 200 scientific papers to his credit. He currently serves on the board of directors of Africa Healthcare Network, Ltd, a dialysis provider, as the Chairman of the Board, the board of directors of KalVista Pharmaceuticals, Inc. (Nasdaq: KALV), a pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors for diseases with significant unmet need, the board of directors of Cullinan Pearl Corp, a privately held biotechnology company and a subsidiary of Cullinan Oncology, Inc. (Nasdaq: CGEM), an oncology company. He was the former Executive Chairman of the board of directors of Abeona Therapeutics Inc. (Nasdaq: ABEO), a clinical-stage biopharmaceutical company developing gene and cell therapies for serious diseases. Dr. Pereira is a graduate of St. John’s Medical College, Bangalore, India and has an MBA from the Kellogg Business School, Northwestern University. Dr. Pereira obtained his D.M. in Nephrology and M.D. in Internal Medicine from Post Graduate Institute, Chandigarh, India. We believe Dr. Pereira’s qualifications to serve on the Board include his extensive experience with pharmaceutical companies, and his years of experience providing services to pharmaceutical and biotechnology organizations, including evaluating business plans involving clinical trials.

Uma Sinha, Ph.D.

Dr. Sinha has served on the Board and on the GP Board since the Closing. Dr. Sinha was a member of the SCS Board from September 2021 until the Closing. In April, 2016, Dr. Sinha was appointed the Chief Scientific Officer of BridgeBio Pharma, Inc. (“BridgeBio”) and serves as the Chief Scientific Officer of other BridgeBio subsidiaries, including Eidos Therapeutics. Prior to that, Dr. Sinha served as Chief Scientific Officer of Global Blood Therapeutics, Inc., a clinical-stage biopharmaceutical company, from 2014 to 2015 and as Senior Vice President of research from 2013 to 2014. She was Vice President, head of biology at Portola Pharmaceuticals, Inc., a clinical-stage biotechnology company, from 2010 to 2012 and was the Vice President of translational biology from 2004 to 2010. Previously, Dr. Sinha held senior research positions at Millennium Pharmaceuticals, Inc., a biopharmaceutical company, and COR Therapeutics, Inc., a biopharmaceutical company. Dr. Sinha received her Ph.D. in biochemistry from the University of Georgia and her B.Sc. with honors in chemistry from Presidency College. We believe Dr. Sinha’s qualifications to serve on the Board include her significant scientific experience in the biopharmaceutical industry.

Family Relationships

There are no family relationships among any of ProKidney’s directors or executive officers.

Corporate Governance

Composition of the Board of Directors

ProKidney's business and affairs is organized under the direction of the Board. Mr. Legorreta serves as the Chairperson of the Board. The primary responsibilities of Board are to provide oversight, strategic guidance, counseling and direction to ProKidney's management. The Board meets on a regular basis and additionally as required.

In accordance with the terms of the Charter, the Board may establish the authorized number of directors from time to time by resolution. The Board consists of nine members and is divided into three classes with staggered three-year terms. At each annual general meeting of shareholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual general meeting following election. ProKidney's directors is divided among the three classes as follows:

- the Class I directors are William F. Doyle, Alan M. Lotvin, M.D., Brian J. G. Pereira, M.D., and their terms will expire at the annual general meeting of shareholders to be held in 2023;
- the Class II directors are Jennifer Fox, John M. Maraganore, Ph.D. and José Ignacio Jiménez Santos, and their terms will expire at the annual general meeting of shareholders to be held in 2024; and
- the Class III directors are Tim Bertram, Ph.D., Pablo Legorreta and Uma Sinha, Ph.D., and their terms will expire at the annual general meeting of shareholders to be held in 2025.

The division of the Board into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Board Leadership Structure

ProKidney believes that all members of the Board should have a voice in the affairs and the management of ProKidney. The Board believes that ProKidney's shareholders are best served at this time by having Mr. Legorreta, who plays an integral part of the board of director leadership structure and a critical aspect of effective corporate governance, serves as the Chairperson. The active involvement of the independent directors, combined with the qualifications and significant responsibilities of ProKidney's Chairperson, provide balance and promote strong oversight of ProKidney's management and affairs. ProKidney intends to evaluate its Board leadership structure on a periodic basis, commencing with the first meeting of the Board following the Closing, which evaluations will include, among other things, whether it is appropriate to appoint a lead independent director.

Controlled Company Exemption

Pursuant to the terms of the Voting Agreement, Tolerantia effectively controls a majority of the voting power of all outstanding ProKidney ordinary shares with respect to the election, appointment or removal of any ProKidney director. As a result, ProKidney is a "controlled company" within the meaning of the Nasdaq Listing Rules. Under the Nasdaq Listing Rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance standards, including the requirements that (i) a majority of its board of directors consist of independent directors, (ii) subject to the exception pursuant to Nasdaq Listing Rule 5605(b)(2), its board of directors have a compensation committee that is composed of at least two members, each of whom is an independent director, with a written charter addressing the committee's purpose and responsibilities and (iii) director nominees must be selected, or recommended for the board's selection, either by independent directors constituting a majority of the board's independent directors in a vote in which only independent directors participate, or by a nominating and corporate governance committee comprised solely of independent directors with a written charter addressing the committee's purpose and responsibilities. Under the

[Table of Contents](#)

Business Combination Agreement, immediately following the Closing, a majority of the directors of the Board were required to be “independent” directors for the purposes of the Nasdaq Listing Rules, but for at least some period following the Business Combination, ProKidney could utilize the other exemptions described above. If any of these exemptions are used, you may not have the same protections afforded to shareholders of companies that are subject to all of these corporate governance requirements. If ProKidney ceases to be a “controlled company” and its shares continue to be listed on the Nasdaq, ProKidney will be required to comply with these standards and, depending on the Board’s independence determination with respect to its then-current directors, ProKidney may be required to add additional directors to its board in order to achieve such compliance within the applicable transition period.

Director Independence

An “independent director” is defined generally as a person who has no material relationship with the listed company (either directly or as a partner, shareholder or officer of an organization that has a relationship with the company). The Board has determined that each of William F. Doyle, Alan M. Lotvin, M.D., Brian J. G. Pereira, M.D., John M. Maraganore, Ph.D., Uma Sinha, Ph.D, José Ignacio Jiménez Santos and Jennifer Fox is an independent director under applicable SEC and Nasdaq rules. The independent directors have regularly scheduled meetings at which only independent directors are present.

Role of the Board in Risk Oversight

One of the key functions of the Board is to oversee ProKidney’s risk management process. The Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through various standing committees of the Board that address risks inherent in their respective areas of oversight. In particular, the Board is responsible for monitoring and assessing strategic risk exposure and ProKidney’s audit committee has the responsibility to consider and discuss ProKidney’s major financial risk exposures and the steps its management will take to monitor and control such exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. ProKidney’s compensation committee also assesses and monitors whether ProKidney’s compensation plans, policies and programs comply with applicable legal and regulatory requirements.

Committees of the Board of Directors

The standing committees of Board consist of an audit committee, a compensation committee and a nominating and corporate governance committee. The Board may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

Our audit committee consists of William F. Doyle, who serves as the chairperson, Brian J. G. Pereira, M.D., Jennifer Fox and Alan M. Lotvin, M.D. Each member of the audit committee qualifies as an independent director under the Nasdaq Listing Rules and the independence requirements of Rule 10A-3 under the Exchange Act. The Board has determined that Mr. Doyle qualifies as an “audit committee financial expert” as such term is defined in Item 407(d)(5) of Regulation S-K and possesses financial sophistication, as defined under the rules of the Nasdaq.

The primary purpose of the audit committee is to discharge the responsibilities of the Board with respect to corporate accounting and financial reporting processes, systems of internal control and financial statement audits, and to oversee ProKidney’s independent registered public accounting firm. Specific responsibilities of the audit committee include:

- helping the Board oversee corporate accounting and financial reporting processes;

Table of Contents

- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit ProKidney's consolidated financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, ProKidney's interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually that describes ProKidney's internal quality control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

The Board has adopted a written charter for the audit committee, which is available on ProKidney's website at <https://www.prokidney.com> under Investors—Corporate Governance—Governance Overview.

Compensation Committee

Our compensation committee consists of Alan M. Lotvin, M.D., who serves as the chairperson, William F. Doyle, John M. Maraganore, Ph.D. and Uma Sinha, Ph.D.

The primary purpose of the compensation committee is to discharge the responsibilities of the Board in overseeing the compensation policies, plans and programs and to review and determine the compensation to be paid to executive officers, directors and other senior management, as appropriate. Specific responsibilities of the compensation committee include:

- reviewing and approving the compensation of the chief executive officer, other executive officers and senior management;
- reviewing and recommending to the Board the compensation of directors;
- administering the ProKidney Incentive Equity Plan and other benefit programs;
- reviewing, adopting, amending and terminating incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections and any other compensatory arrangements for the executive officers and other senior management; and
- reviewing and establishing general policies relating to compensation and benefits of the employees, including the overall compensation philosophy.

The Board has adopted a written charter for the compensation committee, which is available on ProKidney's website at <https://www.prokidney.com> under Investors—Corporate Governance—Governance Overview.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of John M. Maraganore, Ph.D., who serves as the chairperson, Brian J.G. Pereira, M.D., Uma Sinha, Ph.D., and José Ignacio Jiménez Santos. The purpose of the nominating and corporate governance committee is to assist the Board in discharging its responsibilities relating to:

- identifying and evaluating candidates, including the nomination of incumbent directors for re-election and nominees recommended by shareholders, to serve on the ProKidney Board;

[Table of Contents](#)

- considering and making recommendations to the Board regarding the composition and chairmanship of the committees of the ProKidney Board;
- developing and making recommendations to the Board regarding corporate governance guidelines and matters, including in relation to corporate social responsibility; and
- overseeing periodic evaluations of the performance of the Board, including its individual directors and committees.

The Board has adopted a written charter for the nominating and corporate governance committee, which is available on ProKidney's website at <https://www.prokidney.com> under Investors—Corporate Governance—Governance Overview.

Code of Ethics

ProKidney has adopted a code of business conduct that applies to all of its directors, officers and employees, including its principal executive officer, principal financial officer and principal accounting officer, which is available on ProKidney's website at <https://www.prokidney.com> under Investors—Corporate Governance—Governance Overview. ProKidney's code of business conduct is a "code of ethics" as defined in Item 406(b) of Regulation S-K. ProKidney will make any legally required disclosures regarding amendments to, or waivers of, provisions of its code of ethics on its Internet website.

Compensation of Directors and Executive Officers

Overview

ProKidney's executive compensation program is designed to:

- attract, retain and motivate senior management leaders who are capable of advancing ProKidney's mission and strategy and, ultimately, creating and maintaining its long-term equity value. Such leaders must engage in a collaborative approach and possess the ability to execute its business strategy in an industry characterized by competitiveness and growth;
- reward senior management in a manner aligned with ProKidney's financial performance; and
- align senior management's interests with ProKidney's equity owners' long-term interests through equity participation and ownership.

Decisions with respect to the compensation of ProKidney's executive officers, including its named executive officers, are made by the compensation committee of the Board. Compensation for ProKidney's executive officers has the following components: base salary, cash bonus opportunities, long-term incentive compensation, broad-based employee benefits, and severance benefits. Base salaries, broad-based employee benefits, supplemental executive perquisites and severance benefits are designed to attract and retain senior management talent. ProKidney also uses cash bonuses and long-term equity awards to promote performance-based pay that aligns the interests of its named executive officers with the long-term interests of its equity owners and to enhance executive retention.

See the section entitled "Executive and Director Compensation" below for additional information regarding the compensation paid to ProKidney's named executive officers and non-employee directors.

Base Salary

The base salaries for ProKidney's named executive officers were in effect prior to the Business Combination and are subject to adjustments made by the compensation committee, including in connection with ProKidney's annual review of its named executive officers' base salaries.

[Table of Contents](#)

Annual Bonuses

ProKidney uses annual cash incentive bonuses for the named executive officers to motivate their achievement of short-term performance goals and tie a portion of their cash compensation to performance. Near the beginning of each year, the compensation committee will select the performance targets, target amounts, target award opportunities and other terms and conditions of annual cash bonuses for the named executive officers, subject to the terms of their employment agreements. Following the end of each year, the compensation committee will determine the extent to which the performance targets were achieved and the amount of the award that is payable to the named executive officers.

Share-Based Awards

ProKidney uses share-based awards to promote its interests by providing the executives with the opportunity to acquire equity interests as an incentive for their remaining in its service and aligning the executives' interests with those of ProKidney. Share-based awards will be awarded under the ProKidney Incentive Equity Plan.

Other Compensation

ProKidney maintains various broad-based employee benefit plans, including medical, dental, vision, life and disability insurance and 401(k) plans, paid vacation, sick leave and holidays and employee assistance program benefits in which the named executive officers will participate.

Director Compensation

ProKidney plans to adopt a director compensation program that is designed to align compensation with the Company's business objectives and the creation of shareholder value, while enabling ProKidney to attract, retain, incentivize and reward directors who contribute to the long-term success of ProKidney.

EXECUTIVE AND DIRECTOR COMPENSATION

The following discusses the material components of the executive compensation program for the named executive officers of ProKidney (the “NEOs”) who are identified in the 2021 Summary Compensation Table below. This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. In this section, unless context requires otherwise, references to “we,” “us” “our,” “ProKidney” or “the Company” generally refer to ProKidney Corp. and its subsidiaries following the Closing and to ProKidney LP and its subsidiaries prior to the Closing.

Summary Compensation Table

We have opted to comply with the executive compensation disclosure rules applicable to emerging growth companies, as ProKidney is an emerging growth company. The scaled disclosure rules are those applicable to “smaller reporting companies,” as such term is defined in the rules promulgated under the Securities Act, which require compensation disclosure for ProKidney’s principal executive officer(s), its two most highly compensated executive officers other than the principal executive officer whose total compensation for 2021 exceeded \$100,000 and who were serving as executive officers as of December 31, 2021 and up to two additional individuals for whom disclosure would have been required for the fact that they were not serving as executive officers as of December 31, 2021. We refer to these individuals as “named executive officers” or “NEOs.” For the year ended December 31, 2021, ProKidney’s NEOs were:

- Tim Bertram, Ph.D., Chief Executive Officer;
- Deepak Jain, Ph.D., Chief Operating Officer; and
- Joseph Stavas, M.D., MPH, Senior Vice President of Clinical Development.

The following table sets forth certain information with respect to compensation for the year ended December 31, 2021 earned by, awarded to or paid to ProKidney’s NEOs.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)⁽¹⁾	Non-Incentive Equity Plan (\$)	All Other Compensation (\$)⁽²⁾	Total (\$)
Tim Bertram, Ph.D. <i>Chief Executive Officer</i>	2021	\$ 489,258	\$ 360,000	\$ —	\$ 24,503	\$ 873,761
Deepak Jain, Ph.D. <i>Chief Operating Officer</i>	2021	\$ 401,694	\$ 216,000	\$ —	\$ 14,522	\$ 632,216
Joseph Stavas, M.D., MPH <i>Senior Vice President of Clinical Development</i>	2021	\$ 530,110	\$ 145,000	\$ —	\$ 14,522	\$ 689,632

- (1) Reflects bonuses actually paid for the 12-month period from January 1, 2021 to December 31, 2021, and excludes payments made in 2021 for 2020 bonuses, for each executive officer.
- (2) Reflects the amounts of all other compensation paid to the named individuals for the year ended December 31, 2021, which comprise of (1) the matching contributions to the 401(k) plan; (2) allowance paid to Dr. Bertram, and (3) insurance premiums with respect to a group life insurance policy, a group short-term disability policy, a group long-term disability policy, an accidental death and dismemberment policy, and flexible spending accounts paid on behalf of each of Dr. Bertram, Dr. Jain and Dr. Stavas.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

Below are descriptions of the employment agreements with each of our NEOs setting forth the terms and conditions of such executive's employment with ProKidney-US and ProKidney-KY, respectively. It is expected that each of our NEOs will enter into a new employment agreement with the Company that sets forth new terms and conditions of such executive's employment with the Company which reflect the Company's executive compensation philosophy as a new public company.

Tim Bertram, Ph.D.

On September 17, 2019, ProKidney-KY entered into an employment agreement with Dr. Bertram, pursuant to which Dr. Bertram was employed as ProKidney-KY's Chief Executive Officer, effective as of January 7, 2019. The agreement entitles Dr. Bertram to an initial base salary of \$237,885 and eligibility for ProKidney-KY's annual discretionary bonus program. Dr. Bertram is also eligible to participate in ProKidney-KY's benefit plans and programs, including its retirement plan and medical insurance coverage. Under the terms of this agreement, ProKidney-KY or Dr. Bertram may terminate Dr. Bertram's employment at any time for any or no reason upon three months' written notice. In the event that Dr. Bertram is terminated without Cause (as defined in the agreement and including due to disability or death), Dr. Bertram is entitled to receive any earned but unpaid base salary, payment for any unused vacation days, and any benefits to which he may be entitled under applicable law or ProKidney-KY's employee benefit plans. Unless previously terminated or extended, Dr. Bertram's employment will automatically cease at the end of the month in which he attains 70 years of age.

On the same day, ProKidney-US entered into an employment agreement with Dr. Bertram, pursuant to which Dr. Bertram assumed the role of Chief Executive Officer of ProKidney-US, effective as of January 7, 2019. The agreement entitles Dr. Bertram to an initial base salary of \$237,885 and eligibility in ProKidney-US's annual discretionary bonus program. Dr. Bertram is also eligible to participate in ProKidney-US's benefit plans and programs, including its 401K plan. The agreement further provides that PMEL would grant Dr. Bertram a profits interest, which would indirectly represent 4.5% of the future profits of ProKidney LP measured as of the date of the agreement and as further discussed below, on September 30, 2019, PMEL granted Dr. Bertram 3,698,631 Profits Interests. Under the terms of this agreement, ProKidney-US or Dr. Bertram may terminate his employment at any time for any or no reason upon written notice at any time. In the event that Dr. Bertram is terminated for any or no reason (including due to disability or death), Dr. Bertram is entitled to receive any earned but unpaid base salary, payment for any unused vacation days, and any benefits to which he may be entitled under applicable law or ProKidney-US's employee benefit plans.

Deepak Jain, Ph.D.

ProKidney-US entered into an employment agreement with Dr. Jain on September 17, 2019, pursuant to which Dr. Jain assumed the role of Chief Operating Officer of ProKidney-US effective as of January 7, 2019. The agreement entitles Dr. Jain to an initial base salary of \$378,525 and eligibility in ProKidney-US's annual discretionary bonus program. Dr. Jain is also eligible to participate in ProKidney-US's benefit plans and programs, including its 401K plan. The agreement further provides that PMEL would grant Dr. Jain a profits interest, which would indirectly represent 1.5% of the future profits of ProKidney LP measured as of the date of Dr. Jain's employment agreement and, as further discussed below, on September 30, 2019, PMEL granted Dr. Jain 1,232,877 Profits Interests. Under the terms of this agreement, ProKidney-US or Dr. Jain may terminate his employment at any time for any or no reason upon written notice at any time. In the event that Dr. Jain is terminated for any or no reason (including due to disability or death), Dr. Jain is entitled to receive any earned but unpaid base salary, payment for any unused vacation days, and any benefits to which he may be entitled under applicable law or ProKidney-US's employee benefit plans.

[Table of Contents](#)

Joseph Stavas, M.D., MPH

ProKidney-US entered into an employment agreement with Dr. Stavas on September 17, 2019, pursuant to which Dr. Stavas assumed the role of Senior Vice President of Clinical Development of ProKidney-US beginning October 1, 2019. The agreement entitles Dr. Stavas to an initial base salary of \$500,000 and eligibility in ProKidney-US's annual discretionary bonus program. Dr. Stavas is also eligible to participate in ProKidney-US's benefit plans and programs, including its 401K plan. The agreement further provides that PMEL would grant Dr. Stavas a profits interest, which would indirectly represent 1.5% of the future profits of ProKidney measured as of the date of Dr. Stavas's employment agreement and, as further discussed below, on November 1, 2019, PMEL granted Dr. Stavas 1,232,877 Profits Interests. Under the terms of this agreement, ProKidney-US or Dr. Stavas may terminate his employment at any time for any or no reason upon written notice at any time. In the event that Dr. Stavas is terminated for any or no reason (including due to disability or death), Dr. Stavas is entitled to receive any earned but unpaid base salary, payment for any unused vacation days, and any benefits to which he may be entitled under applicable law or ProKidney-US's employee benefit plans.

2021 Base Salaries

Each NEO's base salary was a fixed component of annual compensation for performing specific duties and functions, and was established by the Legacy GP Board taking into account each individual's role, responsibilities, skills and expertise. Base salaries are reviewed annually, typically in connection with our annual performance review process, and, going forward, will be approved by the compensation committee and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. During 2021, the annual base salaries for Dr. Bertram, Dr. Jain and Dr. Stavas, were \$489,258, \$401,694 and \$530,110, respectively.

2021 Bonuses

For the fiscal year ended December 31, 2021, each of ProKidney's NEOs was eligible to earn an annual bonus based on the achievement of certain predetermined corporate performance objectives. During 2021, the annual bonuses awarded to Dr. Bertram, Dr. Jain, and Dr. Stavas, were \$360,000, \$216,000, and \$145,000, respectively. The annual bonus earned by each NEO with respect to the fiscal year ended December 31, 2021 is reported under the "Bonus" column in the Summary Compensation Table above and were determined by the Legacy GP Board on a discretionary basis based on ProKidney's overall performance for the year, as well as each individual's performance, subject to each NEO's continued employment through the payment date.

Outstanding Equity Awards at December 31, 2021

The outstanding equity incentive awards held by the NEOs as of December 31, 2021, prior to the Business Combination, consisted of Profits Interests issued in 2019 (as detailed in the table below) (the "2019 Profits Interests"). No Profits Interests were granted to the NEOs in 2020 or 2021. On January 17, 2022, PMEL issued Profits Interests, some of which were granted subject to vesting and some of which were purchased fully-vested, to employees, directors and other service providers, including to each of the NEOs and certain independent directors of the Legacy GP Board and the ProKidney-KY Board, under the ProKidney Limited Partnership Agreement and the related Limited Liability Company Agreement of PMEL then in effect (the "2022 Profits Interests"). Dr. Bertram, Dr. Jain and Dr. Stavas were issued 2,337,045, 680,913 and 50,000 2022 Profits Interests, respectively, and, each of Mr. Doyle, Dr. Lotvin and Dr. Pereira were issued 1,848,352 2022 Profits Interests. In addition, on June 1, 2022, Mr. Maraganore was issued 200,000 Profits Interests.

The purpose of awarding the Profits Interests was to promote the interests of ProKidney by attracting and retaining key employees, managers, independent contractors or other service providers of ProKidney and its subsidiaries and to enable such individuals to acquire an equity interest in and participate in the long-term growth and financial success of ProKidney. The Profit Interests represented an indirect partnership interest in ProKidney

Table of Contents

LP and generally entitled the holder to receive distributions from PMEL (which PMEL received from ProKidney LP once a specified threshold equity value of ProKidney was reached, in each case as provided in the ProKidney Limited Partnership Agreement and the related Limited Liability Company Agreement of PMEL then in effect). Under these agreements, the Closing qualified as an “Extraordinary Event,” pursuant to which the holders of Profits Interests were also entitled to receive disproportionate distributions in ProKidney until each of their threshold equity value had been reduced to zero in order to “catch up” each such holder’s distributions to its pro rata share of aggregate cumulative distributions.

ProKidney measured compensation expense for Profits Interests based on estimated fair values at the time of grant and estimates the fair value of Profits Interests using generally accepted valuation procedures. ProKidney recognized compensation expense, on a straight-line basis, for the portion of the Profit Interests value that was expected to vest over the requisite period of service provided by the recipient of the Profits Interests. ProKidney also recorded forfeitures of Profits Interest as they occurred.

In general, awards of Profits Interests were 25% vested on the first anniversary of the recipient’s employment, in the case of Dr. Bertram and Dr. Jain, and the first anniversary of the date of award of the Profits Interests, in the case of Dr. Stavas, with the remainder of each award to vest in increments of 6.25% each calendar quarter following the first anniversary of the grant date, subject generally to the holder’s continuous employment with ProKidney-US or its affiliates on each vesting date. The 2022 Profits Interests generally vest in increments of 25% on each anniversary following the grant date, subject generally to the holder’s continuous employment with ProKidney-US or its affiliates on each vesting date. With respect to those 2022 Profits Interests that are subject to vesting conditions, in the event that an NEO’s employment is terminated without Cause (as defined in the NEO’s employment agreement) prior to January 17, 2023, the tranche of 2022 Profits Interests that would have vested on January 17, 2023 will immediately vest subject to, among other things, the NEO signing and not revoking a release of claims. All of the 2022 Profits Interests issued to Dr. Stavas were purchased fully vested, and a portion of the 2022 Profits Interests issued to Dr. Bertram and Dr. Jain were purchased fully vested, in each case, subject to certain transfer restrictions as provided in the applicable award agreement and the Limited Liability Company Agreement of PMEL. A portion of the 2022 Profits Interests granted to the independent directors of the Legacy GP Board (who have since gone on to serve as members of the GP Board) and ProKidney-KY Board vest in increments of 33.33% on each anniversary following the grant date, subject generally to the director’s continuous service on the board on each vesting date. A portion of the 2022 Profits Interests issued to such directors were purchased fully vested, subject to certain transfer restrictions as provided in the applicable award agreement and the Limited Liability Company Agreement of PMEL.

The following table summarizes the number of outstanding Profits Interests held by each of the NEOs as of December 31, 2021. Such NEOs do not hold any outstanding equity awards other than the Profits Interests.

Name	Grant Date	Equity Awards ⁽¹⁾			
		Number of Profits Interest that Have Vested (#)	Market Value of Profits Interest Units that Have Vested (\$)	Number of Profits Interest that Have Not Vested (#)	Market Value of Profits Interest Units that Have Not Vested (\$) ⁽³⁾
Tim Bertram, Ph.D.	9/30/2019 ⁽²⁾	2,773,973	\$ 998,630	924,658	\$ 332,877
Deepak Jain, Ph.D.	9/30/2019 ⁽³⁾	924,657	\$ 332,877	308,220	\$ 110,959
Joseph Stavas, M.D., MPH	11/1/2019 ⁽⁴⁾	693,493	\$ 249,657	539,384	\$ 194,178

- (1) There was no public market for the Profits Interests. For purposes of this disclosure, the equity value of the Profits Interests was determined using contemporaneous valuations using methodologies consistent with the *American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation*, as of December 31, 2021. As of December 31, 2021, the weighted average grant date fair value of the Profits Interests granted was \$0.36 per Class B Unit.

Table of Contents

- (2) Represents 3,698,631 Profits Interests granted on September 30, 2019, with the first 25% of such Profits Interests vested on January 7, 2020, and the remaining 75% vested in increments of 6.25% each calendar quarter thereafter, subject to continued employment of the NEO on each vesting date.
- (3) Represents 1,232,877 Profits Interests granted on September 30, 2019, with the first 25% of such Profits Interests vested on January 7, 2020, and the remaining 75% vested in increments of 6.25% each calendar quarter thereafter, subject to continued employment of the NEO on each vesting date.
- (4) Represents 1,232,877 Profits Interests granted on November 1, 2019, with the first 25% of such Profits Interests vested on November 1, 2020, and the remaining 75% vested in increments of 6.25% each calendar quarter thereafter, subject to continued employment of the NEO on each vesting date.

Actions Taken in Connection with this Business Combination

Effective as of January 17, 2022, the ProKidney Limited Partnership Agreement was amended to provide that, if, as a result of a De-SPAC Transaction or Qualified IPO (each as defined in the ProKidney Limited Partnership Agreement), a Profits Interest holder was allocated aggregate cumulative distributions in an amount at least equal to his or her pro rata share of the applicable threshold equity value, then such holder's Profits Interests would immediately and automatically be converted into ProKidney Class B Units. In connection with and by virtue of the Business Combination and immediately prior to the Closing, ProKidney converted all outstanding Profits Interests into Class B Units of ProKidney (the "Converted Profits Interests") in accordance with the foregoing. As contemplated by and pursuant to the terms of the Business Combination Agreement and the Second Amended and Restated ProKidney Limited Partnership Agreement, each Converted Profits Interest that was not vested pursuant to the terms of the applicable award agreement with the applicable holder as of immediately prior to the Closing was recapitalized into a PMEL RCU and each Converted Profits Interest that was vested pursuant to the terms of the applicable award agreement with the applicable holder as of immediately prior to the Closing was recapitalized into a Post-Combination ProKidney Common Unit. Each PMEL RCU will remain subject to vesting and forfeiture terms provided under the applicable existing award agreement with the holder and each Post-Combination ProKidney Common Unit will remain subject to the forfeiture terms of the applicable existing award agreement. Pursuant to the terms of the Second Amended and Restated ProKidney Limited Partnership Agreement and our Charter, upon the vesting of a PMEL RCU, such PMEL RCU and the corresponding ProKidney Class B PMEL RSR will automatically vest and each PMEL RCU will immediately and automatically convert, in accordance with the terms of the Second Amended and Restated ProKidney Limited Partnership Agreement, into one Post-Combination ProKidney Common Unit and, as promptly as reasonably practicable following such vesting event, the Company will settle such ProKidney Class B PMEL RSR by issuing to the holder thereof one ProKidney Class B ordinary share.

ProKidney Incentive Equity Plan

In connection with the Business Combination, the SCS Board adopted, and the SCS shareholders approved, the ProKidney Incentive Equity Plan, under which New ProKidney employees, non-employee directors, individual consultants, advisors and other service providers are eligible to receive awards based on the compensation committee's determination, in its sole discretion, that an award to such individual will further the ProKidney Incentive Equity Plan's stated purpose of promoting the long-term success of ProKidney by motivating employees and other individuals to perform at the highest level and contributing significantly to the success of ProKidney, thereby furthering the best interests of ProKidney and its shareholders. The ProKidney Incentive Equity Plan is administered by the compensation committee and is the primary means by which ProKidney will provide equity-based compensation to its employees and other service providers. As of the date hereof, no grants have been made or awarded under the ProKidney Incentive Equity Plan.

The ProKidney Incentive Equity Plan provides for the issuance of 23,226,419 ProKidney Class A ordinary shares, which equals 10% of the number of ProKidney Class A ordinary shares outstanding immediately after the completion of the Business Combination on a fully diluted basis. In addition, the ProKidney Incentive Equity Plan provides for an annual increase on the first day of each fiscal year during the period beginning with fiscal

[Table of Contents](#)

year 2023 and ending on the second day of fiscal year 2032 equal to the lesser of (a) 5% of the number of outstanding ProKidney Class A ordinary shares on the last day of the immediately preceding fiscal year on a fully diluted basis, and (b) an amount determined by the compensation committee. The number of ProKidney Class A ordinary shares that may be subject to incentive stock options granted under the ProKidney Incentive Equity Plan is 75,567,000.

In the event of a change in control, as defined in the ProKidney Incentive Equity Plan, the compensation committee may take certain actions with respect to outstanding awards, including the continuation or assumption of awards, substitution or replacement of awards by a successor entity, acceleration of vesting and lapse of restrictions, determination of the attainment of performance conditions for performance awards or cancellation of awards in consideration of a payment.

ProKidney Employee Stock Purchase Plan

In connection with the completion of the Business Combination, the SCS Board adopted, and the SCS shareholders approved, the ProKidney Employee Stock Purchase Plan. The ProKidney Employee Stock Purchase Plan is administered by the compensation committee and provides our employees and employees of participating subsidiaries with an opportunity to acquire a proprietary interest in ProKidney through the purchase of Class A ordinary shares. Initially, the ProKidney Employee Stock Purchase Plan is not intended to qualify as an “employee stock purchase plan” under Section 423 of the Code. However, from and after such date as the compensation committee determines that the ProKidney Employee Stock Purchase Plan is able to satisfy the requirements under Section 423 of the Code, the ProKidney Employee Stock Purchase Plan will be intended to qualify as an “employee stock purchase plan” under Section 423 and the ProKidney Employee Stock Purchase Plan will be interpreted in a manner that is consistent with that intent.

The maximum number of our ProKidney Class A ordinary shares that may be issued pursuant to rights granted under the ProKidney Employee Stock Purchase Plan is 4,645,284 ProKidney Class A ordinary shares, which equals 2% of the number of ProKidney Class A ordinary shares outstanding immediately after the Closing on a fully diluted basis. The number of ProKidney ordinary shares reserved for issuance under the ProKidney Employee Stock Purchase Plan will automatically increase on the first day of each calendar year during the term of the ProKidney Employee Stock Purchase Plan, commencing on January 1, 2023 through January 1, 2032, by the least of (i) 5,037,800 ProKidney Class A ordinary shares, (ii) 1% of the total number of ProKidney Class A ordinary shares outstanding on a fully diluted basis on December 31 of the immediately preceding calendar year or (iii) such smaller number of our ProKidney Class A ordinary shares as determined by the Board.

Other Compensation

All of ProKidney’s NEOs are eligible to participate in its employee benefit plans, including its medical, dental, vision, life and disability insurance plans, in each case on the same basis as all of ProKidney’s other employees. ProKidney generally provides perquisites or personal benefits to its NEOs in limited circumstances.

401(k) Plan

ProKidney maintains a 401(k) plan for its ProKidney-US employees. The 401(k) plan is intended to qualify under Section 401(k) of the Code, so that contributions to the 401(k) plan by ProKidney-US employees or by ProKidney, and the investment earnings thereon, are not taxable to the employees until withdrawn from the 401(k) plan, and so that contributions by ProKidney, if any, will be deductible by ProKidney when made. Full-time employees are eligible to participate in the ProKidney-US plan. Under the 401(k) plan, ProKidney-US employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit and to have the amount of such reduction contributed to the 401(k) plan. The 401(k) plan permits ProKidney to make contributions up to the limits allowed by law on behalf of all eligible ProKidney-US employees. As of December 31, 2021, ProKidney matched 50% of participating ProKidney-US employees’ contribution up to 8% of salary to the ProKidney 401(k) plan.

Defined Contribution Plan

ProKidney maintains a defined contribution plan for its ProKidney-KY employees within the Cayman Islands as required by the National Pensions Act (2012 Revision). The plan is administered by an approved provider. All of ProKidney-KY's employees between the ages of 18 and 65 are eligible to participate in the plan, other than domestic helpers or employees who have been working in the Cayman Islands for a continuous period of less than 9 months. Under the plan, ProKidney-KY employees may contribute on earnings up to CI\$87,000 (approximately US\$107,000, above which level earnings are not pensionable), which contributions are matched by ProKidney-KY. The basic contribution rate (and the maximum mandatory contribution for employees) is 5%, but ProKidney-KY may choose to contribute in excess of this percentage and reduce the employee contribution commensurately. As of December 31, 2021, ProKidney contributed 7% of ProKidney-KY employees salaries to the ProKidney-KY defined contribution plan.

Board Compensation

In the year ended December 31, 2021, no member of the Legacy GP Board received cash, equity or other compensation for service on the Legacy GP Board. In January 2022, Legacy GP and ProKidney-KY each entered into separate letter agreements with each of Mr. Doyle, Dr. Lotvin and Dr. Pereira (collectively, the "Director Agreements") that provided for Mr. Doyle, Dr. Lotvin and Dr. Pereira to serve on the Legacy GP Board and ProKidney-KY Board, effective as of January 15, 2022. The Director Agreements with Legacy GP provided that each of Mr. Doyle, Dr. Lotvin and Dr. Pereira would be paid, as compensation for their services as a member of the board of directors of Legacy GP, a \$50,000 annual retainer (payable in arrears on a quarterly basis). The Director Agreements provided that PMEL would issue, subject to the terms of the Director Agreement and the Limited Liability Company Agreement of PMEL, 1,848,352 2022 Profits Interests in the aggregate to each such director, some of which were granted subject to vesting and some of which were purchased fully vested. In addition, on June 1, 2022, Mr. Maraganore was issued 200,000 Profits Interests. Dr. Bertram did not receive additional compensation for his services as a member of Legacy GP Board. Effective as of the Closing, Legacy GP resigned as the general partner of ProKidney LP, and each of the directors of Legacy GP has served on the GP Board.

ProKidney intends to develop a board of directors' compensation program that is designed to align compensation with ProKidney's business objectives and the creation of shareholder value, while enabling ProKidney to attract, retain, incentivize and reward directors who contribute to the long-term success of ProKidney.

ProKidney's compensation committee will determine the annual compensation to be paid to the members of the Board. Directors' fees after the Business Combination have yet to be determined, but are expected to consist of two components: a cash payment and the issuance of equity or equity-based awards under the ProKidney Incentive Equity Plan. Pursuant to the Director Agreements with Legacy GP, it is anticipated that the following non-employee directors – Alan M. Lotvin, M.D., Brian J.G. Pereria, M.D., William F. Doyle and John M. Maraganore, Ph.D. – will hold at least five times his annual retainer in the form of ProKidney equity within five years of the completion of the Business Combination.

Limitations on Liability and Indemnification Matters

The Charter provides that, subject to certain limitations, ProKidney shall indemnify its directors and officers, including former directors and officers (each an "indemnified person") against any liability, action, proceeding, claim, demand, costs, damages or expenses, including legal expenses, whatsoever which they or any of them may incur as a result of any act or failure to act in carrying out their functions other than such liability (if any) that they may incur by reason of their own actual fraud, wilful neglect or wilful default. No person shall be found to have committed actual fraud, wilful neglect or wilful default under the Charter unless or until a court of competent jurisdiction shall have made a finding to that effect. The termination of any proceedings by any judgment, order, settlement, conviction or the entering of a *nolle prosequi* does not, by itself, create a presumption that the liability was incurred by reason of their own actual fraud, wilful neglect or wilful default.

[Table of Contents](#)

ProKidney entered into agreements with its officers and directors to provide contractual indemnification in addition to the indemnification provided for in the Charter. The Charter also permits ProKidney to purchase and maintain insurance on behalf of any officer or director of ProKidney against any liability which, by virtue of any rule of law, would otherwise attach to such person in respect of any negligence, default, breach of duty or breach of trust of which such person may be guilty in relation to ProKidney, whether or not ProKidney has or would have had the power to indemnify the person against the liability as provided in the Charter. ProKidney purchased a policy of directors' and officers' liability insurance that insures its officers and directors against the cost of defense, settlement or payment of a judgment in some circumstances and insures ProKidney against its obligations to indemnify its officers and directors.

These provisions may discourage shareholders from bringing a lawsuit against ProKidney's directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against officers and directors, even though such an action, if successful, might otherwise benefit ProKidney and its shareholders. Furthermore, a shareholder's investment may be adversely affected to the extent ProKidney pays the costs of settlement and damage awards against officers and directors pursuant to these indemnification provisions.

We believe that these provisions, and the insurance and the indemnity agreements, are necessary to attract and retain talented and experienced officers and directors.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In this section, unless the context otherwise requires, references to “we,” “us,” “our,” and the “Company” refer to ProKidney Corp. and its subsidiaries after the Closing; “ProKidney” refers to ProKidney LP and its subsidiaries prior to the Closing and to ProKidney Corp. following the Closing; and “SCS” refers to SCS prior to the Closing.

SCS Related Party Transaction

Founder Shares

On March 2, 2021, the Sponsor paid \$25,000 to cover certain offering and formation costs of SCS in consideration for which the Sponsor received 5,750,000 SCS Class B ordinary shares (the “Founder Shares”). On June 29, 2021, SCS effected a share capitalization with respect to its SCS Class B ordinary shares of 575,000 shares thereof, resulting in the Sponsor holding an aggregate of 6,325,000 Founder Shares. The Founder Shares included an aggregate of up to 825,000 shares that were subject to forfeiture depending on the extent to which the underwriters’ over-allotment option was exercised. As a result of the underwriters’ election to partially exercise their over-allotment option, a total of 750,000 Founder Shares were no longer subject to forfeiture and 75,000 Founder Shares were forfeited, resulting in an aggregate of 6,250,000 Founder Shares then outstanding. In June 2021, the Sponsor transferred 30,000 Founder Shares to Marc Semigran, M.D., an independent director of SCS.

The Sponsor and the SCS’s directors and officers agreed, subject to limited exceptions, not to transfer, assign or sell any of their Founder Shares until the earlier of: (A) one year after the completion of the Business Combination and (B) commencing at least 150 days after the Business Combination, the day on which the last reported sale price of the Class A ordinary shares has equaled or exceeded \$12.00 per share (as adjusted for share sub-divisions, share dividends, rights issuances, consolidations, reorganizations, recapitalizations and other similar transactions) for any 20 trading days within any 30-trading day period. At the Closing, the Founder Shares became ProKidney Class A ordinary shares, and ProKidney, the Sponsor and certain Closing ProKidney Unitholders entered into new lock-up agreements as described under “*Lock-Up Agreements.*”

Registration Rights

SCS, the Sponsor and certain other security holders entered into a registration rights agreement on June 29, 2021 (the “SCS Registration Rights Agreement”). The SCS Registration Rights Agreement granted these holders certain demand and “piggy back” registration rights with SCS obligated to bear the expenses incurred in connection with the filing of any such registration statements.

At the Closing, ProKidney entered into the Amended and Restated Registration Rights Agreement, which replaced the SCS Registration Rights Agreement. See “*Amended and Restated Registration Rights Agreement*” below.

Subscription Agreements with SCS Related PIPE Investors

Concurrently with the execution of the Business Combination Agreement, SCS entered into Subscription Agreements with the certain sponsor-related PIPE Investors (“the Sponsor Related PIPE Investors”) pursuant to which the Sponsor Related PIPE Investors subscribed for SCS Class A ordinary shares. The Sponsor Related PIPE Investors funded \$156,400,000 of the PIPE Investment, for which they will received 15,640,000 SCS Class A ordinary shares. Specifically, (i) SC Master Holdings, LLC, an entity affiliated with Mr. Chamath Palihapitiya, SCS’s Chief Executive Officer and Chairman of its board of directors, subscribed for 12,500,000 SCS Class A ordinary shares and (ii) Averill Master Fund, Ltd., an entity affiliated with Mr. Kishan Mehta, director and President of SCS’s, subscribed for 3,140,000 SCS Class A ordinary shares. The PIPE Investment was consummated concurrently with the Closing, and the SCS Class A ordinary shares purchased by the PIPE Investors became ProKidney Class A ordinary shares.

Administrative Services Agreement

SCS entered into an agreement, pursuant to which it paid an affiliate of the Sponsor \$10,000 per month, commencing on June 30, 2021 and remaining in effect until the Closing, for office space, administrative and support services. For the period from February 25, 2021 (inception) through the Closing, SCS paid \$120,000 for these services.

SCS Promissory Notes—Related Party

On March 2, 2021, SCS issued an unsecured promissory note to the Sponsor (the “Pre-IPO SCS Promissory Note”), pursuant to which SCS could borrow up to an aggregate principal amount of \$300,000. The Pre-IPO SCS Promissory Note was non-interest bearing and payable on the earlier of December 31, 2021 and the completion of the initial public offering. The outstanding balance under the Pre-IPO SCS Promissory Note of \$300,000 was repaid at the closing of the initial public offering on July 2, 2021.

On April 20, 2022, SCS issued the SCS Promissory Note to the Sponsor, pursuant to which SCS could borrow up to an aggregate principal amount of \$1,500,000. The SCS Promissory Note was non-interest bearing, unsecured and payable upon the earlier of July 2, 2023 and the Closing. The SCS Promissory Note was subject to customary events of default. On April 26, 2022, SCS drew \$250,000 under the SCS Promissory Note. At the Closing, SCS repaid the balance under the SCS Promissory Note.

ProKidney Related Party Transactions

Consulting Services Agreement between ProKidney-KY and Nefro Health

On January 1, 2020, ProKidney-KY (formerly known as inRegen) entered into a consulting services agreement with Nefro Health (“Nefro”), an Irish partnership controlled and majority-owned by Mr. Pablo Legorreta, a director of Legacy GP and a holder of over 5% of ProKidney Class A Units, pursuant to which Nefro provides consulting services for the research and development of ProKidney’s product candidates, including the conduct of clinical trials in North America and the European Union, the design and manufacturing of ProKidney’s product candidates as well as pre-commercialization activities, which are primarily performed by Mr. Pablo Legorreta. Under the agreement, Nefro receives \$25,000 per quarter and is reimbursed for any out-of-pocket expenses incurred in connection with activities Nefro conducted under the agreement. ProKidney-KY has paid Nefro an aggregate of \$100,000 and \$100,000, respectively, for the years ended December 31, 2020 and December 31, 2021. The initial term of the consulting services agreement continued through December 31, 2020 and was renewed pursuant to the provision allowing for automatic renewals for additional periods of one year each unless terminated by either party by providing written notice to the other party at least ninety (90) days prior to the scheduled termination date. Either party may terminate this agreement upon the occurrence of a material breach by the other party in the performance of its obligations under the agreement or in respect of any provision, representation, warranty or covenant if such breach has not been cured within thirty (30) days after receiving written notice from the non-breaching party. Additionally, either of the parties may terminate the consulting services agreement for any reason upon giving thirty (30) days’ advance notice of such termination to the other party. In the event of such termination, ProKidney-KY will be obligated to pay Nefro any earned but unpaid consulting fee as of the termination date.

Consulting Services Agreement between ProKidney-US and Nefro Health

On January 1, 2020, ProKidney-US (formerly known as Twin City Bio, LLC) entered into a consulting services agreement with Nefro, pursuant to which Nefro provides consulting services for the research and development of ProKidney’s product candidates, including the conduct of clinical trials in North America and the European Union, the design and manufacturing of ProKidney’s product candidates as well as pre-commercialization activities, which are primarily performed by Mr. Pablo Legorreta, a director of Legacy

GP. Under the agreement, Nefro receives \$25,000 per quarter and is reimbursed for any out-of-pocket expenses incurred in connection with activities Nefro conducted under the agreement. ProKidney-US has paid Nefro an aggregate of \$100,000 and \$100,000, respectively, for the years ended December 31, 2020 and December 31, 2021. The initial term of the consulting services agreement continued through December 31, 2020 and was renewed pursuant to the provision allowing for automatic renewals for additional periods of one year each unless terminated by either party by providing written notice to the other party at least ninety (90) days prior to the scheduled termination date. Either party may terminate this agreement upon the occurrence of a material breach by the other party in the performance of its obligations under the agreement or in respect of any provision, representation, warranty or covenant if such breach has not been cured within thirty (30) days after receiving written notice from the non-breaching party. Additionally, either of the parties may terminate the consulting services agreement for any reason upon giving thirty (30) days' advance notice of such termination to the other party. In the event of such termination, ProKidney-US will be obligated to pay Nefro any earned but unpaid consulting fee as of the termination date.

Contributions to ProKidney Bermuda and ProKidney by Pablo Legorreta and entities controlled by Pablo Legorreta

Pursuant to the Limited Liability Company Agreement of ProKidney Bermuda by and between ProKidney Bermuda and Mr. Pablo Legorreta, dated as of December 12, 2018 (as amended, the "ProKidney Bermuda Agreement"), ProKidney Bermuda issued Mr. Pablo Legorreta 45,000,000 Class A Units (as defined in the ProKidney Bermuda Agreement) in exchange for a capital contribution of \$45,000,000. Mr. Legorreta was admitted as the sole member of ProKidney Bermuda. The ProKidney Bermuda Agreement was amended and restated on December 31, 2018 to admit an additional member that contributed to ProKidney Bermuda an aggregate of \$30,000,000 as consideration for 30,000,000 Class A Units of ProKidney Bermuda. On or around October 23, 2019, ProKidney Bermuda issued additional Class A Units to its members, including Mr. Legorreta, in accordance with the terms and conditions of the ProKidney Bermuda Agreement, in exchange for an aggregate of \$20,000,000 in capital contributions (the "2019 Contribution"). Mr. Legorreta made a capital contribution of \$12,000,000 to ProKidney Bermuda in exchange for 12,000,000 Class A Units in the 2019 Contribution. Given the effect of the 2019 Contribution, Mr. Legorreta held an aggregate of 57,000,000 Class A Units of ProKidney Bermuda.

Effective as of January 1, 2020, Mr. Legorreta transferred 100% of his equity interests in ProKidney Bermuda to Nefro pursuant to a certain contribution, assignment and assumption agreement by and between Mr. Legorreta and Nefro, and in accordance with the terms of the ProKidney Bermuda Agreement. As a result, Mr. Legorreta ceased to be a member of ProKidney Bermuda, and Nefro became a substituted member of ProKidney Bermuda. On or around August 12, 2020, ProKidney Bermuda issued additional Class A Units to its members, including Nefro, in accordance with the terms and conditions of the ProKidney Bermuda Agreement, in exchange for an aggregate of \$20,000,000 in capital contributions (the "2020 Contribution"). Nefro made a capital contribution of \$15,000,000 to ProKidney Bermuda in exchange for 15,000,000 Class A Units in the 2020 Contribution. As a result of the 2020 Contribution, Nefro held an aggregate of 72,000,000 Class A Units of ProKidney Bermuda.

Effective as of February 1, 2021, Nefro transferred 100% of its equity interests in ProKidney Bermuda to Tolerantia, a Delaware limited liability company and a wholly owned subsidiary of Nefro, pursuant to a certain contribution, assignment and assumption agreement by and between Mr. Legorreta and Nefro, dated as of February 1, 2020, and in accordance with the terms of the ProKidney Bermuda Agreement. As a result, Nefro ceased to be a member of ProKidney Bermuda, and Tolerantia became a substituted member of ProKidney Bermuda. Between February 2021 and May 2021, ProKidney Bermuda issued additional Class A Units to its members, including Tolerantia, in accordance with the terms and conditions of the ProKidney Bermuda Agreement, in exchange for an aggregate of \$30,000,000 in capital contributions (the "First 2021 Contribution"). Tolerantia made a capital contribution in an aggregate amount of \$15,000,000 to ProKidney Bermuda in exchange for 15,000,000 Class A Units in the First 2021 Contribution. Given the effect of the First 2021

[Table of Contents](#)

Contribution, Tolerantia held an aggregate of 87,000,000 Class A Units of ProKidney Bermuda. On June 29, 2021, ProKidney Bermuda issued additional Class A Units to its members, including Tolerantia, in accordance with the terms and conditions of the ProKidney Bermuda Agreement, in exchange for an aggregate of \$11,500,000 in capital contributions (the “*Second 2021 Contribution*”). Tolerantia made a capital contribution of \$6,900,000 to ProKidney Bermuda in exchange for 6,900,000 Class A Units in the Second 2021 Contribution. Given the effect of the Second 2021 Contribution, Tolerantia held an aggregate of 93,900,000 Class A Units of ProKidney Bermuda.

On August 5, 2021, ProKidney was formed as a limited partnership under the laws of Ireland. The members of ProKidney Bermuda, including Tolerantia, contributed all of their holdings in ProKidney Bermuda as a contribution *in specie* to ProKidney. As a result, ProKidney Bermuda became a wholly owned subsidiary of ProKidney and Tolerantia became one of the partners of ProKidney, holding an aggregate of 93,900,000 Legacy Class A Units. On October 15, 2021, ProKidney issued additional Legacy Class A Units to its partners, including Tolerantia, in accordance with the terms and conditions of the ProKidney Limited Partnership Agreement, in exchange for an aggregate contribution of \$30,000,000 (the “*Third 2021 Contribution*”). Tolerantia, as one of the partners of ProKidney, made a contribution of \$18,000,000 to ProKidney in exchange for 18,000,000 Legacy Class A Units pursuant to the ProKidney Limited Partnership Agreement. Given the effect of the Third 2021 Contribution, Tolerantia held an aggregate of 111,900,000 Class A Units of ProKidney. At the Closing, the ProKidney Class A Units held by Tolerantia were recapitalized into Post-Combination ProKidney Common Units and ProKidney Class B ordinary shares pursuant to the terms of the Business Combination Agreement.

Contributions to ProKidney Bermuda and ProKidney by CEC and entities controlled by CEC

On December 12, 2018, ProKidney Bermuda entered into the ProKidney Bermuda Agreement with Mr. Pablo Legorreta, which was amended and restated on December 31, 2018 to admit Inversora Carso, S.A. de C.V., a Mexican corporation (“INCA”), as an additional member. INCA contributed to ProKidney Bermuda an aggregate of \$30,000,000 as consideration for 30,000,000 Class A Units of ProKidney Bermuda. In the 2019 Contribution, INCA made an additional capital contribution of \$8,000,000 to ProKidney Bermuda in exchange for 8,000,000 Class A Units. Given the effect of the 2019 Contribution, INCA held an aggregate of 38,000,000 Class A Units of ProKidney Bermuda.

On June 30, 2020, INCA merged with and into CEC, with CEC surviving the merger. In accordance with the terms of the ProKidney Bermuda Agreement, INCA ceased to be a member of ProKidney Bermuda and CEC became a substituted member of ProKidney Bermuda. In the 2020 Contribution, CEC made another capital contribution of \$5,000,000 to ProKidney Bermuda in exchange for 5,000,000 Class A Units. As a result of the 2020 Contribution, CEC held an aggregate of 43,000,000 Class A Units of ProKidney Bermuda.

In the First 2021 Contribution, CEC made a capital contribution in an aggregate amount of \$15,000,000 to ProKidney Bermuda in exchange for 15,000,000 Class A Units. Given the effect of the First 2021 Contribution, CEC held an aggregate of 58,000,000 Class A Units of ProKidney Bermuda. In the Second 2021 Contribution, CEC made a capital contribution of \$4,600,000 to ProKidney Bermuda in exchange for 4,600,000 Class A Units. Given the effect of the Second 2021 Contribution, CEC held an aggregate of 62,600,000 Class A Units of ProKidney Bermuda.

On August 5, 2021, ProKidney was formed as a limited partnership under the laws of Ireland. The members of ProKidney Bermuda, including CEC, contributed all of their holdings in ProKidney Bermuda as a contribution *in specie* to ProKidney. As a result, ProKidney Bermuda became a wholly owned subsidiary of ProKidney, and CEC became one of the partners of ProKidney, holding an aggregate of 62,600,000 Legacy Class A Units. In the Third 2021 Contribution, CEC, as one of the partners of ProKidney, made a capital contribution of \$12,000,000 to ProKidney in exchange for 12,000,000 Legacy Class A Units pursuant to the ProKidney Limited Partnership Agreement. Given the effect of the Third 2021 Contribution, CEC held an aggregate of 74,600,000 Class A Units

[Table of Contents](#)

of ProKidney. At the Closing, the ProKidney Class A Units held by CEC were recapitalized into Post-Combination ProKidney Common Units and ProKidney Class B ordinary shares pursuant to the terms of the Business Combination Agreement.

Promissory Notes with Tolerantia and CEC

On January 18, 2022, in connection with the Business Combination Agreement, ProKidney entered into promissory note agreements with (a) Tolerantia, pursuant to which ProKidney may borrow up to an aggregate principal amount of \$60,000,000, and (b) CEC, pursuant to which ProKidney may borrow up to an aggregate principal amount of \$40,000,000 (collectively, the “ProKidney Promissory Notes”). The ProKidney Promissory Notes bear interest at a rate of 3% per annum and are payable on the earlier of the Closing Date and January 17, 2023. Pursuant to the ProKidney Promissory Notes, on March 24, 2022, ProKidney submitted a drawdown request to each of Tolerantia and CEC for \$12,000,000 and \$8,000,000, respectively, and on March 25, 2022, each of Tolerantia and CEC delivered the requested amount to ProKidney. In June 2022, ProKidney submitted a drawdown request to each of Tolerantia and CEC for \$9,000,000 and \$6,000,000, respectively, and each of Tolerantia and CEC delivered the requested amounts to ProKidney. At the Closing, ProKidney repaid the amounts outstanding under the ProKidney Promissory Notes.

Subscription Agreements with ProKidney Related PIPE Investors

Concurrently with the execution of the Business Combination Agreement, ProKidney entered into Subscription Agreements with the ProKidney Related PIPE Investors, pursuant to which the ProKidney Related PIPE Investors have subscribed for SCS Class A ordinary shares. The ProKidney Related PIPE Investors funded \$50,000,000 of the PIPE Investment, for which they received 5,000,000 Post-Combination ProKidney Common Units in lieu of SCS Class A ordinary shares. Specifically, (i) Tolerantia, a member of ProKidney affiliated with Mr. Pablo Legorreta, subscribed for 3,000,000 SCS Class A ordinary shares and elected to purchase 3,000,000 Post-Combination ProKidney Common Units in lieu thereof, and (ii) CEC, an entity affiliated with Mr. Carlos Slim, subscribed for 2,000,000 SCS Class A ordinary shares and elected purchase 2,000,000 Post-Combination ProKidney Common Units in lieu thereof. The PIPE Investment was consummated substantially concurrently with the Closing.

Voting Agreement by CEC

On February 14, 2022, CEC executed the Voting Agreement, pursuant to which CEC agreed, (1) subject to the constitution of Legacy GP, from February 14, 2022 until the Closing, to vote all of its voting shares in the capital of Legacy GP to exercise its rights of nomination and approval under the constitution of Legacy GP as directed by Tolerantia, solely with respect to (a) the appointment of any director to Legacy GP Board; and (b) the removal of any director from the Legacy GP Board; and (2) subject to the organizational documents of ProKidney, from the Closing until the third anniversary of the Closing, to vote all of its voting shares in the capital of ProKidney in a manner proportionate to the manner in which all other ProKidney Class B ordinary shares not held by CEC are voted, solely with respect to (a) the election of any director to the Board at any meeting of shareholders at which directors are to be elected; (b) the appointment of any director to fill any vacancy created by the failure of any director to complete a term on the Board; and (c) any removal of a director from the Board.

Tax Receivable Agreement

At the Closing, ProKidney entered into the Tax Receivable Agreement, pursuant to which, among other things, ProKidney is required to pay the Closing ProKidney Unitholders party thereto 85% of certain tax savings recognized by ProKidney, as a result of the increases in tax basis attributable to exchanges by the Closing ProKidney Unitholders of Post-Combination ProKidney Common Units for ProKidney Class A ordinary shares or, subject to certain restrictions, cash, pursuant to the Exchange Agreement and certain other tax attributes of ProKidney and tax benefits related to entering into the Tax Receivable Agreement.

Exchange Agreement

At the Closing, ProKidney entered into the Exchange Agreement with certain Closing ProKidney Unitholders pursuant to which, subject to the procedures and restrictions therein, from and after the waiver or expiration of any contractual lock-up period (including pursuant to the Lock-Up Agreements, described below), the holders of Post-Combination ProKidney Common Units (or certain permitted transferees thereof) acquired the right from time to time at and after 180 days following the Closing to exchange their Post-Combination ProKidney Common Units and an equal number of ProKidney Class B ordinary shares (referred to herein as “Paired Interests”) on a one-for-one basis for ProKidney Class A ordinary shares (the “Exchange”); provided, that, subject to certain exceptions, ProKidney, at its sole election, subject to certain restrictions, may, other than in the case of certain secondary offerings, instead settle all or a portion of the Exchange in cash based on a volume weighted average price of a ProKidney Class A ordinary share. The Exchange Agreement provides that, as a general matter, a holder of Post-Combination ProKidney Common Units do not have the right to exchange Post-Combination ProKidney Common Units if ProKidney determines that such exchange would be prohibited by law or regulation or would violate other agreements with ProKidney and its subsidiaries to which the holder of Post-Combination ProKidney Common Units may be subject, including the Second Amended and Restated ProKidney Limited Partnership Agreement and the Exchange Agreement. Additionally, the Exchange Agreement contains restrictions on redemptions and exchanges intended to prevent ProKidney from being treated as a “publicly traded partnership” for U.S. federal income tax purposes. These restrictions are modeled on certain safe harbors provided for under applicable U.S. federal income tax law. ProKidney may impose additional restrictions on exchanges that it determines to be necessary or advisable so that ProKidney is not treated as a “publicly traded partnership” for U.S. federal income tax purposes.

Amended and Restated Registration Rights Agreement

At the Closing, ProKidney entered into the Amended and Restated Registration Rights Agreement with the Sponsor and certain Closing ProKidney Unitholders. The Amended and Restated Registration Rights Agreement replaced the SCS Registration Rights Agreement. Under the Amended and Restated Registration Rights Agreement, Class A ordinary shares held by the Holders party thereto (as well as their permitted transferees) and by parties to the Exchange Agreement are entitled to registration rights. The Amended and Restated Registration Rights Agreement provides for ProKidney to, within 30 days after the Closing Date, submit or file with the SEC a shelf registration statement registering the resale of the ProKidney ordinary shares held by the Holders and use its commercially reasonable efforts to have such registration statement declared effective as soon as practicable after the submission or filing thereof, but in no event later than (a) 90 days following the submission or filing deadline, if the SEC notifies ProKidney that it will “review” the Registration Statement and (b) the tenth (10th) business day after the date ProKidney is notified (orally or in writing, whichever is earlier) by the SEC that the registration statement will not be “reviewed” or will not be subject to further review. In addition, the Holders have certain “piggy-back” registration rights. ProKidney will bear the expenses incurred in connection with the filing of any registration statements filed pursuant to the terms of the Amended and Restated Registration Rights Agreement.

Lock-Up Agreement

At the closing of the Business Combination, ProKidney, the Sponsor and certain Closing ProKidney Unitholders entered into lock-up agreements (collectively referred to herein as the “Lock-Up Agreement”). The Lock-Up Agreement contains certain restrictions on transfer with respect to the Sponsor and the ProKidney Unitholders party thereto. Such restrictions begin at the Closing and end on the earlier of (i) the date that is 180 days after the Closing and (ii)(a) for 33% of the Lock-Up Shares (other than the Earnout Shares and the Private Placement Shares)(as each such term is defined in the Lock-Up Agreement), the date on which the last reported sale price of a ProKidney Class A ordinary share equals or exceeds \$12.50 per share for any 20 trading days within any 30-trading day period commencing at least 30 days after the Closing and (b) for an additional 50% of the Lock-Up Shares (other than the Earnout Shares and the Private Placement Shares), the date on which the last

[Table of Contents](#)

reported sale price of a ProKidney Class A ordinary share equals or exceeds \$15.00 per share for any 20 trading days within any 30-trading day period commencing at least 30 days after the Closing. Notwithstanding the above, (i) the lock-up period for any Earnout Shares will expire not earlier than 180 days after such Earnout Shares are issued; (ii) 50% of the Lock-Up Shares held by certain Closing ProKidney Unitholders and their affiliates will remain locked up until the earlier of four years following the Closing and the date that ProKidney receives notice of any regulatory market authorization, including full or conditional authorization, to market REACT (but, in any event, not earlier than 180 days following the Closing or (in the case of Earnout Shares) the date of issuance); and (iii) the lock-up period for the Private Placement Shares will expire 30 days after the Closing. The restrictions on transfer set forth in the Lock-Up Agreement are subject to customary exceptions.

Executive Officer and Director Compensation Arrangements

Please see the section entitled “*Executive Compensation*” for information regarding compensation arrangements with the executive officers and directors of ProKidney, which include, among other things, employment, termination of employment and change in control arrangements, equity awards and certain other benefits.

Indemnification Agreements with Officers and Directors and Directors’ and Officers’ Liability Insurance

The Second Amended and Restated ProKidney Limited Partnership Agreement provides for indemnification for, among others, its partners and its partners’ directors, officers and employees to the fullest extent permitted by applicable law. In connection with this Business Combination, ProKidney entered into indemnification agreements with each of ProKidney’s executive officers and directors. The indemnification agreements and Charter require that ProKidney indemnify its directors to the fullest extent not prohibited by Cayman Islands law. ProKidney also maintains a general liability insurance policy, which covers certain liabilities of its directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

Policies and Procedures for Related Person Transactions

Upon consummation of the Business Combination, ProKidney adopted a written related person transaction policy that sets forth the following policies and procedures for the review and approval or ratification of related person transactions. A “*Related Person Transaction*” is a transaction, arrangement or relationship in which ProKidney or any of its subsidiaries was, is or will be a participant, the amount of which involved exceeds the lesser of \$120,000 per year or 1% of the average of ProKidney’s total assets for the last two completed fiscal years, and in which any Related Person had, has or will have a direct or indirect material interest. A “*Related Person*” means:

- any person who is, or at any time during the applicable period was, one of ProKidney’s officers or one of ProKidney’s directors;
- any person who is known by ProKidney to be the beneficial owner of more than five percent (5%) of its voting shares; or
- any immediate family member of any of the foregoing persons, which means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, daughter-in-law, brother-in-law or sister-in-law of a director, executive officer or a beneficial owner of more than five percent (5%) of its voting shares, and any person (other than a tenant or employee) sharing the household of such director, executive officer or beneficial owner of more than five percent (5%) of its voting shares.

ProKidney has policies and procedures designed to minimize potential conflicts of interest arising from any dealings it may have with its affiliates and to provide appropriate procedures for the disclosure of any real or potential conflicts of interest that may exist from time to time. Specifically, pursuant to its charter, the audit committee has the responsibility to review related party transactions.

CERTAIN MATERIAL U.S. AND NON-U.S. INCOME TAX CONSIDERATIONS⁸

The following is a discussion of certain material U.S. federal income tax consequences of the acquisition, ownership and disposition of shares of Class A ordinary shares. This discussion is limited to certain U.S. federal income tax considerations to beneficial owners of the Class A ordinary shares who are initial purchasers of such ordinary shares pursuant to this offering and hold the Class A ordinary shares as a capital asset within the meaning of Section 1221 of the Code. This discussion assumes that any distributions made by ProKidney on the Class A ordinary shares and any consideration received by a holder in consideration for the sale or other disposition of the Class A ordinary shares will be in U.S. dollars.

This summary is based upon U.S. federal income tax laws as of the date of this prospectus, which is subject to change or differing interpretations, possibly with retroactive effect. This discussion is a summary only and does not describe all of the tax consequences that may be relevant to you in light of your particular circumstances, including but not limited to the alternative minimum tax, the Medicare tax on certain net investment income and the different consequences that may apply if you are subject to special rules that apply to certain types of investors, including but not limited to:

- financial institutions or financial services entities;
- broker-dealers;
- governments or agencies or instrumentalities thereof;
- regulated investment companies;
- real estate investment trusts;
- expatriates or former long-term residents of the United States;
- persons that actually or constructively own five percent or more (by vote or value) of our shares;
- persons that acquired our Class A ordinary shares pursuant to an exercise of employee share options, in connection with employee share incentive plans or otherwise as compensation;
- insurance companies;
- dealers or traders subject to a mark-to-market method of accounting with respect to our Class A ordinary shares;
- persons holding our Class A ordinary shares as part of a “straddle,” constructive sale, hedge, conversion or other integrated or similar transaction;
- U.S. Holders (as defined below) whose functional currency is not the U.S. dollar;
- partnerships (or entities or arrangements classified as partnerships or other pass-through entities for U.S. federal income tax purposes) and any beneficial owners of such partnerships;
- tax-exempt entities;
- controlled foreign corporations; and
- passive foreign investment companies.

If a partnership (including an entity or arrangement treated as a partnership or other pass-thru entity for U.S. federal income tax purposes) holds our Class A ordinary shares, the tax treatment of a partner, member or other beneficial owner in such partnership will generally depend upon the status of the partner, member or other beneficial owner, the activities of the partnership and certain determinations made at the partner, member or other beneficial owner level. If you are a partner, member or other beneficial owner of a partnership holding our Class A ordinary shares you are urged to consult your tax advisor regarding the tax consequences of the acquisition, ownership and disposition of our Class A ordinary shares.

⁸ NTD: Non-U.S. tax disclosures to be provided by local counsel.

[Table of Contents](#)

This discussion is based on the Code, and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations as of the date hereof, which are subject to change, possibly on a retroactive basis, and changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein. This discussion does not address any aspect of state, local or non-U.S. taxation, or any U.S. federal taxes other than income taxes (such as gift and estate taxes).

We have not sought, and do not expect to seek, a ruling from the U.S. Internal Revenue Service (the “IRS”) as to any U.S. federal income tax consequence described herein. The IRS may disagree with the discussion herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion. You are urged to consult your tax advisor with respect to the application of U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any state, local or foreign jurisdiction.

THIS DISCUSSION IS ONLY A SUMMARY OF CERTAIN U.S. FEDERAL INCOME TAX CONSIDERATIONS ASSOCIATED WITH THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR CLASS A ORDINARY SHARES. EACH PROSPECTIVE INVESTOR IN OUR CLASS A ORDINARY SHARES IS URGED TO CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR CLASS A ORDINARY SHARES, INCLUDING THE APPLICABILITY AND EFFECT OF ANY U.S. FEDERAL NON-INCOME, STATE, LOCAL, AND NON-U.S. TAX LAWS.

U.S. Holders

This section applies to you if you are a “U.S. Holder.” A U.S. Holder is a beneficial owner of our Class A ordinary shares who or that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation) organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust, if (i) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more United States persons (as defined in the Code) have authority to control all substantial decisions of the trust or (ii) it has a valid election in effect under Treasury Regulations to be treated as a United States person.

You should consult your own tax advisors about the consequences of the acquisition, ownership and disposition of the Class A ordinary shares, including the relevance to your particular situation of the considerations discussed below and any consequences arising under non-U.S., state, local or other tax laws.

Taxation of Distributions

Subject to the discussion below under “*PFIC Considerations*,” if we pay distributions in cash or other property (other than certain distributions of our shares or rights to acquire our shares) to U.S. Holders of shares of our Class A ordinary shares, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, which will generally be includible in your taxable income as ordinary dividend income on the day on which you receive the dividend and will not be eligible for the dividends-received deduction allowed to U.S. corporations under the Code. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. Holder’s adjusted tax basis in our Class A ordinary shares. Any remaining excess will be treated as gain

[Table of Contents](#)

realized on the sale or other disposition of the Class A ordinary shares. Because we believe it is likely that ProKidney will be a PFIC for its current taxable year (as discussed below under “—*PFIC Considerations—PFIC Status of ProKidney*”) dividends ProKidney pays to a non-corporate U.S. Holder generally will not constitute “qualified dividends” that would be taxable at a reduced rate.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Class A Ordinary Shares

Subject to the discussion below under “*PFIC Considerations*,” upon a sale or other taxable disposition of our Class A ordinary shares, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. Holder’s adjusted tax basis in the Class A ordinary shares. Any such capital gain or loss generally will be long-term capital gain or loss if the U.S. Holder’s holding period for the Class A ordinary shares so disposed of exceeds one year. Long-term capital gains recognized by non-corporate U.S. Holders may be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to limitations.

Generally, the amount of gain or loss recognized by a U.S. Holder is an amount equal to the difference between (i) the sum of the amount of cash and the fair market value of any property received in such disposition and (ii) the U.S. Holder’s adjusted tax basis in its ordinary shares so disposed of. A U.S. Holder’s adjusted tax basis in its ordinary shares generally will equal the U.S. Holder’s acquisition cost less any prior distributions treated as a return of capital.

PFIC Considerations

Definition of a PFIC

A foreign (i.e., non-U.S.) corporation will be classified as a PFIC for U.S. federal income tax purposes if either (i) at least 75% of its gross income in a taxable year, including its pro rata share of the gross income of any corporation in which it is considered to own at least 25% of the shares by value, is passive income or (ii) at least 50% of its assets in a taxable year (generally determined based on fair market value and averaged quarterly over the year), including its pro rata share of the assets of any corporation in which it is considered to own at least 25% of the shares by value, are held for the production of, or produce, passive income. Passive income generally includes dividends, interest, rents and royalties (other than rents or royalties derived from the active conduct of a trade or business) and gains from the disposition of passive assets.

PFIC Status of ProKidney

Based upon the composition of its income and assets, and upon a review of its financial statements, ProKidney believes that it likely was a PFIC for its most recent taxable year ended on December 31, 2021 and will likely be considered a PFIC for its current taxable year.

In the event that we are classified as a PFIC in any year during which a U.S. Holder holds our Class A ordinary shares and the U.S. Holder has not timely made (a) a QEF Election (as defined below) for the first taxable year in which the U.S. Holder owned such Class A ordinary shares or in which ProKidney was a PFIC, whichever is later (or a QEF Election along with a purging election), or (b) a mark-to-market election (as defined below) with respect to such Class A ordinary shares, then the tax on any gain recognized by such U.S. Holder would be imposed based on a complex set of computational rules designed to offset the tax deferral with respect to the undistributed earnings of ProKidney. Under these rules:

- the U.S. Holder’s gain will be allocated ratably over the U.S. Holder’s holding period for such U.S. Holder’s Class A ordinary shares;
- the amount of gain allocated to the U.S. Holder’s taxable year in which the U.S. Holder recognized the gain, or to the period in the U.S. Holder’s holding period before the first day of the first taxable year in which ProKidney was a PFIC, will be taxed as ordinary income;

[Table of Contents](#)

- the amount of gain allocated to other taxable years (or portions thereof) of the U.S. Holder and included in such U.S. Holder's holding period would be taxed at the highest tax rate in effect for that year and applicable to the U.S. Holder; and
- an additional tax equal to the interest charge generally applicable to underpayments of tax will be imposed on the U.S. Holder in respect of the tax attributable to each such other taxable year of such U.S. Holder.

ALL U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS REGARDING THE EFFECTS OF THE PFIC RULES ON THE EXERCISE OF REDEMPTION RIGHTS.

QEF Election and Mark-to-Market Election

The impact of the PFIC rules on a U.S. Holder of Class A ordinary shares will depend on whether the U.S. Holder has made a timely and effective election to treat ProKidney as a "qualified electing fund" under Section 1295 of the Code for the taxable year that is the first year in the U.S. Holder's holding period of Class A ordinary shares during which ProKidney qualified as a PFIC (a "QEF Election") or, if in a later taxable year, the U.S. Holder made a QEF Election along with a purging election. A purging election creates a deemed sale of the U.S. Holder's Class A ordinary shares at their then fair market value and requires the U.S. Holder to recognize gain pursuant to the purging election subject to the special PFIC tax and interest charge rules described above. As a result of any such purging election, the U.S. Holder would have a new basis and holding period in its Class A ordinary shares. U.S. Holders are urged to consult their tax advisors as to the application of the rules governing purging elections to their particular circumstances.

A U.S. Holder's ability to make a QEF Election (or a QEF Election along with a purging election) with respect to ProKidney is contingent upon, among other things, the provision by ProKidney of a "PFIC Annual Information Statement" (within the meaning of the applicable Treasury Regulations) to such U.S. Holder. ProKidney provided PFIC Annual Information Statements to U.S. Holders of ProKidney Class A ordinary shares, upon request, with respect to its taxable year that ended on December 31, 2021 and will endeavor to continue to provide to a U.S. Holder such information upon request. There is no assurance, however, that ProKidney will continue to timely provide such information. A U.S. Holder that made a QEF Election (or a QEF Election along with a purging election) may be referred to as an "Electing Shareholder" and a U.S. Holder that did not make a QEF Election may be referred to as a "Non-Electing Shareholder."

The impact of the PFIC rules on a U.S. Holder of Class A ordinary shares may also depend on whether the U.S. Holder has made an election under Section 1296 of the Code. U.S. Holders who hold (actually or constructively) stock of a foreign corporation that is classified as a PFIC may annually elect to mark such stock to its market value if such stock is "marketable stock" (within the meaning of the applicable Treasury Regulations), generally, stock that is regularly traded on a national securities exchange that is registered with the SEC, including Nasdaq, or on a foreign exchange or market that the IRS determines has rules sufficient to ensure that the market price represents a legitimate and sound fair market value (a "mark-to-market election"). No assurance can be given that the Class A ordinary shares are considered to be marketable stock for purposes of the mark-to-market election or whether the other requirements of this election are satisfied. If such an election is available and has been made, such U.S. Holders will generally not be subject to the special taxation rules discussed herein. U.S. Holders are urged to consult their tax advisors regarding the availability and tax consequences of a mark-to-market election with respect to Class A ordinary shares under their particular circumstances.

THE RULES DEALING WITH PFICS ARE VERY COMPLEX AND ARE IMPACTED BY VARIOUS FACTORS IN ADDITION TO THOSE DESCRIBED ABOVE. ALL U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS REGARDING THE CONSEQUENCES TO THEM OF THE PFIC RULES, INCLUDING, WITHOUT LIMITATION, WHETHER A QEF ELECTION (OR A QEF ELECTION ALONG WITH A PURGING ELECTION), A MARK-TO-MARKET ELECTION OR ANY OTHER ELECTION IS AVAILABLE.

Foreign Financial Asset Reporting

Certain U.S. Holders who are individuals that own “specified foreign financial assets” with an aggregate value in excess of \$50,000 are generally required to file an information statement along with their tax returns, currently on IRS Form 8938, with respect to such assets. “Specified foreign financial assets” include any financial accounts held at a non-U.S. financial institution, as well as securities issued by a non-U.S. issuer (which would include the Class A ordinary shares) that are not held in accounts maintained by financial institutions. Higher reporting thresholds apply to certain individuals living abroad and to certain married individuals. Regulations extend this reporting requirement to certain entities that are treated as formed or availed of to hold direct or indirect interests in specified foreign financial assets based on certain objective criteria. U.S. Holders that fail to report the required information could be subject to substantial penalties. In addition, the statute of limitations for assessment of tax would be suspended, in whole or part. Prospective investors should consult their own tax advisors concerning the application of these rules to their investment in the Class A ordinary shares, including the application of the rules to their particular circumstances.

Information Reporting Requirements and Backup Withholding

Information returns will be filed with the IRS in connection with payments of dividends on and the proceeds from a sale or other disposition of Class A ordinary shares and backup withholding may also apply. Backup withholding will not apply, however, to a U.S. Holder who furnishes a correct taxpayer identification number and makes other required certifications, or who is otherwise exempt from backup withholding and establishes such exempt status. Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will generally be allowed as a credit against such U.S. Holder’s U.S. federal income tax liability and may entitle such U.S. Holder to a refund, provided that the required information is furnished by such U.S. Holder to the IRS in a timely manner.

EACH PROSPECTIVE INVESTOR IN OUR CLASS A ORDINARY SHARES IS URGED TO CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR CLASS A ORDINARY SHARES, INCLUDING THE APPLICABILITY AND EFFECT OF ANY U.S. FEDERAL NON-INCOME, STATE, LOCAL, AND NON-U.S. TAX LAWS.

Cayman Islands Tax Considerations

The following is a discussion on certain Cayman Islands income tax consequences of an investment in the securities of the Company. The discussion is a general summary of present law, which is subject to prospective and retroactive change. It is not intended as tax advice, does not consider any investor’s particular circumstances, and does not consider tax consequences other than those arising under Cayman Islands law. Payments of dividends and capital in respect of our securities will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of a dividend or capital to any holder of the securities nor will gains derived from the disposal of the securities be subject to Cayman Islands income or corporation tax. The Cayman Islands currently have no income, corporation or capital gains tax and no estate duty, inheritance tax or gift tax.

No stamp duty is payable in respect of the issue of the warrants. An instrument of transfer in respect of a warrant is stampable if executed in or brought into the Cayman Islands.

No stamp duty is payable in respect of the issue of our Class A ordinary shares or on an instrument of transfer in respect of such shares. An instrument of transfer in respect of Class A ordinary shares is stampable if executed in or brought into the Cayman Islands.

The Company has been incorporated under the laws of the Cayman Islands as an exempted company with limited liability and, as such, has obtained an undertaking from the Government of the Cayman Islands in the following form:

The Tax Concessions Act

(as amended)

Undertaking as to Tax Concessions

In accordance with the provision of Section 6 of The Tax Concessions Act (as amended), the following undertaking is hereby given to ProKidney Corp. (the “Company”):

1. That no law which is hereafter enacted in the Islands imposing any tax to be levied on profits, income, gains or appreciations shall apply to the Company or its operations; and
2. In addition, that no tax to be levied on profits, income, gains or appreciations or which is in the nature of estate duty or inheritance tax shall be payable:
 - 2.1 On or in respect of the shares, debentures or other obligations of the Company; or
 - 2.2 by way of the withholding in whole or part, of any relevant payment as defined in Section 6(3) of the Tax Concessions Act (as amended).

These concessions shall be for a period of 30 years from the date hereof.

PLAN OF DISTRIBUTION

We are registering the resale by the Selling Securityholders of up to 232,530,000 our Class A ordinary shares.

The Selling Securityholders may offer and sell, from time to time, their Class A ordinary shares covered by this prospectus. The Selling Securityholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then current market price or in negotiated transactions. The Selling Securityholders may sell their securities by one or more of, or a combination of, the following methods:

- purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- block trades in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- an over-the-counter distribution in accordance with the rules of the Nasdaq;
- through trading plans entered into by a Selling Securityholder pursuant to Rule 10b5-1 under the Exchange Act that are in place at the time of an offering pursuant to this prospectus and any applicable prospectus supplement hereto that provide for periodic sales of their securities on the basis of parameters described in such trading plans;
- short sales;
- distribution to employees, members, limited partners or stockholders of the Selling Securityholders;
- through the writing or settlement of options or other hedging transaction, whether through an options exchange or otherwise;
- by pledge to secured debts and other obligations;
- delayed delivery arrangements;
- to or through underwriters or agents;
- in “at the market” offerings, as defined in Rule 415 under the Securities Act, at negotiated prices, at prices prevailing at the time of sale or at prices related to such prevailing market prices, including sales made directly on a national securities exchange or sales made through a market maker other than on an exchange or other similar offerings through sales agents;
- in privately negotiated transactions;
- in options transactions; and
- through a combination of any of the above methods of sale, as described below, or any other method permitted pursuant to applicable law.

In addition, any securities that qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution. In connection with distributions of the securities or otherwise, the Selling Securityholders may enter into hedging transactions with broker-dealers or other financial institutions. In

Table of Contents

connection with such transactions, broker-dealers or other financial institutions may engage in short sales of the securities in the course of hedging the positions they assume with Selling Securityholders. The Selling Securityholders may also sell the securities short and redeliver the securities to close out such short positions. The Selling Securityholders may also enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The Selling Securityholders may also pledge securities to a broker-dealer or other financial institution, and, upon a default, such broker-dealer or other financial institution, may effect sales of the pledged securities pursuant to this prospectus (as supplemented or amended to reflect such transaction).

In effecting sales, broker-dealers or agents engaged by the Selling Securityholders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the Selling Securityholders in amounts to be negotiated immediately prior to the sale.

In offering the securities covered by this prospectus, the Selling Securityholders and any broker-dealers who execute sales for the Selling Securityholders may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. Any profits realized by the Selling Securityholders and the compensation of any broker-dealer may be deemed to be underwriting discounts and commissions. Certain of our shareholders have entered into lock-up agreements.

In order to comply with the securities laws of certain states, if applicable, the securities must be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

We will make copies of this prospectus available to the Selling Securityholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The Selling Securityholders may indemnify any broker-dealer that participates in transactions involving the sale of the securities against certain liabilities, including liabilities arising under the Securities Act.

At the time a particular offer of securities is made, if required, a prospectus supplement will be distributed that will set forth the number of securities being offered and the terms of the offering, including the name of any underwriter, dealer or agent, the purchase price paid by any underwriter, any discount, commission and other item constituting compensation, any discount, commission or concession allowed or reallocated or paid to any dealer, and the proposed selling price to the public.

We have agreed to indemnify certain of the Selling Securityholders against certain liabilities, including certain liabilities under the Securities Act, the Exchange Act or other federal or state law.

We have agreed with certain Selling Securityholders pursuant to the Amended and Restated Registration Rights Agreement to use our commercially reasonable efforts to keep the registration statement of which this prospectus constitutes a part effective until such time as all securities covered by this prospectus have been sold or otherwise cease to be registrable securities.

Amended and Restated Registration Rights Agreement

At the Closing, ProKidney, the Sponsor and certain Closing ProKidney Unitholders entered into the Amended and Restated Registration Rights Agreement, pursuant to which, among other things, the Sponsor, Closing Company Unitholders and their affiliates and permitted transferees were granted certain registration rights with respect to their respective Class A ordinary shares on the terms and subject to the conditions therein.

LEGAL MATTERS

Walkers (Cayman) LLP has passed upon the validity of the Class A ordinary shares and Class B ordinary shares offered by this prospectus and matters of Cayman Islands law.

EXPERTS

The financial statements of SCS as of December 31, 2021 and for the period from February 25, 2021 (inception) through December 31, 2021 included in this prospectus have been audited by Marcum LLP, independent registered public accounting firm, as set forth in their report thereon, appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The consolidated financial statements of ProKidney LP at December 31, 2021 and 2020, and for each of the two years in the period ended December 31, 2021, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 2 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1, including exhibits, under the Securities Act of 1933, as amended, with respect to the ordinary shares offered by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our securities, you should refer to the registration statement and our exhibits.

In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public on a website maintained by the SEC located at www.sec.gov. We also maintain a website at www.prokidney.com. Through our website, we make available, free of charge, annual, quarterly and current reports, proxy statements and other information as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that may be accessed through, our website is not part of, and is not incorporated into, this prospectus.

INDEX TO CONSOLIDATED FINANCIAL INFORMATION

	<u>PAGE</u>
Audited Consolidated Financial Statements for Social Capital Suvretta Holdings Corp. III	
Report of Independent Registered Public Accounting Firm	FS-2
Balance Sheets as of December 31, 2021	FS-3
Statements of Operations for the period from February 25, 2021 (inception) through December 31, 2021	FS-4
Statement of Changes in Temporary Equity and Permanent Deficit for the period from February 25, 2021 (inception) through December 31, 2021	FS-5
Statements of Cash Flows for the period from February 25, 2021 (inception) through December 31, 2021	FS-6
Notes to Financial Statements	FS-7
Unaudited Consolidated Financial Statements for Social Capital Suvretta Holdings Corp. III	
Condensed Balance Sheets at March 31, 2022 (Unaudited) and December 31, 2021	FS-20
Condensed Statements of Operations for the three months ended March 31, 2022 and for the period from February 25, 2021 (inception) through March 31, 2021 (Unaudited)	FS-21
Condensed Statements of Changes in Temporary Equity and Permanent Deficit for the three months ended March 31, 2022 and for the period from February 25, 2021 (inception) through March 31, 2021 (Unaudited)	FS-22
Condensed Statements of Cash Flows for the three months ended March 31, 2022 and for the period from February 25, 2021 (inception) through March 31, 2021 (Unaudited)	FS-23
Notes to Condensed Financial Statements (Unaudited)	FS-24
Audited Consolidated Financial Statements for ProKidney LP and Subsidiaries	
Report of Independent Auditors	FS-39
ProKidney LP and Subsidiaries Consolidated Balance Sheets at December 31, 2020 and December 31, 2021	FS-40
ProKidney LP and Subsidiaries Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2020 and December 31, 2021	FS-41
ProKidney LP and Subsidiaries Consolidated Statements of Changes in Members' Equity for the years ended December 31, 2020 and December 31, 2021	FS-42
ProKidney LP and Subsidiaries Consolidated Statement of Cash Flows for the years ended December 31, 2020 and December 31, 2021	FS-43
ProKidney and Subsidiaries Notes to Consolidated Financial Statements	FS-44
Unaudited Consolidated Financial Statements for ProKidney LP and Subsidiaries	
ProKidney LP and Subsidiaries Consolidated Balance Sheets at March 31, 2022 and December 31, 2021	FS-56
ProKidney LP and Subsidiaries Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2022 and 2021 (Unaudited)	FS-57
ProKidney LP and Subsidiaries Consolidated Statements of Changes in Members' Equity for the three months ended March 31, 2022 and 2021 (Unaudited)	FS-58
ProKidney LP and Subsidiaries Consolidated Statement of Cash Flows for the three months ended March 31, 2022 and 2021 (Unaudited)	FS-59
Notes to Condensed Financial Statements (Unaudited)	FS-60

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Social Capital Suvretta Holdings Corp. III

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Social Capital Suvretta Holdings Corp. III (the “Company”) as of December 31, 2021, the related statements of operations, changes in temporary equity and permanent deficit and cash flows for the period from February 25, 2021 (inception) through December 31, 2021, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for the period from February 25, 2021 (inception) through December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph—Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company’s business plan is dependent on the completion of a business combination and the Company’s cash and working capital as of December 31, 2021 are not sufficient to complete its planned activities. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans with regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (the “PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We have served as the Company’s auditor since 2021.

New York, NY
March 23, 2022

SOCIAL CAPITAL SUVRETTA HOLDINGS CORP. III
BALANCE SHEET
DECEMBER 31, 2021

ASSETS	
Current Assets	
Cash	\$ 440,488
Prepaid expenses	504,189
Total Current Assets	944,677
Non-current prepaid insurance	247,500
Marketable Securities held in Trust Account	250,008,324
TOTAL ASSETS	<u>\$ 251,200,501</u>
LIABILITIES, TEMPORARY EQUITY AND PERMANENT DEFICIT	
Current liabilities	
Accounts payable	\$ 5,000
Accrued expense	1,864,796
Advances from related party	10,000
Total Current Liabilities	1,879,796
Deferred underwriting fee payable	7,700,000
TOTAL LIABILITIES	<u>9,579,796</u>
Commitments and Contingencies (Note 6)	
Temporary Equity	
Class A ordinary shares subject to possible redemption, 25,000,000 shares at redemption value	<u>250,008,324</u>
Permanent Deficit	
Preference shares, \$0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—
Class A ordinary shares, \$0.0001 par value; 500,000,000 shares authorized; 640,000 shares issued and outstanding (excluding 25,000,000 shares subject to possible redemption)	64
Class B ordinary shares, \$0.0001 par value; 50,000,000 shares authorized; 6,250,000 shares issued and outstanding	625
Additional paid-in capital	—
Accumulated deficit	(8,388,308)
Total Permanent Deficit	<u>(8,387,619)</u>
TOTAL LIABILITIES, TEMPORARY EQUITY AND PERMANENT DEFICIT	<u>\$ 251,200,501</u>

The accompanying notes are an integral part of the financial statements.

SOCIAL CAPITAL SUVRETTA HOLDINGS CORP. III
STATEMENT OF OPERATIONS
FOR THE PERIOD FROM FEBRUARY 25, 2021 (INCEPTION) THROUGH DECEMBER 31, 2021

Operating and formation costs	\$ 2,332,953
Loss from operations	(2,332,953)
Other income:	
Interest earned on marketable securities held in Trust Account	8,324
Net loss	\$ (2,324,629)
Basic and diluted weighted average shares outstanding, Class A ordinary shares	15,101,877
Basic and diluted net loss per share, Class A ordinary shares	\$ (0.11)
Basic and diluted weighted average shares outstanding, Class B ordinary shares	5,852,751
Basic and diluted net loss per share, Class B ordinary shares	\$ (0.11)

The accompanying notes are an integral part of the financial statements.

SOCIAL CAPITAL SUVRETTA HOLDINGS CORP. III
STATEMENT OF CHANGES IN TEMPORARY EQUITY AND PERMANENT DEFICIT
FOR THE PERIOD FROM FEBRUARY 25, 2021 (INCEPTION) THROUGH DECEMBER 31, 2021

	Temporary Equity		Class A Ordinary Shares		Class B Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Total Permanent Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance—February 25, 2021 (inception)	—	\$ —	—	\$ —	—	\$ —	\$ —	\$ —	\$ —
Issuance of Class B ordinary shares to Sponsor	—	—	—	—	6,325,000	633	24,367	—	25,000
Sale of 25,000,000 Public Shares, net of underwriting discounts and offering expenses	25,000,000	237,520,334	—	—	—	—	—	—	—
Remeasurement of Class A ordinary shares to redemption value	—	12,487,990	—	—	—	—	(6,424,311)	(6,063,679)	(12,487,990)
Sale of 640,000 Private Placement Shares	—	—	640,000	64	—	—	6,399,936	—	6,400,000
Forfeiture of Founder Shares	—	—	—	—	(75,000)	(8)	8	—	—
Net loss	—	—	—	—	—	—	—	(2,324,629)	(2,324,629)
Balance—December 31, 2021	<u>25,000,000</u>	<u>\$250,008,324</u>	<u>640,000</u>	<u>\$ 64</u>	<u>6,250,000</u>	<u>\$ 625</u>	<u>\$ —</u>	<u>\$(8,388,308)</u>	<u>\$(8,387,619)</u>

The accompanying notes are an integral part of the financial statements.

SOCIAL CAPITAL SUVRETTA HOLDINGS CORP. III
STATEMENT OF CASH FLOWS
FOR THE PERIOD FROM FEBRUARY 25, 2021 (INCEPTION) THROUGH DECEMBER 31, 2021

Cash Flows from Operating Activities:	
Net loss	\$ (2,324,629)
Adjustments to reconcile net loss to net cash used in operating activities:	
Formation costs paid by Sponsor in exchange for issuance of Founder Shares	5,000
Interest earned on marketable securities held in Trust Account	(8,324)
Changes in operating assets and liabilities:	
Prepaid expenses	(751,689)
Accounts payable	5,000
Accrued expenses	1,864,796
Net cash used in operating activities	<u>(1,209,846)</u>
Cash Flows from Investing Activities:	
Investment of cash into Trust Account	(250,000,000)
Net cash used in investing activities	<u>(250,000,000)</u>
Cash Flows from Financing Activities:	
Proceeds from sale of Public Shares, net of underwriting discounts paid	245,600,000
Proceeds from sale of Private Placement Shares	6,400,000
Advances from related party	97,319
Repayment of advances from related party	(87,319)
Proceeds from promissory note—related party	300,000
Repayment of promissory note—related party	(300,000)
Payment of offering costs	(359,666)
Net cash provided by financing activities	<u>251,650,334</u>
Net Change in Cash	<u>440,488</u>
Cash—Beginning of period (inception)	—
Cash—End of period	<u>\$ 440,488</u>
Non-Cash Investing and Financing Activities:	
Offering costs paid by Sponsor in exchange for issuance of Founder Shares	\$ 20,000
Remeasurement of Class A ordinary share subject to possible redemption	\$ 12,487,990
Deferred underwriting fee payable	\$ 7,700,000

The accompanying notes are an integral part of the financial statements.

NOTE 1. DESCRIPTION OF ORGANIZATION, BUSINESS OPERATIONS AND GOING CONCERN

Social Capital Suvretta Holdings Corp. III (the “Company”) is a blank check company incorporated as a Cayman Islands exempted company on February 25, 2021. The Company was incorporated for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses (a “Business Combination”).

As of December 31, 2021, the Company had not commenced any operations. All activity for the period from February 25, 2021 (inception) through December 31, 2021 relates to the Company’s formation, the initial public offering (the “Initial Public Offering”), described below, and, subsequent to the Initial Public Offering, identifying a target company for a Business Combination and activities in connection with the proposed acquisition of ProKidney LP (see Note 9). The Company will not generate any operating revenues until after the completion of a Business Combination, at the earliest. The Company generates non-operating income in the form of interest income from the marketable securities held in the Trust Account (as defined below).

The registration statements for the Company’s Initial Public Offering became effective on June 29, 2021 and June 30, 2021. On July 2, 2021, the Company consummated the Initial Public Offering of 25,000,000 Class A ordinary shares (the “Public Shares”), which includes the partial exercise by the underwriters of their over-allotment option in the amount of 3,000,000 Public Shares, at \$10.00 per Public Share, generating gross proceeds of \$250,000,000, which is described in Note 3. The fair value attributable to the unexercised portion of the over-allotment option was deemed to be immaterial to the financial statements.

Substantially concurrently with the closing of the Initial Public Offering, the Company consummated the sale of 640,000 Class A ordinary shares (the “Private Placement Shares”) at a price of \$10.00 per Private Placement Share in a private placement to SCS Sponsor III LLC, a Cayman Islands limited liability company (the “Sponsor”), generating gross proceeds of \$6,400,000, which is described in Note 4.

Transaction costs amounted to \$12,479,666, consisting of \$4,400,000 of underwriting fees, \$7,700,000 of deferred underwriting fees and \$379,666 of other offering costs.

In connection with the closing of the Initial Public Offering on July 2, 2021, an amount of \$250,000,000 (\$10.00 per Public Share) from the net proceeds of the sale of the Public Shares in the Initial Public Offering and the sale of the Private Placement Shares was placed in a trust account (the “Trust Account”), and invested in U.S. government treasury bills with a maturity of 185 days or less or in money market funds investing solely in U.S. Treasuries and meeting certain conditions of Rule 2a-7 of the Investment Company Act of 1940, as amended (the “Investment Company Act”). Except with respect to interest earned on the funds held in the Trust Account that may be released to the Company to pay its taxes, if any, the funds held in the Trust Account will not be released from the Trust Account until the earliest of: (a) the completion of a Business Combination, and then only in connection with those Public Shares that such shareholder properly elected to redeem, subject to certain limitations; (b) the redemption of any Public Shares properly submitted in connection with a shareholder vote to amend the Company’s Amended and Restated Memorandum and Articles of Association (i) to modify the substance or timing of the Company’s obligation to allow redemption in connection with the Business Combination or to redeem 100% of the Public Shares if the Company does not complete a Business Combination within the Combination Period (as defined below) or (ii) with respect to any other material provisions relating to shareholders’ rights or pre-Business Combination activity; and (c) the redemption of the Public Shares if the Company has not completed a Business Combination within the Combination Period or during any applicable extension period. The proceeds deposited in the Trust Account could become subject to the claims of the Company’s creditors, if any, which could have priority over the claims of the holders of the Public Shares (the “Public Shareholders”).

The Company’s management has broad discretion with respect to the specific application of the net proceeds of the Initial Public Offering and the sale of the Private Placement Shares, although substantially all of

[Table of Contents](#)

the net proceeds are intended to be applied generally toward consummating a Business Combination. The Company must complete one or more Business Combinations having an aggregate fair market value of at least 80% of the value of the assets held in the Trust Account (excluding any deferred underwriting commissions and taxes payable on the income earned on the Trust Account) at the time of the Company signing a definitive agreement in connection with the Business Combination. However, the Company will only complete a Business Combination if the post-Business Combination company owns or acquires 50% or more of the issued and outstanding voting securities of the target or otherwise acquires a controlling interest in the target business sufficient for it not to be required to register as an investment company under the Investment Company Act. There is no assurance that the Company will be able to complete a Business Combination successfully.

The Company will provide the Public Shareholders with the opportunity to redeem all or a portion of their Public Shares upon the completion of the Business Combination, either (a) in connection with a general meeting called to approve the Business Combination or (b) by means of a tender offer. The decision as to whether the Company will seek shareholder approval of a Business Combination or conduct a tender offer will be made by the Company. The Public Shareholders will be entitled to redeem all or a portion of their Public Shares at a per-share price, payable in cash, equal to the aggregate amount then on deposit in the Trust Account, calculated as of two business days prior to the consummation of the Business Combination, including interest (which interest shall be net of taxes payable), divided by the number of then issued and outstanding Public Shares, subject to the limitations described below.

In accordance with the Company's Amended and Restated Memorandum and Articles of Association, in no event will the Company redeem the Public Shares in an amount that would cause the Company's net tangible assets to be less than \$5,000,001 following such redemptions. Redemptions of the Public Shares may also be subject to a higher net tangible asset test or cash requirement pursuant to an agreement relating to the Business Combination.

If a shareholder vote is not required in connection with a Business Combination and the Company does not decide to hold a shareholder vote for business or other reasons, the Company will, pursuant to its Amended and Restated Memorandum and Articles of Association, conduct the redemptions pursuant to the tender offer rules of the Securities and Exchange Commission (the "SEC"), and file tender offer documents with the SEC prior to completing a Business Combination. If, however, shareholder approval of the transaction is required by applicable law or stock exchange listing requirement, or the Company decides to obtain shareholder approval for business or other reasons, the Company will conduct the redemptions in conjunction with a proxy solicitation pursuant to the proxy rules and not pursuant to the tender offer rules and will file proxy materials with the SEC. If the Company seeks shareholder approval in connection with a Business Combination, the Company will complete such Business Combination only if the Company receives an ordinary resolution under Cayman Islands law, which requires the affirmative vote of holders of a majority of ordinary shares who attend and vote at a general meeting of the Company. The Public Shareholders may elect to redeem their Public Shares without voting and, if they do vote, irrespective of whether they vote for or against a Business Combination.

Notwithstanding the foregoing redemption rights, if the Company seeks shareholder approval of the Business Combination and the Company does not conduct redemptions pursuant to the tender offer rules, the Company's Amended and Restated Memorandum and Articles of Association provide that a Public Shareholder, together with any affiliate of such shareholder or any other person with whom such shareholder is acting in concert or as a "group" (as defined under Section 13 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), will be restricted from redeeming its Public Shares with respect to more than an aggregate of 15% of the Public Shares without the Company's prior written consent.

The Sponsor and the Company's directors and officers have agreed to waive: (a) their redemption rights with respect to any Founder Shares, Private Placement Shares and Public Shares held by them, as applicable, in connection with the completion of a Business Combination; (b) their redemption rights with respect to any Founder Shares, Private Placement Shares and Public Shares held by them in connection with a shareholder vote

[Table of Contents](#)

to amend the Company's Amended and Restated Memorandum and Articles of Association (i) to modify the substance or timing of the Company's obligation to allow redemption in connection with the Business Combination or to redeem 100% of the Public Shares if the Company does not complete a Business Combination within the Combination Period, or (ii) with respect to any other material provisions relating to shareholders' rights or pre-Business Combination activity; and (c) their rights to liquidating distributions from the Trust Account with respect to any Founder Shares and Private Placement Shares they hold if the Company fails to complete a Business Combination within the Combination Period or during any applicable extension period (although such persons will be entitled to liquidating distributions from the Trust Account with respect to any Public Shares they hold if the Company fails to complete a Business Combination within the prescribed time frame). If the Company submits the Business Combination to the Public Shareholders for a vote, the Sponsor and the Company's directors and officers have also agreed to vote any Founder Shares, Private Placement Shares and Public Shares held by them in favor of the Business Combination.

The Company will have until July 2, 2023 to complete a Business Combination (the "Combination Period"), or such longer period as a result of a shareholder vote to amend such time period pursuant to the Company's Amended and Restated Memorandum and Articles of Association. However, if the Company has not completed a Business Combination within such Combination Period or during any applicable extension period, the Company will: (a) cease all operations except for the purpose of winding up; (b) as promptly as reasonably possible but not more than ten business days thereafter, redeem the Public Shares, at a per-share price, payable in cash, equal to the aggregate amount then on deposit in the Trust Account, including interest (less up to \$100,000 of interest to pay dissolution expenses and which interest shall be net of taxes payable) divided by the number of then issued and outstanding Public Shares, which redemption will completely extinguish the Public Shareholders' rights as shareholders (including the right to receive further liquidating distributions, if any); and (c) as promptly as reasonably possible following such redemption, subject to the approval of the Company's remaining shareholders and its board of directors, liquidate and dissolve, subject in each case to the Company's obligations under Cayman Islands law to provide for claims of creditors and the requirements of other applicable law.

The Sponsor has agreed that it will be liable to the Company if and to the extent any claims by a third party (other than the Company's independent auditors) for services rendered or products sold to the Company, or a prospective target business with which the Company has discussed entering into a transaction agreement, reduce the amount of funds in the Trust Account to below (1) \$10.00 per Public Share or (2) such lesser amount per Public Share held in the Trust Account as of the date of the liquidation of the Trust Account, due to reductions in the value of the trust assets, in each case net of the interest which may be withdrawn to pay taxes, except as to any claims by a third party that executed a waiver of any and all rights to seek access to the Trust Account and except as to any claims under the Company's indemnity of the underwriters of the Initial Public Offering against certain liabilities, including liabilities under the Securities Act of 1933, as amended (the "Securities Act"). In the event that an executed waiver is deemed to be unenforceable against a third party, the Sponsor will not be responsible to the extent of any liability for such third-party claims. The Company has not independently verified whether the Sponsor has sufficient funds to satisfy its indemnity obligations and believes that the Sponsor's only assets are securities of the Company and, therefore, the Sponsor may not be able to satisfy those obligations. The Company has not asked the Sponsor to reserve for such obligations. None of the Company's directors or officers will indemnify the Company for claims by third parties, including, without limitation, claims by vendors and prospective target businesses.

Risks and Uncertainties

Management continues to evaluate the impact of the COVID-19 pandemic and has concluded that while it is reasonably possible that the pandemic could have a negative effect on the Company's business, financial position, results of operations and/or the search for a target company, the specific impact is not readily determinable as of the date of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Liquidity and Going Concern

As of December 31, 2021, the Company had \$440,488 in its operating bank accounts and working capital deficit of \$935,119.

Until the consummation of a Business Combination, the Company will be using the funds not held in the Trust Account for identifying and evaluating prospective acquisition candidates, performing due diligence on prospective target businesses, paying for travel expenditures, selecting the target business to acquire, and structuring, negotiating and consummating the Business Combination.

The Company may need to raise additional capital through loans or additional investments from its Sponsor, shareholders, officers, directors, or third parties. The Company's officers, directors and Sponsor may, but are not obligated to, loan the Company funds, from time to time or at any time, in whatever amount they deem reasonable in their sole discretion, to meet the Company's working capital needs. Accordingly, the Company may not be able to obtain additional financing. If the Company is unable to raise additional capital, it may be required to take additional measures to conserve liquidity, which could include, but not necessarily be limited to, curtailing operations, suspending the pursuit of a potential transaction, and reducing overhead expenses. The Company cannot provide any assurance that new financing will be available to it on commercially acceptable terms, if at all. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time, which is considered to be one year from the issuance date of the financial statements. These financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying financial statements are presented in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the SEC.

Emerging Growth Company

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

[Table of Contents](#)

Use of Estimates

The preparation of the financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statements, which management considered in formulating its estimate, could change in the near term due to one or more future confirming events. Significant accounting estimates include the determination of the fair value of Class A ordinary shares subject to possible redemption and the fair value of Founder Shares transferred to directors. Accordingly, the actual results could differ significantly from those estimates.

Cash and Cash Equivalents

The Company considers all short-term investments with an original maturity of three months or less when purchased to be cash equivalents. The Company did not have any cash equivalents as of December 31, 2021.

Marketable Securities Held in Trust Account

At December 31, 2021, substantially all of the assets held in the Trust Account were held in money market funds which are invested primarily in U.S. Treasury securities.

Class A Ordinary Shares Subject to Possible Redemption

The Company accounts for its Class A ordinary shares subject to possible redemption in accordance with the guidance in Financial Accounting Standards Board (“FASB”) ASC 480, “Distinguishing Liabilities from Equity.” Class A ordinary shares subject to mandatory redemption are classified as a liability instrument and are measured at redemption value. Conditionally redeemable ordinary shares (including ordinary shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company’s control) are classified as temporary equity. At all other times, ordinary shares are classified as shareholders’ equity. The Company’s Class A ordinary shares feature certain redemption rights that are considered to be outside of the Company’s control and subject to occurrence of uncertain future events. Accordingly, Class A ordinary shares subject to possible redemption are presented at redemption value as temporary equity, outside of the permanent deficit section of the Company’s balance sheet.

The Company recognizes changes in redemption value immediately as they occur and adjusts the carrying value of redeemable ordinary shares to equal the redemption value at the end of each reporting period. Increases or decreases in the carrying value of redeemable ordinary shares are affected by charges against additional paid-in capital (to the extent available) and accumulated deficit.

At December 31, 2021, the Class A ordinary shares subject to possible redemption reflected in the balance sheet are reconciled in the following table:

Gross proceeds	\$250,000,000
Less:	
Class A ordinary shares issuance costs	(12,479,666)
Plus:	
Increase of carrying value to redemption value	12,487,990
Class A ordinary shares subject to possible redemption	<u>\$250,008,324</u>

Offering Costs

The Company complies with the requirements of the ASC 340-10-S99-1. Offering costs consisted of legal, accounting, underwriting fees and other costs incurred through the Initial Public Offering that were directly related to the Initial Public Offering. The Company incurred offering costs amounting to \$12,479,666 as a result of the Initial Public Offering, consisting of \$4,400,000 of underwriting commissions, \$7,700,000 of deferred underwriting commissions, and \$379,666 of other offering costs. The offering costs were charged to temporary equity and additional paid-in capital upon the completion of the Initial Public Offering. Immediately thereafter, temporary equity was remeasured and an adjustment was recognized through additional paid in capital and accumulated deficit to adjust temporary equity to the redemption value.

Share-Based Payment Arrangements

The Company accounts for stock awards in accordance with ASC 718, “Compensation—Stock Compensation,” which requires that all equity awards be accounted for at their “fair value.” Fair value is measured on the grant date and is equal to the underlying value of the stock.

Costs equal to these fair values are recognized ratably over the requisite service period based on the number of awards that are expected to vest, in the period of grant for awards that vest immediately and have no future service condition, or in the period the awards vest immediately after meeting a performance condition becomes probable (i.e., the occurrence of a Business Combination). For awards that vest over time, cumulative adjustments in later periods are recorded to the extent actual forfeitures differ from the Company’s initial estimates; previously recognized compensation cost is reversed if the service or performance conditions are not satisfied and the award is forfeited.

Income Taxes

The Company accounts for income taxes under ASC 740, “Income Taxes” (“ASC 740”). ASC 740 requires the recognition of deferred tax assets and liabilities for both the expected impact of differences between the financial statement and tax basis of assets and liabilities and for the expected future tax benefit to be derived from tax loss and tax credit carry forwards. ASC 740 additionally requires a valuation allowance to be established when it is more likely than not that all or a portion of deferred tax assets will not be realized.

ASC 740 also clarifies the accounting for uncertainty in income taxes recognized in an enterprise’s financial statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The Company’s management has determined that the Cayman Islands is the Company’s major tax jurisdiction. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of December 31, 2021. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position. The Company is subject to income tax examinations by major taxing authorities since inception.

The Company is considered to be an exempted Cayman Islands company and is presently not subject to income taxes or income tax filing requirements in the Cayman Islands or the United States. As such, the Company’s tax provision was zero for the period presented.

Net Loss Per Ordinary Share

Net loss per ordinary share is computed by dividing net loss by the weighted-average number of ordinary shares outstanding during the period. The Company has two classes of shares, which are referred to as Class A

[Table of Contents](#)

ordinary shares and Class B ordinary shares. Losses are shared pro rata between the two classes of shares. Charges associated with the redeemable Class A ordinary shares are excluded from net loss per ordinary share as the redemption value approximates fair value.

As of December 31, 2021, the Company did not have any dilutive securities or other contracts that could, potentially, be exercised or converted into ordinary shares and then share in the earnings of the Company. As a result, diluted net loss per ordinary share is the same as basic net loss per ordinary share for the periods presented.

The following table reflects the calculation of basic and diluted net loss per ordinary share (in dollars, except per share amounts):

	For the Period from February 25, 2021 (Inception) Through December 31, 2021	
	Class A	Class B
Basic and diluted net loss per ordinary share		
Numerator:		
Allocation of net loss	\$ (1,675,346)	\$ (649,283)
Denominator:		
Basic and diluted weighted average shares outstanding	15,101,877	5,852,751
Basic and diluted net loss per ordinary share	\$ (0.11)	\$ (0.11)

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash accounts in a financial institution which, at times may exceed the Federal Depository Insurance Corporation coverage limit of \$250,000. The Company has not experienced losses on these accounts.

Fair Value of Financial Instruments

The fair value of the Company's assets and liabilities, which qualify as financial instruments under ASC Topic 820, "Fair Value Measurement," approximates the carrying amounts represented in the accompanying balance sheet, primarily due to their short-term nature.

Recent Accounting Standards

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years, with early adoption permitted. We adopted ASU 2020-06 effective as of January 1, 2021. The adoption of ASU 2020-06 did not have an impact on our financial statements.

Management does not believe that any recently issued, but not yet effective, accounting standards, if currently adopted, would have a material effect on the Company's financial statements.

Accrued Expense

Accrued expenses includes \$1,506,528 of accrued legal expense, \$5,000 of accrued printing expense, \$282,500 of accrued due diligence expense, \$70,000 of accrued regulatory filing fee and \$770 of accrued accounting expense.

NOTE 3. INITIAL PUBLIC OFFERING

Pursuant to the Initial Public Offering, the Company sold 25,000,000 Public Shares, which includes a partial exercise by the underwriters of their over-allotment option in the amount of 3,000,000 Public Shares, at a price of \$10.00 per Public Share. Unlike some other initial public offerings of special purpose acquisition companies, investors in the Initial Public Offering did not receive any warrants (which would typically become exercisable following completion of the Business Combination). The fair value attributable to the unexercised portion of the over-allotment option was deemed to be immaterial to the financial statements.

NOTE 4. PRIVATE PLACEMENT

Substantially concurrently with the closing of the Initial Public Offering, the Sponsor purchased 640,000 Private Placement Shares at a price of \$10.00 per Private Placement Share, for an aggregate purchase price of \$6,400,000. Each Private Placement Share is identical to the Class A ordinary shares sold in the Initial Public Offering, subject to certain limited exceptions as described in Note 7. A portion of the proceeds from the sale of the Private Placement Shares was added to the net proceeds from the Initial Public Offering held in the Trust Account. If the Company does not complete a Business Combination within the Combination Period or during any applicable extension period, the proceeds from the sale of the Private Placement Shares held in the Trust Account will be used to fund the redemption of the Public Shares (subject to the requirements of applicable law) and the Private Placement Shares will be worthless.

NOTE 5. RELATED PARTY TRANSACTIONS

Founder Shares

On March 2, 2021, the Sponsor paid \$25,000 to cover certain offering and formation costs of the Company in consideration for which the Sponsor received 5,750,000 Class B ordinary shares (the "Founder Shares"). On June 29, 2021, the Company effected a share capitalization with respect to its Class B ordinary shares of 575,000 shares thereof, resulting in the Company's initial shareholders holding an aggregate of 6,325,000 Founder Shares. All share and per-share amounts have been retroactively restated to reflect the share capitalization. The Founder Shares included an aggregate of up to 825,000 shares that were subject to forfeiture depending on the extent to which the underwriters' over-allotment option was exercised. As a result of the underwriters' election to partially exercise their over-allotment option, a total of 750,000 Founder Shares are no longer subject to forfeiture and 75,000 Founder Shares were forfeited, resulting in an aggregate of 6,250,000 Founder Shares outstanding.

In June 2021, the Sponsor transferred 30,000 Founder Shares to Marc Semigran, an independent director of the Company. The sale of the Founders Shares to the Company's director is in the scope of FASB ASC Topic 718, "Compensation-Stock Compensation" ("ASC 718"). Under ASC 718, stock-based compensation associated with equity-classified awards is measured at fair value upon the grant date. The fair value of the 30,000 shares granted to the Company's director was \$214,160 or approximately \$7.14 per share. The Founders Shares were effectively sold subject to a performance condition (i.e., the occurrence of a Business Combination). Compensation expense related to the Founders Shares is recognized only when the performance condition is probable of occurrence. As of December 31, 2021, the Company determined that a Business Combination is not considered probable, and, therefore, no stock-based compensation expense has been recognized. Stock-based compensation would be recognized at the date a Business Combination is considered probable (i.e., upon consummation of a Business Combination) in an amount equal to the number of Founders Shares times the grant date fair value per share (unless subsequently modified) less the amount initially received for the purchase of the Founders Shares.

[Table of Contents](#)

The Sponsor and the Company's directors and officers have agreed, subject to limited exceptions, not to transfer, assign or sell any of their Founder Shares until the earlier of: (A) one year after the completion of a Business Combination and (B) subsequent to a Business Combination, (x) if the last reported sale price of the Class A ordinary shares equals or exceeds \$12.00 per share (as adjusted for share sub-divisions, share dividends, rights issuances, consolidations, reorganizations, recapitalizations and other similar transactions) for any 20 trading days within any 30-trading day period commencing at least 150 days after a Business Combination, or (y) the date on which the Company completes a liquidation, merger, amalgamation, share exchange, reorganization or other similar transaction that results in all of the Public Shareholders having the right to exchange their Class A ordinary shares for cash, securities or other property.

Administrative Services Agreement

The Company entered into an agreement in which it will pay an affiliate of the Sponsor \$10,000 per month, commencing on June 30, 2021, for office space, administrative and support services. Upon completion of a Business Combination or its liquidation, the Company will cease paying these monthly fees. For the period from February 25, 2021 (inception) through December 31, 2021, the Company incurred \$60,000 in fees for these services, of which such amount was recognized in Operating and Formation Costs in the accompanying statement of operations.

Advances from Related Party

As of December 31, 2021, the Sponsor had advanced the Company \$97,319 for working capital purposes, inclusive of the administrative services agreement noted above, of which \$87,319 was repaid during the period ended December 31, 2021. As of December 31, 2021, the outstanding balance was \$10,000.

Promissory Note—Related Party

On March 2, 2021, the Sponsor issued an unsecured promissory note to the Company (the "Promissory Note"), pursuant to which the Company could borrow up to an aggregate principal amount of \$300,000. The Promissory Note was non-interest bearing and payable on the earlier of December 31, 2021 and the completion of the Initial Public Offering. The outstanding balance under the Promissory Note of \$300,000 was repaid at the closing of the Initial Public Offering on July 2, 2021. Borrowings are no longer available under the Promissory Note.

Related Party Loans

In order to fund working capital deficiencies or finance transaction costs in connection with a Business Combination, the Sponsor or an affiliate of the Sponsor or certain of the Company's officers and directors may, but are not obligated to, loan the Company funds as may be required ("Working Capital Loans"). If the Company completes a Business Combination, it may repay such loaned amounts out of the proceeds of the Trust Account. In the event that the Business Combination does not close, the Company may use a portion of the working capital held outside the Trust Account to repay such loaned amounts but no proceeds from the Trust Account would be used to repay such loaned amounts. As of December 31, 2021, there were no outstanding amounts under the Working Capital Loans.

NOTE 6. COMMITMENTS AND CONTINGENCIES

Registration Rights

Pursuant to a registration rights agreement entered into on June 29, 2021, the holders of the Founder Shares, Private Placement Shares and any Private Placement Shares that may be issued on conversion of Working Capital Loans (and any Class A ordinary shares issuable upon the conversion of the Founder Shares) are entitled

[Table of Contents](#)

to registration rights requiring the Company to register such securities for resale (in the case of the Founder Shares, only after conversion to the Class A ordinary shares). The holders of these securities will be entitled to make up to three demands, excluding short form registration demands, that the Company register such securities. In addition, the holders have certain “piggy-back” registration rights with respect to registration statements filed subsequent to the completion of a Business Combination and rights to require the Company to register for resale such securities pursuant to Rule 415 under the Securities Act. The Company will bear the expenses incurred in connection with the filing of any such registration statements.

Underwriting Agreement

The underwriters are entitled to a deferred underwriting commission of \$7,700,000 in the aggregate. The deferred fee will become payable to the underwriters from the amounts held in the Trust Account solely in the event that the Company completes a Business Combination, subject to the terms of the underwriting agreement.

Restricted Stock Unit Award

In September 2021, pursuant to a Director Restricted Stock Unit Award Agreement, dated September 24, 2021, between the Company and Uma Sinha, Ph.D., the Company agreed to grant 30,000 restricted stock units (“RSUs”) to Dr. Sinha, which grant is contingent on both the consummation of a Business Combination and a shareholder approved equity plan. The RSUs will vest upon the consummation of such Business Combination and represent 30,000 Class A ordinary shares of the Company that will settle on a date determined in the sole discretion of the Company that shall occur between the vesting date and March 15 of the year following the year in which vesting occurs.

The RSUs to be granted by the Company are in the scope of ASC 718. Under ASC 718, stock-based compensation associated with equity-classified awards is measured at fair value upon the grant date. The RSUs to be granted are subject to a performance condition (i.e., the occurrence of a Business Combination). Compensation expense related to the RSUs is recognized only when the performance condition is probable of occurrence under the applicable accounting literature in this circumstance. As of December 31, 2021, the Company did not have a shareholder approved equity plan and also determined that a Business Combination is not considered probable, therefore, no stock-based compensation expense has been recognized. Stock-based compensation would be recognized at the date a Business Combination is considered probable (i.e., upon consummation of a Business Combination) in an amount equal to the number of RSUs times the grant date fair value per share (unless subsequently modified).

NOTE 7. TEMPORARY EQUITY AND PERMANENT DEFICIT

Preference Shares—The Company is authorized to issue 5,000,000 preference shares, with a par value of \$0.0001 per share. The Company’s board of directors will be authorized to fix the voting rights, if any, designations, powers, preferences, the relative, participating, optional or other special rights and any qualifications, limitations and restrictions thereof, applicable to the shares of each series. The Company’s board of directors will be able to, without shareholder approval, issue preference shares with voting and other rights that could adversely affect the voting power and other rights of the holders of the Company’s ordinary shares and could have anti-takeover effects. At December 31, 2021, there were no preference shares issued or outstanding.

Class A Ordinary Shares—The Company is authorized to issue 500,000,000 Class A ordinary shares, with a par value of \$0.0001 per share. At December 31, 2021, there were 640,000 Class A ordinary shares issued and outstanding, excluding 25,000,000 Class A ordinary shares subject to possible redemption which are presented as temporary equity.

Class B Ordinary Shares—The Company is authorized to issue 50,000,000 Class B ordinary shares, with a par value of \$0.0001 per share. At December 31, 2021, there were 6,250,000 Class B ordinary shares issued and outstanding.

[Table of Contents](#)

Holders of record of Class A ordinary shares and Class B ordinary shares are entitled to one vote for each share held on all matters to be voted on by shareholders and vote together as a single class, except as required by law; provided that prior to a Business Combination, holders of Class B ordinary shares will have the right to appoint all of the Company's directors and remove members of its board of directors for any reason, and holders of Class A ordinary shares will not be entitled to vote on the appointment of directors during such time.

The Class B ordinary shares will automatically convert into Class A ordinary shares at the time of the Business Combination, or earlier at the option of the holder, on a one-for-one basis, subject to adjustment for share sub-divisions, share dividends, rights issuances, consolidations, reorganizations, recapitalizations and the like. Additionally, in the event that additional (in excess of the amounts issued in the Initial Public Offering) Class A ordinary shares, or equity-linked securities, are issued or deemed issued in connection with the closing of the Business Combination, the ratio at which the Class B ordinary shares will convert into Class A ordinary shares will be adjusted (unless the holders of a majority of the issued and outstanding Class B ordinary shares agree to waive such anti-dilution adjustment with respect to any such issuance or deemed issuance) so that the number of Class A ordinary shares issuable upon conversion of all Class B ordinary shares will equal, in the aggregate, 20% of the sum of the total number of Class A ordinary shares outstanding after such conversion (after giving effect to any redemptions of Class A ordinary shares by Public Shareholders, and excluding the Private Placement Shares), including any Class A ordinary shares issued or deemed issued, or issuable upon the conversion or exercise of any equity-linked securities or rights issued or deemed issued, by the Company in connection with the Business Combination, excluding any Class A ordinary shares or equity-linked securities exercisable for or convertible into Class A ordinary shares issued, or to be issued, to any seller in the Business Combination and any private placement shares issued to the Sponsor or its affiliates upon conversion of Working Capital Loans; provided that such conversion of Class B ordinary shares will never occur on a less than one-for-one-basis.

Private Placement Shares—The Private Placement Shares are not transferable, assignable, or salable until 30 days after the completion of a Business Combination (except, among other limited exceptions, to the Company's directors and officers and other persons or entities affiliated with the Sponsor). Holders of the Private Placement Shares are entitled to certain registration rights. If the Company does not complete a Business Combination within the Combination Period or during any applicable extension period, the proceeds from the sale of the Private Placement Shares held in the Trust Account will be used to fund the redemption of the Public Shares (subject to the requirements of applicable law) and the Private Placement Shares will be worthless.

NOTE 8. FAIR VALUE MEASUREMENTS

The Company follows the guidance in ASC Topic 820 for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually.

The fair value of the Company's financial assets and liabilities reflects management's estimate of amounts that the Company would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from independent sources) and to minimize the use of unobservable inputs (internal assumptions about how market participants would price assets and liabilities). The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value the assets and liabilities:

- Level 1: Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

[Table of Contents](#)

- Level 2: Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.
- Level 3: Unobservable inputs based on our assessment of the assumptions that market participants would use in pricing the asset or liability.

The following table presents information about the Company's assets that are measured at fair value on a recurring basis at December 31, 2021, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

<u>Description</u>	<u>Level</u>	<u>December 31, 2021</u>
Assets:		
Marketable securities held in Trust Account	1	\$ 250,008,324

NOTE 9. SUBSEQUENT EVENTS

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the financial statements were issued. Based upon this review, other than as described below, the Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements, except as follows:

Proposed ProKidney Business Combination

On January 18, 2022, the Company entered into a Business Combination Agreement (the "ProKidney Business Combination Agreement") with ProKidney LP, a limited partnership registered under the laws of Ireland ("ProKidney"), acting through its general partner ProKidney GP Limited, a private limited company incorporated under the laws of Ireland ("Legacy GP").

The ProKidney Business Combination Agreement provides that, among other things and upon the terms and subject to the conditions thereof, prior to or at the closing of the ProKidney Business Combination Agreement (the "Closing"), the following transactions will occur (together with the other transactions contemplated by the ProKidney Business Combination Agreement, the "ProKidney Business Combination"): (1) ProKidney will issue to the Company a number of common units of ProKidney ("Post-Combination ProKidney Common Units") equal to the number of fully diluted outstanding ordinary shares of the Company as of immediately prior to the Closing (but after giving effect to all redemptions of Public Shares and the purchase of Class A ordinary shares pursuant to one or more subscription agreements (the "PIPE Investment")), in exchange for (a) (x) new Class B ordinary shares ("New ProKidney Class B ordinary shares"), which shares will have no economic rights but will entitle the holders thereof to vote on all matters on which shareholders of the Company are entitled to vote generally, and (y) restricted stock rights in respect of New ProKidney Class B ordinary shares ("New ProKidney Class B PMEL RSRs"), which restricted stock rights shall convert into New ProKidney Class B ordinary shares upon the vesting of the associated restricted common unit of ProKidney, (b) an amount in cash equal to the aggregate proceeds obtained by the Company in the PIPE Investment and (c) an amount in cash equal to the aggregate proceeds available for release to the Company from the Trust Account (after giving effect to all redemptions of Public Shares and after payment of any deferred underwriting commissions being held in the Trust Account and payment of certain transaction expenses); (2) Legacy GP will resign as the general partner of ProKidney and a private limited company incorporated under the laws of Ireland ("New GP") will be admitted as the general partner of ProKidney; (3) ProKidney will distribute to the ProKidney unitholders the New ProKidney Class B ordinary shares and New ProKidney Class B PMEL RSRs received pursuant to clause (i)(a) (x) and (y) above; and (4) certain holders of ProKidney units will receive an aggregate of 17,500,000 restricted common units of ProKidney ("Earnout RCUs") and 17,500,000 restricted stock rights of the Company ("Earnout RSRs" and, together with the Earnout RCUs, the "Earnout Rights"), which Earnout Rights will vest in three equal

[Table of Contents](#)

tranches upon the trading price of a Class A ordinary share reaching \$15.00/share, \$20.00/share and \$25.00/share, respectively, on the terms set forth in the ProKidney Business Combination Agreement, or upon certain change of control events. When vested, the Earnout RCUs will automatically convert into Post-Combination ProKidney Common Units and the associated Earnout RSRs will automatically convert into New ProKidney Class B ordinary shares, respectively.

On January 18, 2022, the Company entered into subscription agreements (the “Subscription Agreements”) with certain investors (“PIPE Investors”) pursuant to which the PIPE Investors have subscribed for an aggregate of 57,500,000 Class A ordinary shares for a price of \$10.00 per share for an aggregate purchase price of \$575,000,000, of which (1) \$156,400,000 is committed by certain existing directors, officers and equityholders of, or investment funds managed by Suvretta Capital Management, LLC, the Company, the Sponsor and/or their respective affiliates participating in the PIPE Investment, and (2) at least \$50,000,000 (which may, at the election of such investors, be increased to up to \$100,000,000) is committed by certain existing directors, officers and unitholders of ProKidney and/or its affiliates participating in the PIPE Investment (the “ProKidney Related PIPE Investors”); provided that the ProKidney Related PIPE Investors may elect instead to purchase Post-Combination ProKidney Common Units, together with a corresponding number of Class B ordinary shares, in lieu of Class A ordinary shares. The Subscription Agreements are subject to certain conditions, including that there shall not be in force any injunction or order enjoining or prohibiting the issuance and sale of the shares under the Subscription Agreements; the terms of the ProKidney Business Combination Agreement shall not have been amended, and the minimum cash condition therein shall not have been waived, in a manner that is materially adverse to the investor party to the Subscription Agreement; and the representation and warranties of the parties to the Subscription Agreement shall be accurate (subject to agreed materiality thresholds).

Following the Closing, the combined company will be organized in an umbrella partnership-C corporation (a so called “Up-C”) structure, and the Company’s direct assets will consist of ProKidney Common Units and equity interests of New GP, and substantially all of the operating assets and business of the Company will be held indirectly through ProKidney.

The consummation of the proposed ProKidney Business Combination is subject to certain conditions as further described in the ProKidney Business Combination Agreement.

Legal Proceedings

Certain purported shareholders of the Company sent demand letters (the “Demands”) alleging deficiencies and/or omissions in the ProKidney Disclosure Statement filed by the Company with the SEC on February 14, 2022. The Demands seek additional disclosures to remedy these purported deficiencies. We believe that the allegations in the Demands are meritless.

Promissory Note: Unaudited

On April 20, 2022, the Company issued an unsecured promissory note (the “Promissory Note”) to the Sponsor pursuant to which the Company may borrow up to an aggregate principal amount of \$1,500,000. The Promissory Note is non-interest bearing, unsecured and payable upon the earlier of July 2, 2023 and the effective date of the Company’s Business Combination. The Promissory Note is subject to customary events of default which could, subject to certain conditions, cause the Promissory Note to become immediately due and payable. On April 26, 2022, the Company drew \$250,000 under the Promissory Note.

SOCIAL CAPITAL SUVRETTA HOLDINGS CORP. III
CONDENSED BALANCE SHEETS

	March 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets		
Cash	\$ 51,889	\$ 440,488
Prepaid expenses	543,088	504,189
Total Current Assets	594,977	944,677
Non-current prepaid insurance	123,750	247,500
Marketable securities held in Trust Account	250,033,500	250,008,324
TOTAL ASSETS	\$ 250,752,227	\$ 251,200,501
LIABILITIES, TEMPORARY EQUITY AND PERMANENT DEFICIT		
Current liabilities		
Accounts payable	\$ 26,735	\$ 5,000
Accrued expense	5,342,189	1,864,796
Advances from related party	43,623	10,000
Total current liabilities	5,412,547	1,879,796
Deferred underwriting fee payable	7,700,000	7,700,000
Total Liabilities	13,112,547	9,579,796
Commitments and Contingencies (Note 6)		
Temporary Equity		
Class A ordinary shares subject to possible redemption, 25,000,000 shares at redemption value as of March 31, 2022 and December 31, 2021	250,000,000	250,008,324
Permanent Deficit		
Preference shares, \$0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding as of March 31, 2022 and December 31, 2021	—	—
Class A ordinary shares, \$0.0001 par value; 500,000,000 shares authorized; 640,000 shares issued and outstanding (excluding 25,000,000 shares subject to possible redemption) as of March 31, 2022 and December 31, 2021	64	64
Class B ordinary shares, \$0.0001 par value; 50,000,000 shares authorized; 6,250,000 shares issued and outstanding as of March 31, 2022 and December 31, 2021	625	625
Additional paid-in capital	—	—
Accumulated deficit	(12,361,009)	(8,388,308)
Total Permanent Deficit	(12,360,320)	(8,387,619)
TOTAL LIABILITIES, TEMPORARY EQUITY AND PERMANENT DEFICIT	\$ 250,752,227	\$ 251,200,501

The accompanying notes are an integral part of the unaudited condensed financial statements.

SOCIAL CAPITAL SUVRETTA HOLDINGS CORP. III
CONDENSED STATEMENTS OF OPERATIONS
(UNAUDITED)

	For the Three Months Ended March 31, 2022	For the Period from February 25, 2021 (Inception) Through March 31, 2021
Operating and formation costs	\$ 4,006,201	\$ 5,182
Loss from operations	(4,006,201)	(5,182)
Other income:		
Interest earned on marketable securities held in Trust Account	25,176	—
Net loss	\$ (3,981,025)	\$ (5,182)
Basic and diluted weighted average shares outstanding, Class A ordinary shares	25,640,000	—
Basic and diluted net loss per share, Class A ordinary shares	\$ (0.12)	\$ —
Basic and diluted weighted average shares outstanding, Class B ordinary shares	6,250,000	5,500,000
Basic and diluted net loss per share, Class B ordinary shares	\$ (0.12)	\$ (0.0)

The accompanying notes are an integral part of the unaudited condensed financial statements.

SOCIAL CAPITAL SUVRETTA HOLDINGS CORP. III
CONDENSED STATEMENTS OF CHANGES IN TEMPORARY EQUITY AND PERMANENT DEFICIT
(UNAUDITED)
FOR THE THREE MONTHS ENDED MARCH 31, 2022

	Temporary Equity		Class A Ordinary Shares		Class B Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Total Permanent Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance—January 1, 2022	25,000,000	\$250,008,324	640,000	\$ 64	6,250,000	\$ 625	\$ —	\$ (8,388,308)	\$ (8,387,619)
Remeasurement for Class A ordinary shares to redemption amount	—	(8,324)	—	—	—	—	—	8,324	8,324
Net loss	—	—	—	—	—	—	—	(3,981,025)	(3,981,025)
Balance—March 31, 2022	25,000,000	\$250,000,000	640,000	\$ 64	6,250,000	\$ 625	\$ —	\$ (12,361,009)	\$ (12,360,320)

FOR THE PERIOD FROM FEBRUARY 25, 2021 (INCEPTION) THROUGH MARCH 31, 2021

	Temporary Equity		Class A Ordinary Shares		Class B Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Total Permanent Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance—February 25, 2021 (inception)	—	\$ —	—	\$ —	—	\$ —	\$ —	\$ —	\$ —
Issuance of Class B ordinary shares to Sponsor	—	—	—	—	6,325,000	633	24,367	—	25,000
Net loss	—	—	—	—	—	—	—	(5,182)	(5,182)
Balance—March 31, 2021	—	\$ —	—	\$ —	6,325,000	\$ 633	\$ 24,367	\$ (5,182)	\$ 19,818

The accompanying notes are an integral part of the unaudited condensed financial statements.

SOCIAL CAPITAL SUVRETTA HOLDINGS CORP. III
CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	For the Three Months Ended March 31, 2022	For the Period from February 25, 2021 (Inception) Through March 31, 2021
Cash Flows from Operating Activities:		
Net loss	\$ (3,981,025)	\$ (5,182)
Adjustments to reconcile net loss to net cash used in operating activities:		
Formation costs paid by Sponsor in exchange for issuance of Founder Shares		5,000
Interest earned on marketable securities held in Trust Account	(25,176)	—
Changes in operating assets and liabilities:		
Prepaid expenses	84,851	—
Advances from related party	33,623	—
Accrued expenses and accounts payable	3,499,128	44
Net cash used in operating activities	(388,599)	(138)
Cash Flows from Financing Activities:		
Proceeds from promissory note—related party	—	255
Payment of offering costs	—	(117)
Net cash provided by financing activities	—	138
Net Change in Cash	(388,599)	—
Cash—Beginning of period (inception)	440,488	—
Cash—End of period	\$ 51,889	\$ —
Non-Cash Investing and Financing Activities:		
Offering costs paid by Sponsor in exchange for issuance of Founder Shares	\$ —	\$ 20,000
Remeasurement of Class A ordinary shares subject to possible redemption	\$ —	\$ —
Offering costs included in accrued offering costs	\$ —	\$ 5,000

The accompanying notes are an integral part of the unaudited condensed financial statements.

SOCIAL CAPITAL SUVRETTA HOLDINGS CORP. III
NOTES TO CONDENSED FINANCIAL STATEMENTS
MARCH 31, 2022
(Unaudited)

NOTE 1. DESCRIPTION OF ORGANIZATION, BUSINESS OPERATIONS AND GOING CONCERN

Social Capital Suvretta Holdings Corp. III (the “Company”) is a blank check company incorporated as a Cayman Islands exempted company on February 25, 2021. The Company was incorporated for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses (a “Business Combination”). The Company is an early stage and emerging growth company and, as such, the Company is subject to all of the risks associated with early stage and emerging growth companies.

As of March 31, 2022, the Company had not commenced any operations. All activity for the period from February 25, 2021 (inception) through March 31, 2022 relates to the Company’s formation, the initial public offering (the “Initial Public Offering”), described below, and, subsequent to the Initial Public Offering, identifying a target company for a Business Combination and activities in connection with the proposed acquisition of ProKidney LP (see Note 6). The Company will not generate any operating revenues until after the completion of a Business Combination, at the earliest. The Company generates non-operating income in the form of interest income from the marketable securities held in the Trust Account (as defined below).

The registration statements for the Company’s Initial Public Offering became effective on June 29, 2021 and June 30, 2021. On July 2, 2021, the Company consummated the Initial Public Offering of 25,000,000 Class A ordinary shares (the “Public Shares”), which includes the partial exercise by the underwriters of their over-allotment option in the amount of 3,000,000 Public Shares, at \$10.00 per Public Share, generating gross proceeds of \$250,000,000, which is described in Note 3. The fair value attributable to the unexercised portion of the over-allotment option was deemed to be immaterial to the condensed financial statements.

Substantially concurrently with the closing of the Initial Public Offering, the Company consummated the sale of 640,000 Class A ordinary shares (the “Private Placement Shares”) at a price of \$10.00 per Private Placement Share in a private placement to SCS Sponsor III LLC, a Cayman Islands limited liability company (the “Sponsor”), generating gross proceeds of \$6,400,000, which is described in Note 4.

Transaction costs amounted to \$12,479,666, consisting of \$4,400,000 of underwriting fees, \$7,700,000 of deferred underwriting fees and \$379,666 of other offering costs.

In connection with the closing of the Initial Public Offering on July 2, 2021, an amount of \$250,000,000 (\$10.00 per Public Share) from the net proceeds of the sale of the Public Shares in the Initial Public Offering and the sale of the Private Placement Shares was placed in a trust account (the “Trust Account”), and invested in U.S. government treasury bills with a maturity of 185 days or less or in money market funds investing solely in U.S. Treasuries and meeting certain conditions of Rule 2a-7 of the Investment Company Act of 1940, as amended (the “Investment Company Act”). Except with respect to interest earned on the funds held in the Trust Account that may be released to the Company to pay its taxes, if any, the funds held in the Trust Account will not be released from the Trust Account until the earliest of: (a) the completion of a Business Combination, and then only in connection with those Public Shares that such shareholder properly elected to redeem, subject to certain limitations; (b) the redemption of any Public Shares properly submitted in connection with a shareholder vote to amend the Company’s Amended and Restated Memorandum and Articles of Association (i) to modify the substance or timing of the Company’s obligation to allow redemption in connection with the Business Combination or to redeem 100% of the Public Shares if the Company does not complete a Business Combination within the Combination Period (as defined below) or (ii) with respect to any other material provisions relating to shareholders’ rights or pre-Business Combination activity; and (c) the redemption of the Public Shares if the

Table of Contents

Company has not completed a Business Combination within the Combination Period or during any applicable extension period. The proceeds deposited in the Trust Account could become subject to the claims of the Company's creditors, if any, which could have priority over the claims of the holders of the Public Shares (the "Public Shareholders").

The Company's management has broad discretion with respect to the specific application of the net proceeds of the Initial Public Offering and the sale of the Private Placement Shares, although substantially all of the net proceeds are intended to be applied generally toward consummating a Business Combination. The Company must complete one or more Business Combinations having an aggregate fair market value of at least 80% of the value of the assets held in the Trust Account (excluding any deferred underwriting commissions and taxes payable on the income earned on the Trust Account) at the time of the Company signing a definitive agreement in connection with the Business Combination. However, the Company will only complete a Business Combination if the post-Business Combination company owns or acquires 50% or more of the issued and outstanding voting securities of the target or otherwise acquires a controlling interest in the target business sufficient for it not to be required to register as an investment company under the Investment Company Act. There is no assurance that the Company will be able to complete a Business Combination successfully.

The Company will provide the Public Shareholders with the opportunity to redeem all or a portion of their Public Shares upon the completion of the Business Combination, either (a) in connection with a general meeting called to approve the Business Combination or (b) by means of a tender offer. The decision as to whether the Company will seek shareholder approval of a Business Combination or conduct a tender offer will be made by the Company. The Public Shareholders will be entitled to redeem all or a portion of their Public Shares at a per-share price, payable in cash, equal to the aggregate amount then on deposit in the Trust Account, calculated as of two business days prior to the consummation of the Business Combination, including interest (which interest shall be net of taxes payable), divided by the number of then issued and outstanding Public Shares, subject to the limitations described below.

In accordance with the Company's Amended and Restated Memorandum and Articles of Association, in no event will the Company redeem the Public Shares in an amount that would cause the Company's net tangible assets to be less than \$5,000,001 following such redemptions. Redemptions of the Public Shares may also be subject to a higher net tangible asset test or cash requirement pursuant to an agreement relating to the Business Combination.

If a shareholder vote is not required in connection with a Business Combination and the Company does not decide to hold a shareholder vote for business or other reasons, the Company will, pursuant to its Amended and Restated Memorandum and Articles of Association, conduct the redemptions pursuant to the tender offer rules of the Securities and Exchange Commission (the "SEC"), and file tender offer documents with the SEC prior to completing a Business Combination. If, however, shareholder approval of the transaction is required by applicable law or stock exchange listing requirement, or the Company decides to obtain shareholder approval for business or other reasons, the Company will conduct the redemptions in conjunction with a proxy solicitation pursuant to the proxy rules and not pursuant to the tender offer rules and will file proxy materials with the SEC. If the Company seeks shareholder approval in connection with a Business Combination, the Company will complete such Business Combination only if the Company receives an ordinary resolution under Cayman Islands law, which requires the affirmative vote of holders of a majority of ordinary shares who attend and vote at a general meeting of the Company. The Public Shareholders may elect to redeem their Public Shares without voting and, if they do vote, irrespective of whether they vote for or against a Business Combination.

Notwithstanding the foregoing redemption rights, if the Company seeks shareholder approval of the Business Combination and the Company does not conduct redemptions pursuant to the tender offer rules, the Company's Amended and Restated Memorandum and Articles of Association provide that a Public Shareholder, together with any affiliate of such shareholder or any other person with whom such shareholder is acting in concert or as a "group" (as defined under Section 13 of the Securities Exchange Act of 1934, as amended (the

Table of Contents

“Exchange Act”)), will be restricted from redeeming its Public Shares with respect to more than an aggregate of 15% of the Public Shares without the Company’s prior written consent.

The Sponsor and the Company’s directors and officers have agreed to waive: (a) their redemption rights with respect to any Founder Shares, Private Placement Shares and Public Shares held by them, as applicable, in connection with the completion of a Business Combination; (b) their redemption rights with respect to any Founder Shares, Private Placement Shares and Public Shares held by them in connection with a shareholder vote to amend the Company’s Amended and Restated Memorandum and Articles of Association (i) to modify the substance or timing of the Company’s obligation to allow redemption in connection with the Business Combination or to redeem 100% of the Public Shares if the Company does not complete a Business Combination within the Combination Period, or (ii) with respect to any other material provisions relating to shareholders’ rights or pre-Business Combination activity; and (c) their rights to liquidating distributions from the Trust Account with respect to any Founder Shares and Private Placement Shares they hold if the Company fails to complete a Business Combination within the Combination Period or during any applicable extension period (although such persons will be entitled to liquidating distributions from the Trust Account with respect to any Public Shares they hold if the Company fails to complete a Business Combination within the prescribed time frame). If the Company submits the Business Combination to the Public Shareholders for a vote, the Sponsor and the Company’s directors and officers have also agreed to vote any Founder Shares, Private Placement Shares and Public Shares held by them in favor of the Business Combination.

The Company will have until July 2, 2023 to complete a Business Combination (the “Combination Period”), or such longer period as a result of a shareholder vote to amend such time period pursuant to the Company’s Amended and Restated Memorandum and Articles of Association. However, if the Company has not completed a Business Combination within such Combination Period or during any applicable extension period, the Company will: (a) cease all operations except for the purpose of winding up; (b) as promptly as reasonably possible but not more than ten business days thereafter, redeem the Public Shares, at a per-share price, payable in cash, equal to the aggregate amount then on deposit in the Trust Account, including interest (less up to \$100,000 of interest to pay dissolution expenses and which interest shall be net of taxes payable) divided by the number of then issued and outstanding Public Shares, which redemption will completely extinguish the Public Shareholders’ rights as shareholders (including the right to receive further liquidating distributions, if any); and (c) as promptly as reasonably possible following such redemption, subject to the approval of the Company’s remaining shareholders and its board of directors, liquidate and dissolve, subject in each case to the Company’s obligations under Cayman Islands law to provide for claims of creditors and the requirements of other applicable law.

The Sponsor has agreed that it will be liable to the Company if and to the extent any claims by a third party (other than the Company’s independent auditors) for services rendered or products sold to the Company, or a prospective target business with which the Company has discussed entering into a transaction agreement, reduce the amount of funds in the Trust Account to below (1) \$10.00 per Public Share or (2) such lesser amount per Public Share held in the Trust Account as of the date of the liquidation of the Trust Account, due to reductions in the value of the trust assets, in each case net of the interest which may be withdrawn to pay taxes, except as to any claims by a third party that executed a waiver of any and all rights to seek access to the Trust Account and except as to any claims under the Company’s indemnity of the underwriters of the Initial Public Offering against certain liabilities, including liabilities under the Securities Act of 1933, as amended (the “Securities Act”). In the event that an executed waiver is deemed to be unenforceable against a third party, the Sponsor will not be responsible to the extent of any liability for such third-party claims. The Company has not independently verified whether the Sponsor has sufficient funds to satisfy its indemnity obligations and believes that the Sponsor’s only assets are securities of the Company and, therefore, the Sponsor may not be able to satisfy those obligations. The Company has not asked the Sponsor to reserve for such obligations. None of the Company’s directors or officers will indemnify the Company for claims by third parties, including, without limitation, claims by vendors and prospective target businesses.

Proposed ProKidney Business Combination

On January 18, 2022, the Company entered into a Business Combination Agreement (the “ProKidney Business Combination Agreement”) with ProKidney LP, a limited partnership registered under the laws of Ireland (“ProKidney”), acting through its general partner ProKidney GP Limited, a private limited company incorporated under the laws of Ireland (“Legacy GP”).

The ProKidney Business Combination Agreement provides that, among other things and upon the terms and subject to the conditions thereof, prior to or at the closing of the ProKidney Business Combination Agreement (the “Closing”), the following transactions will occur (together with the other transactions contemplated by the ProKidney Business Combination Agreement, the “ProKidney Business Combination”): (1) ProKidney will issue to the Company a number of common units of ProKidney (“Post-Combination ProKidney Common Units”) equal to the number of fully diluted outstanding ordinary shares of the Company as of immediately prior to the Closing (but after giving effect to all redemptions of Public Shares and the purchase of Class A ordinary shares pursuant to one or more subscription agreements (the “PIPE Investment”)), in exchange for (a) (x) new Class B ordinary shares (“New ProKidney Class B ordinary shares”), which shares will have no economic rights but will entitle the holders thereof to vote on all matters on which shareholders of the Company are entitled to vote generally, and (y) restricted stock rights in respect of New ProKidney Class B ordinary shares (“New ProKidney Class B PMEL RSRs”), which restricted stock rights shall convert into New ProKidney Class B ordinary shares upon the vesting of the associated restricted common unit of ProKidney, (b) an amount in cash equal to the aggregate proceeds obtained by the Company in the PIPE Investment and (c) an amount in cash equal to the aggregate proceeds available for release to the Company from the Trust Account (after giving effect to all redemptions of Public Shares and after payment of any deferred underwriting commissions being held in the Trust Account and payment of certain transaction expenses); (2) Legacy GP will resign as the general partner of ProKidney and a private limited company incorporated under the laws of Ireland (“New GP”) will be admitted as the general partner of ProKidney; (3) ProKidney will distribute to the ProKidney unitholders the New ProKidney Class B ordinary shares and New ProKidney Class B PMEL RSRs received pursuant to clause (i)(a) (x) and (y) above; and (4) certain holders of ProKidney units will receive an aggregate of 17,500,000 restricted common units of ProKidney (“Earnout RCUs”) and 17,500,000 restricted stock rights of the Company (“Earnout RSRs” and, together with the Earnout RCUs, the “Earnout Rights”), which Earnout Rights will vest in three equal tranches upon the trading price of a Class A ordinary share reaching \$15.00 per share, \$20.00 per share and \$25.00 per share, respectively, on the terms set forth in the ProKidney Business Combination Agreement, or upon certain change of control events. When vested, the Earnout RCUs will automatically convert into Post-Combination ProKidney Common Units and the associated Earnout RSRs will automatically convert into New ProKidney Class B ordinary shares, respectively.

On January 18, 2022, the Company entered into subscription agreements (the “Subscription Agreements”) with certain investors (“PIPE Investors”) pursuant to which the PIPE Investors have subscribed for an aggregate of 57,500,000 Class A ordinary shares for a price of \$10.00 per share for an aggregate purchase price of \$575,000,000, of which (1) \$156,400,000 is committed by certain existing directors, officers and equityholders of, or investment funds managed by Suvretta Capital Management, LLC, the Company, the Sponsor and/or their respective affiliates participating in the PIPE Investment (collectively, the “Sponsor Related PIPE Investors”), and (2) at least \$50,000,000 (which may, at the election of such investors, be increased to up to \$100,000,000) is committed by certain existing directors, officers and unitholders of ProKidney and/or its affiliates participating in the PIPE Investment (the “ProKidney Related PIPE Investors”); provided that the ProKidney Related PIPE Investors may elect instead to purchase Post-Combination ProKidney Common Units, together with a corresponding number of Class B ordinary shares, in lieu of Class A ordinary shares. The Subscription Agreements are subject to certain conditions, including that there shall not be in force any injunction or order enjoining or prohibiting the issuance and sale of the shares under the Subscription Agreements; the terms of the ProKidney Business Combination Agreement shall not have been amended, and the minimum cash condition therein shall not have been waived, in a manner that is materially adverse to the investor party to the Subscription Agreement; and the representation and warranties of the parties to the Subscription Agreement shall be accurate (subject to agreed materiality thresholds).

[Table of Contents](#)

Following the Closing, the combined company will be organized in an umbrella partnership-C corporation (a so called “Up-C”) structure, and the Company’s direct assets will consist of ProKidney Common Units and equity interests of New GP, and substantially all of the operating assets and business of the Company will be held indirectly through ProKidney.

The consummation of the proposed ProKidney Business Combination is subject to certain conditions as further described in the ProKidney Business Combination Agreement.

Risks and Uncertainties

Management continues to evaluate the impact of the COVID-19 pandemic and has concluded that while it is reasonably possible that the pandemic could have a negative effect on the Company’s business, financial position, results of operations and/or the search for a target company, the specific impact is not readily determinable as of the date of these condensed financial statements. The condensed financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Liquidity and Going Concern

As of March 31, 2022, the Company had \$51,889 in its operating bank account and working capital deficit of \$4,817,570.

Until the consummation of a Business Combination, the Company will be using the funds not held in the Trust Account for identifying and evaluating prospective acquisition candidates, performing due diligence on prospective target businesses, paying for travel expenditures, selecting the target business to acquire, and structuring, negotiating and consummating the Business Combination.

The Company may need to raise additional capital through loans or additional investments from its Sponsor, shareholders, officers, directors, or third parties. The Company’s officers, directors and Sponsor may, but are not obligated to (other than pursuant to the Promissory Note (as defined in Note 9)), loan the Company additional funds, from time to time or at any time, in whatever amount they deem reasonable in their sole discretion, to meet the Company’s working capital needs. Accordingly, the Company may not be able to obtain such additional financing. If the Company is unable to raise additional capital, it may be required to take additional measures to conserve liquidity, which could include, but not necessarily be limited to, curtailing operations, suspending the pursuit of a potential transaction, and reducing overhead expenses. The Company cannot provide any assurance that new financing will be available to it on commercially acceptable terms, if at all. These conditions raise substantial doubt about the Company’s ability to continue as a going concern for a reasonable period of time, which is considered to be one year from the issuance date of the condensed financial statements. These condensed financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

We have performed an assessment of going concern considerations in accordance with Financial Accounting Standard Board’s Accounting Standards Update (“ASU”) 2014-15, “Disclosures of Uncertainties about an Entity’s Ability to Continue as a Going Concern.” We have until July 2, 2023 to consummate a Business Combination, which date may be extended pursuant to its Amended and Restated Memorandum and Articles of Association. It is uncertain that the Company will be able to consummate a Business Combination by July 2, 2023. If a Business Combination is not consummated by this date and such date is not extended pursuant to the Company’s Amended and Restated Memorandum and Articles of Association, there will be a mandatory liquidation and subsequent dissolution of the Company. Management has determined that the mandatory liquidation, should a Business Combination not occur within the required time period, and potential subsequent dissolution raises substantial doubt about the Company’s ability to continue as a going concern. No adjustments have been made to the carrying amounts of assets or liabilities should the Company be required to liquidate after July 2, 2023.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and in accordance with the instructions to Form 10-Q and Article 8 of Regulation S-X of the SEC. Certain information or footnote disclosures normally included in condensed financial statements prepared in accordance with GAAP have been condensed or omitted, pursuant to the rules and regulations of the SEC for interim financial reporting. Accordingly, they do not include all the information and footnotes necessary for a complete presentation of financial position, results of operations, or cash flows. In the opinion of management, the accompanying unaudited condensed financial statements include all adjustments, consisting of a normal recurring nature, which are necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented.

The accompanying unaudited condensed financial statements should be read in conjunction with the audited financial statements contained in the Company’s Annual Report on Form 10-K for the period ended December 31, 2021 filed with the SEC on March 24, 2022. The interim results for the three months ended March 31, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022 or for any future periods.

Emerging Growth Company

The Company is an “emerging growth company,” as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company’s condensed financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Use of Estimates

The preparation of the condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed financial statements and the reported amounts of revenues and expenses during the reporting period.

[Table of Contents](#)

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the condensed financial statements, which management considered in formulating its estimate, could change in the near term due to one or more future confirming events. Significant accounting estimates include the determination of the fair value of Class A ordinary shares subject to possible redemption and the fair value of Founder Shares transferred to directors. Accordingly, the actual results could differ significantly from those estimates.

Cash and Cash Equivalents

The Company considers all short-term investments with an original maturity of three months or less when purchased to be cash equivalents. The Company did not have any cash equivalents as of March 31, 2022 and December 31, 2021.

Marketable Securities Held in Trust Account

At March 31, 2022 and December 31, 2021, substantially all of the assets held in the Trust Account were held in a money market fund which is invested primarily in U.S. Treasury securities.

Class A Ordinary Shares Subject to Possible Redemption

The Company accounts for its Class A ordinary shares subject to possible redemption in accordance with the guidance in Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 480, “Distinguishing Liabilities from Equity.” Class A ordinary shares subject to mandatory redemption are classified as a liability instrument and are measured at redemption value. Conditionally redeemable ordinary shares (including ordinary shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company’s control) are classified as temporary equity. At all other times, ordinary shares are classified as permanent deficit. The Company’s Class A ordinary shares feature certain redemption rights that are considered to be outside of the Company’s control and subject to occurrence of uncertain future events. Accordingly, Class A ordinary shares subject to possible redemption are presented at redemption value as temporary equity, outside of the permanent deficit section of the Company’s condensed balance sheets.

The Company recognizes changes in redemption value immediately as they occur and adjusts the carrying value of redeemable ordinary shares to equal the redemption value at the end of each reporting period. Increases or decreases in the carrying value of redeemable ordinary shares are affected by charges against additional paid-in capital (to the extent available) and accumulated deficit.

At March 31, 2022 and December 31, 2021, the Class A ordinary shares subject to possible redemption reflected in the condensed balance sheets are reconciled in the following table:

Gross proceeds	\$ 250,000,000
Less:	
Class A ordinary shares issuance costs	(12,479,666)
Plus:	
Accretion of carrying value to redemption value	<u>12,487,990</u>
Class A ordinary shares subject to possible redemption, December 31, 2021	<u>250,008,324</u>
Plus:	
Remeasurement of carrying value to redemption value	<u>(8,324)</u>
Class A ordinary shares subject to possible redemption, March 31, 2022	<u>\$ 250,000,000</u>

Offering Costs

The Company complies with the requirements of the ASC 340-10-S99-1. Offering costs consisted of legal, accounting, underwriting fees and other costs incurred through the Initial Public Offering that were directly related to the Initial Public Offering. The Company incurred offering costs amounting to \$12,479,666 as a result of the Initial Public Offering, consisting of \$4,400,000 of underwriting commissions, \$7,700,000 of deferred underwriting commissions, and \$379,666 of other offering costs. As the shares sold in the IPO are redeemable, the offering costs were charged to temporary equity and additional paid-in capital upon the completion of the Initial Public Offering. Immediately thereafter, temporary equity was remeasured and an adjustment was recognized through additional paid in capital and accumulated deficit to adjust temporary equity to the redemption value.

Share-Based Payment Arrangements

The Company accounts for stock awards in accordance with ASC 718, “Compensation—Stock Compensation,” which requires that all equity awards be accounted for at their “fair value.” Fair value is measured on the grant date and is equal to the underlying value of the stock.

Costs equal to these fair values are recognized ratably over the requisite service period based on the number of awards that are expected to vest, in the period of grant for awards that vest immediately and have no future service condition, or in the period the awards vest immediately after meeting a performance condition becomes probable (i.e., the occurrence of a Business Combination). For awards that vest over time, cumulative adjustments in later periods are recorded to the extent actual forfeitures differ from the Company’s initial estimates; previously recognized compensation cost is reversed if the service or performance conditions are not satisfied and the award is forfeited.

Income Taxes

The Company accounts for income taxes under ASC 740, “Income Taxes” (“ASC 740”). ASC 740 requires the recognition of deferred tax assets and liabilities for both the expected impact of differences between the condensed financial statement and tax basis of assets and liabilities and for the expected future tax benefit to be derived from tax loss and tax credit carry forwards. ASC 740 additionally requires a valuation allowance to be established when it is more likely than not that all or a portion of deferred tax assets will not be realized.

ASC 740 also clarifies the accounting for uncertainty in income taxes recognized in an enterprise’s condensed financial statements and prescribes a recognition threshold and measurement process for condensed financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The Company’s management has determined that the Cayman Islands is the Company’s major tax jurisdiction. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of March 31, 2022 and December 31, 2021. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position. The Company has been subject to income tax examinations by major taxing authorities since inception.

The Company is considered to be an exempted Cayman Islands company and is presently not subject to income taxes or income tax filing requirements in the Cayman Islands or the United States. As such, the Company’s tax provision was zero for the periods presented.

Net Loss per Ordinary Share

Net loss per ordinary share is computed by dividing net loss by the weighted-average number of ordinary shares outstanding during the period. The Company has two classes of ordinary shares, which are referred to as

[Table of Contents](#)

Class A ordinary shares and Class B ordinary shares. Losses are shared pro rata between the two classes of shares. Charges associated with the redeemable Class A ordinary shares are excluded from net loss per ordinary share as the redemption value approximates fair value.

As of March 31, 2022 and 2021, the Company did not have any dilutive securities or other contracts that could, potentially, be exercised or converted into ordinary shares and then share in the earnings of the Company. As a result, diluted net loss per ordinary share is the same as basic net loss per ordinary share for the periods presented.

The following table reflects the calculation of basic and diluted net loss per ordinary share (in dollars, except per share amounts):

	For the Three Months Ended March 31, 2022		For the Period from February 25, 2021 (Inception) Through March 31, 2021	
	Class A	Class B	Class A	Class B
Basic and diluted net loss per ordinary share				
Numerator:				
Allocation of net loss	\$ (3,200,799)	\$ (780,226)	\$ —	\$ (5,182)
Denominator:				
Basic and diluted weighted average shares outstanding	25,640,000	6,250,000	—	5,500,000
Basic and diluted net loss per ordinary share	\$ (0.12)	\$ (0.12)	\$ —	\$ (0.00)

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash accounts in a financial institution which, at times may exceed the Federal Depository Insurance Corporation coverage limit of \$250,000. The Company has not experienced losses on these accounts.

Fair Value of Financial Instruments

The fair value of the Company's assets and liabilities, which qualify as financial instruments under ASC Topic 820, "Fair Value Measurement," ("ASC 820"), approximates the carrying amounts represented in the accompanying condensed balance sheet, primarily due to their short-term nature.

Recent Accounting Standards

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years, with early adoption permitted. The Company adopted ASU 2020-06 effective as of January 1, 2021. The adoption of ASU 2020-06 did not have an impact on the Company's condensed financial statements.

Management does not believe that any recently issued, but not yet effective, accounting standards, if currently adopted, would have a material effect on the Company's condensed financial statements.

Accrued Expenses

At March 31, 2022, accrued expenses includes \$4,095,414 of legal expense, \$283,348 of printing expense, \$529,688 of due diligence expense, \$363,740 of professional fee expense and \$70,000 of regulatory fee expense, of which \$2,500,000 of legal expense, \$247,188 of consulting expense and \$534,906 of other transactional related expenses incurred in connection with the Business Combination with ProKidney.

At December 31, 2021, accrued expenses includes \$1,506,528 of legal expense, \$5,000 of printing expense, \$282,500 of due diligence expense, \$70,000 of regulatory filing fee and \$770 of accounting expense.

NOTE 3. INITIAL PUBLIC OFFERING

Pursuant to the Initial Public Offering, the Company sold 25,000,000 Public Shares, which includes a partial exercise by the underwriters of their over-allotment option in the amount of 3,000,000 Public Shares, at a price of \$10.00 per Public Share. Unlike some other initial public offerings of special purpose acquisition companies, investors in the Initial Public Offering did not receive any warrants (which would typically become exercisable following completion of the Business Combination). The fair value attributable to the unexercised portion of the over-allotment option was deemed to be immaterial to the condensed financial statements.

NOTE 4. PRIVATE PLACEMENT

Substantially concurrently with the closing of the Initial Public Offering, the Sponsor purchased 640,000 Private Placement Shares at a price of \$10.00 per Private Placement Share, for an aggregate purchase price of \$6,400,000. Each Private Placement Share is identical to the Class A ordinary shares sold in the Initial Public Offering, subject to certain limited exceptions as described in Note 7. A portion of the proceeds from the sale of the Private Placement Shares was added to the net proceeds from the Initial Public Offering held in the Trust Account. If the Company does not complete a Business Combination within the Combination Period or during any applicable extension period, the proceeds from the sale of the Private Placement Shares held in the Trust Account will be used to fund the redemption of the Public Shares (subject to the requirements of applicable law) and the Private Placement Shares will be worthless.

NOTE 5. RELATED PARTY TRANSACTIONS

Founder Shares

On March 2, 2021, the Sponsor paid \$25,000 to cover certain offering and formation costs of the Company in consideration for which the Sponsor received 5,750,000 Class B ordinary shares (the “Founder Shares”). On June 29, 2021, the Company effected a share capitalization with respect to its Class B ordinary shares of 575,000 shares thereof, resulting in the Company’s initial shareholders holding an aggregate of 6,325,000 Founder Shares. All share and per-share amounts have been retroactively restated to reflect the share capitalization. The Founder Shares included an aggregate of up to 825,000 shares that were subject to forfeiture depending on the extent to which the underwriters’ over-allotment option was exercised. As a result of the underwriters’ election to partially exercise their over-allotment option, a total of 750,000 Founder Shares are no longer subject to forfeiture and 75,000 Founder Shares were forfeited, resulting in an aggregate of 6,250,000 Founder Shares outstanding.

In June 2021, the Sponsor transferred 30,000 Founder Shares to Marc Semigran, an independent director of the Company. The sale of the Founders Shares to the Company’s director is in the scope of FASB ASC Topic 718, “Compensation-Stock Compensation” (“ASC 718”). Under ASC 718, stock-based compensation associated with equity-classified awards is measured at fair value upon the grant date. The fair value of the 30,000 shares granted to the Company’s director was \$214,160 or approximately \$7.14 per share. The Founders Shares were effectively sold subject to a performance condition (i.e., the occurrence of a Business Combination).

[Table of Contents](#)

Compensation expense related to the Founders Shares is recognized only when the performance condition is probable of occurrence under the applicable accounting literature in this circumstance. As of March 31, 2022, the Company determined that a Business Combination is not considered probable, and, therefore, no stock-based compensation expense has been recognized. Stock-based compensation would be recognized at the date a Business Combination is considered probable (i.e., upon consummation of a Business Combination) in an amount equal to the number of Founders Shares times the grant date fair value per share (unless subsequently modified) less the amount initially received for the purchase of the Founders Shares.

The Sponsor and the Company's directors and officers have agreed, subject to limited exceptions, not to transfer, assign or sell any of their Founder Shares until the earlier of: (A) one year after the completion of a Business Combination and (B) subsequent to a Business Combination, (x) if the last reported sale price of the Class A ordinary shares equals or exceeds \$12.00 per share (as adjusted for share sub-divisions, share dividends, rights issuances, consolidations, reorganizations, recapitalizations and other similar transactions) for any 20 trading days within any 30-trading day period commencing at least 150 days after a Business Combination, or (y) the date on which the Company completes a liquidation, merger, amalgamation, share exchange, reorganization or other similar transaction that results in all of the Public Shareholders having the right to exchange their Class A ordinary shares for cash, securities or other property.

Administrative Services Agreement

The Company entered into an agreement in which it will pay an affiliate of the Sponsor \$10,000 per month, commencing on June 30, 2021, for office space, administrative and support services. Upon completion of a Business Combination or its liquidation, the Company will cease paying these monthly fees. For the three months ended March 31, 2022, the Company incurred \$30,000 in fees for these services, of which is included in due to related party in the accompanying condensed balance sheet. For the period from February 25, 2021 (inception) through March 31, 2021, the Company did not incur any fees for these services.

Due to Related Party

As of March 31, 2022, an affiliate of the Sponsor had advanced the Company \$33,623 for working capital purposes, of which \$0 was repaid during the three months ended March 31, 2022. As of March 31, 2022, and December 31, 2021, the outstanding balance under the advances amounted to \$43,623 and \$10,000 respectively.

Promissory Note—Related Party

On March 2, 2021, the Company issued an unsecured promissory note to the Sponsor (the "Pre-IPO Sponsor Promissory Note"), pursuant to which the Company could borrow up to an aggregate principal amount of \$300,000. The Pre-IPO Sponsor Promissory Note was non-interest bearing and payable on the earlier of December 31, 2021 and the completion of the Initial Public Offering. The outstanding balance under the Pre-IPO Sponsor Promissory Note of \$300,000 was repaid at the closing of the Initial Public Offering on July 2, 2021. Borrowings are no longer available under the Pre-IPO Sponsor Promissory Note.

Related Party Loans

In order to fund working capital deficiencies or finance transaction costs in connection with a Business Combination, the Sponsor or an affiliate of the Sponsor or certain of the Company's officers and directors may, but are not obligated to (other than pursuant to the Promissory Note (see Note 9)), loan the Company additional funds as may be required ("Working Capital Loans"). If the Company completes a Business Combination, it may repay such loaned amounts out of the proceeds of the Trust Account. In the event that the Business Combination does not close, the Company may use a portion of the working capital held outside the Trust Account to repay such loaned amounts but no proceeds from the Trust Account would be used to repay such loaned amounts. As of March 31, 2022 and December 31, 2021, there were no outstanding amounts under the Working Capital Loans.

Subscription Agreements

Concurrently with the execution of the ProKidney Business Combination Agreement, the Company entered into Subscription Agreements with the Sponsor Related PIPE Investors, pursuant to which the Sponsor Related PIPE Investors have subscribed for Class A ordinary shares. The Sponsor Related PIPE Investors are expected to fund \$156,400,000 of the PIPE Investment, for which they will receive 15,640,000 Class A ordinary shares. Specifically, (i) SC Master Holdings, LLC, an entity affiliated with Mr. Palihapitiya, subscribed for 12,500,000 Class A ordinary shares and (ii) Averill Master Fund, Ltd., an entity affiliated with Mr. Mehta, subscribed for 3,140,000 Class A ordinary shares. The PIPE Investment will be consummated substantially concurrently with the Closing.

NOTE 6. COMMITMENTS AND CONTINGENCIES

Registration Rights

Pursuant to a registration rights agreement entered into on June 29, 2021, the holders of the Founder Shares, Private Placement Shares and any Private Placement Shares that may be issued on conversion of Working Capital Loans (and any Class A ordinary shares issuable upon the conversion of the Founder Shares) are entitled to registration rights requiring the Company to register such securities for resale (in the case of the Founder Shares, only after conversion to the Class A ordinary shares). The holders of these securities will be entitled to make up to three demands, excluding short form registration demands, that the Company register such securities. In addition, the holders have certain “piggy-back” registration rights with respect to registration statements filed subsequent to the completion of a Business Combination and rights to require the Company to register for resale such securities pursuant to Rule 415 under the Securities Act. The Company will bear the expenses incurred in connection with the filing of any such registration statements. At the closing of the ProKidney Business Combination, the Company will enter into the Registration Rights Agreement, with the Sponsor, the Company’s directors and the Closing ProKidney unitholders, which will replace the existing registration rights agreement.

Certain purported shareholders of the Company sent demand letters (the “Demands”) alleging deficiencies and/or omissions in the ProKidney Disclosure Statement filed by the Company with the SEC on February 14, 2022. The Demands seek additional disclosures to remedy these purported deficiencies. We believe that the allegations in the Demands are meritless.

Underwriting Agreement

The underwriters are entitled to a deferred underwriting commission of \$7,700,000 in the aggregate. The deferred fee will become payable to the underwriters from the amounts held in the Trust Account solely in the event that the Company completes a Business Combination, subject to the terms of the underwriting agreement.

Restricted Stock Unit Award

In September 2021, pursuant to a Director Restricted Stock Unit Award Agreement, dated September 24, 2021, between the Company and Uma Sinha, Ph.D., the Company agreed to grant 30,000 restricted stock units (“RSUs”) to Dr. Sinha, which grant is contingent on both the consummation of a Business Combination and a shareholder approved equity plan. The RSUs will vest upon the consummation of such Business Combination and represent 30,000 Class A ordinary shares of the Company that will settle on a date determined in the sole discretion of the Company that shall occur between the vesting date and March 15 of the year following the year in which vesting occurs.

The RSUs granted by the Company are in the scope of ASC 718. Under ASC 718, stock-based compensation associated with equity-classified awards is measured at fair value upon the grant date. The RSUs granted are subject to a performance condition (i.e., the occurrence of a Business Combination). Compensation expense related to the RSUs is recognized only when the performance condition is probable of occurrence under

the applicable accounting literature in this circumstance. As of March 31, 2022, the Company did not have a shareholder approved equity plan and also determined that a Business Combination is not considered probable, and, therefore, no stock-based compensation expense has been recognized. Stock-based compensation would be recognized at the date a Business Combination is considered probable (i.e., upon consummation of a Business Combination) in an amount equal to the number of RSUs times the grant date fair value per share (unless subsequently modified).

NOTE 7. TEMPORARY EQUITY AND PERMANENT DEFICIT

Preference Shares—The Company is authorized to issue 5,000,000 preference shares, with a par value of \$0.0001 per share. The Company's board of directors will be authorized to fix the voting rights, if any, designations, powers, preferences, the relative, participating, optional or other special rights and any qualifications, limitations and restrictions thereof, applicable to the shares of each series. The Company's board of directors will be able to, without shareholder approval, issue preference shares with voting and other rights that could adversely affect the voting power and other rights of the holders of the Company's ordinary shares and could have anti-takeover effects. At March 31, 2022 and December 31, 2021, there were no preference shares issued or outstanding.

Class A Ordinary Shares—The Company is authorized to issue 500,000,000 Class A ordinary shares, with a par value of \$0.0001 per share. At March 31, 2022 and December 31, 2021, there were 640,000 Class A ordinary shares issued and outstanding, excluding 25,000,000 Class A ordinary shares subject to possible redemption which are presented as temporary equity.

Class B Ordinary Shares—The Company is authorized to issue 50,000,000 Class B ordinary shares, with a par value of \$0.0001 per share. At March 31, 2022 and December 31, 2021, there were 6,250,000 Class B ordinary shares issued and outstanding.

Holders of record of Class A ordinary shares and Class B ordinary shares are entitled to one vote for each share held on all matters to be voted on by shareholders and vote together as a single class, except as required by law; provided that prior to a Business Combination, holders of Class B ordinary shares will have the right to appoint all of the Company's directors and remove members of its board of directors for any reason, and holders of Class A ordinary shares will not be entitled to vote on the appointment of directors during such time.

The Class B ordinary shares will automatically convert into Class A ordinary shares at the time of the Business Combination, or earlier at the option of the holder, on a one-for-one basis, subject to adjustment for share sub-divisions, share dividends, rights issuances, consolidations, reorganizations, recapitalizations and the like. Additionally, in the event that additional (in excess of the amounts issued in the Initial Public Offering) Class A ordinary shares, or equity-linked securities, are issued or deemed issued in connection with the closing of the Business Combination, the ratio at which the Class B ordinary shares will convert into Class A ordinary shares will be adjusted (unless the holders of a majority of the issued and outstanding Class B ordinary shares agree to waive such anti-dilution adjustment with respect to any such issuance or deemed issuance) so that the number of Class A ordinary shares issuable upon conversion of all Class B ordinary shares will equal, in the aggregate, 20% of the sum of the total number of Class A ordinary shares outstanding after such conversion (after giving effect to any redemptions of Class A ordinary shares by Public Shareholders, and excluding the Private Placement Shares), including any Class A ordinary shares issued or deemed issued, or issuable upon the conversion or exercise of any equity-linked securities or rights issued or deemed issued, by the Company in connection with the Business Combination, excluding any Class A ordinary shares or equity-linked securities exercisable for or convertible into Class A ordinary shares issued, or to be issued, to any seller in the Business Combination and any private placement shares issued to the Sponsor or its affiliates upon conversion of Working Capital Loans; provided that such conversion of Class B ordinary shares will never occur on a less than one-for-one-basis.

[Table of Contents](#)

Private Placement Shares—The Private Placement Shares are not transferable, assignable, or salable until 30 days after the completion of a Business Combination (except, among other limited exceptions, to the Company’s directors and officers and other persons or entities affiliated with the Sponsor). Holders of the Private Placement Shares are entitled to certain registration rights. If the Company does not complete a Business Combination within the Combination Period or during any applicable extension period, the proceeds from the sale of the Private Placement Shares held in the Trust Account will be used to fund the redemption of the Public Shares (subject to the requirements of applicable law) and the Private Placement Shares will be worthless.

NOTE 8. FAIR VALUE MEASUREMENTS

The Company follows the guidance in ASC Topic 820 for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually.

The fair value of the Company’s financial assets and liabilities reflects management’s estimate of amounts that the Company would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from independent sources) and to minimize the use of unobservable inputs (internal assumptions about how market participants would price assets and liabilities). The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value the assets and liabilities:

- Level 1: Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.
- Level 2: Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.
- Level 3: Unobservable inputs based on the Company’s assessment of the assumptions that market participants would use in pricing the asset or liability.

The following table presents information about the Company’s assets that are measured at fair value on a recurring basis at March 31, 2022 and December 31, 2021, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

<u>Description</u>	<u>Level</u>	<u>March 31, 2022</u>	<u>December 31, 2021</u>
Assets:			
Marketable securities held in Trust Account	1	\$250,033,500	\$ 250,008,324

NOTE 9. SUBSEQUENT EVENTS

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the condensed financial statements were issued. Based upon this review, other than as described below, the Company did not identify any subsequent events that would have required adjustment or disclosure in the condensed financial statements.

On April 20, 2022, the Company issued an unsecured promissory note (the “Promissory Note”) to the Sponsor pursuant to which the Company may borrow up to an aggregate principal amount of \$1,500,000.

[Table of Contents](#)

The Promissory Note is non-interest bearing, unsecured and payable upon the earlier of July 2, 2023 and the effective date of the Company's Business Combination. The Promissory Note is subject to customary events of default which could, subject to certain conditions, cause the Promissory Notes to become immediately due and payable. On April 26, 2022, the Company drew \$250,000 under the Promissory Note.

Report of Independent Registered Public Accounting Firm

To the Members and the Board of Directors of ProKidney LP

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ProKidney LP (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, statements of changes in members' equity and cash flows for the years then ended and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations, has a net capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

Adoption of ASC 842, Leases

As discussed in Note 5 to the consolidated financial statements, the Company changed its method of accounting for leases in the year ended December 31, 2020 due to the adoption of ASC 842, Leases. Our opinion is not modified with respect to this matter.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

Raleigh, North Carolina
April 11, 2022

ProKidney LP and Subsidiaries
Consolidated Balance Sheets
(in thousands)

	<u>December 31,</u>	
	<u>2021</u>	<u>2020</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 20,558	\$ 4,578
Prepaid assets	588	202
Prepaid clinical	6,100	753
Other current assets	25	52
Total current assets	<u>27,271</u>	<u>5,585</u>
Fixed assets, net	11,358	8,914
Right of use assets, net	1,241	1,559
Intangible assets, net	428	642
Total assets	<u>\$ 40,298</u>	<u>\$ 16,700</u>
Liabilities and Equity		
Current liabilities		
Accounts payable	\$ 2,834	\$ 781
Lease liabilities	267	225
Accrued expenses and other	9,213	4,496
Total current liabilities	<u>12,314</u>	<u>5,502</u>
Lease liabilities, net of current portion	1,067	1,334
Commitments and contingencies		
Members' equity:		
Class A Units (186,500,000 and 115,000,000 issued and outstanding as of December 31, 2021 and 2020, respectively)	186,500	115,000
Class B Units (7,767,122 issued and outstanding as of December 31, 2021 and 2020)	1,927	1,228
Accumulated deficit	<u>(161,510)</u>	<u>(106,364)</u>
Total members' equity	26,917	9,864
Total liabilities and equity	<u>\$ 40,298</u>	<u>\$ 16,700</u>

(The accompanying notes are an integral part of the consolidated financial statements.)

ProKidney LP and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except for share and per share data)

	<u>Years Ended December 31,</u>	
	<u>2021</u>	<u>2020</u>
Revenue	\$ —	\$ —
Operating expenses		
Research and development	46,255	21,042
General and administrative	8,855	5,982
Total operating expenses	<u>55,110</u>	<u>27,024</u>
Operating loss	(55,110)	(27,024)
Other income		
Interest income	<u>2</u>	<u>43</u>
Net loss before income taxes	(55,108)	(26,981)
Income tax expense (benefit)	38	(232)
Net and comprehensive loss	<u>\$ (55,146)</u>	<u>\$ (26,749)</u>
Weighted average Class A Units outstanding:		
Basic and diluted	150,706,849	104,986,301
Net loss per Class A Unit:		
Basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.25)</u>

(The accompanying notes are an integral part of the consolidated financial statements.)

ProKidney LP and Subsidiaries
Consolidated Statements of Changes in Members' Equity
(in thousands, except for share data)

	Class A		Class B	Accumulated Deficit	Total Members' Equity
	Units	Amount	Profits Interests		
Balance as of January 1, 2020	95,000,000	\$ 95,000	\$ 498	\$ (79,615)	\$ 15,883
Capital contribution	20,000,000	20,000	—	—	20,000
Equity-based compensation	—	—	730	—	730
Net loss	—	—	—	(26,749)	(26,749)
Balance as of December 31, 2020	115,000,000	115,000	1,228	(106,364)	9,864
Capital contribution	71,500,000	71,500	—	—	71,500
Equity-based compensation	—	—	699	—	699
Net loss	—	—	—	(55,146)	(55,146)
Balance as of December 31, 2021	<u>186,500,000</u>	<u>\$ 186,500</u>	<u>\$ 1,927</u>	<u>\$ (161,510)</u>	<u>\$ 26,917</u>

(The accompanying notes are an integral part of the consolidated financial statements.)

ProKidney LP and Subsidiaries
Consolidated Statements of Cash Flows
(in thousands)

	<u>Years Ended December 31,</u>	
	<u>2021</u>	<u>2020</u>
Cash flows from operating activities		
Net loss	\$ (55,146)	\$ (26,749)
Adjustments to reconcile net loss to net cash flows		
Depreciation and amortization	1,984	964
Equity-based compensation	699	730
Changes in operating assets and liabilities		
Other assets	(5,704)	(809)
Accounts payable and accrued expenses	7,868	683
Net cash flows used in operating activities	(50,299)	(25,181)
Cash flows used in investing activities		
Proceeds from sale of equipment	1	—
Purchase of equipment and facility expansion	(5,192)	(5,456)
Net cash flows used in investing activities	(5,191)	(5,456)
Cash flows from financing activities		
Payments on finance leases	(30)	(11)
Net cash contribution	71,500	20,000
Net cash flows from financing activities	71,470	19,989
Net change in cash and cash equivalents	15,980	(10,648)
Cash, beginning of period	4,578	15,226
Cash, end of period	<u>\$ 20,558</u>	<u>\$ 4,578</u>
Supplemental disclosure of non-cash investing activities:		
Equipment and facility expansion included in accounts payable and accrued expenses	<u>\$ 1,295</u>	<u>\$ 1,840</u>

(The accompanying notes are an integral part of the consolidated financial statements.)

ProKidney and Subsidiaries
Notes to Consolidated Financial Statements
Years Ended December 31, 2021 and 2020

Note 1: The Company

ProKidney LLC was formed as a Bermuda limited liability company on December 12, 2018 and funded with \$75,000,000 on December 31, 2018. On January 9, 2019 (the "Acquisition Date"), ProKidney LLC acquired all of the equity interests in inRegen and Twin City Bio LLC ("TC Bio") for \$62,000,000. inRegen was duly incorporated under the Cayman Islands Companies Act (as amended) on December 21, 2015 as an exempted company. During 2020, inRegen's name was changed to ProKidney (and is referred to herein as "ProKidney-KY"), and TC Bio's name was changed to ProKidney, LLC (and is referred to herein as "ProKidney-US"). ProKidney-US was formed as a limited liability company under the laws of Delaware on December 18, 2015. In August 2021, ProKidney LP was organized as a limited partnership under the laws and regulations of Ireland, with ProKidney LLC becoming a wholly owned subsidiary of ProKidney LP (and is referred to herein as "ProKidney"). Following this reorganization on August 5, 2021 and for the purposes of these financial statements, the term "ProKidney," as used herein, refers to ProKidney LP following this reorganization, and the financial information presented herein is that of ProKidney LP and its wholly owned subsidiaries.

ProKidney acquired the equity interests in ProKidney-KY to develop its Renal Advanced Cell Therapy, which has the potential to stabilize or improve renal function in patients with chronic kidney disease or delay or eliminate the need for dialysis and organ transplantation. ProKidney acquired ProKidney-US to provide contractual development and manufacturing services to ProKidney-KY, which is ProKidney-US's only customer.

Because ProKidney is a limited partnership, the debts, obligations and liabilities of the Company (as defined below), whether arising in contract, tort or otherwise, are solely the debts, obligations and liabilities of the Company, and no holder of equity interests in ProKidney ("members' equity") is obligated personally for any such debt, obligation or liability of the Company solely by reason of being a holder of members' equity.

Note 2: Significant Accounting Policies

Basis of Presentation

The consolidated financial statements reflect the operations of ProKidney and its wholly-owned subsidiaries consisting of ProKidney-KY and ProKidney-US (together, the "Company"). All intercompany transactions and accounts have been eliminated.

The accompanying consolidated financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). These consolidated financial statements are presented in U.S. Dollars.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company performed an analysis of its ability to continue as a going concern. As of December 31, 2021, the Company had an accumulated deficit of \$161,510,000. The Company has generated losses from operations for each year since its inception including losses from operations of \$55,146,000 and \$26,749,000 for the years ended December 31, 2021 and 2020, respectively. The Company intends to continue to conduct significant

[Table of Contents](#)

additional research, development, and clinical study activities which, together with expenses incurred for general and administrative expenses, are expected to result in continuing operating losses for the foreseeable future. The amount of future losses and when, if ever, the Company will achieve profitability are uncertain. The Company's ability to achieve profitability will depend, among other things, on successfully completing clinical studies, obtaining requisite regulatory approvals, establishing appropriate pricing for its product with payers, and raising sufficient funds to finance the Company's activities. No assurance can be given that the Company's clinical development efforts will be successful, that regulatory approvals will be obtained, or that the Company will be able to achieve appropriate pricing and market access or that profitability, if achieved, can be sustained. These matters raise substantial doubt about the Company's ability to continue as a going concern. The Company believes that, based on its current business plan, its existing cash and cash equivalents of \$20,558,000 at December 31, 2021 will not be sufficient to fund its obligations for the next 12 months. The consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

Our ability to execute our operating plan depends on our ability to obtain additional funding through equity offerings, debt financings or potential licensing and collaboration arrangements. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. Even if we raise additional capital, we may also be required to modify, delay or abandon some of our plans which could have a material adverse effect on our business, operating results and financial condition and our ability to achieve our intended business objectives.

Use of Estimates

The preparation of consolidated financial statements, in accordance with GAAP, requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the amounts of expenses during the reported periods. Certain estimates in these consolidated financial statements have been made in connection with the calculation of research and development expenses, equity-based compensation expense and the provision for or benefit from income taxes. The Company bases its estimates on historical experience and various other assumptions, including in certain circumstances future projections, which management believes to be reasonable under the circumstances. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less on the date of purchase to be cash equivalents. The carrying value of cash and cash equivalents approximates fair value due to the short-term nature of these items.

Concentrations of Credit Risk

Cash and equivalents are financial instruments that are potentially subject to concentrations of credit risk. The Company's cash and equivalents are deposited in accounts at large financial institutions, and amounts may exceed federally insured limits.

[Table of Contents](#)

Accrued Expenses

Accrued expenses which have been presented on the consolidated balance sheets as of December 31, 2021 and 2020 consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Compensation	\$ 1,832	\$ 1,085
Clinical study related costs	2,031	1,154
Facility expansion costs	19	1,709
Accrued legal	964	—
Manufacturing improvement costs	4,164	—
Other accrued expenses	203	548
Total accrued expenses and other	<u>\$ 9,213</u>	<u>\$ 4,496</u>

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, benefits, third party license fees, and external costs of outside vendors engaged to conduct manufacturing and preclinical development activities and clinical trials.

The Company records accruals based on estimates of services received, efforts expended, and amounts owed pursuant to contracts with numerous contract research organizations. In the normal course of business, the Company contracts with third parties to perform various clinical study activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events and the completion of portions of the clinical study or similar conditions. The objective of the Company's accrual policy is to match the recording of expenses in its financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical studies are recognized based on the company's estimate of the degree of completion of the event or events specified in the specific clinical study.

The Company records nonrefundable advance payments it makes for future research and development activities as prepaid expenses. Prepaid expenses are recognized as expense in the Statement of Operations and Comprehensive Loss as the Company receives the related goods or services.

Costs incurred in obtaining technology licenses are charged to research and development expense as purchased in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use.

Fixed Assets

Fixed assets are stated at cost, less accumulated depreciation. Generally, expenditures for maintenance and repairs are charged to expense and major improvements or replacements are capitalized. The Company computes depreciation and amortization using the straight-line method over the estimated useful life of the asset. Leasehold improvements are amortized over the lesser of, the life of the lease or the estimated useful life of the leasehold improvement. The estimated useful lives are as follows:

Computer equipment and software	3-5 years
Furniture and equipment	5-7 years
Leasehold improvements	remainder of lease term

[Table of Contents](#)

Fixed assets consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Furniture and equipment	\$ 2,180	\$ 2,011
Computer equipment and software	569	130
Leasehold improvements	10,517	76
Construction in progress	351	7,854
Less: accumulated depreciation	(2,259)	(1,157)
Total fixed assets, net	<u>\$ 11,358</u>	<u>\$ 8,914</u>

Depreciation expense for the years ended December 31, 2021 and 2020 was \$1,451,000 and \$606,000, respectively.

Intangible Assets

Intangible assets are comprised of acquired assembled workforce, which are accounted for in accordance with ASC 350—Intangibles—Goodwill and Other. The acquired assembled workforce is amortized on a straight-line basis over the useful life of five years. The following table summarizes information related to the Company's assembled workforce intangible asset (in thousands):

	December 31, 2021	December 31, 2020
Gross carrying amount	\$ 1,073	\$ 1,073
Accumulated amortization	645	431
Net carrying amount	<u>\$ 428</u>	<u>\$ 642</u>

Estimated amortization expense for each of the years 2022 through 2023 is \$215,000 and \$5,000 for 2024. Amortization expense relating to the assembled workforce intangible asset was \$214,000 for the year ended December 31, 2021 and \$215,000 for the year ended December 31, 2020.

Impairment of Long-Lived Assets

Long-lived assets such as fixed assets and intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. No impairment charges have been recorded for the years ended December 31, 2021 or 2020.

Income Taxes

The Company was organized as a limited liability company, is now a limited partnership and is classified as a partnership for U.S. income tax purposes, and as such, only records a provision for federal and state income taxes on its subsidiaries organized as C corporations or which have elected to be treated as corporations for U.S. federal income tax purposes. ProKidney-US is a limited liability company and has elected to be treated as a C corporation. Therefore, a provision for federal and state taxes has been recorded. ProKidney-KY has been granted, by the Government in Council of the Cayman Islands, tax concessions under an undertaking certificate exempting it from any tax levied on profits, income, gains or appreciations in relation to its operations or in the nature of estate duty or inheritance tax for a period of twenty years from January 20, 2016. ProKidney-KY elected to be treated as an entity disregarded from its owner for U.S. tax purposes, and as a result, it has not recorded an income tax provision.

[Table of Contents](#)

The Company uses the liability method in accounting for income taxes as required by ASC Topic 740 — Income Taxes, under which deferred tax assets and liabilities are recorded for the future tax consequences attributable to the differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is recorded to reduce the carrying amounts of deferred tax assets unless it is more likely than not that such assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, available taxes in the carryback periods, projected future taxable income and tax planning strategies in making this assessment. Accordingly, the Company has provided a full valuation allowance to offset the net deferred tax assets at December 31, 2021.

Interest and penalties related to income taxes are included in the benefit (provision) for income taxes in the Company's Consolidated Statements of Operations. The Company has not incurred any significant interest or penalties related to income taxes in any of the periods presented.

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. A three-level fair value hierarchy that prioritizes the inputs used to measure fair value is described below. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities
- Level 2 – Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable through correlation with market data
- Level 3 – Unobservable inputs that are supported by little or no market data, which require the reporting entity to develop its own assumptions

The carrying values of cash equivalents, accounts payable, and accrued liabilities approximate fair value due to the short-term nature of these instruments. There are no available-for-sale securities included in cash and cash equivalents as of December 31, 2021 and 2020.

Leases

The Company determines if an arrangement is a lease at inception. Balances recognized related to the Company's operating and finance leases are included in right-of-use assets, net and lease liabilities in the Consolidated Balance Sheets. Right of use assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Lease terms may include options to extend or terminate the lease if it is reasonably certain that the Company will exercise the option. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of future payments. The right of use asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The Company has elected a practical expedient to not separate its lease and non-lease components and instead account for them as a single lease component. Leases with a term of 12 months or less are not recorded on the balance sheet.

Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Lease payments for short-term leases are recorded to operating expense on a straight-line basis and variable lease payments are recorded in the period in which the obligation for those payments is incurred.

Contingent Liabilities

The Company records reserves for contingent liabilities when it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements, and the amount of the loss can be reasonably estimated.

Equity-Based Compensation

The Deed for the Establishment of a Limited Partnership of ProKidney LP, dated as of August 5, 2021 (the “Limited Partnership Agreement”) which replaced the Amended and Restated Limited Liability Company Agreement of ProKidney LLC as the governing document of the parent entity in the Company, allows for the issuance of Profits Interests (as defined in the Limited Partnership Agreement) to employees, directors, other service providers of the Company and others denominated in the form of one or more Class B Units (as defined in the Limited Partnership Agreement). The Company measures compensation expense for Profits Interests based on estimated fair values at the time of grant. The Company estimates the fair value of Profits Interests using generally accepted valuation procedures. The Company recognizes compensation expense, on a straight-line basis, for the portion of the Profits Interests’ value that is expected to vest over the requisite service period. The Company records forfeitures of Profits Interests as they occur.

Defined Contribution Plan

The Company sponsors a 401(k) plan for its ProKidney-US employees and a defined contribution plan for its ProKidney-KY employees. Full-time employees are eligible to participate in the ProKidney-US plan. The Company matches 50% of participating ProKidney-US employees’ contributions up to 8% of salary. The costs of the ProKidney-US plan were \$161,000 and \$119,000 for the years ended December 31, 2021 and 2020, respectively. The Company contributes 7% of ProKidney-KY employee salaries to the ProKidney-KY defined contribution plan. The costs of the ProKidney-KY plan were \$8,000 and \$20,000 for the years ended December 31, 2021 and 2020, respectively.

Segments

The Company operates in only one segment.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which requires lessees to recognize a right-of-use asset and a liability on the balance sheet for all leases, with the exception of short-term leases. The lease liability will be equal to the present value of lease payments, and the right-of-use asset will be based on the lease liability, subject to adjustment such as for initial direct costs. Leases will continue to be classified as either operating or finance leases in the income statement. The guidance is effective for annual periods beginning after December 15, 2021, with early adoption permitted. The Company early adopted ASU No. 2016-02, Leases (Topic 842), as of January 1, 2021. For additional detail, see Note 4, Leases.

Subsequent Events

The Company has evaluated subsequent events through April 11, 2022, which is the date the consolidated financial statements were available to be issued. See additional information in Notes 5 and 8.

Note 3: Income Taxes

The Company’s subsidiary, ProKidney-US, is treated as a C corporation, and therefore a provision for federal and state taxes has been recorded.

[Table of Contents](#)

The provision for income tax expense consisted of the following for the year ended December 31, 2021 and 2020 (in thousands):

	December 31, 2021	December 31, 2020
Current:		
Federal	\$ 72	\$ (242)
State	(34)	10
Total current income tax expense (benefit)	38	(232)
Deferred:		
Federal	—	—
State	—	—
Total deferred income tax expense	—	—
Income tax expense (benefit)	<u>\$ 38</u>	<u>\$ (232)</u>

The difference between the statutory rate for federal income tax and the effective income tax rate was as follows:

	December 31, 2021	December 31, 2020
Current:		
Income taxes at statutory rate	21.0%	21.0%
State taxes, net of federal benefit	—	—
LLC flow-through structure	(21.4)	(21.5)
Federal Credits	1.8	2.3
Provision to return adjustment	—	0.2
Change in valuation allowance	(1.3)	(1.1)
Other	(0.2)	—
Effective income tax rate	<u>(0.1)%</u>	<u>0.9%</u>

Components of the Company's deferred tax assets and liabilities included in the consolidated balance sheet consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Deferred tax assets:		
Accrued bonus	\$ 376	\$ 243
Fixed assets	—	108
Federal credit carryforwards	939	331
Leases	28	—
Start-up costs	39	48
Deferred tax assets before valuation allowance	1,382	730
Valuation allowance	1,237	560
Total deferred tax assets	<u>145</u>	<u>170</u>
Deferred tax liabilities:		
Intangible assets	90	148
Fixed assets	47	—
Prepaid expenses	8	22
Total deferred tax liabilities	<u>145</u>	<u>170</u>
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

[Table of Contents](#)

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, available taxes in the carryback periods, projected future taxable income and tax planning strategies in making this assessment. Accordingly, the Company has provided a valuation allowance of \$1,237,000 and \$560,000 respectively for December 31, 2021 and 2020, to offset the net deferred tax assets.

The Company has \$1,118,000 in Research Credit Carryforwards that begin to expire in 2040.

A reconciliation of the beginning and ending amount of total unrecognized tax benefits for the years ended December 31, 2021 and 2020 consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Unrecognized tax benefits (gross):		
Benefits at the beginning of the year	\$ —	\$ —
Increase related to prior year tax positions	94	—
Decrease related to prior year tax positions	—	—
Increase related to current year tax positions	86	—
Benefits at the end of the year	<u>\$ 180</u>	<u>\$ —</u>

There are no net unrecognized tax benefits as of December 31, 2021 which, if recognized, would affect our effective tax rate. We expect none of the gross unrecognized tax benefits will decrease within the next year.

In March 2020, the World Health Organization declared coronavirus (COVID-19) a global pandemic. This contagious disease outbreak, which continued to spread, and the related adverse public health developments, have adversely affected work forces, economies and financial markets globally. As a result, governments around the world have enacted legislation to provide aid and stimulate economies. In the U.S., The Coronavirus, Aid, Relief and Economic Security Act (“CARES Act”), was enacted on March 27, 2020, The Consolidated Appropriations Act, 2021 was enacted on December 27, 2020, and the American Rescue Plan Act of 2021 was enacted on March 11, 2021. All of these acts included both income tax and non-income tax provisions to assist companies. No provisions in these acts had a material impact on the income tax provision or any other area of the Company’s financial statements.

Tax years 2018 through 2021 remain subject to examination by federal and state authorities.

Note 4: Leases

In February 2016, the FASB issued ASU 2016-02: Leases (Topic 842). This ASU requires a lessee to recognize a right-of-use asset and a lease liability on its balance sheet for most operating leases. ASU 2016-02 is effective for annual and interim periods beginning after December 15, 2018, including interim periods within those fiscal years. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which provides companies with an additional optional transition method to apply the new standard to leases in effect at the adoption date through a cumulative effect adjustment. The Company adopted the new lease standard as of January 1, 2021 using the modified retrospective transition method.

The Company elected the package of practical expedients referenced in ASU 2016-02, which permits companies to retain original lease identification and classification without reassessing initial direct costs for existing leases. The Company also elected the practical expedient that exempts leases with an initial lease term of 12 months or less, as well as the practical expedient that allows companies to select, by class of underlying asset,

[Table of Contents](#)

not to separate lease and non-lease components. Adoption of this standard resulted in the recognition of a right-of-use asset and a lease liability on the Company's January 1, 2021 Consolidated Balance Sheet of \$1,560,000 and \$1,559,000 respectively. There was no material impact on the Company's Consolidated Statement of Comprehensive Loss.

The Company has operating leases for real estate (primarily office space) and certain equipment with various expiration dates. The Company also has one finance lease for certain equipment. Rent expense was \$434,000 and \$314,000, for the years ended December 31, 2021 and 2020, respectively.

The following table summarizes the classification of operating and finance lease assets and obligations in the Company's Consolidated Balance Sheets as of December 31, 2021 and December 31, 2020 (in thousands):

	December 31, 2021	December 31, 2020
Operating leases:		
Right of use assets	\$ 1,139	\$ 1,415
Operating lease liabilities, current	235	195
Operating lease liabilities, noncurrent	985	1,219
Total operating lease liabilities	<u>\$ 1,220</u>	<u>\$ 1,414</u>
Finance leases:		
Right of use assets	\$ 102	\$ 145
Finance lease liabilities, current	32	30
Finance lease liabilities, noncurrent	82	115
Total finance lease liabilities	<u>\$ 114</u>	<u>\$ 145</u>

Maturities of lease liabilities for the Company's operating and finance leases are as follows for the year ending December 31, 2021 (in thousands):

	Operating Leases	Finance Leases	Total
2022	\$ 326	\$ 40	\$ 366
2023	332	40	372
2024	341	40	381
2025	282	7	289
2026	180	—	180
Thereafter	—	—	—
Total lease payments	1,461	127	1,588
Less: imputed interest	(241)	(13)	(254)
Present value of lease liabilities	<u>\$ 1,220</u>	<u>\$ 114</u>	<u>\$1,334</u>

The weighted average remaining lease term for operating leases is 4.4 years, and 3.3 years for the finance lease. The weighted average discount rate is 8.5%.

Note 5: Members' Equity

Ownership interests in the Company are represented by two classes of units, Class A Units and Class B Units. The terms of the units are governed by the LLC Agreement. As of December 31, 2021, there were 190,000,000 Class A and 10,000,000 Class B Units authorized.

[Table of Contents](#)

Holders of Class A Units have voting rights and rights to profits and losses of the Company and distributions from the Company. The following is a summary of the activity of the Class A Units:

Units outstanding January 1, 2020	95,000,000
Issued 2020	20,000,000
Units outstanding December 31, 2020	115,000,000
Issued 2021	71,500,000
Units outstanding December 31, 2021	186,500,000

The Class B Units are reserved for issuance of Profits Interests and do not have voting rights. The Profits Interests are designed so that the holders of Profits Interests only participate in a qualified distribution event and only if its valuation threshold is attained in such a distribution event as set forth in the Limited Partnership Agreement; provided, however, that the Limited Partnership Agreement (as amended and restated on January 17, 2022 as contemplated by Note 8 below) provides that certain qualified distribution events will result in the holders of Profits Interests receiving disproportionate distributions from ProKidney until each such holder's threshold value has been reduced to zero in order to "catch up" such holder's distributions to its pro rata share of aggregate cumulative distributions, and once sufficient distributions to a holder of Profits Interests have been made in accordance with the foregoing, the associated Class B Units will automatically be converted into Class A Units.

Note 6: Net Loss per Share

Basic loss per share ("EPS") was computed by dividing net loss by the number of weighted average units of Class A Units outstanding during the period. Diluted EPS was calculated to give effect to potentially issuable dilutive units of common units using the treasury method. For all periods presented, the vested Profits Interests have been excluded from the diluted EPS calculation as their effect would be anti-dilutive. The following table sets forth the calculation of basic and diluted earnings per share for the periods indicated based on the weighted average number of common shares outstanding:

	Years Ended December 31,	
	2021	2020
Numerator		
Net loss available to Class A Unit holders	\$ (55,146)	\$ (26,749)
Denominator		
Weighted average Class A Units outstanding, basic and diluted	150,706,849	104,986,301
Net loss per Class A Unit		
Net loss per Class A Unit, basic and diluted	\$ (0.37)	\$ (0.25)

Note 7: Equity Based Compensation

The issuance of Profits Interests to employees, directors, and other service providers of the Company ("Plan Participants") is administered at the discretion of ProKidney GP Limited, the general partner of ProKidney (the "General Partner"). Profits Interests allow the Plan Participants to participate in the residual profits of the Company after the distribution of proceeds reach a minimum threshold value. The threshold value is the amount of proceeds that must be distributed to the holders of Class A Units before the Plan Participants can participate in a distribution.

[Table of Contents](#)

Under the Limited Partnership Agreement, the General Partner determines the terms and conditions of the Profits Interests issued. The threshold value assigned to each grant shall not be less than the fair market value of the Company on the date of grant. Profits Interests awards vest at a rate of 25% on the latter of the first anniversary of employment and the first anniversary of the Acquisition Date with the remaining 75% to vest in increments of 25% on each anniversary following the first anniversary date or in increments of 6.25% each calendar quarter following the first anniversary date. The Profits Interests are subject to a repurchase option should the plan participant no longer be employed by the Company.

Under the Limited Partnership Agreement (prior to its amendment and restatement on January 17, 2022), there are 10,000,000 Class B Units authorized for issuance.

The following table summarizes the activity related to the Company's Profits Interest awards for the year ended December 31, 2021:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Awards outstanding at December 31, 2020	4,402,398	\$ 0.36
Vested	(1,941,781)	0.36
Awards outstanding at December 31, 2021	<u>2,460,617</u>	<u>\$ 0.36</u>

No Class B Units were granted to employees during the year ended December 31, 2021. As of December 31, 2021, 2,232,878 Class B Units remained unissued. Given that these instruments meet the criteria for being considered profits interest, the Company has recognized no tax benefit related to these awards.

During the years ended December 31, 2021 and 2020, respectively, the Company recognized equity-based compensation expense of \$699,000 and \$730,000.

As of December 31, 2021, the unrecognized compensation expense was \$868,000. The current weighted average remaining period over which the unrecognized compensation expense is expected to be recognized is 1.4 years. The weighted average grant date fair value of the Profits Interests granted during the year ended December 31, 2020 was \$0.36 per Class B unit.

Fair Value Estimate

The Company is privately held with no active public market for its equity instruments. Therefore, for financial reporting purposes, management may periodically determine the estimated per share fair value of the Company's equity shares (including Profits Interests) using contemporaneous valuations. These contemporaneous valuations are done using methodologies consistent with the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, also known as the Practice Aid.

The valuation approach utilized the Option Pricing Method (OPM), where the fair value of the total equity of the Company within each scenario is first estimated using a back-solve method wherein the equity value is derived from a recent transaction in the Company's own securities, and then the total equity value is allocated to the various components of the capital structure, including the Profits Interests, using an OPM or a waterfall approach based on the specific rights of each of the equity classes. The OPM uses the fair value of the total equity of the Company within a scenario as a starting point and incorporates assumptions made regarding the expected returns and volatilities that are consistent with the expectations of market participants, and distribution of equity values is produced which cover the range of events that an informed market participant might expect.

[Table of Contents](#)

This process creates a range of equity values both between and within scenarios. The fair value measurement is sensitive to changes in the unobservable inputs. Changes in those inputs might result in a higher or lower fair value measurement.

In performing these valuations, management considered all objective and subjective factors that they believed to be relevant, including management's best estimate of the Company business condition, prospects, and operating performance at each valuation date. Within the valuations performed, a range of factors, assumptions, and methodologies were used. The significant factors included trends within the industry, the prices at which the Company sold Class A Units, the rights and preferences of the Class A Units relative to the Class B Units at the time of each measurement date, the results of operations, financial position, status of research and development efforts, stage of development and business strategy, the lack of an active public market for the units, and the likelihood of achieving an exit event in light of prevailing market conditions.

The following reflects the key assumptions used in the OPM valuation:

Total equity value (in thousands)	\$ 78,100
Expected volatility of total equity	80%
Discount for lack of market	30%
Expected time to exit event	3 years

Note 8: Subsequent Events

On January 17, 2022, the Company amended and restated its Limited Partnership Agreement (the "Amended and Restated Limited Partnership Agreement") in part to authorize the issuance of up to 50,000,000 Class B Units (including Class B-1 Units). Upon authorization of these units, the Company issued Profits Interests to certain Plan Participants in the form of 8,498,488 Class B-1 Units. Additionally, the Company issued 8,848,901 of its Class B-1 Units for total value received by the Company (or its subsidiaries) of \$8,052,000.

The Amended and Restated Limited Partnership Agreement provides that certain qualified distribution events will result in holders of Profits Interests receiving disproportionate distributions from ProKidney until each such holder's valuation threshold has been reduced to zero in order to "catch up" such holder's distributions to its pro rata share of aggregate cumulative distributions, and once sufficient distributions to a holder of Profits Interests have been made in accordance with the foregoing, the associated Class B Units will automatically be converted into Class A Units.

On January 18, 2022, the Company executed a definitive business combination agreement (the "Business Combination Agreement"), with Social Capital Suvretta Holdings Corp. III ("SCS"). Under the terms of the Business Combination Agreement, the Company will become a subsidiary of SCS and will be organized in an umbrella partnership corporation ("Up-C") structure, which provides potential future tax benefits for SCS when the equity holders ultimately exchange their pass-through interests for Class A ordinary shares in SCS.

On January 18, 2022, in connection with the Business Combination Agreement, the Company entered into two promissory note agreements with certain of its existing holders. Through such promissory notes, the existing holders may fund up to \$100,000,000 to support the operational financing needs of the Company prior to the closing of the Business Combination. The Company has borrowed \$20,000,000 against these promissory notes subsequent to December 31, 2021.

ProKidney LP and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 29,802	\$ 20,558
Prepaid assets	592	588
Prepaid clinical	4,855	6,100
Other current assets	—	25
Total current assets	35,249	27,271
Fixed assets, net	11,103	11,358
Right of use assets, net	1,673	1,241
Deferred offering costs	5,108	—
Intangible assets, net	374	428
Total assets	<u>\$ 53,507</u>	<u>\$ 40,298</u>
Liabilities and Equity		
Current liabilities		
Accounts payable	\$ 2,509	\$ 2,834
Lease liabilities	328	267
Accrued expenses and other	8,117	9,213
Income taxes payable	958	—
Related party notes payable	20,000	—
Total current liabilities	31,912	12,314
Lease liabilities, net of current portion	1,428	1,067
Members' equity:		
Class A Units (186,500,000 issued and outstanding as of March 31, 2022 and December 31, 2021)	186,500	186,500
Class B Units (17,354,894 and 7,767,122 issued and outstanding as of March 31, 2022 and December 31, 2021, respectively)	62,663	1,927
Accumulated deficit	(228,996)	(161,510)
Total members' equity	20,167	26,917
Total liabilities and equity	<u>\$ 53,507</u>	<u>\$ 40,298</u>

(The accompanying notes are an integral part of the consolidated financial statements.)

ProKidney LP and Subsidiaries
Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except for share and per share data)

	<u>Three Months Ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Revenue	\$ —	\$ —
Operating expenses		
Research and development	28,490	9,859
General and administrative	37,972	1,744
Total operating expenses	66,462	11,603
Operating loss	(66,462)	(11,603)
Interest expense	(14)	—
Net loss before income taxes	(66,476)	(11,603)
Income tax expense	1,010	6
Net and comprehensive loss	<u>\$ (67,486)</u>	<u>\$ (11,609)</u>
Weighted average Class A Units outstanding:		
Basic and diluted	186,500,000	122,111,111
Net loss per Class A Unit:		
Basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.10)</u>

(The accompanying notes are an integral part of the consolidated financial statements.)

ProKidney LP and Subsidiaries
Unaudited Condensed Consolidated Statements of Changes in Members' Equity
(in thousands, except for share data)

For the three months ended March 31, 2022

	Class a		Class B		Accumulated Deficit	Total Members' Equity
	Units	Amounts	Profits	Interests		
Balance as of December 31, 2021	186,500,000	\$186,500	\$ 1,927		\$ (161,510)	\$ 26,917
Capital contribution	—	—	5,550		—	5,550
Equity-based payments	—	—	55,186		—	55,186
Net loss	—	—	—		(67,486)	(67,486)
Balance as of March 31, 2022	<u>186,500,000</u>	<u>\$186,500</u>	<u>\$ 62,663</u>		<u>\$ (228,996)</u>	<u>\$ 20,167</u>

For the three months ended March 31, 2021

	Class A		Class B		Accumulated Deficit	Total Members' Equity
	Units	Amounts	Profits	Interests		
Balance as of December 31, 2020	115,000,000	\$115,000	\$ 1,228		\$ (106,364)	\$ 9,864
Capital contribution	20,000,000	20,000	—		—	20,000
Equity-based payments	—	—	175		—	175
Net loss	—	—	—		(11,609)	(11,609)
Balance as of March 31, 2021	<u>135,000,000</u>	<u>\$135,000</u>	<u>\$ 1,403</u>		<u>\$ (117,973)</u>	<u>\$ 18,430</u>

(The accompanying notes are an integral part of the consolidated financial statements.)

ProKidney LP and Subsidiaries
Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (67,486)	\$ (11,609)
Adjustments to reconcile net loss to net cash flows		
Depreciation and amortization	710	361
Equity-based compensation expense	52,684	175
Changes in operating assets and liabilities		
Other assets	(3,843)	249
Accounts payable and accrued expenses	1,519	3,568
Income taxes payable	957	—
Net cash flows used in operating activities	(15,459)	(7,256)
Cash flows used in investing activities		
Purchase of equipment and facility expansion	(839)	(1,389)
Net cash flows used in investing activities	(839)	(1,389)
Cash flows from financing activities		
Payments on finance leases	(8)	(7)
Borrowings under related party notes payable	20,000	—
Net cash contribution	5,550	20,000
Net cash flows provided by financing activities	25,542	19,993
Net change in cash and cash equivalents	9,244	11,348
Cash, beginning of period	20,558	4,577
Cash, end of period	<u>\$ 29,802</u>	<u>\$ 15,925</u>
Supplemental disclosure of non-cash investing activities:		
Right of use assets obtained in exchange for lease obligations	<u>\$ 496</u>	<u>\$ —</u>
Equipment and facility expansion included in accounts payable and accrued expenses	<u>\$ 501</u>	<u>\$ 910</u>

(The accompanying notes are an integral part of the consolidated financial statements.)

ProKidney LP and Subsidiaries
Notes to Unaudited Consolidated Financial Statements
Three Months Ended March 31, 2022 and 2021

Note 1: The Company

ProKidney LLC was formed as a Bermuda limited liability company on December 12, 2018 and funded with \$75,000,000 on December 31, 2018. On January 9, 2019 (the “Acquisition Date”), ProKidney LLC acquired all of the equity interests in inRegen and Twin City Bio LLC (“TC Bio”) for \$62,000,000. inRegen was duly incorporated under the Cayman Islands Companies Act (as amended) on December 21, 2015 as an exempted company. During 2020, inRegen’s name was changed to ProKidney (and is referred to herein as “ProKidney-KY”), and TC Bio’s name was changed to ProKidney, LLC (and is referred to herein as “ProKidney-US”). ProKidney-US was formed as a limited liability company under the laws of Delaware on December 18, 2015. In August 2021, ProKidney LP was organized as a limited partnership under the laws and regulations of Ireland, with ProKidney LLC becoming a wholly owned subsidiary of ProKidney LP (and is referred to herein as “ProKidney”). Following this reorganization on August 5, 2021, and for the purposes of these financial statements, the term “ProKidney” as used herein, refers to ProKidney LP following this reorganization, and the financial information presented herein is that of ProKidney LP and its wholly owned subsidiaries.

ProKidney acquired the equity interests in ProKidney-KY to develop its Renal Advanced Cell Therapy, which has the potential to stabilize or improve renal function in patients with chronic kidney disease or delay or eliminate the need for dialysis and organ transplantation. ProKidney acquired ProKidney-US to provide contractual development and manufacturing services to ProKidney-KY, which is ProKidney-US’s only customer.

Because ProKidney is a limited partnership, the debts, obligations and liabilities of the Company (as defined below), whether arising in contract, tort or otherwise, are solely the debts, obligations and liabilities of the Company, and no holder of equity interests in ProKidney (“members’ equity”) is obligated personally for any such debt, obligation or liability of the Company solely by reason of being a holder of members’ equity.

On January 18, 2022, the Company executed a definitive business combination agreement (the “Business Combination Agreement”), with Social Capital Suvretta Holdings Corp. III (“SCS”). Under the terms of the Business Combination Agreement, the Company will become a subsidiary of SCS and will be organized in an umbrella partnership corporation (“Up-C”) structure, which provides potential future tax benefits for SCS when the equity holders ultimately exchange their pass-through interests for Class A ordinary shares in SCS.

Note 2: Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements reflect the operations of ProKidney and its wholly-owned subsidiaries consisting of ProKidney-KY and ProKidney-US (together, the “Company”). All intercompany transactions and accounts have been eliminated.

These unaudited condensed consolidated financial statements have been prepared on the same basis as the Company’s annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of the Company’s financial information. These interim results and cash flows for any interim period are not necessarily indicative of the results to be expected for the full year. Any reference in these notes to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the United States of America (GAAP) as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB). These unaudited consolidated financial statements are presented in U.S. Dollars.

Going Concern

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company performed an analysis of its ability to continue as a going concern. As of March 31, 2022, the Company had an accumulated deficit of \$228,996,000. The Company has generated losses from operations for each year since its inception. The Company intends to continue to conduct significant additional research, development, and clinical study activities which, together with expenses incurred for general and administrative expenses, are expected to result in continuing operating losses for the foreseeable future. The amount of future losses and when, if ever, the Company will achieve profitability are uncertain. The Company's ability to achieve profitability will depend, among other things, on successfully completing clinical studies, obtaining requisite regulatory approvals, establishing appropriate pricing for its product with payers, and raising sufficient funds to finance the Company's activities. No assurance can be given that the Company's clinical development efforts will be successful, that regulatory approvals will be obtained, or that the Company will be able to achieve appropriate pricing and market access or that profitability, if achieved, can be sustained.

These matters raise substantial doubt about the Company's ability to continue as a going concern. As of March 31, 2022, the Company has cash and cash equivalents of \$29,802,000, and remaining availability of \$80,000,000 under its two promissory note agreements with certain holders of its Class A Units (the "Promissory Notes"). The Company believes that these sources of liquidity will not be sufficient to fund its obligations for the next twelve months. The condensed consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

Our ability to execute our operating plan depends on our ability to obtain additional funding through equity offerings, debt financings or potential licensing and collaboration arrangements. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. Even if we raise additional capital, we may also be required to modify, delay or abandon some of our plans which could have a material adverse effect on our business, operating results and financial condition and our ability to achieve our intended business objectives.

Use of Estimates

The preparation of condensed consolidated financial statements, in accordance with GAAP, requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the amounts of expenses during the reported periods. Certain estimates in these condensed consolidated financial statements have been made in connection with the calculation of research and development expenses, equity-based compensation expense and the provision for or benefit from income taxes. The Company bases its estimates on historical experience and various other assumptions, including in certain circumstances future projections, which management believes to be reasonable under the circumstances. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less on the date of purchase to be cash equivalents. The carrying value of cash and cash equivalents approximates fair value due to the short-term nature of these items.

Concentrations of Credit Risk

Cash and equivalents are financial instruments that are potentially subject to concentrations of credit risk. The Company's cash and equivalents are deposited in accounts at large financial institutions, and amounts may exceed federally insured limits.

[Table of Contents](#)

Accrued Expenses

Accrued expenses as presented in the Condensed Consolidated Balance Sheets as of March 31, 2022 and December 31, 2021 consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Compensation	\$ 818	\$ 1,832
Clinical study related costs	653	2,031
Accrued legal	3,095	964
Manufacturing improvement costs	3,137	4,164
Other accrued expenses	414	222
Total accrued expenses and other	<u>\$ 8,117</u>	<u>\$ 9,213</u>

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, benefits, third party license fees, and external costs of outside vendors engaged to conduct manufacturing and preclinical development activities and clinical trials.

The Company records accruals based on estimates of services received, efforts expended, and amounts owed pursuant to contracts with numerous contract research organizations. In the normal course of business, the Company contracts with third parties to perform various clinical study activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events and the completion of portions of the clinical study or similar conditions. The objective of the Company's accrual policy is to match the recording of expenses in its financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical studies are recognized based on the Company's estimate of the degree of completion of the event or events specified in the specific clinical study.

The Company records nonrefundable advance payments it makes for future research and development activities as prepaid expenses. Prepaid expenses are recognized as expense in the Condensed Consolidated Statement of Operations and Comprehensive Loss as the Company receives the related goods or services.

Costs incurred in obtaining technology licenses are charged to research and development expense as purchased in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use.

Fixed Assets

Fixed assets are stated at cost, less accumulated depreciation. Generally, expenditures for maintenance and repairs are charged to expense and major improvements or replacements are capitalized. The Company computes depreciation and amortization using the straight-line method over the estimated useful life of the asset. Leasehold improvements are amortized over the lesser of, the life of the lease or the estimated useful life of the leasehold improvement. The estimated useful lives are as follows:

Computer equipment and software	3-5 years
Furniture and equipment	5-7 years
Leasehold improvements	remainder of lease term

[Table of Contents](#)

Fixed assets consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Furniture and equipment	\$ 2,220	\$ 2,180
Computer equipment and software	589	569
Leasehold improvements	10,520	10,517
Construction in progress	631	351
Less: accumulated depreciation	(2,857)	(2,259)
Total fixed assets, net	<u>\$ 11,103</u>	<u>\$ 11,358</u>

Depreciation expense for the three months ended March 31, 2022 and 2021 was \$593,000 and \$176,000, respectively.

Intangible Assets

Intangible assets are comprised of acquired assembled workforce, which are accounted for in accordance with ASC 350—Intangibles—Goodwill and Other. The acquired assembled workforce is amortized on a straight-line basis over the useful life of five years. The following table summarizes information related to the Company's assembled workforce intangible asset (in thousands):

	March 31, 2022	December 31, 2021
Gross carrying amount	\$ 1,073	\$ 1,073
Accumulated amortization	699	645
Net carrying amount	<u>\$ 374</u>	<u>\$ 428</u>

Estimated amortization expense for the remaining nine months of 2022 is \$154,000, \$215,000 for the year ended December 31, 2023 and \$5,000 for the year ended December 31, 2024. Amortization expense relating to the assembled workforce intangible asset was \$54,000 for each of the three months ended March 31, 2022 and 2021.

Impairment of Long-Lived Assets

Long-lived assets such as fixed assets and intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. No impairment charges have been recorded for the three months ended March 31, 2022 or 2021.

Income Taxes

The Company was organized as a limited liability company, is now a limited partnership and is classified as a partnership for U.S. income tax purposes, and as such, only records a provision for federal and state income taxes on its subsidiaries organized as C corporations or which have elected to be treated as corporations for U.S. federal income tax purposes. ProKidney-US is a limited liability company and has elected to be treated as a C corporation. Therefore, a provision for federal and state taxes has been recorded. ProKidney-KY has been granted, by the Government in Council of the Cayman Islands, tax concessions under an undertaking certificate exempting it from any tax levied on profits, income, gains or appreciations in relation to its operations or in the nature of estate duty or inheritance tax for a period of twenty years from January 20, 2016. ProKidney-KY elected to be treated as an entity disregarded from its owner for U.S. tax purposes, and as a result, it has not recorded an income tax provision.

[Table of Contents](#)

The Company uses the liability method in accounting for income taxes as required by ASC Topic 740 — Income Taxes, under which deferred tax assets and liabilities are recorded for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is recorded to reduce the carrying amounts of deferred tax assets unless it is more likely than not that such assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, available taxes in the carryback periods, projected future taxable income and tax planning strategies in making this assessment. Accordingly, the Company has provided a full valuation allowance to offset the net deferred tax assets at March 31, 2022 and December 31, 2021.

Interest and penalties related to income taxes are included in the benefit (provision) for income taxes in the Company's Condensed Consolidated Statements of Operations and Comprehensive Loss. The Company has not incurred any significant interest or penalties related to income taxes in any of the periods presented.

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. A three-level fair value hierarchy that prioritizes the inputs used to measure fair value is described below. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities
- Level 2 – Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable through correlation with market data
- Level 3 – Unobservable inputs that are supported by little or no market data, which require the reporting entity to develop its own assumptions

The carrying values of cash equivalents, accounts payable, and accrued liabilities approximate fair value due to the short-term nature of these instruments.

Leases

The Company determines if an arrangement is a lease at inception. Balances recognized related to the Company's operating and finance leases are included in right-of-use assets, net and lease liabilities in the Condensed Consolidated Balance Sheets. Right of use assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Lease terms may include options to extend or terminate the lease if it is reasonably certain that the Company will exercise the option. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of future payments. The right of use asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The Company has elected a practical expedient to not separate its lease and non-lease components and instead account for them as a single lease component. Leases with a term of 12 months or less are not recorded on the balance sheet.

Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Lease payments for short-term leases are recorded to operating expense on a straight-line basis and variable lease payments are recorded in the period in which the obligation for those payments is incurred.

[Table of Contents](#)

Contingent Liabilities

The Company records reserves for contingent liabilities when it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements, and the amount of the loss can be reasonably estimated.

Equity-Based Compensation

The Deed for the Establishment of a Limited Partnership of ProKidney LP, dated as of August 5, 2021 (the “Limited Partnership Agreement”) which replaced the Amended and Restated Limited Liability Company Agreement of ProKidney LLC as the governing document of the parent entity in the Company, allows for the issuance of Profits Interests (as defined in the Limited Partnership Agreement) to employees, directors, other service providers of the Company and others denominated in the form of one or more Class B Units (as defined in the Limited Partnership Agreement).

On January 17, 2022, the Company amended and restated its Limited Partnership Agreement (the “Amended and Restated Limited Partnership Agreement”) in part to authorize the issuance of up to 50,000,000 Class B Units (including Class B-1 Units). The Amended and Restated Limited Partnership Agreement provides that certain qualified distribution events will result in holders of Profits Interests receiving disproportionate distributions from ProKidney until each such holder’s valuation threshold has been reduced to zero in order to “catch up” such holder’s distributions to its pro rata share of aggregate cumulative distributions, and once sufficient distributions to a holder of Profits Interests have been made in accordance with the foregoing, the associated Class B Units will automatically be converted into Class A Units.

The Company measures compensation expense for Profits Interests based on estimated fair values at the time of grant. The Company estimates the fair value of Profits Interests using generally accepted valuation procedures. The Company recognizes compensation expense, on a straight-line basis, for the portion of the Profits Interests’ value that is expected to vest over the requisite service period. The Company records forfeitures of Profits Interests as they occur.

Segments

The Company operates in only one segment.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which requires lessees to recognize a right-of-use asset and a liability on the balance sheet for all leases, with the exception of short-term leases. The lease liability will be equal to the present value of lease payments, and the right-of-use asset will be based on the lease liability, subject to adjustment such as for initial direct costs. Leases will continue to be classified as either operating or finance leases in the income statement. The guidance is effective for annual periods beginning after December 15, 2021, with early adoption permitted. The Company early adopted ASU No. 2016-02, Leases (Topic 842), as of January 1, 2021. For additional detail, see Note 4, Leases.

Subsequent Events

The Company has evaluated subsequent events through June 10, 2022, which is the date the consolidated financial statements were available to be issued. See additional information in Note 9.

Note 3: Income Taxes

The Company’s subsidiary, ProKidney-US, is treated as a C corporation, and therefore a provision for federal and state taxes has been recorded. The Company’s income tax provision for the three months ended March 31, 2022 and 2021 were \$1,010,000 and \$6,000, respectively.

[Table of Contents](#)

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, available taxes in the carryback periods, projected future taxable income and tax planning strategies in making this assessment. The difference between the Company's effective tax rate of (1.5)% for the three months ended March 31, 2022 and the U.S. statutory rate of 21% is primarily attributable to the Company and ProKidney-KY being treated as partnerships for income tax purposes.

For tax years beginning after December 31, 2021, the Tax Cuts and Jobs Act of 2017 (the "TCJA") requires specified research and development expenses to be capitalized and amortized ratably over a five-year period. The adoption of this provision of the TCJA is the primary driver of income tax expense recognized during the three months ended March 31, 2022.

There are no net unrecognized tax benefits as of March 31, 2022 which, if recognized, would affect our effective tax rate. We expect none of the gross unrecognized tax benefits will decrease within the next year.

There have been no significant changes in the Company's uncertain tax positions during the three months ended March 31, 2022.

Note 4: Leases

In February 2016, the FASB issued ASU 2016-02: Leases (Topic 842). This ASU requires a lessee to recognize a right-of-use asset and a lease liability on its balance sheet for most operating leases. ASU 2016-02 is effective for annual and interim periods beginning after December 15, 2018, including interim periods within those fiscal years. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which provides companies with an additional optional transition method to apply the new standard to leases in effect at the adoption date through a cumulative effect adjustment. The Company adopted the new lease standard as of January 1, 2021 using the modified retrospective transition method.

The Company elected the package of practical expedients referenced in ASU 2016-02, which permits companies to retain original lease identification and classification without reassessing initial direct costs for existing leases. The Company also elected the practical expedient that exempts leases with an initial lease term of twelve months or less, as well as the practical expedient that allows companies to select, by class of underlying asset, not to separate lease and non-lease components. Adoption of this standard resulted in the recognition of a right-of-use asset and a lease liability on the Company's January 1, 2021 Consolidated Balance Sheet of \$1,560,000 and \$1,559,000 respectively. There was no material impact on the Company's Condensed Consolidated Statement of Operations and Comprehensive Loss.

The Company has operating leases for real estate (primarily office space) and certain equipment with various expiration dates. The Company also has one finance lease for certain equipment. Rent expense was \$89,000 and \$81,000, for the three months ended March 31, 2022 and 2021, respectively.

[Table of Contents](#)

The following table summarizes the classification of operating and finance lease assets and obligations in the Company's Condensed Consolidated Balance Sheets as of March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Operating leases:		
Right of use assets	\$ 1,579	\$ 1,139
Operating lease liabilities, current	295	235
Operating lease liabilities, noncurrent	1,354	985
Total operating lease liabilities	<u>\$ 1,649</u>	<u>\$ 1,220</u>
Finance leases:		
Right of use assets	\$ 94	\$ 102
Finance lease liabilities, current	\$ 33	\$ 32
Finance lease liabilities, noncurrent	74	82
Total finance lease liabilities	<u>\$ 107</u>	<u>\$ 114</u>

Maturities of lease liabilities for the Company's operating and finance leases are as follows for the year ending March 31, 2022 (in thousands):

	Operating Leases	Finance Leases	Total
2022 (remaining nine months)	\$ 315	\$ 30	\$ 345
2023	428	40	468
2024	440	40	480
2025	440	7	447
2026	355	—	355
Thereafter	15	—	15
Total lease payments	1,993	117	2,110
Less: imputed interest	(344)	(10)	(354)
Present value of lease liabilities	<u>\$ 1,649</u>	<u>\$ 107</u>	<u>\$1,756</u>

The weighted average remaining lease term for operating leases is 4.5 years, and 3.0 years for the finance lease. The weighted average discount rate is 8.5%.

Note 5: Related Party Debt

On January 18, 2022, in connection with the Business Combination Agreement, the Company entered into the Promissory Notes. Through such promissory notes, the holders may fund up to \$100,000,000 to support the operational financing needs of the Company prior to the closing of the Business Combination. These notes bear interest at a rate of 3% per annum and are due upon the earliest of either (i) the date on which the Business Combination closes or (ii) January 17, 2023.

Drawdowns on the Promissory Notes may be made in multiples of \$10,000 unless otherwise agreed upon. Once an amount is drawn down under the Promissory Notes, it is no longer available for future drawdown requests even if prepaid.

During the three months ended March 31, 2022, the Company borrowed \$20,000,000 under this agreement, leaving remaining availability of \$80,000,000 as of March 31, 2022.

Note 6: Members' Equity

Ownership interests in the Company are represented by two classes of units, Class A units and Class B units. The terms of the units are governed by the LLC Agreement. As of March 31, 2022, there are 190,000,000 Class A and 50,000,000 Class B Units authorized (including Class B-1 Units).

Holders of Class A units have voting rights and rights to profits and losses of the Company and distributions from the Company. No Class A units were issued during the three months ended March 31, 2022.

During the three months ended March 31, 2022, the Company issued 6,098,901 of its Class B-1 Units for total cash proceeds of \$5,550,000. As these awards were issued for a price below their estimated fair value to employees, board members and other service providers, the provisions of ASC Topic 718 – Stock Compensation apply. Refer to Note 8 for further details.

The Class B Units are reserved for issuance of Profits Interests and do not have voting rights. The Profits Interests are designed so that the holders of Profits Interests only participate in a qualified distribution event and only if its valuation threshold is attained in such a distribution event as set forth in the Limited Partnership Agreement; provided, however, that the Limited Partnership Agreement, as amended and restated in January 2022, provides that certain qualified distribution events will result in the holders of Profits Interests receiving disproportionate distributions from ProKidney until each such holder's threshold value has been reduced to zero in order to "catch up" such holder's distributions to its pro rata share of aggregate cumulative distributions, and once sufficient distributions to a holder of Profits Interests have been made in accordance with the foregoing, the associated Class B Units will automatically be converted into Class A Units.

Note 7: Net Loss per Share

Basic loss per share ("EPS") was computed by dividing net loss by the number of weighted average units of Class A Units outstanding during the period. Diluted EPS was calculated to give effect to potentially issuable dilutive units of common units using the treasury method. For all periods presented, the vested Profits Interests have been excluded from the diluted EPS calculation as their effect would be anti-dilutive. The following table sets forth the calculation of basic and diluted earnings per share for the periods indicated based on the weighted average number of common shares outstanding:

	Three Months Ended March 31,	
	2022	2021
Numerator		
Net loss available to Class A Unit holders	\$ (67,486)	\$ (11,609)
Denominator		
Weighted average Class A Units outstanding, basic and diluted	186,500,000	122,111,111
Net loss per Class A Unit		
Net loss per Class A Unit, basic and diluted	\$ (0.36)	\$ (0.10)

Note 8: Equity Based Compensation*Profits Interests Awards*

The issuance of Profits Interests to employees, directors, and other service providers of the Company ("Plan Participants") is administered at the discretion of ProKidney GP Limited, the general partner of ProKidney (the "General Partner"). Profits Interests allow the Plan Participants to participate in the residual profits of the Company after the distribution of proceeds reach a minimum threshold value. The threshold value is the amount of proceeds that must be distributed to the holders of Class A Units before the Plan Participants can participate in a distribution.

[Table of Contents](#)

Under the Limited Partnership Agreement, the General Partner determines the terms and conditions of the Profits Interests issued. The threshold value assigned to each grant shall not be less than the fair market value of the Company on the date of grant. Profits Interests awards vest at a rate of 25% on the latter of the first anniversary of employment and the first anniversary of the Acquisition Date with the remaining 75% to vest in increments of 25% on each anniversary following the first anniversary date, ratably over a three or four-year period from the date of grant, in annual installments of 33.3% over the three-year period from the date of grant, or in increments of 6.25% each calendar quarter following the first anniversary date. The Profits Interests are subject to a repurchase option should the plan participant no longer be employed by the Company.

The following table summarizes the activity for the three months ended March 31, 2022, related to the Company's Class B and B-1 Units granted as equity awards to its employees, board members and service providers:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested awards outstanding at January 1, 2022	2,460,617	\$ 0.36
Granted	8,498,488	6.03
Vested	(449,486)	0.36
Forfeited	(29,070)	6.03
Unvested awards outstanding at March 31, 2022	<u>10,480,549</u>	<u>\$ 4.94</u>

As of March 31, 2022, the unrecognized compensation expense related to these awards was \$50,020,000. The current weighted average remaining period over which the unrecognized compensation expense is expected to be recognized is 3.6 years. The weighted average grant date fair value of the Profits Interests granted during the three months ended March 31, 2022, was \$6.03 per Class B-1 unit. There were no Profits Interests granted during the three months ended March 31, 2021.

As of March 31, 2022, there remain 22,164,559 Class B Units available for issuance. Given that these instruments meet the criteria for being considered profits interests, the Company has recognized no tax benefit related to these awards.

Modification to Profits Interest Awards

On January 17, 2022, the Limited Partnership Agreement was amended and restated to provide that certain qualified distribution events will result in the holders of Profits Interests receiving disproportionate distributions from ProKidney until each such holder's threshold value has been reduced to zero in order to "catch up" such holder's distributions to its pro rata share of aggregate cumulative distributions, and once sufficient distributions to a holder of Profits Interests have been made in accordance with the foregoing, the associated Class B Units will automatically be converted into Class A Units.

This amendment constitutes a modification to the Class B Units outstanding as of the date of the modification under the provisions of ASC Topic 718. In connection with the modification of its outstanding share-based compensation awards, the Company will recognize total additional compensation expense of \$5,437,000 related to awards granted to its employees. The portion of this additional compensation expense attributable to vested awards of \$3,715,000 was recognized immediately upon modification during the three months ended March 31, 2022.

[Table of Contents](#)

Issuance of Profits Interests to Service Provider

During the three months ended March 31, 2022, the Company issued 2,750,000 fully vested Class B-1 Units to a third party service provider as payment for research and development services provided in prior periods. The Company had previously recognized expense of \$2,502,000 for these services based on the liability related to the services incurred. As the fair value of shares issued to satisfy that obligation was higher than the amount previously expensed, the Company recognized additional research and development expense of \$14,080,000 during the three months ended March 31, 2022.

Purchase of Class B-1 Units

As discussed further in Note 6, certain of the Company's employees, board members and service providers purchased 6,098,901 of its Class B-1 Units for total cash proceeds of \$5,550,000 during the three months ended March 31, 2022. Since these Class B-1 Units were fully vested upon purchase and contain no service requirements, the Company immediately recognized the difference between the purchase price and the estimated fair value for these Class B-1 Units of \$31,226,000 as equity-based compensation expense during the three months ended March 31, 2022.

Compensation Expense

During the three months ended March 31, 2022 and 2021, the Company recognized equity-based compensation expense of \$52,686,000 and \$175,000, respectively.

Compensation expense related to the issuance and purchase of Class B and B-1 Units is included in research and development and general and administrative expense as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	\$ 17,367	\$ —
General and administrative	35,319	175
Total equity-based compensation expense	<u>\$ 52,686</u>	<u>\$ 175</u>

Fair Value Estimate

The Company is privately held with no active public market for its equity instruments. Therefore, for financial reporting purposes, management may periodically determine the estimated per share fair value of the Company's equity shares (including Profits Interests) using contemporaneous valuations. These contemporaneous valuations are done using methodologies consistent with the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, also known as the Practice Aid.

For the Profits Interest Awards granted during the three months ended March 31, 2022, the valuation approach utilized a hybrid method which consists of a combination of an Option Pricing Method (OPM) and a Probability Weighted Expected Return Method (PWERM) approach. Weighting allocations were assigned to the OPM and PWERM methods based upon the expected likelihood of possible future liquidity events, including the Business Combination.

Under the OPM approach, the fair value of the total equity of the Company within each scenario was first estimated using a back-solve method wherein the equity value is derived from a recent transaction in the Company's own securities, and then the total equity value is allocated to the various components of the capital structure, including the Profits Interests, using an OPM or a waterfall approach based on the specific rights of

[Table of Contents](#)

each of the equity classes. The OPM uses the fair value of the total equity of the Company within a scenario as a starting point and incorporates assumptions made regarding the expected returns and volatilities that are consistent with the expectations of market participants, and distribution of equity values is produced which cover the range of events that an informed market participant might expect. This process creates a range of equity values both between and within scenarios. The fair value measurement is sensitive to changes in the unobservable inputs. Changes in those inputs might result in a higher or lower fair value measurement.

The PWERM approach is a scenario-based analysis that estimates the value per share of common stock based on the probability-weighted present value of expected future equity values for the common stock, under various possible future liquidity event scenarios, including the proposed Business Combination, in light of the rights and preferences of each class and series of stock, including the Profits Interests, discounted for a lack of marketability.

In performing these valuations, management considered all objective and subjective factors that they believed to be relevant, including management's best estimate of the Company's business condition, prospects, and operating performance at each valuation date. Within the valuations performed, a range of factors, assumptions, and methodologies were used. The significant factors included trends within the industry, the prices at which the Company sold Class A units, the rights and preferences of the Class A units relative to the Class B units at the time of each measurement date, the results of operations, financial position, status of research and development efforts, stage of development and business strategy, the lack of an active public market for the units, and the likelihood of achieving an exit event in light of prevailing market conditions.

The following reflects the key assumptions used in each of the valuation scenarios:

	<u>OPM</u>	<u>PWERM</u>
Total equity value (in thousands)	\$ 280,400	\$1,750,000
Expected volatility of total equity	95%	60%
Discount for lack of market	30%	15%
Expected time to exit event	3.7 years	0.5 years

Note 9: Subsequent Events

On June 1, 2022, the Company issued Profits Interests to certain Plan Participants in the form of 1,478,590 Class B-1 Units. Additionally, the Company issued 549,451 of its Class B-1 Units for total value received by the Company (or its subsidiaries) of \$500,000.

PROKIDNEY CORP.

Up to 232,530,000 Class A Ordinary Shares

PROSPECTUS

, 2022

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information. You should not assume that the information contained or incorporated by reference in this prospectus is accurate as of any date other than the date of this prospectus. We are not making an offer of these securities in any state where the offer is not permitted.

PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the estimated expenses to be borne by the registrant in connection with the issuance and distribution of the ordinary shares being registered hereby.

<u>Expense</u>	<u>Estimated Amount</u>
Securities and Exchange Commission registration fee	\$ 187,100
Accounting fees and expenses	*
Legal fees and expenses	*
Financial printing and miscellaneous expenses	*
Total	\$ 187,100

* These fees are calculated based on the securities offered and the number of issuances and accordingly cannot be defined at this time.

Item 14. Indemnification of Directors and Officers.

Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our Charter will provide for indemnification of our officers and directors to the maximum extent permitted by law, including for any liability incurred in their capacities as such, except through their own actual fraud, willful default or willful neglect.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is theretofore unenforceable.

Item 15. Recent Sales of Unregistered Securities.***Founder Shares***

On March 2, 2021, the Sponsor paid \$25,000 to cover certain offering and formation costs of SCS in consideration for which the Sponsor received 5,750,000 SCS Class B ordinary shares (the "Founder Shares"). On June 29, 2021, SCS effected a share capitalization with respect to its SCS Class B ordinary shares of 575,000 shares thereof, resulting in the Sponsor holding an aggregate of 6,325,000 Founder Shares. The Founder Shares included an aggregate of up to 825,000 shares that were subject to forfeiture depending on the extent to which the underwriters' over-allotment option was exercised. As a result of the underwriters' election to partially exercise their over-allotment option, a total of 750,000 Founder Shares were no longer subject to forfeiture and 75,000 Founder Shares were forfeited, resulting in an aggregate of 6,250,000 Founder Shares then outstanding. In June 2021, the Sponsor transferred 30,000 Founder Shares to Marc Semigran, M.D., an independent director of SCS. The Founder Shares became ProKidney Class A ordinary shares upon the consummation of the Business Combination.

Such securities were issued in connection with SCS's organization pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act. The Sponsor is an accredited investor for purposes of Rule 501 of Regulation D.

Table of Contents

Subscription Agreements

On the Closing Date, SCS consummated the PIPE Investment, pursuant to which SCS offered and sold to the PIPE Investors, under the Subscription Agreements, an aggregate of 57,480,000 SCS Class A ordinary shares at a price of \$10.00 per share for aggregate gross proceeds of \$574,800,000. The PIPE Investment closed substantially concurrently with the Business Combination. The SCS Class A ordinary shares issued to the PIPE Investors became ProKidney Class A ordinary shares upon consummation of the Business Combination.

The shares issued to the PIPE Investors in the PIPE Investment on the Closing Date were issued pursuant to the exemption from registration under Section 4(a)(2) of the Securities Act and/or Regulation D promulgated under the Securities Act. The PIPE Investors are accredited investors for purposes of Rule 501 of Regulation D.

Item 16. Exhibits and Financial Statements.

(a) *Exhibits.*

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg. Number</u>
2.1†	Business Combination Agreement, dated as of January 18, 2022, by and among ProKidney Corp. (formerly Social Capital Suvretta Holdings Corp. III) and ProKidney LP.		Form 8-K/A (Exhibit 2.1)	01/21/2022	001-40560
3.1	Second Amended and Restated Memorandum and Articles of Association of ProKidney Corp.		Form 8-K (Exhibit 3.1)	07/15/2022	001-40560
5.1	Opinion of Walkers (Cayman) LLP	X			
10.1	Form of Subscription Agreement for Institutional Investors, dated as of January 18, 2022, by and between ProKidney Corp. (formerly Social Capital Suvretta Holdings Corp. III) and the subscriber parties thereto.		Form 8-K/A (Exhibit 10.1)	01/21/2022	001-40560
10.2	Form of Subscription Agreement for Individual Investors, dated as of January 18, 2022, by and between ProKidney Corp. (formerly Social Capital Suvretta Holdings Corp. III) and the subscriber parties thereto.		Form 8-K/A (Exhibit 10.2)	01/21/2022	001-40560
10.3	Sponsor Support Agreement, dated January 18, 2022, by and among ProKidney Corp. (formerly Social Capital Suvretta Holdings Corp. III), SCS Sponsor III LLC, ProKidney LP and the directors and officers named therein.		Form 8-K/A (Exhibit 10.3)	01/21/2022	001-40560
10.4	ProKidney Unitholder Support Agreement, dated January 18, 2022, by and among ProKidney Corp. (formerly Social Capital Suvretta Holdings Corp. III), ProKidney LP and the persons named therein.		Form 8-K/A (Exhibit 10.4)	01/21/2022	001-40560

Table of Contents

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg. Number</u>
10.5+	ProKidney Corp. Employee Stock Purchase Plan.		Form 8-K (Exhibit 10.12)	07/15/2022	001-40560
10.6+	ProKidney Corp. 2022 Incentive Equity Plan.		Form 8-K (Exhibit 10.11)	07/15/2022	001-40560
10.7+	Form of Indemnification Agreement.		Form 8-K (Exhibit 10.13)	07/15/2022	001-40560
10.8	Amended and Restated Registration Rights Agreement, dated as of July 11, 2022, by and among ProKidney Corp. (formerly Social Capital Suvretta Holdings Corp. III), SCS Sponsor III LLC and certain of their securityholders.		Form 8-K (Exhibit 10.4)	07/15/2022	001-40560
10.9	Lock-up Agreement, dated July 11, 2022, by and among ProKidney Corp. (formerly Social Capital Suvretta Holdings Corp. III), SCS Sponsor III LLC and certain holders.		Form 8-K (Exhibit 10.3)	07/15/2022	001-40560
10.10	Second Amended and Restated Limited Partnership Agreement for a Limited Partnership Called ProKidney LP, dated July 11, 2022, by and among ProKidney Corp. (formerly Social Capital Suvretta Holdings Corp. III), ProKidney Corp. GP Limited, ProKidney GP Limited, and the limited partners named therein		Form 8-K (Exhibit 10.5)	07/15/2022	001-40560
10.11	Tax Receivable Agreement, dated July 11, 2022, by and among ProKidney Corp. (formerly Social Capital Suvretta Holdings Corp. III), TRA Party Representative, and other parties named therein.		Form 8-K (Exhibit 10.1)	07/15/2022	001-40560
10.12	Exchange Agreement, by and among ProKidney Corp. (formerly Social Capital Suvretta Holdings Corp. III), ProKidney LP, and certain holders named therein.		Form 8-K (Exhibit 10.2)	07/15/2022	001-40560
10.13	Master Services Agreement, dated February 15, 2021, by and between George Clinical PTY Limited and ProKidney (formerly RegenMed (Cayman) Ltd.)	X			
10.14	Research, Development, Engineering Services and License Memorandum and Agreement, dated January 16, 2022, by and between ProKidney (formerly RegenMed (Cayman) Ltd.) and DEKA Products Limited Partnership	X			

Table of Contents

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg. Number</u>
10.15	Master Services Agreement, dated April 20, 2020, by and between IQVIA RDS Inc. and ProKidney (formerly RegenMed (Cayman) Ltd.)	X			
10.16	Master Agreement for Clinical Trials Services, dated April 2, 2020, by and between ProKidney (formerly RegenMed (Cayman) Ltd.) and Frenova, LLC	X			
10.17	Master Services Agreement, dated May 1, 2019, by and between PPD Development, LP and ProKidney (formerly RegenMed (Cayman) Ltd.)	X			
10.18	Master Services Agreement, dated August 14, 2015, by and between CTI Clinical Trial Services Inc. and RegenMedTX, LLC	X			
10.19	Laboratory Service Agreement, dated August 16, 2016, by and among Covance Central Laboratory Services LP, Covance Central Laboratory Services SA`RL and ProKidney (formerly RegenMed (Cayman) Ltd.)	X			
10.20	Laboratory Service Agreement, dated August 1, 2017, by and among Covance Central Laboratory Services LP, Covance Central Laboratory Services SA`RL and ProKidney (formerly RegenMed (Cayman) Ltd.)	X			
10.21	Laboratory Service Agreement, dated June 21, 2019, by and among Covance Central Laboratory Services LP, Covance Central Laboratory Services SA`RL and ProKidney (formerly RegenMed (Cayman) Ltd.)	X			
10.22	Laboratory Service Agreement, dated September 16, 2021, by and among Labcorp Central Laboratory Services LP, Labcorp Central Laboratory Services SA`RL and ProKidney (formerly RegenMed (Cayman) Ltd.)	X			
21.1	List of Subsidiaries.		Form 8-K (Exhibit 21.1)	07/15/2022	001-40560
23.1	Consent of Marcum LLP, independent registered public accounting firm.	X			

Table of Contents

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg. Number</u>
23.2	Consent of Ernst & Young LLP, independent registered public accounting firm.	X			
23.3	Consent of Walkers (Cayman) LLP (included in Exhibit 5.1).				
24.1	Power of Attorney (included on the signature page hereof)				
101.INS	Inline XBRL Instance Document	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL)	X			
107.1	Calculation of Registration Fee	X			

† Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a) (5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

@ Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets (“[***]”) because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

+ Management contract or compensatory plan or arrangement.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes

Table of Contents

in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement; and

- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness; *provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Winston-Salem, State of North Carolina, on August 8, 2022.

PROKIDNEY CORP.

By: /s/ Tim Bertram, Ph.D.

Tim Bertram, Ph.D.

Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of Tim Bertram and James Coulston, acting alone or together with another attorney-in-fact, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any or all further amendments (including post-effective amendments) to this registration statement (and any additional registration statement related hereto permitted by Rule 462(b) promulgated under the Securities Act (and all further amendments, including post-effective amendments, thereto)), and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dated indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Tim Bertram, Ph.D.</u> Tim Bertram, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	August 8, 2022
<u>/s/ James Coulston, CPA</u> James Coulston, CPA	Chief Financial Officer (Principal Financial and Accounting Officer)	August 8, 2022
<u>/s/ Pablo Legorreta</u> Pablo Legorreta	Chairman	August 8, 2022
<u>/s/ William F. Doyle</u> William F. Doyle	Director	August 8, 2022
<u>/s/ Jennifer Fox</u> Jennifer Fox	Director	August 8, 2022
<u>/s/ José Ignacio Jimenez</u> José Ignacio Jimenez Santos	Director	August 8, 2022
<u>/s/ Alan M. Lotvin, M.D.</u> Alan M. Lotvin, M.D.	Director	August 8, 2022
<u>/s/ John M. Maraganore, Ph.D.</u> John M. Maraganore, Ph.D.	Director	August 8, 2022
<u>/s/ Brian J.G. Pereira, M.D.</u> Brian J.G. Pereira, M.D.	Director	August 8, 2022
<u>/s/ Uma Sinha, Ph.D.</u> Uma Sinha, Ph.D.	Director	August 8, 2022



August 8, 2022

PROKIDNEY CORP.

c/o Walkers Corporate Limited
190 Elgin Avenue
George Town
Grand Cayman KY1-9008
Cayman Islands

Dear Addressees

PROKIDNEY CORP.

We have been asked to provide this legal opinion to you with regard to the laws of the Cayman Islands in connection with the registration for resale from time to time by certain selling securityholders (the "**Selling Securityholders**") of up to an aggregate of 232,530,000 Class A ordinary shares, par value \$0.0001 per share ("**Class A ordinary shares**") of ProKidney Corp. (the "**Company**"), including:

- (a) 50,000 Class A ordinary shares collectively held by certain holders of the Company's securities (the "**Holders**") party to that certain Amended and Restated Registration Rights Agreement, dated as of 11 July 2022, by and among the Company, SCS Sponsor III LLC, and the Holders, their permitted transferees and certain additional holders;
- (b) 180,000,000 Class A ordinary shares issued or issuable pursuant to that certain Exchange Agreement, dated as of 11 July 2022, by and among the Company, ProKidney LP, and certain holders of the Company's securities party thereto; and
- (c) 52,480,000 Class A ordinary shares purchased by certain investors at a purchase price of \$10.00 per share, pursuant to subscription agreements with the Company,

(collectively, the "**Resale Shares**"), in each case under the United States Securities Act of 1933, as amended (the "**Securities Act**") and pursuant to the terms of the Registration Statement (as defined in Schedule 1).

For the purposes of giving this opinion, we have examined and relied solely upon the originals or copies of the documents listed in Schedule 1.

We are Cayman Islands Attorneys at Law and express no opinion as to any laws other than the laws of the Cayman Islands in force and as interpreted at the date of this opinion.

Based upon the foregoing examinations and the assumptions and qualifications set out below and having regard to legal considerations which we consider relevant, and under the laws of the Cayman Islands, as at the date hereof, we give the following opinions in relation to the matters set out below.

1. The Company is an exempted company duly incorporated with limited liability, validly existing under the laws of the Cayman Islands and in good standing with the Registrar of Companies in the Cayman Islands (the “**Registrar**”).
2. The Resale Shares have been duly authorised for issue to the Selling Securityholders by all necessary corporate action of the Company, and upon the issue of the Resale Shares (by the entry of the name of the registered owner thereof in the Register of Members of the Company confirming that such Resale Shares have been issued and credited as fully paid), delivery and payment therefor by the purchaser in accordance with the Memorandum and Articles (as defined in Schedule 1), the Resale Shares will be validly issued, fully paid and non-assessable (meaning that no additional sums may be levied in respect of such Resale Shares on the holder thereof by the Company).

The foregoing opinions are given based on the following assumptions:

1. The originals of all documents examined in connection with this opinion are authentic. The signatures, initials and seals on the Registration Statement and Resolutions (each as defined in Schedule 1) are, or will be, genuine and are, or will be, those of a person or persons stated therein. All documents purporting to be sealed have been, or will be, so sealed. All copies are complete and conform to their originals. The Registration Statement will conform in every material respect to the latest drafts of the same produced to us prior to the date hereof and, where provided in successive drafts, have been marked up to indicate all changes thereto.
2. The Memorandum and Articles will be the memorandum and articles of association of the Company in effect at the time of the issue and sale of the Resale Shares.
3. The Company Records (as defined in Schedule 1) are complete and accurate and all matters required by law and the Memorandum and Articles to be recorded therein are completely and accurately so recorded.
4. The accuracy and completeness of all factual representations made in the Registration Statement and all other documents reviewed by us.
5. The Company will receive or has received consideration in money or money’s worth for each Resale Share offered by the Company when issued at the agreed issue price as per the terms of applicable documents relating to the issue of such Resale Shares to the Selling Securityholders, such price in any event not being less than the stated par or nominal value of each Resale Share.
6. The preparation and filing of the Registration Statement has been duly authorised by or on behalf of the Company prior to the issue and sale of the Ordinary Shares.
7. There is nothing under any law (other than the laws of the Cayman Islands) which would or might affect any of the opinions set forth above.

The opinions expressed above are subject to the following qualifications:

1. We have relied upon the statements and representations of directors, officers and other representatives of the Company as to factual matters.
2. Our opinion as to good standing is based solely upon receipt of the Certificate of Good Standing issued by the Registrar. The Company shall be deemed to be in good standing under section 200A of the Companies Act (as amended) of the Cayman Islands (the “**Companies Act**”) on the date of issue of the certificate if all fees and penalties under the Companies Act have been paid and the Registrar has no knowledge that the Company is in default under the Companies Act.

This opinion is limited to the matters referred to herein and shall not be construed as extending to any other matter or document not referred to herein. This opinion is given solely for your benefit and the benefit of your legal advisers acting in that capacity in relation to this transaction and may not be relied upon by any other person, other than persons entitled to rely upon it pursuant to the provisions of the Securities Act, without our prior written consent.

This opinion shall be construed in accordance with the laws of the Cayman Islands.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and to the references to our firm, as Cayman Islands counsel to the Company, in the Registration Statement.

Yours faithfully

/s/ Walkers (Cayman) LLP
WALKERS (Cayman) LLP

SCHEDULE 1

LIST OF DOCUMENTS EXAMINED

1. A draft of the Form S-1 Registration Statement to be filed by the Company with the United States Securities and Exchange Commission registering the Resale Shares under the Securities Act (as filed, the “**Registration Statement**”).
2. The Certificate of Incorporation dated 25 February 2021, Certificate of Incorporation on Change of Name dated 11 July 2022, Register of Directors and Register of Officers, the Second Amended and Restated Memorandum and Articles of Association of the Company adopted and effective on 11 July 2022 (the “**Memorandum and Articles**”), in each case, of the Company, copies of which have been provided to us by its registered office in the Cayman Islands (together the “**Company Records**”).
3. The Cayman Online Registry Information System (CORIS), the Cayman Islands’ General Registry’s online database, searched on August 8, 2022.
4. A copy of a Certificate of Good Standing dated August 8, 2022 in respect of the Company issued by the Registrar (the “**Certificate of Good Standing**”).
5. A copy of executed written resolutions of the directors of the Company approving various matter, including the Registration Statement (the “**Resolutions**”).



MASTER SERVICES AGREEMENT

BETWEEN

GEORGE CLINICAL PTY LIMITED
ABN 33 098 184 528

AND

REGENMED (CAYMAN) LTD, d/b/a PROKIDNEY

MASTER SERVICES AGREEMENT (MSA)

THIS AGREEMENT is made on 15 February 2021

BETWEEN:

1. **GEORGE CLINICAL PTY LTD** (ABN 33 098 184 528) of Level 5, 1 King Street, Newtown, NSW 2042 AUSTRALIA (**George Clinical**); and
2. RegenMed (Cayman) Ltd., d/b/a PROKIDNEY of 10 Market Street, # 688 Camana Bay, Grand Cayman, KY1-9006, Cayman Islands (**ProKidney**).

BACKGROUND:

- A. George Clinical is a medical research company that performs clinical research services for other medical research companies and commercial entities within the pharmaceutical, medical device and biotechnology industries.
- B. ProKidney is a company that is conducting a clinical trial related to renal autologous cell therapy.
- C. ProKidney wishes to engage George Clinical to provide Services in accordance with the terms of this Agreement.

IT IS AGREED AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATION

1.1. Definitions

In this Agreement unless the context otherwise requires:

Affiliate means an entity which controls, is controlled by, or is under common control with, a Party, but only so long as such control exists, and **control** means the ability to vote 50% or more of the voting securities of any entity or otherwise having the ability to control the policies and direction of an entity;

Applicable Law means all laws, rules and regulations, including any subordinate legislation, applying in the jurisdiction of the Study and the performance of Services and includes: (i) ICH guidelines; (ii) current Good Clinical Practices, and if applicable, current Good Laboratory Practices; and (iii) applicable industry standards in the pharmaceutical industry when performing studies used to support regulatory filings.

Background Intellectual Property of a Party means all Intellectual Property rights owned or controlled by the Party as at the Commencement Date, or independently developed after the Commencement Date, which it makes available for the purpose of carrying out Services for a Research Project, and includes any improvements made solely by that Party to its Intellectual Property.

Business Day means a day that is not a Saturday, Sunday or public holiday in the relevant jurisdiction;

Change Order means an agreement signed by both Parties substantially in the form of Exhibit C to amend a Work Order.

Commencement Date means 15 February, 2021.

Confidential Information means information that is by its nature confidential, is designated by a Party as confidential, or the other Party knows or ought to know is confidential, which is provided by one Party to the other for the purposes of this Agreement and includes all documents, materials, data, works, ideas, know-how, trade secrets, concepts and information, in any form or medium, relating in any way to a Party's affairs, customers, businesses, products, sales, marketing or promotional information; and includes Confidential Information of a Study's sponsor or third parties provided to George Clinical for it to perform Services;

Dispute means a dispute or disagreement arising out of or in connection with this Agreement or a Work Order;

Fee means the amounts payable to George Clinical for the Services, as described in the applicable Work Order;

Intellectual Property means all industrial and intellectual property rights, including patents, copyright, future copyright, trade business, company or domain names, rights in relation to circuit layouts, plant breeders' rights, registered designs, registered and unregistered trademarks, know how, trade secrets and the right to have confidential information kept confidential, and any and all other rights to intellectual property which may exist anywhere in the world, and any application or right to apply for registration of any of the preceding rights;

Investigator Site means a location where a Study is actually conducted.

Parties means George Clinical and ProKidney and **Party**, as the context requires, is a reference to either of them;

Privacy Laws means privacy laws, legislation, codes and/or guidelines that apply to the Services in the applicable jurisdiction;

Representatives means the officers, employees, contractors, agents, authorised representatives and permitted contractors of a Party or its Affiliates;

Research Project means the research project identified in a Work Order.

Services means the services to be performed by George Clinical on behalf of ProKidney as described in the applicable Work Order.

Study means an investigation of a medicine or device as identified in a Work Order.

Study Drug means the medicine or device being trialled or tested in a Study and includes where relevant any placebo.

Term means the period specified in clause 6.

Termination Date means 15 February 2026; and

Work Order means an agreement substantially in the form of Exhibit A, which specifies Services George Clinical will perform for ProKidney in respect of a Study.

1.2. Interpretation

In this Agreement, unless the context requires otherwise:

- (a) headings are for convenience only and do not affect interpretation;
- (b) the singular includes the plural and vice versa, and any words importing a gender include other genders;

- (c) other grammatical forms of defined words or expressions have corresponding meanings;
- (d) a reference to a document, including this Agreement, is to that document as amended, novated, renewed, substituted or supplemented at any time;
- (e) a reference to a clause, paragraph, schedule or annexure is a reference to a clause or paragraph of or schedule, exhibit or annexure to this Agreement and a reference to this Agreement includes any schedules, exhibits and annexures;
- (f) a reference to any legislation or statutory instrument or regulation includes an amendment or re-enactment to that legislation and includes subordinate legislation in force under it;
- (g) a reference to a person means an individual, corporation, government or governmental agency, estate, trust, association or other legal or commercial entity or undertaking.
- (h) a reference to 'writing' includes any means of reproducing words in a tangible and permanently visible form;
- (i) a reference to a Party includes that Party's executors, administrators, successors, substitutes (including persons taking by novation) and permitted assigns;
- (j) mentioning anything after 'include', 'includes' or 'including' does not limit what else might be included;
- (k) a reference to 'dollars' or '\$' is to Australian currency unless such reference specifies otherwise;
- (l) an obligation not to do something includes an obligation not to cause and not to permit it to be done;
- (m) no clause in this Agreement will be construed adversely to a Party on the ground, irrespective of whether or not it is the only ground, that the Party was responsible for the preparation of the clause; and
- (n) a reference to days is to calendar days unless qualified as a Business Day.

2. APPOINTMENT AND SCOPE OF ENGAGEMENT

- 2.1 This Agreement contains the standard terms which apply to Services George Clinical provides to ProKidney in accordance with Work Orders.
- 2.2 ProKidney appoints George Clinical to provide Services during the Term in accordance with this Agreement and applicable Work Orders.
- 2.3 George Clinical agrees to provide Services to ProKidney on a non-exclusive basis, in accordance with this Agreement and applicable Work Orders.
- 2.4 George Clinical is an independent contractor and no relationship of employment, joint venture or agency will come into existence between George Clinical and ProKidney.
- 2.5 George Clinical may use an Affiliate to perform Services but it will remain responsible for its obligations under this Agreement and each applicable Work Order and must ensure that its Affiliate complies with this Agreement and the Work Order.
- 2.6 Neither Party may do any of the following without the other Party's written consent:
 - (a) contract on behalf of or bind the other Party;
 - (b) publish an advertisement or other information relating to the other Party; or

- (c) use the other Party's name or logo.

3. WORK ORDERS

- 3.1 A Work Order is not effective unless it is signed by both Parties. A template Work Order is provided as Exhibit A.
- 3.2 ProKidney determines in its sole discretion if and when it requests Services from George Clinical.
- 3.3 Work Orders must be numbered sequentially and specify the following information or identify that such information is "not applicable" to the Work Order:
 - (a) name of the Study and its basic parameters, including sponsor;
 - (b) the Services and scope of work;
 - (c) estimated dates for deliverables and completion;
 - (d) the budget and approval process for reimbursement of expenses, payment of costs and Fees, the schedule of payments, payment instructions, any prepayments and currency schedules;
 - (e) resource allocation;
 - (f) any transfer of obligations specifying sponsor responsibilities George Clinical assumes on ProKidney's behalf in relation to the Study, substantially in the form of Attachment C to the template Work Order in Exhibit A; and
 - (g) any other specific Services to be performed by George Clinical.
- 3.4 Each Work Order is incorporated by reference into this Agreement.
- 3.5 If ProKidney requests George Clinical to perform "sponsor" responsibilities under a Work Order with respect to a Study, the Work Order must specify which responsibilities ProKidney transfers to George Clinical in a list substantially in the form of Attachment C of the Template Work Order.
- 3.6 A Work Order can only be amended by a Change Order.
- 3.7 In the event of a conflict between the terms of this Agreement and a Work Order, the terms of this Agreement will control unless expressly superseded in the Work Order.

4. CHANGE ORDERS

- 4.1 A Change Order is not effective unless it is signed by both Parties. A template Change Order is provided as Exhibit B.
- 4.2 A Change Order must:
 - (a) be numbered sequentially;
 - (b) refer to the Work Order it amends;
 - (c) list the changes to the Work Order; and
 - (d) state the reason for each change, and the impact on responsibilities, budget, timelines, payment schedules and assumptions (as applicable).

5. STUDY DRUG/ BIOLOGIC – INTENTIONALLY OMITTED

6. TERM

- 6.1 This Agreement commences on the Commencement Date and continues until the Termination Date, unless terminated earlier under clause 11 (**Termination**).
- 6.2 If a Work Order remains active at the Termination Date, this Agreement continues until the Work Order is either completed or terminated.

7. GEORGE CLINICAL'S OBLIGATIONS, REPRESENTATIONS AND WARRANTIES

- 7.1 George Clinical must perform its Services in compliance with the requirements of the applicable Study, as set out in its protocol, this Agreement, the applicable Work Order, Applicable Law and ProKidney's reasonable instructions.
- 7.2 George Clinical must:
- (a) perform the Services in a competent and efficient manner with all necessary skill, care and diligence expected in relation to similar services and must comply with Applicable Law, standards, codes and guidelines relating to the Services;
 - (a) provide ProKidney with prompt progress reports on the Services if ProKidney requests;
 - (b) maintain records, Study subject medical records and other raw data sources relating to the Study in compliance with Applicable Law for the longer of:
 - i. 3 years after the health authority approves the marketing application for the Study Drug;
 - ii. 3 years after the termination or withdrawal of the health regulatory agency exemption under which the Study was conducted; or
 - iii. the period required by Applicable Law; and
 - (c) notify ProKidney promptly if it identifies a breach by an Investigator Site of any of the activities which George Clinical monitors as part of the Services.
- 7.3 Though the Services are aimed at monitoring Investigator Site's regulatory compliance, George Clinical does not guarantee that compliance or any particular Study results. George Clinical is not liable for regulatory non-compliance by Investigator Site or adverse effects associated with the Study or the Services, except to the extent arising from George Clinical's breach of this Agreement, violation of law, or willful misconduct or gross negligence.
- 7.4 ProKidney may inspect or audit George Clinical's records relating to Services with reasonable notice. The inspection or audit must be during normal business hours, at ProKidney's cost, and is to assure compliance with this Agreement and the relevant Work Order.
- 7.5 If either Party becomes aware that a regulatory authority intends to audit or inspect it in relation to any Services, it must notify the other Party in writing, send copies of any correspondence, and inform the other Party of the findings and outcome of the audit or inspection.
- 7.6 When George Clinical completes a Study, it must deliver all relevant records to ProKidney within 30 days. George Clinical may keep a copy of records for verification of the Services performed but remains subject to an obligation of confidence under this Agreement.

- 7.7 If the Services include material scientific input and/or leadership, George Clinical must ensure that the relevant Work Order and agreement with the Sponsor, if applicable, includes rights to scientific attribution and access to data for independent publication for George Clinical.
- 7.8 George Clinical represents and warrants to ProKidney as follows:
- (a) George Clinical is and will remain a corporation or company duly organized, validly existing and in good standing under the laws of its jurisdiction of organization.
 - (b) The execution and delivery of this Agreement by George Clinical has been authorized by all requisite corporate or company action. This Agreement is and will remain a valid and binding obligation of George Clinical, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors.
 - (c) George Clinical is under no contractual or other obligation or restriction that is inconsistent with George Clinical's execution or performance of this Agreement. George Clinical will not enter into any agreement, either written or oral, that would conflict with George Clinical's responsibilities under this Agreement.
 - (d) George Clinical has engaged, will engage and will cause its Affiliates involved in rendering Services to engage, employees and permitted subcontractors including consultants (collectively, **Personnel**) with the proper skill, training, availability and experience to provide Services. Before providing Services, all Personnel must be subject to binding written agreements with George Clinical under which they (a) have confidentiality obligations that are consistent with the terms of this Agreement; and (b) assign and effectively vest in George Clinical any and all rights that such personnel might have in the results of their work without any obligation of ProKidney to pay any royalties or other consideration to such Personnel.
 - (e) George Clinical, its Affiliates, their Personnel and each of their respective officers and directors, as applicable: (i) have not been debarred and will not knowingly use in any capacity in connection with Services any person who has been debarred, pursuant to section 306 of the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 335a; (ii) are not ineligible to participate in any federal and/or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)); (iii) are not disqualified by any government or regulatory authorities from performing specific services; and (iv) have not been convicted of a criminal offense related to the provision of healthcare items or services. Service Provider will notify ProKidney immediately if George Clinical, its Affiliates, any Personnel, or any of their respective officers or directors, as applicable, is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of George Clinical's knowledge, is threatened.

8. PAYMENTS

8.1. Payments

- (a) ProKidney must pay George Clinical the Fee in accordance with the applicable Work Order. The Fee is calculated by reference to the prices, timelines and payment terms agreed in the Work Order.

- (b) If a Work Order provides for prepayments, the Work Order must specify the amount and timing of the prepayment.
- (c) George Clinical will invoice ProKidney monthly.
- (d) ProKidney will pay George Clinical within 45 days of receiving a valid tax invoice.
- (e) If part of an invoice is disputed, ProKidney will pay the undisputed amounts. The Parties will try to resolve the disputed amount in good faith and as soon as possible.
- (f) If any tax or duty must be withheld on a payment, ProKidney must promptly pay the tax or duty to the appropriate taxing authority without deducting any amount owed to George Clinical. ProKidney must obtain an official receipt for the tax paid and send it to George Clinical, to be reimbursed.
- (g) Each Party must pay all costs of bank transfers within its own country and any taxes relating to their income and revenue.
- (h) Unless otherwise expressly stated, all amounts, prices, values or other sums payable or to be provided under this Agreement are exclusive of any value added, general sales or local taxes. Any value added, general sales or local taxes chargeable are to be paid by the ProKidney in addition to the amounts, prices, value or other sums payable under this Agreement.

8.2. **Currency and inflation adjustments**

- (a) The currency for invoices and payments must be agreed in the relevant Work Order. George Clinical may request ProKidney to make a provision for any currency fluctuations.
- (b) If George Clinical incurs expenses in a currency differing from the invoice and payment currency (**Foreign Currency**), those expenses will be converted in the invoice at the average exchange rates of the month in which the expenses were incurred, as published by Reserve Bank of Australia, unless the applicable Work Order provides otherwise.
- (c) Invoices must detail the costs in the invoice and payment currency and include an itemised list per country, detailing each cost in Foreign Currency and the exchange rate(s) used.
- (d) If Services in a Work Order will be performed over multiple calendar years, George Clinical may request ProKidney to pay an increase in fees to account for inflation. If inflation is already built into the Fee then this must be detailed in the Work Order or Change Order.

9. CONFIDENTIALITY

9.1. Obligation of confidence

Each Party must retain in confidence and must not use any Confidential Information or disclose it to any third party except as expressly permitted under this Agreement, to perform Services or with the other Party's written consent.

9.2. Terms of this Agreement

Neither Party may disclose the terms of this Agreement to any third party without the other Party's written consent.

9.3. Exceptions

The obligations of confidence do not apply to Confidential Information that is:

- (a) in the public domain, otherwise than as a result of a breach of obligation of confidence;
- (b) obtained by a Party from a third party who does not have an obligation of confidentiality with respect to such information; or
- (c) disclosed to a Party's professional advisers who have agreed in writing to keep the Confidential Information confidential.

Further, a recipient Party may disclose Confidential Information of the Party that provided the Confidential Information to the extent required by law or order of a judicial or parliamentary body or governmental agency, but only if such recipient Party promptly notifies the providing Party in writing, if legally permissible, provides reasonable cooperation to the providing Party in its efforts to oppose or obtain confidential treatment of such disclosure (and at such providing Party's expense) and only discloses that part of the Confidential Information required by law or order to be disclosed.

9.4. Return and destruction of Confidential Information

- a) If this Agreement expires or is terminated, each Party must immediately return (or if requested by the other Party, destroy) all Confidential Information of the other Party that is in its possession, power or control.
- b) George Clinical may retain a copy of Confidential Information relating to a Study that must be retained under Applicable Law.

9.5 Study results and the Study protocol are regarded as ProKidney's Confidential Information.

9.6 Each Party must limit access to Confidential Information of the other Party to its personnel who have a need to know it to perform Services and must ensure that they comply with the obligations of confidence under this clause as if they were a party to this Agreement.

9.8 Each Party acknowledges that monetary damages are an inadequate remedy for breach of the obligation of confidence under this clause so a Party may seek equitable relief, including an injunction to protect its Confidential Information from unauthorised use or disclosure, without the need to post any bond and without the need to demonstrate actual damages.

10. INTELLECTUAL PROPERTY

10.1. Background Intellectual Property

This Agreement, including any Work Order or Change Order, does not affect the ownership of a Party's Background Intellectual Property. Background Intellectual Property of each Party remains the sole property of that Party.

10.2. Study Intellectual Property

- (a) Any Intellectual Property, deliverables, work product and data arising from the Services (collectively, **Deliverables**) vests immediately in ProKidney upon its creation. George Clinical hereby assigns, and agrees to assign, to ProKidney all of George Clinical's right, title and interest in and to all Deliverables. Each Party will do everything reasonably necessary to effect that assignment, including executing and delivering all requested applications, assignments and other documents, and take such other measures as ProKidney reasonably requests, at ProKidney's expense, in order to perfect and enforce ProKidney's rights in the Deliverables.
- (b) George Clinical must disclose promptly to ProKidney any new Intellectual Property, including inventions which it creates in the course of performing Services or based on ProKidney's Confidential Information.

11. TERMINATION

11.1. Termination of Agreement

- (a) ProKidney may terminate this Agreement or any Work Order for whatever reason by giving 30 days' notice in writing to George Clinical.
- (b) A Party may terminate this Agreement or any applicable Work Order immediately if the other Party:
 - i. becomes insolvent, files for bankruptcy or has a receiver or administrator appointed to it; or
 - ii. breaches a material term of this Agreement, and does not remedy the breach substantially within 30 days of receiving a written notice by the non-breaching Party specifying the nature of the breach.
- (c) Each Party must continue to perform its obligations under this Agreement or a Work Order during the 30 day remedy period if material breach is alleged.

11.2. Termination of Work Orders

- (a) ProKidney may terminate a Work Order immediately if:
 - (i) the relevant Study is terminated; or
 - (ii) George Clinical breaches a material term of this Agreement or does not perform Services to ProKidney's reasonable satisfaction and does not remedy the breach or perform satisfactorily within 30 days of receiving a notice specifying the nature of the breach or non-performance.
- (b) George Clinical may terminate a Work Order by written notice stating the effective date (which may be less than 30 days from the notice date) of termination if it believes on reasonable grounds that continued performance of the Services under the Work Order poses an unacceptable risk to patient safety or may violate regulatory or scientific standards of integrity.
- (c) A termination notice must identify each Work Order that is terminated by its number.

11.3. Consequences on Termination

If this Agreement or a Work Order expires or is terminated for any reason:

- (a) the Parties must meet promptly and in good faith to prepare a close-out schedule, budget and timelines. George Clinical must only work as necessary to close-out the Services or as required by Applicable Law or as specified in a Work Order;
- (b) ProKidney must pay George Clinical for all Services actually performed in accordance with this Agreement and any applicable Work Order and must reimburse all costs and expenses George Clinical incurred in performing those Services, including non-cancelable costs payable to third parties incurred before termination but paid after the t Termination Date;
- (c) ProKidney must pay all George Clinical's actual costs incurred to complete activities associated with the close-out of the Study;
- (d) each Party must return to the other any unused supplies of products or other materials in its control within 60 days;
- (e) the terms of this Agreement continue to apply to each open Work Order until it expires or terminates;
- (f) payment may be based on:
 - (i) 'tasks completed' and ProKidney must pay the unit rate for each completed task as detailed in the applicable Work Order;
 - (ii) milestones, and if some milestones are incomplete, ProKidney must pay George Clinical a pro rata amount for actual work up to the date of termination, (in addition to paying for completed units or milestones); or
 - (iii) a combination of the two, as detailed in the close-out budget prepared under clause 11.3 (a).

12. DISPUTES

- 12.1. A Dispute must be resolved in accordance with this clause. However, nothing in this clause prevents a Party from obtaining urgent injunctive relief, if necessary to protect Intellectual Property rights or its Confidential Information.
- 12.2. The Parties must first attempt to negotiate in good faith to resolve a Dispute.
- 12.3. If the Dispute is not resolved within 14 days after good faith negotiations commence, either Party may refer the Dispute to mediation with the International Chamber of Commerce (ICC). The mediation will be conducted in accordance with the ICC Mediation Rules operating at the time the Dispute is referred. The location for such mediation shall be New York, U.S.A., or, upon mutual written agreement of the Parties, such mediation may be conducted virtually in English. Any information or documents obtained during the mediation must only be used to resolve the Dispute before the ADC.
- 12.4. If the Dispute is not resolved within 21 days of the commencement of mediation, either Party may commence proceedings in any court of competent jurisdiction.
- 12.5. Unless specifically provided otherwise, each Party must continue to perform its obligations under this Agreement, despite the existence of a Dispute.

13. INDEMNITY

13.1. Mutual indemnities

- (a) Each Party (**Indemnifying Party**) indemnifies the other Party, its Affiliates and their Representatives (each an **Indemnified Party**), against any third party loss, liability, expense or cost (collectively **Loss**) an Indemnified Party suffers as a direct result of the existence, performance or termination of this Agreement and which is caused by Indemnifying Party's breach of this Agreement, or negligence or wilful misconduct of Indemnifying Party, or any person it retains to perform this Agreement. Losses constitute a direct payment obligation of the Indemnifying Party.
- (b) The indemnity in paragraph (a) will be reduced proportionally to the extent that the Indemnified Party's negligent act, omission or wilful misconduct contributed to the Loss.
- (c) The Indemnified Party must give the Indemnifying Party prompt written notice of any claim likely to lead to a claim for indemnity and must fully cooperate with the Indemnifying Party and its legal representatives in the investigation and management of any claim.
- (d) Indemnifying Party has the right to manage the defence and settlement of a claim but must obtain Indemnified Party's written consent to settle the claim. Alternatively, Indemnified Party may elect to control defence of the claim itself at its own expense but if it does so, Indemnifying Party has no obligation to indemnify or defend Indemnified Party in relation to that claim.
- (e) Neither Party may withhold its approval of the settlement of a claim unreasonably.
- (f) Indemnified Party must take all reasonable steps to mitigate its Loss.

13.2. ProKidney's indemnity to George Clinical

- (a) Solely in connection with a Work Order under which George Clinical will supervise the conduct of a Study and that expressly requires indemnification, ProKidney indemnifies George Clinical, its Affiliates and their Representatives against any Loss any of them suffers as a direct result of claims brought by third parties arising from or in connection with the administration or use of a Study Drug, any clinical intervention or procedure provided for or required by the Study protocol or a **Local Indemnity** (as defined in paragraph (g)).
- (b) The indemnity in paragraph (a) will be reduced proportionally to the extent that George Clinical's negligent act, omission or wilful misconduct or breach of this Agreement or the Study protocol contributed to the Loss.
- (c) George Clinical must give ProKidney prompt notice of any circumstances likely to lead to a claim for indemnity and must fully cooperate with ProKidney and its legal representatives in the investigation and management of any claim.
- (d) ProKidney may manage the defence and settlement of a claim but must obtain George Clinical's consent to settle the claim. Alternatively, George Clinical may elect to assume control of the defence of the claim itself at its own expense but if it does, ProKidney has no obligation to indemnify or defend George Clinical in relation to that claim.
- (e) Neither Party may withhold its approval of the settlement of a claim unreasonably.

- (f) George Clinical must take all reasonable steps to mitigate its Loss.
- (g) A **Local Indemnity** means an indemnity George Clinical must provide to Investigator Sites or human research ethics review committees against claims arising from a Study on standard terms and conditions applicable in the relevant jurisdiction.
- (h) For avoidance of doubt, ProKidney's indemnity covers all Work Orders and Change Orders executed under this Agreement. George Clinical may request additional indemnity in associated Work Orders depending on the nature of the Services and study sponsor relationship.

14. INSURANCE

- 14.1 Each Party must maintain appropriate insurance policies required by Applicable Law or reasonable professional practice with reputable insurers to cover its obligations to the other Party.
- 14.2 A Party will provide the other Party with certificates of insurance or other evidence of its insurance, if requested in writing.
- 14.3 A Party must not knowingly do anything that might invalidate any insurance policy held by the other Party.

15. FORCE MAJEURE

- 15.1 A Party will not be liable for failure or delay in performing its obligations (except for payment obligations) under this Agreement, or any Work Order, for the period and to the extent that its failure or delay is due to a Force Majeure Event.
- 15.2 A Party relying on this clause must:
 - (a) promptly notify the other Party in writing of the circumstances and effect of the Force Majeure Event; and
 - (b) take all steps reasonably necessary to mitigate the effects of the Force Majeure Event.
- 15.3 If a Force Majeure Event continues for more than 3 months, the other Party may immediately terminate this Agreement and applicable Work Orders by written notice.
- 15.4 In this clause, **Force Majeure Event** means an event, which is out of the reasonable control of a Party and not caused by its own act or omission, including acts of God, natural events, fire, flood, hurricane, earthquake, explosion, volcanic eruption, war, embargo, events of terrorism, industrial action, strike (other than a strike involving the affected Party's labor force), riot, crime and act of government or regulatory agency.

16. LIMITATION OF LIABILITY

- 16.1 Despite any other clause in this Agreement, no Party is liable (including without limitation, in contract, negligence or tort) for any loss of profits, opportunities or goodwill or any type of indirect or consequential damages in connection with this Agreement or any Work Order or Services performed by it.

16.2 Nothing in this Agreement excludes or limits any liability which cannot be excluded under Applicable Law.

17. PRIVACY

- 17.1. Each Party must ensure that it collects, stores and discloses any personal information it obtains as a result of this Agreement in accordance with applicable Privacy Laws.
- 17.2. Each Party must promptly report to the other Party any unauthorised access to, use or disclosure of personal information and must work with the other Party to remedy the incident.

18. NON SOLICITATION

- 18.1 Neither Party may directly or indirectly solicit, recruit or hire an employee of the other Party.
- 18.2 This clause does not apply if an employee applies for employment in response to a public advertisement that is not specifically directed to that employee or responds to a general advertisement.
- 18.3 This clause applies during the term of this Agreement and for 12 months after its expiry or termination.

19. NOTICES

- 19.1 A notice, consent, approval, or other communication in connection with this Agreement (each a **Notice**) must be in writing and delivered or sent to the address or email of the recipient as follows (as amended by Notice):
- (a) if to ProKidney:
ProKidney
Attn: Ashley Johns
8020 Arco Corporate Dr. Ste 118
Raleigh, NC 27617
Email: Ashley.Johns@ProKidney.com
- (b) if to George Clinical:
George Clinical Pty Ltd
Level 5, 1 King Street
Newtown NSW 2042, AUSTRALIA
Email: contracts@georgeclinical.com
Marked for the attention of: CEO
- 19.2 A Notice takes effect from the time received and is taken to be received by the recipient:
- (a) if delivered by hand, on the day of delivery;
- (b) if sent by post, on the third (seventh, if sent to another country) Business Day after the date of posting;

if sent by email, on the day that the recipient acknowledges receipt by return email; However, if received after 5:00pm or on a day that is not a Business Day, it is to be taken to be received at 9:00am on the next Business Day

19.3. Although the Parties may correspond via e-mail for operational purposes, no formal notice required by this Agreement may be given or made via email.

20. MISCELLANEOUS

20.1 Entire Agreement

This Agreement, together with each Work Order and Change Order relating to a Study, contains the entire agreement between the Parties and supersedes all communications, negotiations, arrangements and agreements, whether oral or in writing, in respect of that Study.

20.2 Inconsistency

If, for a particular Study, there is any inconsistency between this Agreement and its Work Order and any Change Order, the clauses of this Agreement prevail, unless expressly provided otherwise in the Work Order or Change Order.

20.3 Amendment

This Agreement may only be amended by a written document signed by both Parties. An amendment to a Work Order must comply with clause 4.

20.4 Waiver

No right under this Agreement is waived except by notice in writing signed by the Party waiving the right. A failure or delay to exercise any right, power or remedy under this Agreement will not operate as a waiver. Likewise, a single or partial exercise of any right, power or remedy will not preclude any other or future exercise of that or any other right, power or remedy.

20.5 Assignment and Subcontracting

- (a) A Party must not assign, sub-contract, or transfer its rights or obligations under this Agreement or a Work Order without the prior written consent of the other Party or if it is to an Affiliate under clause 2.5. Such consent should not be unreasonably withheld.
- (b) If George Clinical subcontracts an obligation under this Agreement or any Work Order George Clinical remains responsible and liable for Services performed by its subcontractors.

20.6 Governing Law

The laws applicable in the state of New York, U.S.A., govern this Agreement, without regard to conflicts of laws provisions.

20.7 Severability

Any clause of this Agreement which is prohibited or unenforceable is ineffective to the extent of the prohibition or unenforceability, but the validity or enforceability of the remaining clauses of this Agreement will not be affected.

20.8 Counterparts

This Agreement may be executed in a number of counterparts and all counterparts taken together are regarded as one instrument. A Party may sign any one counterpart. This Agreement may be delivered by email and the Parties may rely on an electronic signature as though it were an original signature.

20.9 Warranty of authority

If this Agreement, or a Work Order or Change Order, is signed by a person for and on behalf of a Party (**signee**), that Party represents and warrants that the signee has authority to enter into and sign this Agreement, or a Work Order or Change Order, on its behalf and constitutes a valid execution on behalf of that Party.

20.10 Survival

Clauses 9 (**Confidentiality**), 10 (**Intellectual Property**), 11.3 (**Consequences on Termination**), 12 (**Disputes**), 13 (**Indemnity**), 14 (**Insurance**), 16 (**Limitation of Liability**), 18 (**Non Solicitation**) and any operational clauses giving effect to these, survive expiry and termination of this Agreement.

EXECUTED as an **Agreement** between the Parties:

Executed for and on behalf of **GEORGE CLINICAL PTY LIMITED** (ABN 33 098 184 528) by:

Signature: /s/ Jacqueline Thorn
Director

Signature: /s/ Sean Hart
Director

Name: Jacqueline Thorn
Please print

Name: Sean Hart
Please print

Date: 16 February 2021

Date: 16 February 2021

Executed for and on behalf of RegenMed (Cayman) Ltd., d/b/a
PROKIDNEY by:

Signature: /s/ Ashley H. Johns
VP Clinical Ops

Name: Ashley H. Johns
Please print

Date: 17 February 2021

Signature: /s/ Chelsey J. Hehl
Sr. Clinical Operations Manager

Name: Chelsey J. Hehl
Please print

Date: 17 February 2021

**RESEARCH, DEVELOPMENT, ENGINEERING SERVICES
AND LICENSE MEMORANDUM AND AGREEMENT**

THIS **RESEARCH, DEVELOPMENT, ENGINEERING SERVICES AND LICENSE MEMORANDUM AND AGREEMENT** (“Agreement”) is made by and among **ProKidney, a Cayman Islands exempted limited company (“ProKidney Cayman”), a wholly-owned subsidiary of ProKidney LP, an Irish limited partnership (“ProKidney Ireland”)** (hereinafter collectively “PROKIDNEY”) and **DEKA PRODUCTS LIMITED PARTNERSHIP, a New Hampshire limited partnership with its principal offices at 340 Commercial Street, Manchester, New Hampshire 03101, and its general partner, DEKA RESEARCH & DEVELOPMENT CORP., a New Hampshire corporation of the same address (hereinafter collectively “DEKA”).** PROKIDNEY and DEKA shall be referred to individually as “Party” and collectively as “Parties.”

WITNESSETH:

WHEREAS, DEKA has expertise in the design, development, and testing of sophisticated mobility technology and DEKA has previously developed and owns and, as a result of the Development Program (as defined herein), has come to develop and own and may further come to develop and own certain patent rights, copyrights, trade secrets, and/or confidential know-how relating to the ProKidney Field (as defined herein); and

WHEREAS, PROKIDNEY desired and continues to desire that DEKA undertake the Development Program (as defined herein) to attempt to develop Licensed Technology (as defined herein), for use within the ProKidney Field, and PROKIDNEY is willing to remunerate DEKA for such work on the Development Program; and

WHEREAS, DEKA desired and continues to desire that the Licensed Technology, if successfully developed, be made available for use within the ProKidney Field, on the terms stated herein; and

WHEREAS, PROKIDNEY wished to and continues to wish to have developed and made available such Licensed Technology, for use within the ProKidney Field, and for PROKIDNEY to obtain an exclusive, worldwide right and license to Commercialize (as defined herein) the Licensed Technology within the ProKidney Field;

WHEREAS, PROKIDNEY and DEKA reached an agreement on August 30, 2021 (the “**Effective Date**”) for DEKA to undertake components of the Development Program to attempt to develop Licensed Technology for use within the ProKidney Field so that PROKIDNEY could develop and make available such Licensed Technology, for use within the ProKidney Field, and for DEKA to grant PROKIDNEY an exclusive, worldwide right and license to Commercialize the Licensed Technology within the ProKidney Field, in return for DEKA being remunerated utilizing DEKA’s Standard Reimbursement Formula (as defined herein), but with amounts so due by PROKIDNEY to DEKA to be settled through the issuance of up to a certain number of Class B-1 Units of ProKidney Ireland (or through the issuance of an equivalent number of Class B-1 Profits Units of ProKidney Management Equity LLC (“**PMEL**”), which units represent an equivalent interest) (collectively, the “**Class B-1 Units**”) to DEKA (with such Class B-1 Units to be valued as at the date the amounts become due by PROKIDNEY to DEKA), and, once the obligation to procure the issuance of all such Class B-1 Units has fallen due, thereafter by cash payment by PROKIDNEY to DEKA; and

WHEREAS, the number of Class B-1 Units available to be issued to DEKA was subject to agreement among PROKIDNEY and its two (indirect) founding investors, and this number was agreed by the founding investors to be 2,750,000 Class B-1 Units; and

WHEREAS, PROKIDNEY and DEKA now wish to memorialize the agreements set forth above in this Agreement and set out further and more detailed terms of such agreements in this Agreement; and

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the Parties hereto confirm the terms agreed and further agree such more detailed terms as follows:

SECTION 1 DEFINITIONS

Where capitalized and used in this Agreement, the following terms shall have the ascribed meanings:

1.1 The term “Affiliate” shall mean any company or other legal entity, other than PROKIDNEY or DEKA, in whatever country organized, now or hereafter controlling, controlled by, or under common control with PROKIDNEY or DEKA, as applicable, for the period during which such control exists. The term “control” means the possession, direct or indirect, of the power (whether or not exercised) to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting securities, by contract, or otherwise, and the term “entity” includes an individual, corporation or other entity.

1.2 The term “Business Day” means a day except a Saturday, a Sunday or other day on which banks in the State of Delaware are authorized or required by a legal requirement to be closed.

1.3 The term “Commercial Introduction” shall mean, with respect to Licensed Technology, the date that Licensed Technology are first made available in commercially reasonable quantities by PROKIDNEY, or PROKIDNEY uses such Licensed Technology within its operations, directly or by or through an Affiliate, in commercially reasonable quantities.

1.4 The term “Confidential Information” shall mean all information, including, without limitation, all data, samples, designs, reports, technologies, software, materials, and other information, and all copies thereof, made or disclosed for or in contemplation of the Development Program by a Party, its employees, or its contractors (the “Disclosing Party”) to another Party, its employees or contractors (the “Receiving Party”), excluding any information that:

a) at the time of the disclosure was known to the Receiving Party, as shown by written records, and was not previously subject to any obligation of confidentiality; or

b) was generally available to the public or was otherwise part of the public domain at the time of its disclosure without breach of a prior obligation of confidentiality; or

c) becomes generally available to the public or otherwise part of the public domain after its disclosure other than through a breach of a confidentiality agreement (including, but not limited to, an act or omission in breach of this Agreement); or

d) becomes known to the Receiving Party by disclosure of a third party, as shown by written records, without an obligation of confidentiality; or

e) is hereafter independently developed by personnel of the Receiving Party that have not been exposed to the Confidential Information of the Disclosing Party, PROVIDED that the burden of proving such independent development shall be on the Receiving Party; or

f) is, or relates, to Intellectual Property that is owned by the Receiving Party pursuant to the terms of this Agreement.

1.5 The term "PROKIDNEY Intellectual Property" shall mean, collectively, any Intellectual Property in existence prior to the commencement of the Development Program, which PROKIDNEY owns, controls, or to which PROKIDNEY is empowered to grant a license. "PROKIDNEY Intellectual Property" shall also include any Intellectual Property developed by PROKIDNEY outside of the Development Program during the term of this Agreement.

1.6 The term "DEKA Intellectual Property" shall mean, collectively, any Intellectual Property: (a) in existence as of the Effective Date and incorporated by DEKA into any Licensed Technology or (b) resulting from the performance of the Development Program, which DEKA owns, controls, or is empowered to grant a license to during the Term.

1.7 The term "Development Contractor" shall mean any person or entity performing services under the Development Program. For the avoidance of doubt, the Advanced Regenerative Manufacturing Institute, which is also providing services to PROKIDNEY, shall not be considered as a Development Contractor to the Development Program, unless otherwise agreed by the Parties.

1.8 The term "Development Program" shall mean all of DEKA's efforts relating to the Licensed Technology for use in the ProKidney Field, including, but not limited, to the development, regulatory approval, design control, continuing engineering, manufacture, and improvement of Licensed Technology, both prior to and after the Effective Date, to attempt to achieve the Development Purpose (as defined in Section 2.1).

1.9 The term "Exclusive Rights and License" shall mean the rights and licenses granted by DEKA to PROKIDNEY under Section 8.1 hereof.

1.10 The term "Improvements" shall mean any modification or enhancement of any Licensed Technology that allows the Licensed Technology, or any portion thereof, to perform the same, substantially similar, or an enhanced purpose in a better, more useful, or more economical way, or which permits a better or more economical means of manufacture or testing of the Licensed Technology, or any portion thereof.

1.11 The term "Intellectual Property" shall mean, collectively, any copyright, trade secret, devices, designs, materials, know-how, technology, information, invention, patent or patent application (including all continuations, continuations-in-part, divisions, renewals, and any other patent or patent application claiming priority thereof, all patents which may be granted thereon, all reissues, reexaminations and extensions thereof, and all foreign counterparts of any of the forgoing), methods, data, testing results, software or algorithms.

1.12 The term “Intellectual Property Losses” shall mean any and all damages, liabilities, claims, costs, charges, judgments, settlements and expenses (including attorney’s fees) or other losses to the extent resulting from, arising out of, or incurred in connection with, or otherwise with respect to any claim by a third-party asserting, arising from or premised upon any Intellectual Property-related right pursuant to Section 11.2.

1.13 The term “ProKidney Field” shall mean the use of Licensed Technology for any purposes relating to the provision of cell therapy for treatment of renal insufficiency (including, but not limited to, collecting cells from kidneys, injecting and/or inserting cells into kidneys, and manufacturing, monitoring, and testing of cells for injection and/or insertion of cells into kidneys).

1.14 The term “Licensed Technology” shall mean any technology resulting from the Development Program, including but not limited to: (a) an injection device, (b) an automated cell digester, (c) a cell stack manipulator, and (d) any other technology development project that is made part of the Development Program pursuant to the Development Plan (as may be as may be amended from time to time by a signed writing between the Parties).

SECTION 2 DEVELOPMENT AND PRODUCT SUPPORT OBLIGATIONS

2.1 Development Purpose. The purpose of the Development Program is to achieve as expeditiously as practicable, the development and testing of Licensed Technology in accordance with the Development Plan agreed upon by the Steering Committee (and as may be amended from time to time) (the “Development Purpose”). PROKIDNEY and DEKA shall undertake the Development Program to attempt to achieve the Development Purpose.

2.2 Joint Steering Committee. To manage the Development Program and attempt to achieve the Development Purpose, PROKIDNEY and DEKA will form a joint steering committee (“Steering Committee”) as follows:

a) Membership; Voting; Meetings. The Steering Committee shall consist of four (4) members in total, with two representatives designated by PROKIDNEY (and reasonably acceptable to DEKA) and two representatives designated by DEKA (and reasonably acceptable to PROKIDNEY). Such Steering Committee shall act by unanimous agreement of all such members, provided, however, that any modifications to the Development Plan shall be subject to the signed approval of the Parties. A Party may change any of its representatives at any time upon written notice to the other Party. The Steering Committee shall meet, either in person or by telephone, approximately once each calendar quarter (unless otherwise agreed by the Steering Committee).

b) Purpose. The Steering Committee shall be responsible for establishing and reviewing the progress of the Development Program toward achieving the Development Purpose.

c) Conflict Resolution. The Steering Committee shall attempt in good faith to resolve any conflict arising within the Steering Committee, PROVIDED that, in the event that a dispute cannot be resolved promptly by the Steering Committee, the dispute may be referred to Dean Kamen (or his successor, as appointed by DEKA) (“Mr. Kamen”), and Tim Bertram (or such person’s successor, as appointed by PROKIDNEY) (“Mr. Bertram”), for resolution. If Mr. Kamen and Mr. Bertram are not able to resolve the matter through good faith negotiations within thirty (30) Business Days of first being presented, then either Party may pursue mediation pursuant to Section 14.4.

2.3 Development Plan. DEKA shall lead the Development Program and, unless otherwise agreed by the Steering Committee (pursuant to the procedures set forth in Section 2.2), DEKA shall be primarily responsible for all activities relating to the Development Program. The Development Program shall be governed by a development plan (“Development Plan”) attached hereto as Exhibit A (as may be amended from time to time by a signed writing between the Parties), which sets forth a mutually agreed scope of work generally consistent with this Agreement, including a non-binding cost estimate, desired deliverables, and the roles and responsibilities of DEKA and PROKIDNEY. In the event of any inconsistencies between the Development Plan and this Agreement, the terms and conditions of this Agreement shall control.

2.4 DEKA Development Program Efforts. Subject to the terms of this Agreement, DEKA shall perform the obligations assigned to it under the Development Plan and this Agreement, which shall include without limitation:

- a) developing prototypes of Licensed Technology for testing as described in the Development Plan;
- b) conduct preparations and engineering support for trials, as needed, of Licensed Technology;
- c) cooperate with PROKIDNEY to implement an appropriate regulatory strategy for Licensed Technology;
- d) maintain the design history file, provide design control in compliance with DEKA’s quality system (unless otherwise mutually agreed by the Steering Committee), and provide continuing engineering for Licensed Technology;
- e) collaborate with PROKIDNEY to develop an appropriate plan for the manufacture and manufacturing supply chain for the Licensed Technology;
- f) take such other efforts within the scope of this Agreement as set forth in the Development Plan or as otherwise agreed to by the Steering Committee.

DEKA shall ensure that all Development Contractors engaged by DEKA to perform aspects of the Development Program comply with the terms and conditions of this Agreement.

2.5 PROKIDNEY’s Development Program Efforts. Subject to the terms of this Agreement, PROKIDNEY shall perform the efforts assigned to it under the Development Plan (or as otherwise agreed by the Steering Committee) to achieve the Development Purpose.

2.6 No Transfer of Development Program Materials. As part of the Development Program, prototypes, tooling, fixtures, test equipment, and other materials may be utilized (“Development Program Materials”). Subject to the terms of this Agreement, DEKA shall own all Development Program Materials developed by DEKA or its Development Contractors in conjunction with the Development Program. All such Development Program Materials provided by DEKA to PROKIDNEY for analysis, testing, and/or other activities related to the Development Program shall remain the property of DEKA. For the avoidance of doubt, to the extent that any DEKA Intellectual Property is incorporated into any such Development Program Materials (or necessary to utilize any such Development Program Materials), such DEKA Intellectual Property shall be included in the Exclusive Rights and License.

2.7 Disclaimer. Anything in this Agreement to the contrary notwithstanding, DEKA does not extend or make any guarantees, warranties or representations regarding the successful development, testing or commercial viability of any Licensed Technology. PROKIDNEY and DEKA acknowledge that each Party is actively involved in other, unrelated development programs of equal priority, but each Party agrees to use its Commercially Reasonable Efforts to achieve the Development Purpose. PROKIDNEY and DEKA acknowledge that any cost and time estimates provided are non-binding estimates made in good faith based upon the Development Program.

SECTION 3 FUNDING OF RESEARCH AND DEVELOPMENT

3.1 Reimbursement. PROKIDNEY shall reimburse DEKA on a cost plus system for DEKA’s efforts (and the efforts of DEKA’s Development Contractors) under the Development Program as described below in this Section 3.1. DEKA will bill its services at all direct labor incurred plus one hundred sixty percent (160%) labor overhead, plus direct material, plus zero percent (0%) general and administration, plus ten percent (10%) fee; that is, according to the following formula:

$$((L \times 2.6) + M) \times 1.1 = \text{reimbursement}$$

where “L” equals direct labor and “M” equals non-labor direct project costs (such as materials, Development Contractors, consultants, and other direct costs) (“DEKA’s Standard Reimbursement Formula”), PROVIDED that:

a) PROKIDNEY shall be obliged to settle this reimbursement, initially, through procuring that ProKidney Ireland or PMEL, as determined by PROKIDNEY, issues up to 2,750,000 Class B-1 Units to recipients as directed by DEKA and identified to PROKIDNEY on or prior to the date of this agreement (the “DEKA Recipients”), each of whom shall enter into the form of subscription agreement attached as Exhibit B hereto in connection with such issuance of Class B-1 Units (the “Subscription Agreement”), with such Class B-1 Units to be valued for these purposes as at the day the reimbursement falls due to be settled by PROKIDNEY as determined in accordance with the following sentence. The Parties agree that this obligation has fully vested on PROKIDNEY by virtue of work carried out by DEKA up to December 31, 2021 as follows: the total value of the work carried out by DEKA to December 31, 2021 amounts to \$4,163,992.23 and the value of 2,750,000 Class B-1 Units as of December 31, 2021 amounts to \$2,502,500.00. PROKIDNEY hereby acknowledges its present and fully vested obligation to procure the issuance, by ProKidney Ireland or PMEL, as applicable, of these 2,750,000 Class B-1 Units to the DEKA Recipients. The Class B-1 Units issued to the DEKA Recipients in accordance with this Section shall be subject to the provisions of the Subscription Agreements and the governing documents (including applicable transfer restrictions) of ProKidney Ireland or PMEL, as applicable. The parties agree that, as of December 31, 2021, the total cash payment due by PROKIDNEY to DEKA equals \$1,661,492.23; and

b) PROKIDNEY shall thereafter settle all further amounts due under this Section 3.1 through cash payment.

3.2 Taxes. DEKA is responsible for the payment and remittance of all applicable federal, state or local taxes or foreign taxes resulting from payments received from PROKIDNEY, including payments of Class B-1 Units and cash pursuant to Section 3.1 of this Agreement. DEKA acknowledges and agrees that DEKA is obligated to report as income all payments received from PROKIDNEY pursuant to this Agreement. DEKA agrees to and acknowledges the obligation to pay all self-employment and other taxes on such income. DEKA shall pay all applicable unemployment and disability insurance required by the applicable jurisdictions in which DEKA conducts business. DEKA agrees to indemnify, defend and hold PROKIDNEY harmless from any liability for, or assessment of, any claims or penalties or interest with respect to such taxes, labor or employment requirements, including any liability for, or assessment of, taxes imposed on PROKIDNEY by the relevant taxing authorities with respect to any payments made to DEKA pursuant to this Agreement or any liability related to the withholding of such taxes.

SECTION 4 RESEARCH REPORTS AND ACCOUNTING

4.1 Monthly Reporting and Reimbursement. DEKA shall furnish to PROKIDNEY during the Term written monthly reports (“Monthly Report”) within approximately fifteen (15) days following the start of each month, containing an accounting of the reimbursement due for the preceding month. PROKIDNEY shall reimburse DEKA for all undisputed amounts within thirty (30) days of receipt of each Monthly Report. Should PROKIDNEY wish to dispute any amount set forth in a Monthly Report, PROKIDNEY shall notify DEKA in writing, within thirty (30) days of receipt of such Monthly Report, of such disputed amount and PROKIDNEY and DEKA shall use their respective reasonable efforts to amicably resolve the dispute. In the event that PROKIDNEY and DEKA do not amicably resolve a dispute within thirty (30) days of such written notification of dispute, the Parties shall follow the dispute resolution procedures set forth in Section 14.4 herein.

4.2 Audits of Books and Records. DEKA shall keep full, true and accurate books and records which account for the services rendered by DEKA under the Development Program, which account for the payments due to DEKA under this Section 4. Such books and records shall be maintained until the fifth (5th) anniversary of the termination of this Agreement or the completion of the final Milestone on any Project (as described in Exhibit A) unless a longer timeframe for records maintenance is provided in an SOW or the Development Plan. PROKIDNEY, at its own expense, shall have the right during normal business hours on ten (10) days’ prior written notice to DEKA and not more than once in any calendar year to have a nationally recognized independent public accounting firm selected by PROKIDNEY and acceptable to DEKA examine the relevant books and records of DEKA for the two (2) preceding years for the purpose of verifying the payments under this Section 4 for those two (2) years (PROVIDED that payments for such years have not been the subject of a prior audit). Such accounting firm shall not work on a contingency fee basis, shall execute and deliver to DEKA a standard confidentiality agreement and shall not

disclose to PROKIDNEY any information relating to DEKA's business, except whether DEKA's invoices are correct or incorrect, and if incorrect, the specific details concerning any discrepancies and the amounts of the payment due under this Section 4. If such examination reveals a discrepancy, and neither party disputes such conclusion, PROKIDNEY shall pay to DEKA any additional amount owed to DEKA, or DEKA shall refund to PROKIDNEY any excess payments made by PROKIDNEY, as appropriate. In the event of a dispute, the provisions of Section 14.4 shall apply.

4.3 Inspections. During the term of this Agreement and for five (5) years thereafter, PROKIDNEY's authorized representative(s) and governmental regulatory authorities, shall be permitted to inspect and audit Service Provider's premises, records, processes, software, and systems used by Service Provider in connection with this Agreement, for quality assurance purposes. Any such PROKIDNEY audit will be conducted at PROKIDNEY's sole expense, during DEKA's regular business hours and upon reasonable prior notice to DEKA. In the event an audit reveals DEKA's noncompliance, DEKA shall immediately implement appropriate corrective action at DEKA's expense.

SECTION 5 COMMERCIALIZATION AND MANUFACTURE

5.1 Support of the Development Program. DEKA and PROKIDNEY shall use Commercially Reasonable Efforts to support the Development Program and to attempt to achieve the Development Purpose as soon as practicable.

5.2 Manufacturing. Upon the request of PROKIDNEY, DEKA (or a DEKA Affiliate) shall provide support for establishing the manufacturing supply chain for, and making arrangements for the production of, Licensed Technology as part of the Development Program, by DEKA (or a DEKA Affiliate) or by one or more third party contract manufacturers, as mutually agreed by the Parties. Any Licensed Technology manufactured by DEKA (or a DEKA Affiliate) shall be supplied pursuant to a supply agreement(s) between DEKA, PROKIDNEY, and any other entity or entities providing contract manufacturing services, which supply agreement(s) shall be negotiated in good faith no later than six (6) months prior to the anticipated Commercial Introduction. If the Parties agree to the use of one or more contract manufacturers for some or all of the manufacturing supply chain and/or production, such support shall include helping to identify such contract manufacturer and assisting with the transfer of the Licensed Technology, and associated know-how, necessary to implement a manufacturing supply chain and production, as appropriate.

SECTION 6 PROPRIETARY INFORMATION

6.1 Treatment of Confidential Information. All Confidential Information of a Disclosing Party disclosed to a Receiving Party shall be treated by the Receiving Party as confidential throughout the Term and for so long thereafter as the information remains Confidential Information. The Receiving Party shall: (i) treat and safeguard such Confidential Information in the same manner as its own proprietary information of a similar type, which in no event shall be less than reasonable care; (ii) limit access to only those employees and contractors who need to know for purposes of this Agreement; (iii) assure that such persons and entities are under the same obligations of confidentiality as are included in this Agreement; and (iv) assure

that such persons do not use such Confidential Information except as necessary to perform its obligations under this Agreement, and use such Confidential Information consistent with Section 7. If this Agreement is terminated for any reason, the Receiving Party, upon request of the Disclosing Party, shall return all Confidential Information in its possession or certify that all Confidential Information in its possession has been destroyed within thirty (30) days of such request, except that the Receiving Party shall be permitted to maintain, at its own cost and expense, one archival copy of any Confidential Information necessary to support its regulatory compliance. Such archival copy shall be maintained subject to the confidentiality requirements of this Agreement and shall only be used for the satisfaction of the regulatory obligations of the Receiving Party.

6.2 Disclosures Required by Law. The Receiving Party shall not be liable to the Disclosing Party for disclosure of any Confidential Information received hereunder if such disclosure is made pursuant to a governmental or judicial mandate, PROVIDED that the Receiving Party shall have given the Disclosing Party prompt notice of such mandate prior to the submission of such Confidential Information, and FURTHER PROVIDED that the Receiving Party shall have cooperated with any efforts by the Disclosing Party to intervene in such proceedings or otherwise prevent such disclosure.

SECTION 7 OWNERSHIP OF LICENSED SUBJECT MATTER

7.1 DEKA Intellectual Property. Subject to the Exclusive Rights and License, and except as expressly set forth in Sections 7.2, DEKA shall own title to any and all Intellectual Property created, developed and/or invented as a result of, or in conjunction with, the Development Program.

7.2 PROKIDNEY Intellectual Property. PROKIDNEY shall own title to any and all Intellectual Property created, developed and/or invented solely by PROKIDNEY independent of any assistance from DEKA as a result of PROKIDNEY's own development efforts separate and apart from the Development Program.

7.3 Cooperation. To the extent the Parties are able to do so, the Parties shall provide each other with reasonable opportunity to advise the other and shall cooperate with each other in the prosecution of all patent applications.

7.4 Party Employee Agreements. Each of the Parties represent and warrant that it and its employees have entered into agreements wherein its employees agreed to assign their rights in and to all inventions, as well as all patents and patent applications directed to such inventions, resulting from their employment with such Party to that Party. DEKA will enforce the same so that DEKA can perfect its title to the DEKA Intellectual Property and PROKIDNEY can perfect its title to the Intellectual Property PROKIDNEY is entitled to own under this Agreement. Furthermore, each of the Parties represents and warrants that it has caused or will cause all additional employees, or personnel performing work pursuant to the Development Program, to execute similar agreements with respect to the rights in and to all inventions, as well as all patents and patent applications directed to such inventions, resulting from their association with such Party and will enforce such agreements so that the Party can perfect its title to the Intellectual Property it is entitled to own under this Agreement.

SECTION 8 EXCLUSIVE RIGHTS AND LICENSE

8.1 Exclusive Rights and License.

a) Exclusive License. DEKA hereby grants to PROKIDNEY a worldwide, exclusive, royalty-free, perpetual, irrevocable (except as set forth in Section 12) license to practice the DEKA Intellectual Property to make, have made, use, offer for sale, sell and import the Licensed Technology and Improvements thereto, all solely within the ProKidney Field.

b) DEKA Development License. DEKA hereby grants PROKIDNEY an exclusive, worldwide, royalty-free, perpetual (except as set forth in Section 12) license to use the DEKA Intellectual Property solely for the purpose of developing, in collaboration with DEKA, the Licensed Technology for commercial use in the ProKidney Field.

c) Sublicense Rights. Subject to the terms of this Agreement, PROKIDNEY shall have the right to grant a sublicense to the rights and license granted under this Section 8.1(a) – (b) (“Exclusive Rights and License”) for use within the ProKidney Field to any ProKidney Affiliate and, subject to DEKA’s prior written approval (not to be unreasonably withheld or delayed), to any third party. DEKA shall provide a response to PROKIDNEY’s notice of intent to sublicense to any third party within ninety (90) days, unless otherwise agreed by the Parties. Any sublicense granted by PROKIDNEY must be consistent herewith and PROKIDNEY shall remain responsible for performance of PROKIDNEY’s obligations hereunder. Any sublicense under this Section 8.1(c) must be subject to a confidentiality agreement no less restrictive than the confidentiality provisions contained in Section 6 herein prior to the grant of such sublicense or transmission of any Confidential Information.

d) PROKIDNEY Improvements. ProKidney shall own all title to any and all Improvements to the Licensed Technology conceived, created, reduced to practice, developed and/or invented solely by ProKidney independent of any assistance from DEKA as a result of PROKIDNEY’s own development efforts separate and apart from the Development Program.

8.2. DEKA Rights to Licensed Patents. For the avoidance of doubt, DEKA reserves all rights to the DEKA Intellectual Property, except as specifically granted in Sections 7 and 8, including, without limitation, the right to utilize (by licensing others and otherwise) the DEKA Intellectual Property outside of the ProKidney Field during the Term.

8.3. Section 365(n) of the Bankruptcy Code. All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to “intellectual property” as defined in Section 101 of such Code. ProKidney, as licensee, may fully exercise all of its rights and elections under the Bankruptcy Code. The parties further agree that, if a Party elects to retain its rights as a licensee under any Bankruptcy Code, such party will be entitled to complete access to any technology licensed to it hereunder and all embodiments of such technology. Such embodiments of the technology will be delivered to the licensee party not later than: (a) the commencement of bankruptcy proceedings against the licensor, upon written request, unless the licensor elects to perform its obligations under the Agreement, or (b) if not delivered under the foregoing clause (a), upon the rejection of this Agreement by or on behalf of the licensor, upon written request. Any agreements supplemental hereto will be deemed to be “agreements supplementary to” this Agreement for purposes of Section 365(n) of the Bankruptcy Code. As used herein, “Bankruptcy Code” means the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets.

SECTION 9 RESERVED

This Section reserved.

SECTION 10 PATENT FILINGS

10.1 Disclosure of Patent Filings. DEKA shall promptly disclose to PROKIDNEY, and PROKIDNEY shall promptly disclose to DEKA, all inventions arising out of the Development Program, including patents and patent applications and any other intellectual property protections.

10.2 DEKA Patent Filing.

a) In the United States. For inventions that DEKA owns pursuant to Section 7.1 herein, DEKA may elect to file and prosecute patent applications directed to any such inventions and such applications shall be filed, prosecuted, and maintained in DEKA's name at DEKA's expense utilizing patent counsel selected by DEKA. Should DEKA elect not to file a certain patent application despite the written request by PROKIDNEY, PROKIDNEY may elect to file, prosecute, and maintain such patent application in DEKA's name and at PROKIDNEY's expense utilizing patent counsel selected by PROKIDNEY and reasonably acceptable to DEKA.

b) Outside the United States. PROKIDNEY shall notify DEKA when PROKIDNEY desires that DEKA file for patent protection in respect to DEKA Intellectual Property in any country other than the United States. Such applications shall be filed, prosecuted, and maintained by DEKA in DEKA's name utilizing patent counsel selected by DEKA and reasonably acceptable to PROKIDNEY. PROKIDNEY shall reimburse DEKA for reasonable mutually agreed outside patent counsel and other out-of-pocket expenses incurred in connection with preparing, filing, and maintaining such patents and patent applications on a quarterly basis, provided, however, that if DEKA has executed a license with a third party who will make use of the patent in such country outside of the PROKIDNEY Field, PROKIDNEY shall only be required to pay its pro rata portion of such fees and expenses. DEKA and PROKIDNEY shall work cooperatively to estimate the patent expenses to be paid on a quarterly basis.

10.3 Cooperation. With respect to all patent applications referred to above, and to the extent the Parties are able to do so, the Parties shall provide each other with reasonable opportunity to advise the other and shall cooperate with each other at its own expense in the prosecution of all such patent applications, such cooperation not to include retention, payment of costs or expenses, and reimbursement of counsel and similar activities unless mutually agreed by the Parties.

SECTION 11 INFRINGEMENT AND INDEMNIFICATION

11.1 DEKA Enforcement Actions. Each Party shall promptly notify the other in writing if the Party becomes aware of any actually or reasonably suspected infringement or misappropriation by a third party of any DEKA or PROKIDNEY Intellectual Property including, without limitation, with such written notice any evidence available to it of such infringement or

misappropriation by such third party. As between the Parties to this Agreement, PROKIDNEY shall have the right, but not the obligation, to bring an Enforcement Action against such third party for infringement of any DEKA Intellectual Property solely within the ProKidney Field and join DEKA as a party plaintiff, PROVIDED that PROKIDNEY shall bear all expenses of such Enforcement Action. DEKA shall reasonably cooperate with PROKIDNEY in such Enforcement Action, including, without limitation, by providing PROKIDNEY with reasonable access to materials and witnesses. DEKA shall have the right to consult with PROKIDNEY and to participate in and be represented by independent counsel in such Enforcement Action. Neither Party shall settle any such litigation, if such settlement would have a material adverse effect on the DEKA Intellectual Property or the PROKIDNEY Intellectual Property, unless the other Party gives prior, written consent, which consent shall be timely and not be unreasonably withheld. Any damages or other monies awarded or received in settlement of an Enforcement Action brought by PROKIDNEY shall be first applied to reimburse PROKIDNEY's reasonable unreimbursed expenses. Any remainder relating to infringement or misappropriation within the ProKidney Field shall then be paid to PROKIDNEY, except that PROKIDNEY shall reimburse DEKA for its reasonable attorneys' fees. For infringement of any DEKA Intellectual Property both within and outside of the ProKidney Field, DEKA and PROKIDNEY will reasonably cooperate with any relevant DEKA licensees to determine an appropriate sharing of responsibilities and expenses for any Enforcement Action.

11.2 Third Party Infringement Claims. In the event PROKIDNEY is charged with infringement of any Intellectual Property-related right by a third-party based on the sale, lease, use, or manufacture of Licensed Technology, each Party shall immediately notify the other Parties of such claim in writing. PROKIDNEY shall have the exclusive to right to defend against such claim and DEKA will reasonably cooperate with PROKIDNEY, including, without limitation, by providing PROKIDNEY with reasonable access to materials and witnesses, in any such action and shall have the right to consult with PROKIDNEY and be represented by its own counsel. PROKIDNEY shall cover all costs of defending against such claim and PROKIDNEY shall have no remedy against DEKA for any Intellectual Property Losses.

11.3 Freedom to Operate Analyses. Upon reasonable request of PROKIDNEY, DEKA shall provide reasonable assistance by conducting with PROKIDNEY appropriate analyses of freedom to operate with respect to Licensed Technology, including (i) sharing lists of identified patents and patent applications that may constitute prior art references to one or more aspects of the Licensed Technology, (ii) providing input regarding the initial prioritization of such potential prior art references, (iii) contributing technical and legal input regarding such potential prior art references, and (iv) conducting regular coordination teleconferences and/or in person meetings between DEKA's counsel and, as needed, technical personnel, and PROKIDNEY's counsel regarding the substance and progress of the freedom to operate analysis. DEKA and PROKIDNEY shall execute promptly a community of interest agreement to facilitate the cooperation between DEKA and PROKIDNEY regarding intellectual property matters relating to the Licensed Technology. If it determined that a license to a third party's intellectual property may be required to practice the Licensed Technology, PROKIDNEY shall be solely responsible for obtaining such third party license.

SECTION 12 TERMINATION

12.1 Term. The term of this Agreement (“Term”) shall extend from the Effective Date through the commercial life of any Licensed Technology, unless sooner terminated by a Party pursuant to this Section 12.

12.2 Termination for Breach.

a) Upon any material breach of, or default under, this Agreement by DEKA, PROKIDNEY may terminate this Agreement: upon ninety (90) days’ written notice to DEKA. Said notice shall become automatically effective at the end of such period unless, during such period, DEKA shall cure such breach or default.

b) In the event of non-payment, DEKA may upon sixty (60) days’ written notice to PROKIDNEY, terminate this Agreement. Said notice shall become automatically effective at the end of such period unless, during such period, PROKIDNEY shall cure such breach or default.

c) In the event PROKIDNEY fails to proceed for a period of one hundred- eighty (180) days to undertake its obligations under the Development Program as reasonably necessary to achieve the Development Purpose, DEKA may send a notice of termination to PROKIDNEY, and termination shall automatically become effective thirty (30) days following PROKIDNEY’s receipt of such notice, unless PROKIDNEY has cured such breach.

d) DEKA’s rights of termination under Sections 12.2 (b) and (c), above are DEKA’s sole rights of termination under this Agreement.

12.3 Termination for Convenience. PROKIDNEY shall have the right to terminate this Agreement on ninety (90) days’ advance written notice to DEKA. During such ninety (90) day period, PROKIDNEY shall cooperate in good faith with DEKA to wind down the Development Program and PROKIDNEY shall continue to reimburse DEKA pursuant to Sections 3 and 4, but the monthly reimbursements due to DEKA during the ninety (90) day period shall not exceed the average monthly reimbursement rate for the prior three (3) months. Upon DEKA’s receipt of such notice, the termination shall be irrevocable.

12.4 Return of Rights to DEKA. If this Agreement is terminated for any reason while work is ongoing on any Project, then, with respect to such Project: a) the Exclusive Rights and License under Section 8.1 related only to any then-uncompleted Milestones shall terminate, and b) any and all rights in and to all Licensed Technology developed under such Milestones shall be returned to DEKA. All other Exclusive Rights and License under Section 8.1 and rights in and to all Licensed Technology shall continue in perpetuity.

SECTION 13 NOTICE

13.1 Notices. All notices given under this Agreement shall be in writing and shall be given, if to:

If to DEKA, to:

DEKA Research & Development Corp.
340 Commercial Street
Manchester, NH 030101
Attention: President

With a copy to:

Maureen K. Toohey
Toohey Law Group LLC
340 Commercial Street
Manchester, NH 030101

If to PROKIDNEY, to:

PROKIDNEY
329 Westpoint Blvd., Suite G
Winston Salem, NC 27103
Attn: Deepak Jain

With a copy to:

PROKIDNEY
329 Westpoint Blvd., Suite G
Winston Salem, NC 27103
Attn: Tim Bertram

Each such notice or other communication shall for all purposes of this Agreement be treated as effective or as having been given: (a) upon delivery, if personally delivered; (b) one (1) Business Day after pre-paid deposit for next Business Day delivery with a commercial courier service (*e.g.*, FedEx); or (c) five (5) Business Days after deposit, postage pre-paid, with first class airmail (which airmail must be certified or registered).

SECTION 14 GENERAL

14.1 Use of Name. Except in furtherance of the obligations owing under, and as contemplated by, this Agreement, no Party to this Agreement shall employ or use the name of the other Party in any promotional materials, advertising, or other publicly communicated materials without the prior written permission of such other Party.

14.2 Indemnification by PROKIDNEY.

a) PROKIDNEY shall indemnify, defend and hold harmless DEKA, its partners, shareholders, members, directors, managers, officers, and employees, from and against any and all demands, claims, actions, suits, proceedings, liabilities, obligations, damages, losses, costs and expenses (including without limitation reasonable attorneys' fees and disbursements) arising out of the following: any claim of a third party (including, without limitation, by any person or entity in connection with the use of Licensed Technology tested or Commercialized by

PROKIDNEY or an Authorized Sublicensee under this Agreement , and any other third party) alleging damages caused by any such Licensed Technology, or any component thereof, alleging product liability, negligence, personal injury, property damage, or any other cause of action of any nature seeking to impose liability.

b) In the event of any claim under Section 14.2(a), DEKA shall promptly notify PROKIDNEY of such claim, PROVIDED that failure to provide such notice shall not release PROKIDNEY from any of its indemnification obligations hereunder unless PROKIDNEY is materially prejudiced by the delay in notification. PROKIDNEY will undertake the defense of any such claim by counsel of PROKIDNEY's choosing and shall have control of the defense of, and have the right to compromise, any such claim. DEKA will provide PROKIDNEY with all information reasonably requested by PROKIDNEY, and will cooperate with PROKIDNEY in defending such claim. DEKA's reasonable actual costs in connection therewith will be reimbursed by PROKIDNEY. DEKA, at its sole option, may participate in such defense through separate counsel of its own choosing and at its own cost.

c) Failure to Assume Defense. In the event, PROKIDNEY, within a reasonable time after notice of any such claim, fails to undertake the defense of such claim, DEKA, upon further notice to PROKIDNEY, shall have the right to undertake the defense, compromise or settlement of such claim, subject to PROKIDNEY's right (and continuing obligation) to assume the defense of such claim, and subject to the DEKA's right to obtain reimbursement to which it is due from PROKIDNEY.

d) No Dispute Resolution Procedures. The provisions of Section 14.4 hereof regarding dispute resolution shall not apply to disputes with third parties arising out of this Section 14.2, but shall apply in determining the respective obligations of PROKIDNEY and DEKA to one another under this Section 14.2.

14.3 Indemnification by DEKA.

a) DEKA shall indemnify, defend and hold harmless PROKIDNEY, its partners, shareholders, members, directors, managers, officers, and employees, from and against any and all demands, claims, actions, suits, proceedings, liabilities, obligations, damages, losses, costs and expenses (including without limitation reasonable attorneys' fees and disbursements) arising out of any claim by a third party alleging damages caused solely by the use of any Licensed Technology by DEKA, or any licensee of DEKA, outside of the ProKidney Field.

b) In the event of any claim under Section 14.3(a), PROKIDNEY shall promptly notify DEKA of such claim, PROVIDED that failure to provide such notice shall not release DEKA from any of its indemnification obligations hereunder unless DEKA is materially prejudiced by the delay in notification. DEKA will undertake the defense of any such claim by counsel of DEKA's choosing and shall have control of the defense of, and have the right to compromise, any such claim. PROKIDNEY will provide DEKA with all information reasonably requested by DEKA, and will cooperate with DEKA in defending such claim. PROKIDNEY's reasonable actual costs in connection therewith will be reimbursed by DEKA. PROKIDNEY, at its sole option, may participate in such defense through separate counsel of its own choosing and at its own cost.

c) Failure to Assume Defense. In the event, DEKA, within a reasonable time after notice of any such claim, fails to undertake the defense of such claim, PROKIDNEY, upon further notice to DEKA, shall have the right to undertake the defense, compromise or settlement of such claim, subject to DEKA's right (and continuing obligation) to assume the defense of such claim, and subject to the PROKIDNEY's right to obtain reimbursement to which it is due from DEKA.

d) No Dispute Resolution Procedures. The provisions of Section 14.4 hereof regarding dispute resolution shall not apply to disputes with third parties arising out of this Section 14.3, but shall apply in determining the respective obligations of PROKIDNEY and DEKA to one another under this Section 14.3.

14.4 Mediation.

a) The Parties will attempt to settle any claim or controversy arising out of this Agreement through consultation and negotiation in good faith and a spirit of mutual cooperation for at least forty-five (45) days after such claim or controversy was brought to the attention of the other Party. If such attempts fail, then the dispute will be mediated pursuant to mutually agreeable rules of mediation by a mutually acceptable mediator, having knowledge of commercial matters as contained in this Agreement, to be chosen by the Parties within forty-five (45) days after written notice by one of the Parties demanding mediation. If the Parties are unable to agree on a mutually acceptable mediator, then the Parties agree that the mediator shall be selected by the American Arbitration Association. Neither Party may unreasonably withhold consent to the selection of a mediator, and the Parties will share the costs of the mediation equally. By mutual agreement the Parties may replace mediation with some other form of alternative dispute resolution, such as neutral fact finding or a mini-trial.

b) Any dispute which the Parties cannot resolve through negotiation, mediation or other form of ADR within six months of the date of the initial demand may then be submitted to a court of proper jurisdiction for resolution. The use of any ADR procedures will not be construed under the doctrines of laches, waiver or estoppel to affect adversely the rights of either party to pursue its legal remedies. Nothing in this Section will prevent either party from resorting to judicial proceedings if (i) good faith efforts to resolve the dispute under these procedures have been unsuccessful or (ii) interim relief from a court is necessary to prevent serious and irreparable injury to a Party or to others.

14.5 Independent Contractor. For all purposes related to this Agreement, each Party shall be deemed an independent contractor of the other Party, and nothing in this Agreement shall be deemed to create a relationship of employment or agency, constitute DEKA and PROKIDNEY as partners or joint venturers, or authorize one Party to bind the other to any third party under contract or otherwise, without the express written authorization of the other Party.

14.6 No Further Warranties. Each Party hereto acknowledges and agrees:

a) that no representation or promise not expressly contained in this Agreement has been made by the other Party hereto or by any of its agents, employees, representatives or attorneys concerning the subject matter of this Agreement;

b) that this Agreement is not being entered into on the basis of or in reliance on any promise or representation, express or implied, covering the subject matter hereof other than those which are set forth expressly in this Agreement ; and

c) that each Party has had the opportunity to be represented by counsel of its own choice in this matter, including without limitation during the negotiations which preceded the execution of this Agreement.

14.7 DEKA Representations and Warranties. DEKA represents and warrants that:

a) DEKA Products Limited Partnership is a limited partnership duly organized, validly existing, and in good standing under the laws of New Hampshire;

b) DEKA Research & Development Corp. is a corporation duly organized, validly existing, and in good standing under the laws of New Hampshire;

c) DEKA has the full right and power to enter into, and perform its obligations under, this Agreement, and that, to the best of its knowledge, there are no outstanding agreements, assignments or encumbrances in existence inconsistent with the provisions of this Agreement; and

d) DEKA is the legal owner of the DEKA Intellectual Property.

e) DEKA represents, warrants and covenants that it is not, and it is not currently using, and will not in the future use, to perform the services hereunder, the services of any person or entity, excluded or debarred pursuant to the Generic Drug Enforcement Act of 1992, 21 U.S.C. §335a, as amended, or any similar state law or regulation, excluded by the Office of Inspector General pursuant to 42 U.S.C. § 1320a-7, et seq., or any state agency from participation in any Federal or state health care program or otherwise disqualified or restricted by the U.S. Food and Drug Administration pursuant to 21 C.F.R. 312.70 or any other regulatory authority (a "Debarred Person"). DEKA further represents, warrants and covenants that, during the term of this Agreement, DEKA will not hire or employ to provide Services under this Agreement any person or entity listed on the General Services Administration's List of Parties Excluded from Federal Programs or on the U.S. Department of Health and Human Services Office of Inspector General's List of Excluded Individuals/Entities (each an "Excluded Person"). DEKA shall immediately notify PROKIDNEY in writing if it becomes aware that any person or entity (including DEKA) who is performing services hereunder is or becomes a Debarred Person or Excluded Person, or to its knowledge, if any action, suit, claim, investigation, or other legal or administrative proceeding is pending or threatened, that would make any person or entity (including DEKA) performing services hereunder a Debarred Person or Excluded Person, and DEKA shall ensure that such person or entity does not perform services under this Agreement.

14.8 PROKIDNEY Representations and Warranties. PROKIDNEY represents and warrants that:

a) PROKIDNEY is duly organized, validly existing, and in good standing under the laws of the Cayman Islands;

b) PROKIDNEY has the full right and power to enter into, and perform its obligations under, this Agreement, and that, to the best of its knowledge, there are no outstanding agreements, assignments or encumbrances in existence inconsistent with the provisions of this Agreement.

14.9 Limitation of Liability Regarding Representations and Warranties. A Party shall have no liability for any breach of any representation or warranty herein, including but not limited to any representations and warranties set forth in Sections 14.6 and 14.7, that exceeds one million U.S. dollars (\$USD 1,000,000) in the aggregate.

14.10 Force Majeure. No Party shall be liable for any failure to perform as required by this Agreement to the extent such failure to perform is caused by any reason beyond the Party's control, or by reason of any of the following: labor disturbances or disputes, accidents, civil disorders, acts of aggression, acts of God, disease, or similar occurrences. This section shall not apply to any obligation to make any payment to the other Party.

14.11 Compliance with Anti-Corruption Laws. In connection with this Agreement, the Parties have complied and will comply with all applicable local, national, and international laws, regulations, and industry codes dealing with government procurement, conflicts of interest, corruption or bribery, including without limitation, if applicable, the U.S. Foreign Corrupt Practices Act of 1977, as amended, and any laws enacted to implement the Organization of Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions.

14.12 Assignment. Neither this Agreement nor any rights hereunder may be assigned or otherwise transferred by a Party without the prior written consent of the other Party, which consent shall not be unreasonably conditioned, withheld, or delayed, except that PROKIDNEY may assign this Agreement and its rights hereunder to a purchaser of all or substantially all of the assets of PROKIDNEY regardless of the form of the transaction. Subject to the foregoing, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

14.13 Severability. If any part of this Agreement is held (by final judicial decree) void, invalid or unenforceable, such ruling shall not affect the validity or enforceability of the remainder of this Agreement, but such part shall be deemed modified to the extent necessary, in the opinion of the judicial authority, to render such term or condition enforceable, and the rights and obligations of the Parties shall be construed and enforced accordingly, preserving to the fullest permissible extent the intent and agreements of the Parties as set forth in this Agreement.

14.14 Entire Agreement. This Agreement contains the entire agreement between the Parties relating to the subject matter hereof. No amendments or modifications to this Agreement shall be effective unless made in writing and signed by an authorized representative of each Party. Further, the Parties agree that the Recitals and the Attachments attached hereto are specifically incorporated into the Agreement by reference herein.

14.15 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to any choice of law provision or rule that would cause the application of the laws of any other jurisdiction.

14.16 No Public Announcements. No Party, except as required by law, shall originate any publicity, news release or public announcement, written or oral, whether to the public or press, stockholders or otherwise, relating to this Agreement, including without limitation its existence, the subject matter to which it relates, or any of its terms, to any amendment hereto or performance hereunder, without the express written permission of the other Party, which permission will not be unreasonably withheld. The Parties expressly agree that PROKIDNEY may disclose the existence of this Agreement, the subject matter to which it relates, its terms, amendments or either Party's performance hereunder, in each case to the extent such disclosure is required by the Securities Exchange Act of 1934 or any other law ("Required Disclosure"), which may include, without limitation, PROKIDNEY's filing of this Agreement, or some portion thereof, with the Securities and Exchange Commission pursuant to a Current Report on Form 8-K or other Exchange Act report.

14.17 Compliance with Export Laws. This Agreement is subject to any law, regulation, order or other restriction on the export or re-export of technology licensed under this Agreement as may be imposed from time to time by the governments of the United States, or any other country, or any agency thereof. No Party shall knowingly export or re-export or cause to be exported or re-exported, directly or indirectly, any technology licensed under this Agreement from any other Party to any country for which the United States or any other government, or any agency thereof, requires an export license or other government approval at the time of such export without first obtaining any required license or approval.

14.18 Amendments; Waivers. No provision of this Agreement may be waived except by an instrument in writing executed by the Party against whom the waiver is to be effective. No provision of this Agreement may be amended or otherwise modified except by an instrument in writing executed by or on behalf of the Parties.

14.19 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument.

14.20 Headings. The headings contained in this Agreement are for convenience only and shall not affect the meaning or interpretation of this Agreement.

****Signature Page Follows****

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement by their duly authorized officers or representatives.

Date:

DEKA PRODUCTS LIMITED PARTNERSHIP
By DEKA Research & Development Corp., its sole general partner

By: /s/ Dean Kamen
Dean Kamen, President

Date:

DEKA RESEARCH & DEVELOPMENT CORP.

By: /s/ Dean Kamen
Dean Kamen, President

Date: January 16, 2022

PROKIDNEY

By: /s/ Pablo Legorreta
Pablo Legorreta

Signature Page to DEKA PROKIDNEY RDEL Agreement

MASTER SERVICES AGREEMENT

This Master Services Agreement (“Agreement”) is made effective as of April 20, 2020 (“Effective Date”) by and between inRegen, a Cayman Islands company, which has a place of business at 10 Market St., #688 Camana Bay, Grand Cayman KY1-9006 Cayman Islands (“Customer”) and IQVIA RDS Inc. a North Carolina corporation having its principal place of business at 4820 Emperor Boulevard, Durham, NC 27703 USA, IQVIA Ltd. a company organized under the laws of England and Wales having its principal place of business at 3 Forbury Place, 23 Forbury Road, Reading, United Kingdom, RG1 3JH, and IQVIA RDS East Asia Ltd. a company organized under the laws of Singapore having its principal place of business at 79 Anson Road, #19-01, Singapore 079906 (collectively “IQVIA”). When signed by the parties, this Agreement will set forth the terms and conditions under which IQVIA agrees to provide certain services to Customer as set forth herein.

Recitals:

A. Customer is in the business of developing, manufacturing and/or distributing pharmaceutical products and/or biotechnology products. IQVIA is in the business of providing clinical trial services, research, and other services for the pharmaceutical, medical device and biotechnology industries.

B. Customer and IQVIA desire to enter into this Agreement to provide the terms and conditions upon which Customer or its affiliates may engage IQVIA or its affiliates from time-to-time to provide services for individual studies or projects by executing individual Work Orders (as defined below) specifying the details of the services.

Agreement:**1. Agreement and Work Orders.**

- 1.1 Scope of Agreement. As a master form of contract, this Agreement allows the parties to contract for multiple projects through the issuance of multiple Work Orders (as discussed in Section 1.3 below), without having to re-negotiate the basic terms and conditions contained herein.
- 1.2 Nature of Services. The services covered by this Agreement may include strategic planning, expert consultation, clinical trial services, statistical programming and analysis, data processing, data management, regulatory, project management, pharmacovigilance, central laboratory services, clinical pharmacology services, electrocardiogram (ECG) services, the IQVIA Technology services (as defined in Section 5.3), and other services requested by Customer, and agreed to by IQVIA as set forth in the relevant Work Order (collectively, the “Services”). IQVIA and Customer, where appropriate or required by law, shall cooperate in the completion of a Transfer of Obligations Form in conjunction with the relevant Work Order. Any responsibilities not specifically transferred in the Transfer of Obligations Form shall remain the regulatory responsibility of Customer. The Transfer of Obligations Form will be filed with the Food and Drug Administration (“FDA”) by Customer where appropriate, or as required by law or regulation.

- 1.3 **Work Orders.** The specific details of the Services for each project under this Agreement (each a “Project”) shall be set forth in a work order signed by the parties (a “Work Order”). A form Work Order is attached hereto as Exhibit A. Each Work Order will include, as appropriate, the scope of work, time line, and budget and payment schedule. Each Work Order shall be subject to all of the terms and conditions of this Agreement, in addition to the specific details set forth in the Work Order. To the extent any terms or provisions of a Work Order conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement shall control, except to the extent that the applicable Work Order expressly and specifically states an intent to supersede this Agreement on a specific matter. All exhibits hereto shall be deemed to be incorporated herein by reference.
- 1.4 **Change Orders.** Any change in the details of a Work Order or the assumptions upon which the Work Order is based, that requires changes in the budget and/or time lines, shall require a written amendment to the Work Order (a “Change Order”) executed by both parties. IQVIA reserves the right to postpone effecting material changes in the Project’s scope until such time as the parties agree to and execute the corresponding Change Order. For any Change Order that affects the scope of the regulatory obligations that have been transferred to IQVIA, IQVIA and Customer shall execute a corresponding amendment to the Transfer of Obligations Form. Customer shall file such amendment with the FDA as required by law or regulation.
- 1.5 **Relationship with Affiliates.** IQVIA may use the services of its affiliates as subcontractors to fulfill IQVIA’ s obligations under this Agreement or any Work Order, provided that (a) the affiliate shall be bound in writing by confidentiality and intellectual property provisions at least as restrictive as those contained herein and (b) the IQVIA entity that is the party to the Work Order shall remain responsible for all such Services performed by its affiliates. Any affiliate of IQVIA or Customer may enter into a Work Order under this Agreement. The terms, conditions and rights in this Agreement shall be incorporated into the Work Order. The term “affiliate” shall mean all entities controlling, controlled by or under common control with IQVIA or Customer, as the case may be.
- 2. Payment of Fees and Expenses.**
- 2.1 **Project Budget.** Customer will pay IQVIA the fees, expenses and pass-through costs in accordance with the budget and payment schedule contained in each Work Order. Depending on the estimated cash flow of the Project and the payment terms, Customer agrees that a prepayment may be needed for IQVIA to maintain cash neutrality over the term of the Project. For Projects extending over more than one calendar year, the budget may include an annual cost adjustment.

The parties hereby authorize the IQVIA entity that is party to each Work Order to invoice, collect, and receive, in the applicable affiliate’s name and on behalf of such affiliate, for all Services rendered by such affiliate pursuant to this Agreement and all other amounts payable to such affiliate under each Work Order. Unless the applicable affiliate and IQVIA otherwise agree to a different form and timing of remittance, IQVIA shall remit to the applicable affiliate the portion of the payments collected or received from Customer on behalf of the affiliate for its provision of Services pursuant to this Agreement and undertaking of the related functions, activities and risks associated with the performance of Services.

- 2.2 **Invoices.** IQVIA will invoice Customer in accordance with the budget and payment schedule in each Work Order for IQVIA's fees, and monthly for its expenses and pass-through costs incurred in performing the Services. All invoice payments shall be made to IQVIA within thirty (30) days of the invoice date if an invoice is delivered electronically, or from the date of receipt if Customer requests a paper invoice, except for prepayment and investigator invoices as required in a Work Order, which are due and payable upon receipt. Expenses and pass-through costs will be supported by a detailed summary sheet. If any portion of an invoice is disputed, then Customer shall pay the undisputed amounts as set forth above and the parties shall use good faith efforts to reconcile the disputed amount as soon as practicable. IQVIA reserves the right to impose, and Customer agrees to pay if imposed by IQVIA, interest from thirty (30) days after the due date of the invoice in an amount equal to one percent (1%) per month (or the maximum lesser amount permitted by law) of all undisputed amounts owing hereunder. If Customer requires a purchase order ("PO") related to an IQVIA invoice, then Customer will provide the PO prior to invoicing by IQVIA. If no PO is provided, IQVIA will invoice Customer without the PO. If resubmission of an invoice is required based on Customer's PO requirement or based upon Customer request, IQVIA's re-submission of that invoice will not change the due date for payment based on the original invoice. Any provisions contained within a PO that modify, conflict with or contradict any term or provision of this Agreement shall be deemed to be null and void.
- 2.3 **Taxes.** Customer shall pay all sales and use taxes, including all applicable goods and services tax, value added tax, local taxes, applicable duties, electronic delivery taxes, excise taxes, levies and import fees (collectively, "Taxes") that are imposed by legislation in connection with the provision of Services and that are not recoverable by IQVIA. All fees set forth in a Work Order are exclusive of Taxes. Where Taxes are paid by IQVIA, IQVIA will provide an invoice showing the Taxes included. Where any Taxes are paid directly to a tax authority or government by Customer, Customer shall not deduct this amount from any amount due to IQVIA. The requirements of this provision shall not apply to any employment-related taxes, duties, income taxes or withholding and shall only apply to Taxes applicable to the Services.
- 2.4 **Foreign Currency Exchange.** The currency to be used for invoicing and payment shall be the currency stated in the budget or table attached to the applicable Work Order (the "Contract Currency").
- (a) **Pass-Through Costs.** If IQVIA incurs pass-through costs in a currency other than the Contract Currency, then Customer shall reimburse IQVIA for IQVIA's actual costs in the Contract Currency based on the Oanda foreign currency exchange rate (Oanda.com) for the applicable currencies on the last business day of the month immediately preceding the month in which such pass-through costs are paid by IQVIA.

- (b) **IQVIA' s Fees.** If any Work Order involves the performance of Services by IQVIA or its affiliates in any country that uses a currency other than the Contract Currency, the Budget for those Services will be based on the local rates in the currency used by IQVIA for pricing in that country (the “Non-Contract Currency”), but converted to and reflected in the Contract Currency based on the Oanda foreign currency exchange rate (Oanda.com) for the applicable currencies on the last business day of the month immediately preceding the month in which such fees are invoiced to Customer by IQVIA. If the portion of the fees based on Non-Contract Currencies exceeds the equivalent of US \$3,000,000 (based on the assumptions in the Budget) in any Work Order, inclusive of executed Change Orders, IQVIA will perform an annual reconciliation (at the anniversary of the effective date of the applicable Work Order each year during the term — the “Contract Anniversary”) of the fees billed in the 12 months prior to the Contract Anniversary compared to the fees that would have been billed based on the application of the Oanda quarterly weighted average Contract Currency exchange rates to Non-Contract Currency fees. The reconciliation will be performed on the final invoice if the term of the applicable Work Order is less than 12 months. If the reconciliation establishes a difference of more than 3%, plus or minus, the amount exceeding 3% will be charged or credited to Customer. By way of example only, if the amount of fees billed in Non-Contract Currencies is \$1,000,000 in the 12 months prior to the annual reconciliation, and the annual reconciliation determines that the amount that would have been billed during this same time period utilizing the quarterly foreign currency exchange rates equals \$950,000, then the difference equals \$50,000, or 5%. Under this example, IQVIA would credit to Customer the amount of \$20,000 (\$50,000—(3% x \$1,000,000)).
- 2.5 **Information Requests.** If Customer has failed to make any undisputed payments hereunder, and does not cure such failure within five (5) business days of its receipt of written notice thereof, IQVIA may request that Customer share financial details (such as audited financials, if available) that reasonably demonstrate Customer’s continuing ability to meet its payment obligations under this Agreement and associated Work Orders (each, an “Information Request”). If Customer declines to provide such financial data within thirty (30) days, then IQVIA may, at its discretion, notify Customer and deliver an invoice to the Customer, which the Customer agrees to pay upon request, for an additional deposit for a value of up to two (2) months estimated fees and expenses under the applicable Work Order following the date of notification, with this deposit to be held until the end of the Project and then reconciled against final invoices for the Project. Additionally, Customer shall promptly notify IQVIA upon becoming insolvent or commencing bankruptcy proceedings. Any information shared with IQVIA pursuant to an Information Request will be subject to IQVIA’s obligations of confidentiality set forth in Section 4.1.

3. Term and Termination.

- 3.1 **Term.** This Agreement shall commence on the Effective Date and shall continue for a period of five (5) years, or until terminated by either party in accordance with this Section 3. The Agreement will automatically renew each year thereafter for a period of one year, unless either party notifies the other party in writing at least ninety (90) days prior to the renewal date that the notifying party does not want to renew the Agreement. If this Agreement expires but a Work Order hereunder has not been completed or terminated, the terms of this Agreement will continue to apply to such Work Order as if the Agreement had not expired until such Work Order is completed or terminated. Termination of this Agreement shall terminate all Work Orders. Termination of Work Order shall not result in termination of this Agreement.
- 3.2 **Termination without Cause.** Customer may terminate this Agreement or any Work Order without cause at any time during the term of the Agreement on sixty (60) days' prior written notice to IQVIA.
- 3.3 **Termination for Cause.** Either party may terminate this Agreement or any Work Order (and to the extent IQVIA is providing Local or Legal Representation Services, it may terminate the provision of such Services) for material breach upon thirty (30) days' written notice specifying the nature of the breach, if such breach has not been substantially cured within the thirty (30) day period, provided, however, in the event Customer fails to timely pay any undisputed amounts, IQVIA may at its discretion upon providing five (5) business days prior written notice thereof, cease extension of credit privileges to Customer; suspend Services (including data transmission) except to the extent that any suspension would reasonably be expected to cause harm to any subject in a clinical trial; and/or withhold payment of refunds to Customer until such undisputed amounts are paid.
- 3.4 **Standards.** If IQVIA reasonably determines that its continued performance of the Services contemplated by one or more Work Orders would constitute a potential or actual violation of regulatory, scientific or ethical standards of integrity, then IQVIA may, in the case of any actual violation, suspend Services under the applicable Work Order(s) (and to the extent IQVIA is providing Local or Legal Representation Services, it may suspend the provision of such Services) by giving written notice stating the effective date (which may be less than thirty (30) days from the notice date) of such suspension. The parties shall then cooperate to negotiate a Change Order for the applicable Work Order to correct such potential or actual violation, upon which IQVIA shall resume the Services. If the parties fail to execute a Change Order within forty-five (45) days following the suspension of Services, either party may terminate the Work Order.
- 3.5 **Bankruptcy.** Either party may terminate this Agreement or any Work Orders immediately upon provision of written notice if the other party becomes insolvent or files for bankruptcy.
- 3.6 **Identification of Work Order.** Any written termination notice shall identify the specific Work Order or Work Orders that are being terminated.

- 3.7 **Payment.** Customer shall pay IQVIA for all Services performed and reimburse IQVIA for all costs and expenses incurred in accordance with this Agreement and any applicable Work Order, even if the parties' original payment schedule spreads out payments for certain services or defers payments for certain services until the end of the Project, with payments to include all non-cancelable and non-avoidable costs incurred prior to termination but paid after the termination date. If payments are unit or milestone based, and the Agreement or a Work Order is terminated after costs have been incurred toward achieving portions of one or more incomplete units or milestones, Customer will pay IQVIA on a pro-rated basis for actual work performed toward those incomplete units or milestones up to the date of termination, in addition to paying for completed units or milestones.
- 3.8 **Closeout.** Upon termination of a Work Order, the parties shall promptly meet to prepare a close-out schedule, and IQVIA shall cease performing all work not necessary for the orderly close-out of the Services or required by laws or regulations. Customer shall pay for all actual costs, including time spent by IQVIA personnel (at the agreed upon rates), incurred to complete activities reasonably necessary for the termination and close-out of affected Projects, including the fulfillment of any regulatory requirements. In addition, if the termination is by Customer without cause, or by IQVIA for cause, Customer shall also pay IQVIA for any IQVIA personnel exclusively assigned to the affected Projects at the rates set forth in the Work Order (provided that such personnel's time is not already being billed for close-out Services) from the date of termination until such personnel have been assigned to another project, or until forty-five (45) days from the date of termination, whichever comes first. IQVIA shall make all reasonable efforts to promptly re-assign such personnel.
- 4. Confidentiality.**
- 4.1 **Confidential Information.** Customer and its affiliates possess certain confidential and proprietary data and information, including without limitation Customer Technology (as defined in Section 5.1 below) and Customer Property (as defined in Section 5.2 below) ("Customer Confidential Information"), and IQVIA and its affiliates possess certain confidential and proprietary information pertaining to its operations, methods and pricing, including without limitation IQVIA Property (as defined in Section 5.2 below)("IQVIA Confidential Information") (Customer Confidential Information and IQVIA Confidential Information, including the terms of this Agreement and any Work Order, are each referred to herein as "Confidential Information"). "Confidential Information" does not include information that is (a) already in the receiving party's possession at the time of disclosure, as evidenced by the receiving party's prior written records; (b) part of or becomes part of the public domain through no fault of the receiving party; (c) received from a third party authorized to provide it; or (d) independently developed by the receiving party, as evidenced by the receiving party's contemporaneous written records.
- 4.2 **Obligations.** The Confidential Information shall be used by the receiving party, its affiliates and their employees only for purposes of performing the receiving party's obligations hereunder. Each party shall keep confidential all Confidential Information received from the other party or its affiliates, and will not disclose or publish Confidential Information to third parties without the other party's prior written consent, provided, however, that IQVIA may disclose limited Confidential Information to third parties performing on behalf of IQVIA or Customer in connection with this Agreement who have a need to know such Confidential Information, provided that such third party is not a

competitor of Customer and is bound by confidentiality obligations substantially similar to those set forth herein. Upon the disclosing party's request or upon completion of the Services, the receiving party shall promptly cease all use of the disclosing party's Confidential Information and return it to the disclosing party or, at the disclosing party's option, certify to the destruction of all Confidential Information; provided, however, that the receiving party may retain one copy of the disclosing party's Confidential Information for archival purposes only and Customer may retain IQVIA Confidential Information that is incorporated into any work product and deliverables. These obligations of confidentiality and nondisclosure shall remain in effect for a period of five (5) years after the completion or termination of this Agreement or the applicable Work Order, whichever is later.

- 4.3 **Permitted Disclosures.** The receiving party may disclose the disclosing party's Confidential Information to the extent required pursuant to any judicial or administrative process or order; provided that the receiving party shall, as soon as practicable and where not prohibited, prior to any such disclosure, give the disclosing party sufficient notice and reasonable assistance to contest such requirement or order should it wish to do so. The receiving party agrees to reasonably cooperate with the disclosing party, at disclosing party's expense, in seeking any protective order or other remedy.
- 4.4 **Publicity.** Neither party will use the other party's name in connection with any publication or promotion without the other party's prior express written consent.
- 4.5 **Equitable Relief.** The parties recognize that any threatened breach or breach of this Section 4 may cause irreparable harm that may be inadequately compensable in damages and that, in addition to other remedies that may be available at law or equity, a party is entitled to seek injunctive relief for such threatened or actual breach, and the entry of such injunctive relief, shall not preclude a party from seeking any damages or other relief to which it may be entitled under law.
- 5. Ownership and Inventions.**
- 5.1 **Customer Property.** Excluding IQVIA Property (as defined below), all data and information provided by IQVIA to Customer as deliverables under this Agreement, and any inventions that are conceived of as the direct result of Services performed by IQVIA under this Agreement, and all intellectual property rights thereto, shall be the sole property of Customer ("Customer Property"). IQVIA hereby assigns title and interest in all Customer Property to Customer. At Customer's request and expense, IQVIA shall, and shall cause its affiliates and employees to, execute all documents and take all actions that Customer reasonably deems necessary to perfect Customer's ownership of the Customer Property.
- 5.2 **IQVIA Property.** IQVIA Property is defined as data, data models, databases, inventions, processes, know-how, copyrights, trade secrets, analytical methods, procedures and techniques, manuals, personnel data, pricing, financial information, technical expertise, software, and other intellectual property rights that are owned by IQVIA or its affiliates prior to the Effective Date. IQVIA Property shall include property that is independently developed by or for IQVIA and its affiliates without incorporation of Customer's Confidential Information or Intellectual Property; and any improvements, modifications and enhancements made to the foregoing during the term of this Agreement that do not incorporate any Customer Confidential Information or Intellectual Property. IQVIA and its affiliates own all right title and interest in and to the IQVIA Property.

- 5.3 **IQVIA Technology.** IQVIA Property shall also include its proprietary systems, platforms and applications (collectively, the “IQVIA Technology”). To the extent that IQVIA provides Services using the IQVIA Technology, Customer grants to IQVIA all rights necessary to use and manage the data entered into the IQVIA Technology solely for the benefit of Customer and in accordance with this Agreement and applicable laws. If permitted in the applicable Work Order, pursuant to the terms and conditions of this Agreement and that Work Order, Customer shall have the non-exclusive right, during the term specified in that Work Order, to use the IQVIA Technology. Upon expiration or termination of the applicable Work Order, Customer shall promptly cease use of the IQVIA Technology. Customer shall have no right to use the IQVIA Technology for any purpose other than specifically allowed under this Agreement. IQVIA makes no representations or warranties as to the accuracy of the data entered into the IQVIA Technology provided to IQVIA or entered by Customer or third parties. IQVIA does not warrant that use of the IQVIA Technology will be uninterrupted or error free, nor does IQVIA make any warranty as to the results to be obtained from the use of the IQVIA Technology.
- 5.4 Except as otherwise stated in this Agreement or any Work Order, THE IQVIA TECHNOLOGY, THE SERVICES AND THE DELIVERABLES DELIVERED HEREUNDER ARE PROVIDED AND DISTRIBUTED ON AN “AS IS” BASIS WITHOUT WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.
- 6. Records and Materials.**
- 6.1 **Maintenance of Records.** IQVIA shall maintain and retain records relating to the Services and Projects as provided in each Work Order and per IQVIA SOPs. IQVIA shall ensure that records are protected from destruction or damage and are maintained within IQVIA’s control during the Term of each Work Order unless agreed upon otherwise in a Post-Study Archiving Agreement.
- 6.2 **Return of Customer Materials.** At the completion of the Services under a Work Order or upon termination of this Agreement, IQVIA will deliver to Customer all materials, information and all other data owned by Customer, regardless of the method of storage or retrieval, in such form as is then currently in the possession of IQVIA or as specified in a Work Order. IQVIA, however, reserves the right to retain, at its own cost and subject to the confidentiality provisions herein, one (1) copy of information as necessary to satisfy regulatory requirements or to resolve disputes regarding the Services.

7. Relationship of the Parties.

- 7.1 Independent Contractor. The parties hereto are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint venturers. Neither party shall have the power nor right to bind or obligate the other party, and neither party shall hold itself out as having such authority.
- 7.2 Local Representative. If Customer desires to conduct a trial in one or more countries that require a local sponsor or representative (the “Local Representative”): (a) to indemnify sites for harm caused by the trial drug, or (b) otherwise assume primary responsibility for: (i) the trial drug, (ii) acting as the importer of record for any trial drug, devices or other goods, or (iii) the trial in general, including without limitation any procedures required by the protocol, Customer may request that IQVIA serve as Local Representative in such countries and IQVIA will confirm in writing whether or not it agrees that one or more of its affiliates will act as Local Representative for Customer for a particular project or trial (“Local Representation Services”).
- 7.3 Legal Representative in European Union. If Customer is not based in the European Union (“EU”) and services will be performed in the EU, Customer may request that IQVIA serve as its legal representative in the EU and IQVIA will confirm in writing whether or not it agrees that one or more of its affiliates will act as Legal Representative for Customer for a particular project or trial.

8. Regulatory Compliance.

- 8.1 General. IQVIA agrees that its Services will be conducted in compliance with all applicable laws, rules and regulations, with the standard of care customary in the contract research organization industry. IQVIA’s standard operating procedures will be used in performance of the Services, unless otherwise specifically stated in the applicable Work Order. Customer further represents that it will reasonably cooperate with IQVIA in taking any actions necessary to comply with the regulatory obligations that have been transferred to IQVIA pursuant to a Transfer of Obligations Form.
- 8.2 Debarment. IQVIA represents that it is not and has never been, and neither its employees nor its affiliates’ employees, nor any subcontractor who will be rendering Services hereunder is currently, (a) debarred or voluntarily excluded or convicted of a crime for which a person can be debarred under 21 U.S.C. § 335(a), as amended, or any equivalent thereof, in any country in which any portion of the Services are conducted, nor (b) to IQVIA’s knowledge, threatened to be debarred or voluntarily excluded or indicted for a crime or otherwise engaged in conduct for which a person can be debarred under § 335(a), or subject to any governmental sanction that would prevent the rendering of Services hereunder in any jurisdiction in which the study is to be conducted, nor (c) excluded from participation in any federally-funded health-care program. In the event that, during the Term, IQVIA becomes so debarred or excluded, IQVIA shall promptly notify Customer and, upon receipt of such notice, Customer shall have the right to terminate this Agreement immediately. In the event that, during the Term, IQVIA becomes aware of the debarment or exclusion any person or entity providing Services under this Agreement, IQVIA shall notify Customer promptly and cease activities with such person or entity in connection with the Services.

- 8.3 **Data Protection.** Both parties shall at all times abide by all applicable privacy laws and regulations, and this Agreement, including the Data Processing Agreement attached in Exhibit B. In addition, IQVIA shall at all times abide by its privacy policies and Customer's instructions when processing personal data under this Agreement. If the Services will involve the collection or processing of personal data (as defined by applicable data protection legislation) within the European Union ("EU"), then Customer shall serve as the controller of such personal data, as defined by the General Data Protection Regulation (Regulation (EU) 2016/679 Regulation of the European Parliament and the Council on the Protection of individuals with regard to the processing of personal data and on the free movement of such data) ("GDPR"), and IQVIA shall act only under the instructions of the Customer in regard to such personal data. If Customer is not based in the EU, Customer must appoint a third party to act as its local data protection representative or arrange for a co-controller established in the EU for data protection purposes in order to comply with GDPR as IQVIA does not provide this service.
- 8.4 **Pharmacovigilance Databases and Systems.** In the event a project does not utilize IQVIA's Pharmacovigilance Databases and System, Customer shall be responsible for verifying such systems and databases are of an adequate standard and compliant with applicable law.
- 9. Audits and Regulatory Inspections.**
- 9.1 **Customer Audits.** During the term of this Agreement, IQVIA will permit Customer's representatives (provided that (a) such representatives are not competitors of IQVIA; and (b) prior to any audit Customer shall procure that its non-employee representative enter into a confidentiality agreement with IQVIA on terms at least as stringent as the confidentiality terms herein) to examine or audit the work performed hereunder and the facilities at which the work is conducted upon reasonable advance notice during regular business hours to determine that the Project assignment is being conducted in accordance with the agreed task and that the facilities utilized are adequate. Customer agrees that it shall not disclose to any third party any information ascertained by Customer in connection with any such audit or examination, except to the extent required by law or regulation.
- 9.2 **Regulatory Inspections.** Each party acknowledges that the other party may respond independently to any regulatory correspondence or inquiry in which such party or its affiliates is named. Each party, however, shall notify the other party promptly of any FDA or other governmental or regulatory inspection or inquiry concerning any study or Project of Customer for which IQVIA is providing Services. During any such inspection or inquiry, the parties agree to make reasonable efforts to disclose only the information required to be disclosed.

9.3 **Audit and Inspection Costs.** Except as provided below, Customer shall reimburse IQVIA for its time and expenses (including reasonable attorney fees and the costs of responding to findings) associated with any inspection, audit or investigation relating to the Services instigated by Customer or by a governmental authority, unless and to the extent such inspection, audit or investigation reveals that IQVIA breached this Agreement or any applicable law or regulation; provided, however, during the term of this Agreement Customer shall have the right to audit IQVIA once per year for up to five (5) days and to conduct reasonable follow up to an audit revealing IQVIA's breach of this Agreement or any applicable law or regulation, each at IQVIA's cost (excluding expenses).

10. Investigators.

10.1 **Agreements with Investigators.** If the applicable Work Order provides that IQVIA will enter into agreements with investigators or investigative sites (collectively, "Investigators"), IQVIA will use its local Clinical Trial Agreement forms ("CTAs") unless an industry-standard form is required in the country in question or a site-specific form is required by a site that has been selected. If no local CTA, site-specific or industry-standard form exists for the country or Investigator as applicable, IQVIA will use its global CTA. Any applicable Local CTAs, industry-standard forms, site-specific forms, and the Global CTA will be made available for inspection and approval by the Customer. IQVIA and Customer will mutually agree upon CTA negotiation guidelines (the "CTA Guidelines") in order to allow IQVIA to negotiate CTAs on the Customer's behalf. If an Investigator insists upon any material changes to any provisions that are not allowed under or addressed by the CTA Guidelines, IQVIA shall submit the proposed change to Customer, and Customer shall review, comment on and/or approve such proposed changes within ten (10) working days. IQVIA's responsibilities with respect to Investigators shall be limited to those responsibilities specifically set forth in this Agreement or the applicable Work Order.

10.2 **Payment to Investigators.** If IQVIA will be paying Investigators on behalf of Customer: (a) IQVIA will only pay Investigators from pre-payments received from Customer, (b) IQVIA will not be responsible for delays in a study or Project to the extent that such delays are caused by Customer's failure to make such pre-payment, and (c) such payments to Investigators will be separate from payments to IQVIA for its Services. When Customer must publicly report to certain government or regulatory authorities, information regarding payments or transfers of value made to certain healthcare professionals by or on behalf of Customer to comply with applicable law, IQVIA will prepare and submit financial reports to Customer on a quarterly basis in a mutually agreeable format.

11 **Anti-Bribery.** Each party undertakes to the other party that:

- (a) it will not, and will procure that each of its affiliates and each of their respective employees, directors, officers, subcontractors and agents will not, (i) offer, promise or give an advantage to another person, or (ii) request, agree to receive or accept a financial or other advantage in violation of any anticorruption laws, rules, regulations and decrees applicable to the respective party (collectively, "Legislation"), including the United States Foreign Corrupt Practices Act, as amended, the United Kingdom Bribery Act 2010 and any implementing legislation under the OECD Convention Against the Bribery of Foreign Government Officials in International Business Transactions. It is each party's responsibility to be familiar with, and comply with, the provisions of the applicable Legislation; and
- (b) from time to time, at the reasonable request of the other party, it will confirm in writing that it has complied with its undertakings under Section 11(a) above and will provide any information reasonably requested by the other party in support of such compliance.

12. Limitation of Liability.

- 12.1 Consequential Damages. Except for breach of Section 4 (Confidentiality), neither IQVIA, Customer, their affiliates nor any of their respective directors, officers, employees, subcontractors or agents shall have any liability (including without limitation, contract, negligence and tort liability) for any loss of profits, opportunities or goodwill or any type of indirect or consequential damages in connection with this Agreement or any Work Order or the Services performed by IQVIA.
- 12.2 Direct Damages Cap. Except for breach of Section 4 (Confidentiality), or in connection with the obligations under Section 13 (Indemnification) to the extent any claim involves the gross negligence, willful misconduct, or in connection with Third Party Claims for which the third party is not a governmental or regulatory agency, in no event shall the collective, aggregate liability (including without limitation, contract, negligence and tort liability) of IQVIA or its affiliates, directors, officers, employees, subcontractors or agents under this Agreement exceed the amount of fees actually received by IQVIA from Customer under the applicable Work Order.
- 12.3 Damages. For purposes of this Section 12, the following, additionally and without limitation, will be deemed to be direct damages and not consequential damages: (a) court costs and reasonable attorneys', accounting and other consulting fees and expenses, (b) necessary and appropriate investigatory and third party forensics provider fees and expenses for the purpose of determining if data was subject to unauthorized access or misappropriation, governmental and regulatory fines, penalties, assessments and/or settlements, (c) the reasonable costs of providing notice to government or regulatory agencies, media, the public and/or affected individuals whose personal information was misappropriated, provided that any notice is legally required to be provided, (d) the reasonable costs of remediation (including the cost of twelve (12) months of credit monitoring for individuals whose personal information was misappropriated, call center support and identity theft protection).

13. Indemnification.

- 13.1 Customer Indemnification. Customer shall indemnify, defend and hold harmless IQVIA and its affiliates, and its and their directors, officers, employees and agents (each, an "IQVIA Indemnified Party"), from and against any and all losses, damages, liabilities, fines, reasonable attorney fees, court costs, and expenses (collectively "Losses"), resulting or arising from any third-party claims, actions, proceedings, investigations (including subpoenas or other legal process) or litigation ("Third-Party Claims") arising from this Agreement, any Work Order, or the Services contemplated herein (including, without limitation, any Losses arising from or in connection with the provision of Local Representation Services and/or any device, product or potential product to which this Agreement or any Work Order relates), except to the extent such Losses result directly from (a) the gross negligence or intentional misconduct of IQVIA or any IQVIA Indemnified Party or (b) breach of its obligations under this Agreement by IQVIA.
- 13.2 IQVIA Indemnification. IQVIA shall indemnify, defend and hold harmless Customer and its affiliates, and its and their directors, officers and employees (each, a "Customer Indemnified Party"), from and against any and all Losses, resulting or arising from any Third-Party Claims arising from this Agreement, any Work Order, or the Services contemplated herein, to the extent such Losses result directly from (a) the gross negligence or intentional misconduct of IQVIA or any IQVIA Indemnified Party or (b) breach of its obligations under this Agreement by IQVIA.

- 13.3 **Indemnification Procedure.** A party seeking indemnification or reimbursement hereunder shall give the other party prompt notice of any such claim or lawsuit (including a copy thereof) served upon it and shall fully cooperate with the indemnifying party and its legal representatives in the investigation of any matter the subject of indemnification. The party seeking indemnification shall not unreasonably withhold its approval of the settlement of any claim, liability, or action covered by Section 13.1 or Section 13.2, as applicable, will cooperate with counsel of the indemnifying or reimbursing party, and reserves the right to engage its own counsel at the indemnified party's expense.
14. **Cooperation; Disclosure of Hazards.** Customer shall forward to IQVIA in a timely manner all documents, materials and information in Customer's possession or control necessary for IQVIA to conduct the Services. IQVIA shall not be liable to Customer nor be deemed to have breached this Agreement for errors, delays or other consequences arising from Customer's failure to timely provide documents, materials or information or to otherwise cooperate with IQVIA in order for IQVIA to timely and properly perform its obligations, and any such failure by Customer shall automatically extend any timelines affected by a time period reasonably commensurate to take into account such failure, unless Customer agrees in writing to pay any additional costs that would be required to meet the original timeline. Customer shall provide IQVIA with all information available to Customer regarding known or potential hazards associated with the use of any substances supplied to IQVIA by Customer, and Customer shall comply with all current legislation and regulations concerning the shipment of substances by the land, sea or air.
15. **Force Majeure.** In the event either party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles (except for strikes, lockouts, labor troubles involving the affected party's labor force), inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, Acts of God, inclement weather or other reason or cause beyond that party's control, then performance of such act (except for the payment of money owed) shall be excused for the period of such delay.

16. **Notices and Deliveries.** Any notice required or permitted to be given hereunder by either party shall be made in writing and via email if an email address is provided below. Notice shall be deemed given on the date received if delivered personally, by a reputable overnight delivery service, or three (3) days after the date postmarked if sent by regular, registered or certified mail, return receipt requested, postage prepaid to the following addresses:

If to IQVIA:

IQVIA RDS Inc.
Office of the General Counsel
P.O. Bo 13979
Research Triangle Park, NC
27709-3979
Attention: General Counsel
[Email: officeofgeneralcounsel@iqvia.com](mailto:officeofgeneralcounsel@iqvia.com)

If to Customer:

inRegen
do Twin City Bio, LLC
3929 WestPoint BLVD
Suite G
Winston-Salem, NC 27103
Attention: CEO

17. **Insurance.**

- 17.1 Customer. During the term of this Agreement and for three (3) years after the expiration or earlier termination of this Agreement or any Work Order hereunder, whichever is later, Customer shall maintain insurance coverage to cover its obligations under this Agreement and any Work Orders hereunder as follows: (a) clinical trials and/or product liability by Customer in an amount of at least US \$5,000,000 and (b) general liability in amounts of at least US \$1,000,000; provided, however, in the event IQVIA is acting as Local Representative hereunder Customer shall maintain clinical trials and/or product liability by Customer in an amount of at least US \$10,000,000 and general liability in amounts of at least US \$3,000,000. The Parties acknowledge that clinical trial coverage amounts available and/or required locally may be less than the limits set forth above, and in such case Customer may meet the full requirements above through a global policy in addition to any local coverage. Customer represents and warrants that it will (a) maintain product liability/clinical trials insurance that does not contain any conditions or exclusions in the policy that would not normally be included in insurance of this type, and (b) include IQVIA as an additional insured on all applicable clinical trials and/or product liability policies.
- 17.2 IQVIA. During the term of this Agreement and for four (4) years after the expiration or earlier termination of this Agreement or any Work Order hereunder, whichever is later, IQVIA shall maintain insurance coverage to cover its obligations under this Agreement and any Work Orders hereunder as follows: (a) professional liability insurance coverage in an amount of at least US \$5,000,000 and (b) general liability in amounts of at least US\$1,000,000. IQVIA represents and warrants that it will make Customer an additional insured on IQVIA's general liability policy.

- 17.3 **General Requirements.** All insurance coverage under this Section 17 must be issued by an insurance company that is rated at least A-, VII by A.M. Best. All insurance amounts under this Section 17 may be obtained by full, individual primary policy amount; a primary amount of less than minimum requirement enhanced by a blanket excess umbrella policy; or a combination of either. Each party shall provide the other party with a certificate of insurance upon request. Each party shall provide the other party with at least thirty (30) days prior written notice of any cancellation or expiration of the above-required insurance or any material change to such insurance that causes it to no longer comply with the provisions above. In no event shall the obligations set out in this Section 17 in any way limit or reduce any of either party's other obligations under this Agreement, including, without limitation, either party's indemnification obligations set out in Section 13.
18. **Binding Agreement and Assignment.** This Agreement shall be binding upon and inure to the benefit of Customer and IQVIA and their respective successors and permitted assigns. Neither party may assign any of its rights or obligations under this Agreement to any party without the express, written consent of the other party, except in event of a merger or acquisition of substantially all of the assets of the assignor to an assignee with the financial resources to be able to perform the obligations under this Agreement.
19. **Choice of Law, Waiver and Enforceability.** This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of the State of New York, exclusive of its conflicts of law provisions. The failure to enforce any right or provision herein shall not constitute a waiver of that right or provision. Any waiver of a breach of a provision shall not constitute a waiver of any subsequent breach of that provision. If any provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with applicable laws, it is the intent of the parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.
20. **Survival.** The rights and obligations of Customer and IQVIA, which by intent or meaning have validity beyond such termination (including, but not limited to, rights with respect to inventions, confidentiality, discoveries and improvements, indemnification, insurance, data protection and liability limitations) shall survive the termination of this Agreement or any Work Order.
21. **Entire Agreement, Headings and Modification.** This Agreement, as amended from time to time, together with the applicable Work Orders, contains the entire understandings of the parties with respect to the subject matter herein, and supersedes all previous agreements (oral and written), negotiations and discussions. The descriptive headings of the sections of this Agreement are inserted for convenience only and shall not control or affect the meaning or construction of any provision hereof. Any modifications to the provisions herein must be in writing and signed by the parties.
22. **Counterparts.** This Agreement, a Work Order, Change Order or amendment may be executed by electronic means (including **.PDF**) and in any number of counterparts, each of which when executed and delivered, shall constitute an original, but all of which together shall constitute one agreement binding on all parties, notwithstanding that all parties are not signatories to the same counterpart.

IN WITNESS WHEREOF, this Agreement has been executed by the parties hereto through their duly authorized officers.

ACKNOWLEDGED, ACCEPTED AND AGREED TO:

IQVIA RDS Inc.

By: /s/ Stan Patterson
Print Name: Stan Patterson
Title: VP, Commercial Operations
Date: 4/30/2020

inRegen

By: /s/ Timothy A. Bertram
Print Name: Timothy A. Bertram
Title: CEO
Date: 29 April 2020

IQVIA Ltd.

By: /s/ Nicola Kerr
Print Name: Nicola Kerr
Title: VP, GBO
Date: 4/30/2020

IQVIA RDS East Asia Ltd.

By: /s/ Roy Toh
Print Name: Roy Toh
Title: Vice President
Date: 5/3/2020



**Master Agreement for
Clinical Trials Services**

This Master Agreement for Clinical Trials Management Services (the “**Agreement**”) is made and entered into on April 2nd, 2020, (the “**Effective Date**”),
by and between

inRegen, a Cayman Islands company, with offices at
10 Market Street #688 Camana Bay
Grand Cayman Islands, KY1-9006
(hereinafter referred to as “**Sponsor**”)
and

Frenova, LLC d/b/a Frenova Renal Research, 920 Winter Street,
Waltham, Massachusetts 02451-1457
(hereinafter referred to as “**Frenova**”).
Each is sometimes referred to as “**Party**”

Sponsor is engaged in the business of developing and marketing cell-based products and desires to engage Frenova to perform services in connection with certain clinical trials under development by or under control of Sponsor.

Frenova, among other things, is engaged in the business of providing certain services related to the implementation and management of clinical development programs for the pharmaceutical, biotechnology and medical device industries, which may include certain contract research organization related services. This Agreement sets forth terms under which Sponsor will engage Frenova to provide such services and is comprised of the following Articles:

1. Definitions
2. Services and Standards
3. Financial Terms and Conditions
4. Term and Termination
5. Confidentiality and Proprietary Rights
6. Representations and Warranties
7. Indemnification and Insurance
8. Miscellaneous Clauses

By signing below, each Party agrees to the terms of this Agreement.

Frenova, LLC

/s/ Franklin W. Maddux

Name: Franklin W. Maddux, MD, FACP

Title: Global Chief Medical Officer

Date: April 2, 2020

inRegen

/s/ Timothy A. Bertram

Name: Timothy A. Bertram

Title: CEO inRegen/TCBIO

Date: 02 April 2020

1.0 RECITALS AND DEFINITIONS

1.1 Definitions

- 1.1.1 Affiliates: With respect to either Party, an Affiliate is an entity that is controlled by, controls or is under common control with such Party. A person, corporation or other entity will be regarded as in control of another corporation or entity if such first person, corporation or other entity owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other ownership interest of the other corporation or entity, or if such first person, corporation or other entity possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the other corporation or other entity or the power to elect or appoint fifty percent (50%) or more of the members of the governing body of the other corporation or other entity.
- 1.1.2 Amendment: A written specification of changes to a Statement of Work signed by each Party's authorized representatives.
- 1.1.3 Case Report Form ("CRF"): The printed, optical, or electronic document designed to record all the Protocol required information to be reported to Sponsor on each Study Subject.
- 1.1.4 Facility: The location at which the clinical trial is actually conducted (e.g., end stage renal disease facility or, if applicable, for certain studies this may reference a medical practice) under the supervision of an Investigator.
- 1.1.5 Frenova Project Manager: The Frenova representative assigned to lead the Frenova project team, act as the principal liaison between Frenova and Sponsor, and provide general oversight in the delivery of Services with regard to a specific Statement of Work.
- 1.1.6 Good Clinical Practice ("GCP"): The standard defined in the ICH Harmonised Tripartite Guideline For Good Clinical Practice E6(R1) Current Step 4 version dated 10 June 1996 (including the Post Step 4 corrections) and applicable EU regulations, e.g. EU Directive 2001/20/EC and Regulation (EU) No. 536/2014 and DIN ISO 14155 and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., 21 C.F.R. Parts 11, 50, 54, 56, and 312; the Good Clinical Practices adopted as guidance by the U.S. Food and Drug Administration; or comparable state, federal or local law.

- 1.1.7 HIPAA: means the United States Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009 and its applicable regulations.
- 1.1.8 Institutional Review Board (“IRB”): Any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects constituted in accordance with and in compliance with 21 C.F.R. Part 56, EU Directive 2001/20/EC Art. 2 k) and Regulation (EU) No. 536/2014 Art. 2 (11). The primary purpose of such review is to assure the protection of the rights and welfare of human subjects. An IRB may also be referred to as an independent ethics committee or ethics committee.
- 1.1.9 Invention: Inventions or discoveries, whether patentable or not, which are conceived or first actually reduced to practice in the performance of the Study or the Services including any related patent, trade secret, copyright or other proprietary right. For the purpose of clarity, conception of an invention shall be dictated by inventorship in accordance with United States patent law.
- 1.1.10 Investigator: A person responsible for the conduct of the clinical trial at a Facility. If a trial is conducted by a team of individuals at a Trial Site, the Investigator is the responsible leader of the team and may be called the Principal Investigator.
- 1.1.11 Investigator Budget: A subset of the Pass-Through Budget which sets forth the estimated costs related to the services to be provided by the Investigator in conducting the Study as set forth in the Statement of Work.
- 1.1.12 Key Personnel: The Frenova Project Manager and other key Frenova personnel assigned to the Services as set forth in a Statement of Work.
- 1.1.13 Pass-Through Budget: The estimated costs of Pass-Through expenses for goods and materials incurred by Frenova on behalf of Sponsor, in connection with the performance of the Services as set forth in a Statement of Work.
- 1.1.14 Payment Schedule: The schedule of payments due to be made for Services delivered and Pass-Through expenses incurred, as set forth in a Statement of Work.

- 1.1.15 **Project Specifications**: The specific Services to be provided, statement of assumptions used in preparing the Services Budget, Pass-Through Budget, and assignment of project-related responsibilities between the Parties as set forth in a Statement of Work.
- 1.1.16 **Protocol**: A written document that describes a Study and sets forth specific activities to be performed in accordance with 21 C.F.R. Section 312.23(a)(6), 21 C.F.R. 812.25(b), EU Directive 2001/20/EC Art. 2 h) or Regulation (EU) No. 536/2014 Art. 2 (22), as may be amended from time to time.
- 1.1.17 **Services**: The services to be provided by Frenova, its Affiliates and its Subcontractors (if applicable) under this Agreement as specifically outlined in a Statement of Work, Amendment or winding down plan.
- 1.1.18 **Services Budget**: The estimated cost of the Services, based upon the Project Specifications as set forth in a Statement of Work.
- 1.1.19 **Statement of Work**: A written specification of Services to be performed by Frenova under this Agreement, including the Project Specifications, Contact Information, Services Budget, Pass-Through Budget, Investigator Budget and Payment Schedule.
- 1.1.20 **Study**: A clinical trial performed at one or more Trial Sites under the supervision of one or more Investigator(s) pursuant to a study Protocol.
- 1.1.21 **Study Agent**: The drug(s), biologic(s) or device(s), if any, that are the subject of the Study as specified in the Protocol.
- 1.1.22 **Study Subject**: individuals who are screened for a Study and/or are participating in a Study.
- 1.1.23 **Subcontractor**: An individual or company engaged by Frenova to conduct some elements of a Statement of Work, such as clinical laboratories, patient recruitment services, interactive voice recognition systems and other services, which shall exclude reference to contract employees as set forth in Section 2.3.3.
- 1.1.24 **Trial Site(s)**: Any public or private entity or agency specifically identified related to or pursuant to Statement of Work which performs clinical research, and is engaged to perform a Study by Frenova or Sponsor and the location(s) where trial-related activities are actually conducted.

2.0 SERVICES AND STANDARDS

The Parties will agree on all Services to be provided and the performance of those Services will be authorized in writing through the execution of a Statement of Work. Frenova will not begin work on any Services without an executed Statement of Work or other written document authorizing commencement of the Services, except with respect to an agreed upon letter of agreement which may be executed between the parties to permit Frenova to perform preliminary work involving a Study as the specific Statement of Work for such Study is being negotiated and finalized and signed by the Parties. Statements of Work may be entered into by Frenova or any of its Affiliates, which by execution of such a Statement of Work, will agree to be bound to the terms of this Agreement. Each and every Statement of Work is subject to the agreement of both Parties and each Party reserves the right to decline to enter any Statement of Work.

2.1 Statements of Work

Frenova will provide Services as specified in one or more Statements of Work.

- 2.1.1 Project Specifications. The Statement of Work will include Project Specifications, which may include items such as a description of the Study Protocol, Trial Sites, Facilities, subjects, CRFs, reports and Services to be provided by Frenova, including potential Facilities, potential Trial Sites and potential Investigators.
- 2.1.2 Services Budget. Each Statement of Work will include a Services Budget and will include the costs related to the Services to be provided. Frenova will not exceed the total cost outlined in the Services Budget without the prior written approval of Sponsor, unless specifically authorized by an Amendment, as set out in Section 2.2 below. Sponsor agrees that the Services Budget presented in each Statement of Work is an estimate based upon the Project Specifications. Any changes to the Project Specifications, including without limitation, a request by Sponsor for compression of the timelines or extensions of the timelines for any reason, may result in changes to the Statement of Work, which will be documented in accordance with Section 2.2 below.
- 2.1.3 Pass-Through Budget. Each Statement of Work may include a Pass-Through Budget, which will contain an estimate of anticipated Pass-Through expenses to be incurred on Sponsor's behalf in connection with performance of the Services. Sponsor agrees that the Pass-Through Budget contains an estimate based on the Project Specifications, and information supplied by third party suppliers, and that such costs cannot be predicted with complete certainty at the outset of a Study. Sponsor will reimburse all of Frenova's actual direct costs for Pass-Through expenses incurred in performance of the Services, in accordance with Article 3 below. Frenova will notify Sponsor in writing of any increases or decreases in the Pass-Through Budget upon receipt of such information from third party suppliers or other sources, as the case may be, and such information will be included in an Amendment to the applicable Statement of Work.

- 2.1.4 Investigator Budget. While a subset of the Pass-Through Budget, each Statement of Work may include an Investigator Budget including the costs related to the services to be provided by the Investigator in conducting the Study which will be the basis of the budget attached to the clinical trial agreements to be executed with Investigators. Sponsor agrees that the Investigator Budget generally contains a per procedure fee structure based on the specific Study protocol schedule of events, prorated according to Study Subject participation, and that such costs may be subject to change in the event of changes to the Study protocol. Sponsor will reimburse all of Frenova's actual direct costs for the expenses incurred by the Investigator in performance of the Study, in accordance with Article 3 below. Frenova will notify Sponsor in writing of any increases or decreases in the Investigator Budget upon receipt of such information from Investigators or other sources, as the case may be, and such information will be included in an Amendment to the applicable Statement of Work.
- 2.1.5 Payment Schedule. Each Statement of Work will contain a Payment Schedule, which will specify the manner and timing of all payments for Services and pass-through expenses described in the Statement of Work. Any changes to the Project Specifications, and corresponding changes to the Services Budget or Pass-Through Budget, will be reflected in a corresponding change in the Payment Schedule.
- 2.1.6 Contact Information and Designation of Key Personnel. Each Statement of Work will identify the Key Personnel as the Parties may agree are to be included and their contact information.
- 2.1.7 Territory-Specific Requirements. A Statement of Work may contain terms and conditions supplemental to or different from the terms and conditions set forth in this Agreement, as are necessary for territory-specific matters. In such case, the Statement of Work shall explicitly state that it will govern with respect to such terms and such territory-specific terms shall take precedence over this Agreement with respect to such terms in such territory.

2.2 Amendments

Any changes to a Statement of Work, including but not limited to changes to the Project Specifications, Services Budget, Pass-Through Budget or Investigator Budget, will be agreed upon by the Parties and documented in an Amendment to the Statement of Work. Sponsor agrees that Frenova will not perform any out-of-scope work described in an Amendment until it is approved in writing by both Parties.

- 2.2.1 Unanticipated Changes. Sponsor agrees that changes in costs resulting from, for example, changes to Project Specifications due to modifications to the Study Protocol, delays in receipt of Study Agent from Sponsor, changes in amounts charged by third party suppliers or poor subject enrollment due to changes in clinical practices, cannot be reasonably anticipated in advance. Upon identification by either Party of changes to the Project assumptions or other unanticipated changes to the Project Specifications, the Parties will prepare an Amendment to accommodate increases or decreases to the Project Budget (including the Services Budget and Pass-Through Budget, or Payment Schedule that are reasonably associated with any such adjustments. Such unanticipated changes may include, but are not limited to, any of the following:
- 2.2.1.1 delays in receiving from Sponsor technical information or Sponsor's acceptance of documents submitted by Frenova in the performance of its duties under this Agreement or any Statement of Work, or any other delay on the part of Sponsor;
 - 2.2.1.2 delay in receipt of regulatory approval from a regulatory agency, IRB or Ethics Committee;
 - 2.2.1.3 delay in performance by a Subcontractor not selected by Frenova;
 - 2.2.1.4 delay in shipment of Study Agent, clinical samples and/or clinical supplies to Trial Sites;
 - 2.2.1.5 delay due to changes in standard of care imposed by law, regulation or changes in medical practice affecting participating Trial Sites; or Facilities;
 - 2.2.1.6 commencement of a new clinical trial with the same target patient population as the Study which is undertaken by Frenova on behalf of Sponsor;
 - 2.2.1.7 delay by reason of force majeure as defined herein;
 - 2.2.1.8 Sponsor requested changes to the Services or Protocol;
 - 2.2.1.9 delays due to questions received by either Party from regulatory agencies or ethics committees regarding submission materials that relate to characteristics of the Study Agent or Protocol design;
 - 2.2.1.10 delays due to any changes in applicable law or regulatory environment; or
 - 2.2.1.11 changes for any other reason agreed upon in writing by Sponsor.

2.3 Project Staffing

In performing the Services, Frenova will reasonably allocate personnel who are adequately trained, qualified and experienced to conduct the work as specified in a Statement of Work. Sponsor will have the right, before executing a Statement of Work to review the qualifications of any Key Personnel and raise any concerns which Sponsor may have in that regard and, if such concerns cannot be sufficiently addressed to both parties satisfaction, then such Statement of Work shall not be executed by the parties. In the event that Sponsor has concerns regarding the performance of any Key Personnel, Sponsor shall raise such concerns to Frenova, and the parties shall in good faith seek to resolve such concerns.

- 2.3.1 Key Personnel. Frenova will assign a Frenova Project Manager and/or other employees whose participation in a project is expected for the duration of the project, who will serve as Key Personnel. Frenova will use reasonable efforts to seek the continuity of Key Personnel's participation in a project for the duration of the project. Frenova will provide thirty (30) days' notice to Sponsor, whenever practical, of any changes to the Key Personnel. Frenova will provide project-specific training to replacement Key Personnel at its own expense. Sponsor will have the right to review the qualifications of any Key Personnel replacements and raise any reasonable concerns which Sponsor may have in that regard and, both parties shall seek in good faith to address such concerns.
- 2.3.2 Project Team. Frenova will assign non-Key Personnel at its sole discretion, as needed to perform the Services in accordance with the Statement of Work.
- 2.3.3 Use of Contract Employees. Frenova may, at its own discretion, assign some elements of the Services to contract employees. Frenova agrees that any contract employees used to perform the Services will be adequately qualified, experienced and trained as required to perform the Services in the same manner as Frenova qualifies and trains its own employees. Frenova will remain responsible for satisfactory performance of all Services performed by contract employees.

2.4 Use of Subcontractors

Frenova may use Subcontractors to conduct some elements of a Statement of Work. Frenova will notify Sponsor in advance of its use of Subcontractors. In the event that Sponsor objects, for reasonable cause, to any such Frenova Subcontractors, Frenova will replace the Subcontractor within a mutually agreeable timeframe.

- 2.4.1 Sponsor-Selected Subcontractors. In the event that Sponsor requires Frenova to use a specific Subcontractor that is not otherwise agreeable to Frenova, Frenova will not be responsible for the performance of the Subcontractor, and Sponsor will manage the performance of the Subcontractor and be responsible for any delays or changes to the Project Budget that result from the performance of the Subcontractor. Frenova will notify Sponsor promptly of any performance issues arising out of the use of any such Subcontractors. If Sponsor engages a Subcontractor, but requires that Frenova manage or oversee the performance of the Subcontractor, then Sponsor will supply Frenova with a copy of the relevant contract with the Subcontractor.

2.4.2 Frenova-Selected Subcontractors. For Subcontractors selected and contracted directly by Frenova, Frenova will manage the performance of the Subcontractor in coordination with Frenova.

2.5 Engagement of Trial Sites and Investigators

If required in the terms of a Statement of Work, Frenova will coordinate execution of contracts with Trial Sites and Principal Investigators for the performance of each Study (which may include, by example, clinical trial agreements and facility use agreements) using templates mutually agreeable to Frenova and Sponsor. Unless otherwise agreed upon in any Statement of Work, if an Investigator or other relevant party insists upon any material changes to any provisions of the applicable template agreement(s), then Frenova shall submit the proposed material change to Sponsor, and Sponsor shall promptly review, comment on, reject and/or approve such proposed changes. Each such contract will include terms, to the extent applicable, pertaining to Confidentiality, Proprietary Rights, Inspections and any other pertinent matters as the Parties may decide, which shall be no less restrictive than those of this Agreement without the consent of Sponsor.

2.6 Applicable Standards

Frenova shall perform Services pursuant to this Agreement any Statement of Work in compliance with the specifications of that Statement of Work, GCP and applicable United States, EU laws and regulations, and/or laws of regulations of the specific territories where Services are being performed. The Statement of Work shall specify to what extent Frenova or Sponsor shall provide standard operation procedures in the performance of the Services.

2.7 Sponsor-Provided Systems

2.7.1 In the event that Sponsor requires Frenova to use Sponsor's information systems and associated processes pursuant to a Statement of Work, Sponsor will be responsible for all costs associated with installation and operation of the systems, including costs for hardware and software licenses, and for training of Frenova personnel assigned to the project in the use of Sponsor system(s). Sponsor shall allow Frenova to access the EDC System (defined below) to review and approve Trial Site visit activity for the purpose of processing payments to the Trial Sites.

2.7.2 Sponsor acknowledges that Frenova shall contract with and/or license from an electronic data capture vendor ("EDC Vendor") such that Sponsor may utilize the EDC Vendor software applications to serve as Sponsor's electronic data capture system for any particular Study. Sponsor's rights to use such EDC Vendor software, including, but not limited to, any derivative works, modifications, updates and enhancements thereto, and/or services ("EDC System") for purposes of electronic data capture are subject to Sponsor's compliance with the following terms and conditions:

- a. Only Sponsor's employees and contractors conducting or performing services directly related to the Study pursuant to a Statement of Work and/or clinical trial agreement executed thereto (the "Authorized Users") may access the EDC System on behalf of Sponsor.
- b. Sponsor shall use the EDC System only for lawful purposes and in accordance with this Agreement, the Statement of Work (including clinical trial agreements executed thereto), consistent with industry standards, and for purposes related to a Study. Any data that Sponsor plans to collect in the EDC System that is the proprietary information of Fresenius Medical Care Holdings, Inc. and any of its Affiliates, shall be subject to approval by Frenova, which shall not be unreasonably withheld.
- c. Sponsor acknowledges that the EDC System is proprietary to the EDC Vendor, and such EDC Vendor owns all right, title and interest in the EDC System, including, but not limited to, any derivative works, modifications, updates and enhancements. The Authorized Users shall protect and treat the EDC System and materials as confidential using the same care as required under the Agreement with respect to Sponsor's Confidential Information, but no less than reasonable care. Sponsor understands and agrees that the EDC System may only be used by Sponsor and its Authorized Users in accordance with the terms set forth above and that Sponsor will not (1) modify, copy or create derivative works based on the EDC System, or (2) reverse engineer, disassemble or decompile the EDC System or any portion thereof in any manner. Sponsor agrees to execute any additional documentation as Frenova's and/or EDC Vendor's request setting forth any such additional obligations or use restrictions as may be required for Authorized Users to access and/or utilize the EDC System.
- d. Sponsor acknowledges that errors may exist or occur in any software program. Frenova makes no warranty or representation that the EDC System shall operate uninterrupted or be error-free and assumes no responsibility for obsolescence of the EDC System.

2.7.3 Frenova shall in good faith seek to enforce on behalf of Sponsor, at Sponsor's expense, warranties which Frenova may hold pursuant to Frenova's license and/or contractual arrangement with the EDC Vendor.

Except as otherwise stated in this Agreement, the EDC SYSTEM, THE SERVICES PROVIDED IN CONNECTION WITH THE EDC SYSTEM, AND THE DELIVERABLES DELIVERED THROUGH USE OF THE EDC SYSTEM ARE PROVIDED AND DISTRIBUTED ON AN "AS IS" BASIS WITHOUT WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

2.7.4 EDC Vendor shall provide to Sponsor at the completion of the Study a download of the Study data contained in the EDC System for such Study. Frenova shall in good faith seek to facilitate the execution of additional documentation as to the nature, timing, and extent of such download of Study data by and among Frenova, EDC Vendor and Sponsor as may be reasonably requested.

2.7.5 To the extent that Frenova utilizes, or Sponsor otherwise requires the use of, additional software services or an additional software vendor in addition that provided by the EDC Vendor, then the provisions with respect to the use and scope of services to be provided pursuant to such software services or software vendor shall be addressed in the applicable Statement of Work.

2.8 Inspections

- 2.8.1 Inspection by Sponsor: During the term of this Agreement, Frenova will permit representatives of Sponsor who are not competitors of Frenova in the dialysis services business to examine, at Sponsor's cost, at a reasonable time during normal business hours and subject to at least ten (10) business days prior written notice to Frenova: (i) the facilities where the Services are being, will be or have been conducted; (ii) documentation directly related to the conduct of the Study as necessary for Sponsor to confirm that the Services are being or will be or have been conducted in conformance with applicable specific Statements of Work, this Agreement and in compliance with applicable laws and regulations. Frenova may exclude from any such inspection any of its proprietary or confidential information that is not otherwise required to be provided to Sponsor in connection with this Agreement.
- 2.8.2 Inspection by Regulatory Authorities: Sponsor acknowledges that Frenova may respond independently to any correspondence, inquiry or inspection request from a regulatory authority in which Frenova or its Affiliates is named if it is not practicable to inform and work cooperate with Sponsor in such regard. To the extent any such request is related to a Study, Frenova shall: (i) notify Sponsor promptly of any regulatory authority inspection or inquiry, including, but not limited to, inspections of Trial Sites, Facilities, subcontractors or laboratories; (ii) forward to Sponsor copies of any correspondence from any regulatory authority relating to such inspection or inquiry, including, but not limited to, FDA Form 483 notices, and FDA refusal to file, rejection or warning letters; (iii) notify Sponsor of the results of any such inspection or inquiry, including requested or required improvements, changes or modifications to Frenova's operations; and (iv) notify Sponsor of any actions taken in response to or anticipation of such an inspection or inquiry. Where reasonably practicable, Frenova will give Sponsor the opportunity to have a representative present during an inspection by a regulatory authority. Sponsor, however, acknowledges that it may not direct the manner in which Frenova fulfills its obligations to permit inspection by regulatory authorities.

- 2.8.3 **Inspections of Trial Site(s) by Frenova:** To the extent required pursuant to the Statement of Work and/or in connection with Frenova's provision of Services as specified in this Agreement and any associated Statement of Work, Frenova may conduct monitoring visits and/or inspections of participating Trial Sites, and Facilities. Based on Frenova's observations during such Trial Site or Facility visits and inspections, Frenova may decide: (i) that enrollment should be suspended at the Trial Site or Facility; (ii) that a Trial Site's or Facility's non-compliance needs to be reported to Sponsor and/or regulatory authorities; and/or (iii) Trial Site's or Facility's participation in a Study needs to be terminated. Upon such a determination, Frenova will present to Sponsor a basis for its decision. If Sponsor disagrees with the basis for Frenova's decision, Frenova will assign its contract with the Trial Site or Facility to Sponsor and Sponsor agrees to accept such assignment and to be responsible for all contractual duties and obligations to the Trial Site and/or Facility.

2.9 Steering Committee

Both Parties hereby may, upon mutual agreement, establish a joint review committee ("Joint Review Committee") which shall be responsible for reviewing and discussing operational, clinical quality, implementation of current and potential clinical trials. If established, each Party shall appoint two representatives (or more, upon mutual agreement) to the Joint Review Committee, which representatives shall include appropriate leadership for both Parties. The Joint Review Committee shall convene quarterly at mutually agreeable dates and times. Agendas for the Joint Review Committee meetings can include, but not be limited to, discussions of issues related to operations, quality, strategy, and future opportunities.

2.10 Participation in Protocol Review

Because of Frenova expertise in the conduct and administration of clinical trials involving patients with end stage renal disease or other patients with kidney disease, Sponsor may include as part of the Statement of Work Frenova's review, consultation and advisement on the Protocol for improving implementation and administration to the target subject population and potentially Study design, as applicable.

2.11 Potential Trial Sites/Investigators Generally

Frenova as part of the Services pursuant to a Statement of Work, may routinely provide to Sponsor a list of potential Trial Sites and potential Investigators (including potential Facilities). Consistent with Section 5, such potential Trial Site(s) and potential Investigators and potential Facilities are deemed Confidential Information of Frenova. Sponsor hereby agrees that it shall not knowingly seek to directly contract with any potential Trial Site or any potential Investigator that are contractually obligated to facilitate Frenova's involvement for any clinical trial that he/she would conduct for Sponsor at least in part at a facility owned or operated by Frenova or its Affiliates.

3.0 FINANCIAL TERMS AND CONDITIONS

The Parties agree that the fees and other reimbursements that Frenova will receive for performing the Services hereunder will be outlined in each Statement of Work and are subject to the following terms and conditions.

3.1 Compensation for Services

For Services provided, Sponsor will pay Frenova in accordance with the terms in this section of the Agreement and each applicable Statement of Work. The timing and frequency of payments will be governed by the Payment Schedule detailed in each Statement of Work.

3.2 Services Budget

All fees for Services shall be paid in the amounts and at the times indicated in the Payment Schedule.

3.3 Pass-Through Budget

In order to provide funding for Pass-Through expenses, exclusive of Trial Site/Investigator payments described below, Sponsor will make an advance payment to Frenova of an amount to be specified in each Statement of Work. Frenova will submit to Sponsor detailed monthly invoices for amounts incurred during the relevant billing period. The advance payment will be retained by Frenova until the completion of the Services, at which time a reconciliation of expenses will be done to ensure that Sponsor pays for only those expenses actually incurred. The advance payment will then be applied to the final invoice, if unpaid, and any remaining advance payment will be refunded to Sponsor within thirty (30) days from the date of the final reconciliation.

3.4 Trial Site/Investigator Payments and Reconciliation

In order to provide for timely payments to Trial Sites/Investigators, Sponsor will make an initial advance payment to Frenova of an amount to be determined in each Statement of Work. The Statement of Work shall specify, as the parties may mutually agree, any additional advance payments shall be made from Sponsor to Frenova and the process of invoicing and reconciliation of such advance payments, to the extent applicable. In the event Frenova has any remaining advance payment upon the completion of Services, Frenova shall apply such advanced payment to the final invoice, if unpaid, and any remaining advance payment will be refunded to Sponsor within thirty (30) days from the date of the final reconciliation.

3.5 Invoices

- 3.5.1 Invoices for Services and Pass-Through expenses will be submitted in accordance with the Payment Schedule associated with the relevant Statement of Work and will be prepared monthly, or as frequently as necessary.

- 3.5.2 All invoices under this Agreement will be forwarded to the Sponsor representative designated in the relevant Statement of Work.
- 3.5.3 All payments under this Agreement will be remitted to the Frenova Affiliate named in the Statement of Work, to the address and in the manner set forth in the Payment Schedule of the applicable Statement of Work.

3.6 Payment Terms

Sponsor agrees to pay for Services and Pass-Through expenses in accordance with the Payment Schedule outlined in each Statement of Work or associated Amendment. Sponsor will pay for all Services, Pass-Through expenses and other correctly invoiced items within forty-five (45) days of receipt of invoice. All payments will be made in the currency noted in the Payment Schedule of the Statement of Work. All fees for Services and Pass-Through expenses are exclusive of VAT (including non-refundable VAT) and other local taxes (excluding taxes based on Frenova's income), which Sponsor will pay when applicable. All Frenova invoices are payable within forty-five (45) days of receipt by Sponsor. Undisputed payments from Sponsor which are received 30 days past due will incur a 1.0% penalty per month calculated daily and compounded monthly or, if lower, the highest rate permitted under applicable law. Sponsor will use reasonable efforts to inform Frenova in writing of any claimed errors on the invoice or invoice items being disputed within fifteen (15) business days of Sponsor's receipt of the invoices and the basis of such dispute ("disputed items") (payment of undisputed items shall be required consistent with this Section). Sponsor acknowledges and agrees that any discrepancies identified through verification of Study documentation that may result in an adjustment to payment must be resolved in a timely and satisfactory manner. The parties shall in good faith seek to resolve any disputed items within thirty (30) days of any such items being deemed "disputed" as set forth above. If the parties cannot resolve such disputed items within such time frame, then a party may pursue all of its rights in law and equity with respect to such disputed items.

3.7 Final Payments

Any final payments specified in a Statement of Work will be invoiced upon completion of the Services and delivery to Sponsor of any final Study databases, reports or other deliverables as specified in the Statement of Work. If a final payment is specified in a Statement of Work, it will be due within forty-five (45) days of Sponsor's receipt of invoice unless Sponsor notifies Frenova in writing of any deficiencies in the Services. Frenova will correct any such deficiencies within thirty (30) days of notice and will resubmit the final invoice to Sponsor immediately upon final shipment of the corrected project deliverable(s).

3.8 Currency Management

The Parties agree that all amounts to be paid to Frenova for Services rendered and all Pass-Through expenses, including Trial Site/Investigator payments, shall be paid in U. S. Dollars unless otherwise set forth in an applicable Statement of Work.

4.0 TERM AND TERMINATION

4.1 Term

Unless earlier terminated according to Section 4.2, 4.3, or 4.4 below, this Agreement will remain in effect for an initial term of five (5) years from the Effective Date, and thereafter will renew automatically for successive terms of one (1) year unless either Party notifies the other Party of termination of the Agreement no later than sixty (60) days prior to renewal hereof. In the event of non-renewal by either Party, the term of this Agreement applicable under any outstanding Statement of Work will continue until completion of the Services described in such Statement of Work or appropriate termination of the Statement of Work.

4.2 Termination by Sponsor

4.2.1 Sponsor may terminate this Agreement or any Statement of Work upon sixty (60) days prior written notice to Frenova for any reason. Sponsor will pay Frenova for all Services properly rendered and Pass-Through expenses, including Trial Site/Investigator/Facility expenses incurred pursuant to this Agreement or any terminated Statement of Work. Sponsor will also pay for Services and Pass-Through expenses, including Trial Site/Investigator/Facility expenses, necessary to conduct an orderly winding down of the administration of this Agreement, or any terminated Statement of Work, which amount will not exceed the remaining unpaid balance of the Project Budget of the Statement of Work, unless special circumstances warrant otherwise.

4.2.2 As soon as practicable following receipt of notice of termination under this Section 4.2, Frenova will submit an itemized accounting of Pass-Through expenses and costs incurred, costs anticipated, and payments received in order to determine a balance to be paid by either Party to the other. Such balance will be paid by Sponsor or Frenova within thirty (30) days of completion of work.

4.3 Termination by Frenova

4.3.1 Failure of Sponsor to comply with any of the material terms or conditions of this Agreement or to respond to Frenova's inquiries or requests for information will entitle Frenova to give written notice of default of this Agreement or a Statement of Work via certified/return receipt mail or overnight courier to ensure receipt by Sponsor. If Sponsor does not cure the default within sixty (60) days of receipt of notice (or for such reasonable amount of time thereafter, if the default is not susceptible of cure within sixty (60) days), this Agreement or the affected Statement of Work may be terminated by Frenova, which will

cease performance of Services. The cessation of Services in accordance with this Section will not be a default of performance obligations by Frenova, nor will it be a breach of this Agreement or any Statement of Work. Sponsor will pay to Frenova all amounts due and owing for Services performed, Pass-Through expenses (including Trial Site/Investigator expenses) incurred, costs associated with winding up activities described in Section 4.2 above, as well as any late fees which may be due, pursuant to Section 3.6 above.

- 4.3.2 Additionally, Frenova may terminate any Statement of Work upon thirty (30) days prior written notice if: (i) Sponsor cancels or materially delays the requested Services; (ii) unanticipated material changes to the project assumptions or project specifications cannot be addressed to both Parties' satisfaction through an Amendment; (iii) changes to the Study Protocol cause enrollment targets to become commercially unreasonable; (iv) Sponsor is unable to make timely payments to Frenova resulting in Frenova lacking funds to process payments to Trial Sites.

4.4 Termination for Other Reasons

- 4.4.1 If in the reasonable assessment of Frenova or Sponsor, the continued performance of the Services contemplated by this Agreement or any Statement of Work could constitute a potential or actual violation of legal, regulatory, ethical or scientific standards and/or patient safety and welfare is jeopardized, then either Party may terminate this Agreement or any Statement of Work by giving written notice stating the effective date of such termination and notice period, if any. The parties shall use all reasonable efforts to rectify the alleged violation prior to the end of the notice period, if any.
- 4.4.2 Either Party may terminate this Agreement and all Statements of Work hereunder, effective immediately upon written notice to the other Party, if the other Party: (i) files a voluntary petition in bankruptcy or has an involuntary bankruptcy petition filed against it, which is not dismissed within thirty (30) days after its institution, (ii) is adjudged as bankrupt, (iii) becomes insolvent, (iv) has a receiver, trustee, conservator or liquidator appointed for all or a substantial part of its assets, (v) ceases to do business, (vi) commences any dissolution, liquidation or winding up, (vii) makes an assignment of its assets for the benefit of its creditors, (viii) is excluded, suspended, sanctioned or otherwise restricted from participating in federal health care programs, including but not limited to, Medicare or Medicaid, or is (ix) is convicted of a felony.

4.5 Survival

Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. In addition, the following sections: Financial Terms and Conditions, Term and Termination, Confidentiality and Proprietary Rights, Representations and Warranties, Indemnification and Insurance, Non-Solicitation of Employees, Governing Law, as well as any other sections which by their nature should survive, will survive expiration or termination of this Agreement indefinitely, or for the period of time noted in the specific clause.

5.0 CONFIDENTIALITY AND PROPRIETARY RIGHTS

5.1 During the term of this Agreement and thereafter, the Parties and their Representatives (as defined below) shall neither disclose nor use for any purpose except as expressly provided in this Agreement below, Confidential Information (as defined below) that is provided by Sponsor or Frenova (including without limitation their affiliates, customers, and licensors), directly or indirectly, pursuant to this Agreement, whether oral or in written form, or other tangible medium, and whether or not marked confidential. "Confidential Information" means all Sponsor or Frenova (including without limitation their Affiliates, customers and licensors) information and data, including, but not limited to, technical data, trade secrets, know-how, ideas, research, prototypes, samples, formulas, compounds, methods, plans, specifications, characteristics, raw material data, software, inventions, discoveries, processes, designs, drawings, schematics whether or not patentable, and information concerning Sponsor's or Frenova's financial condition, product plans, services, customers, potential customers, potential Trial Site lists and potential Investigator lists, distribution systems, suppliers, markets, business, technology, marketing plans, sales, manufacturing, purchasing and accounting methods, strategy, budgets, contracts, grants, costs, profits, employees and consultants, plans for future development, and other information of a similar nature. For the sake of clarity, the potential Trial Site list(s), potential Investigator's list(s), and potential Facility list(s) developed by Frenova, including but not limited to the identity and contact information for potential Investigators, is confidential and proprietary and, subject to 5.3, shall be deemed as Frenova Confidential Information. Notwithstanding any provision herein to the contrary, the medical records of any Study Subject used in the care and treatment of such patient shall be owned by the medical provider(s), as applicable, and their applicable Affiliates, and in no event will this Section 5 be construed to place restrictions on the use of and disclosure of such medical information.

5.2 In consideration of any access the Parties may have to Sponsor's or Frenova's Confidential Information hereunder, during the term of this Agreement and thereafter, the Parties shall:

- 5.2.1 in the case of Frenova, not use such Confidential Information except in the performance of Study related Services in accordance with the applicable Statement of Work;
- 5.2.2 hold the Confidential Information in strict confidence and shall protect such Confidential Information from disclosure and shall use the same degree of care to avoid disclosure of such Confidential Information as the parties employ with respect to their own confidential information of like importance, but in no event less than a reasonable amount of care;

- 5.2.3 not, without the express written permission of Sponsor or Frenova, as applicable, divulge any such Confidential Information to others, except to persons who are (i) employees of the Parties or their Affiliates used in accordance with Section 8.8 or represent a Party or their Affiliate used in accordance with Section 8.8 in a professional capacity; (ii) are bound by obligations of confidentiality and nonuse at least as restrictive as those set forth herein; and (iii) who have a bona fide need to know Confidential Information in connection with the Study related Services (collectively, “**Representatives**”);
- 5.2.4 not use for its own benefit or the benefit of its Representatives or any person or entity, other than the Party owning the information, any such Confidential Information; and
- 5.2.5 not copy, create derivative works of or reverse engineer any such Confidential Information, except such duplication as is necessary in the performance of the Study related Services, or in the case of Sponsor, for the use of the Services.

5.3 Confidential Information shall not include information that the receiving Party can show:

- 5.3.1 was already in their possession without obligation to keep it confidential as evidenced by its written records prepared or received prior to the disclosure;
- 5.3.2 is lawfully disclosed to them by a third party, provided such information was not obtained by such third party directly or indirectly from either Sponsor or Frenova (including without limitation their Affiliates, customers and licensors) on a confidential basis as evidenced by its written records;
- 5.3.3 is independently developed by them (including without limitation their Affiliates) without access to or use of the Confidential Information as evidenced by its written records prepared contemporaneously with the development; or
- 5.3.4 is generally known to the public without violation hereof.

5.4 A Party may make disclosures of the other Party's Confidential Information as required by law or regulation or by an order of a governmental agency, legislative body or court of competent jurisdiction, provided that the Party required to disclose such information: (i) provides the other Party, as applicable, with prompt written notice of such requirement, (ii) cooperates with the other Party, as applicable, in connection with such Party's actions to obtain a protective order and/or confidential treatment for such Confidential Information, and (iii) limits such disclosure of Confidential Information to the fullest extent permitted under applicable law.

5.5 Notwithstanding any language to the contrary in this Agreement, the Parties shall be responsible for any disclosure or use of the other Party's Confidential Information or other prohibited activity involving the other Party's Confidential Information by any of their respective Representatives, person or entity to which the other Party's Confidential Information is disclosed. Each Party shall notify the other in writing immediately upon becoming aware of the occurrence of any unauthorized release of the other Party's Confidential Information or other breach of this Agreement. The Parties each acknowledge and agree that due to the unique nature of the Confidential Information there is no adequate remedy at law for any breach of its or its Representatives' obligations hereunder and that any breach would result in irreparable harm to Sponsor or Frenova, as applicable. Therefore, upon any such breach, Sponsor or Frenova, as applicable, shall be entitled to obtain appropriate equitable relief in addition to its remedies at law.

5.6 Nothing contained in this Agreement shall be construed as granting or conveying to Sponsor or Frenova, or their Representatives, by implication, license, estoppel or otherwise, any right, title or interest in or to the Confidential Information. None of the Confidential Information which may be disclosed hereunder shall constitute any representation, warranty, assurance, guarantee, or inducement by Sponsor or Frenova as to the non-infringement of patents, trademarks, copyrights or any intellectual property rights or other rights of third parties. All Confidential Information and other written data provided by Sponsor or Frenova hereunder shall be and remain the property of Sponsor or Frenova, as applicable.

5.7 In the event Sponsor shall come into contact with any Subject's medical records, Sponsor shall hold in confidence the identity of such Subject and shall comply with all applicable law(s) and contractual obligations regarding the confidentiality of such Subject's records.

5.8 Sponsor and Frenova each agree to hold the terms of this Agreement in confidence. Notwithstanding anything in this Agreement to the contrary, Frenova may, however, disclose such Confidential Information to potential Principal Investigator(s) or Principal Investigator(s) and/or their designees, provided that such parties have agreed to protect the confidential nature of the information disclosed to them.

5.9 Return or Destruction of Information

Upon a Party's written request, Sponsor or Frenova shall promptly deliver to the other or to destroy if so requested, as applicable, all originals, copies, and summaries of documents, materials, and other tangible manifestations of Confidential Information and any other property of Sponsor or Frenova, as applicable, that the Party shall have in its possession or under their control, in whatever media; provided, however, that each Party shall be entitled to retain in confidence under this Agreement, including without limitation (i) one (1) archived copy of the other Party's Confidential Information and all materials created by such Party and containing the other Party's Confidential Information, including without limitation notes and memoranda, solely for the purpose of administering a Party's obligations under this Agreement; and (ii) Confidential Information contained in such Party's electronic back-up files that are created and maintained in the normal course of business pursuant to such Party's standard protocol for preserving its electronic backup records.

5.10 Proprietary Rights

- 5.10.1 The entire right, title and interest in and to any Invention that is related to an indication, use, formulation or dosage, or to the manufacture, of the Study Agent shall be the property of Sponsor (“**Sponsor Inventions**”). Frenova hereby assigns and agrees to assign all Sponsor Inventions to Sponsor. Any Inventions that are related to dialysis devices and processes (including disposables related thereto) shall be owned by Frenova or its designee (“**Frenova Inventions**”). Sponsor hereby assigns and agrees to assign all Frenova Inventions to Frenova.
- 5.10.2 The parties hereto acknowledge and agree that the inventions and technologies of Sponsor and Frenova or their respective Affiliates that pre-exist this Agreement or are made or conceived independently of a Study and the Services are their separate property, respectively, and are not affected by this Agreement and no Party hereto shall have any claims to or rights in such pre-existing or independently made or conceived inventions and technologies. The Sponsor and Frenova shall not be deemed to transfer or grant to another Party hereto any rights except insofar as necessary to permit the parties to conduct Study related Services, and as expressly provided in this Agreement.
- 5.10.3 Subject to Section 5.10.1 above, title to any other Inventions made or conceived (i) solely by Sponsor employees or consultants shall be solely owned by Sponsor; (ii) solely by Frenova employees or consultants shall be solely owned by Frenova; and (iii) jointly by Sponsor employees or consultants and/or Frenova employees or consultants shall be jointly owned by the respective employers (“**Joint Inventions**”).
- 5.10.4 The Parties understand and agree that Frenova is in the business of providing dialysis care through its clinics. As such, the Parties agree that with respect to data and results arising out of the performance of the Study related Services, Frenova retains a right to use the Study data in connection with the treatment of patients. Frenova agrees to hold the Study data in confidence and to maintain the Study data as Confidential Information as defined by this Agreement.
- 5.10.5 Each Party hereto agrees to assist the other Party hereto in their efforts to establish and perfect its rights acquired under this Section 5.10, and to execute any documents reasonably necessary to do the same. The Party requesting such assistance shall reimburse the other Party for reasonable expenses incurred in satisfying the obligations under the immediately preceding sentence.

- 5.10.6 With respect to Joint Inventions, Frenova and Sponsor shall each own a one-half undivided interest in the Joint Inventions and, subject to the terms of this Agreement, can sell, license or otherwise transfer its rights to the Joint Inventions without a duty of accounting to the other Party. Each Party hereby grants to the other Party all permissions, consents and waivers with respect to, and all licenses under, such Joint Inventions, throughout the world, necessary to provide the other Party with such rights of practice, use and other exploitation, and will execute documents as necessary to accomplish the foregoing. In addition, the Parties shall cooperate in good faith in connection with (i) preparing, filing and prosecuting patent applications (including reissue, continuing, continuation-in-part, provisional, divisional, and substitute applications and any foreign counterparts thereof); (ii) maintaining any resulting patents; (iii) managing any interference or opposition proceedings relating to the foregoing; and (iv) bringing, pursuing and settling infringement claims against third parties.

5.11 Publicity

Except as may be required by law, a Party shall not use the other Party's name or any of the name of any of the other Party's Affiliates, in any press release, publicity, advertising, or other disclosure without the named party's prior written consent. Furthermore, no Party to this Agreement shall use the names, trade names, trademarks, service marks, logos or other brand-source indicia ("Trademarks") of any other Party in any advertising, promotional or sales literature or in any publicity without the prior written approval of the Party whose Trademarks are to be used. Further, either Party may make such public disclosures as it determines, based on advice of counsel, are reasonably necessary to comply with laws or regulations.

5.12 Publications

Frenova shall not publish any articles or make any presentations relating to the Services, Sponsor Confidential Information or referring to data generated pursuant to any Statement of Work issued hereunder, without the prior written consent of Sponsor. Sponsor shall not publish any articles or make any presentations including Frenova Confidential Information, without the prior written consent of Frenova. Nothing in this Section 5.12 will prevent Sponsor from publishing any results of any Study.

6.0 REPRESENTATIONS AND WARRANTIES

6.1 Acknowledgements

Sponsor acknowledges and agrees that there can be no assurance, representation or warranty by Frenova that a Study Agent which is the subject of research in any Study to which the Services are related, either during the term of this Agreement or thereafter, will be successfully developed or, if so developed, will receive the required approval by the United States Food and Drug Administration (“**FDA**”) or other regulatory authority.

6.2 Representations and Warranties of Sponsor

- 6.2.1 Sponsor represents and warrants to Frenova as of the Effective Date that, to Sponsor’s knowledge, performance of obligations required of Frenova hereunder will not infringe or violate the intellectual property rights of any third party including but not limited to trademark, trade secrets, copyright, patent, proprietary information rights.
- 6.2.2 Sponsor represents and warrants that neither any assignment nor task requested by Sponsor nor the conduct thereof as provided in this Agreement would necessarily violate any applicable law or regulation. Sponsor shall notify Frenova immediately upon learning of any potential violation of this Agreement or of applicable law pertaining to the Study.
- 6.2.3 Sponsor represents and warrants that it has the right, title and interest in the Study Agent which is the subject of research covered by this Agreement or any Statement of Work (whether such right, title and interest is held solely by Sponsor or jointly with others) and that it has the legal right, authority and power to enter into this Agreement, and to perform any clinical trial which is the subject of a Statement of Work issued hereunder.
- 6.2.4 Sponsor represents and warrants it will provide Frenova with copies of any monitoring visit follow-up letters sent to the Trial Sites, provided that Frenova agrees to limit their use of these monitoring visit follow-up letters to the provision of the Services.

6.3 Representations and Warranties of Frenova

- 6.3.1 Frenova represents and warrants that the personnel assigned to perform Services rendered under this Agreement will be capable professionally, and that it will perform its obligations hereunder in accordance with all applicable federal, international, state or local law or regulation, the terms of this Agreement and any Statement of Work issued hereunder.

- 6.3.2 Frenova further represents and warrants that it will make available to Sponsor or to the responsible regulatory authority relevant records, programs, and data as may be reasonably requested by Sponsor for purposes related to filing and prosecution of Sponsor's related applications for any regulatory approvals.
- 6.3.3 Frenova's sole obligation for material breach of a representation and warranty set out in this Section will be, at Sponsor's option, to correct or re-perform, or refund all amounts paid for that portion of the Services that fails to materially conform thereto.

6.4 Debarment Certification

- 6.4.1 Frenova certifies that it has not been debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §335a(a) or (b) or any equivalent local law or regulation. In the event that Frenova becomes debarred, Frenova agrees to notify Sponsor immediately.
- 6.4.2 Frenova certifies that no individual or entity providing Services hereunder has been or will be debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C §335a (a) or (b) or any equivalent local law or regulation. In the event that Frenova becomes aware of or receives notice of the debarment of any individual or entity providing Services hereunder, Frenova agrees to notify Sponsor immediately.

6.5 No Suspension or Exclusion from Federal Health Care Programs

Each Party represents and warrants that it has not been and will not be excluded, suspended, sanctioned or otherwise restricted from participating in federal health care programs in the U.S., including but not limited to, Medicare or Medicaid. In the event that a Party becomes aware of or receives notice of its exclusion, suspension, sanction or restriction from participating in federal health care programs in the U.S., such Party shall notify the other Party immediately.

6.6 No Other Warranties

The Parties' warranties and representations contained in this Agreement are in lieu of all other warranties expressed or implied.

7.0 INDEMNIFICATION AND INSURANCE

7.1 Indemnification by Sponsor

- 7.1.1 Sponsor will indemnify, defend and hold harmless Frenova, its Affiliates, and their officers, directors, agents, employees, and independent contractors (each an "**Indemnitee**") against any and all losses, damages, liabilities, costs and expenses, settlement payments, judgments, fines, fees, penalties or other charges, including reasonable

attorneys and professional fees (collectively “Losses”) resulting from any claims, causes of action or suits, proceeding, arbitration, pending or threatened, and in each case by a third party (each a “**Claim**”) against Indemnitees arising out of the authorized use or disclosure of Sponsor’s Confidential Information by the Indemnitee or their respective Representatives, the Study, the Services and other work conducted under this Agreement, in each case subject to Section 7.1.3. Frenova will promptly notify Sponsor upon receipt of notice of any Claim (provided that the failure to give such notice will not relieve Sponsor of its obligations under this Section except to the extent, if at all, it is prejudiced thereby) and will permit Sponsor’s attorneys and personnel, at Sponsor’s discretion and cost, to handle and control the defense of any such Claim. Frenova may participate in the defense using its own independent counsel, at Frenova’s expense, without relieving Sponsor of its obligations under this Section.

7.1.2 Under no circumstances, however, will Sponsor accept liability, settle or otherwise compromise any Claims without prior written consent of Frenova, which will not be unreasonably withheld. Frenova will fully cooperate and aid in any such defense.

7.1.3 Sponsor will not be obligated to indemnify, defend, or hold harmless Frenova against any Claim to the extent that such Claim arose as a result of Frenova’s negligence, intentional misconduct or breach of this Agreement or any Statement of Work hereunder. If Sponsor incurs reasonable defense costs that it is not responsible for pursuant to this Section 7.1.3, Frenova will repay to Sponsor all such costs.

7.2 Indemnification by Frenova

7.2.1 Frenova will indemnify, defend and hold harmless Sponsor and its employees, officers, and directors against any and all Losses, resulting from any Claim arising from the authorized use or disclosure of Frenova’s Confidential Information by Sponsor or their respective Representatives, Frenova’s negligence, intentional misconduct, or breach of this Agreement or any Statement of Work hereunder. Sponsor will promptly notify Frenova upon receipt of notice of any Claim for which it intends to seek indemnification hereunder, provided that the failure to give such notice will not relieve Frenova of its obligations under this Section except to the extent, if at all, it is prejudiced thereby. Sponsor will permit Frenova’s attorneys and personnel, at Frenova’s discretion and cost, to handle and control the defense of any such Claim. Sponsor may participate in the defense using its own independent counsel, at Sponsor’s expense, without relieving Frenova of its obligations under this Section.

- 7.2.2 Under no circumstances, however, will Frenova accept liability, settle or otherwise compromise any Claims subject to indemnification under this Section without prior written consent of Sponsor, which will not be unreasonably withheld. Sponsor will fully cooperate and aid in any such defense.
- 7.2.3 Frenova will not be obligated to indemnify, defend or hold harmless Sponsor against any Claim to the extent that such claim arose as a result of Sponsor's negligence, intentional misconduct or breach of this Agreement or any Statement of Work hereunder. If Frenova incurs reasonable defense costs that it is not responsible for pursuant to this Section 7.2.3, Sponsor will repay to Frenova all such costs.

7.3 Limits of Liability

Frenova's liability for direct damages hereunder will not exceed the total fees for Services payable by Sponsor to Frenova under the applicable Statement of Work. Except for any breach of provisions related to Confidential Information in Section 5, in no event will a Party be liable to the other Party for any indirect, incidental, special, consequential, punitive, exemplary damages of any kind (including without limitation, lost profits, lost savings, loss of data, loss of business opportunities) arising out of or related to this Agreement, any Statement of Work, or the transactions contemplated by this Agreement, however caused, under any theory of liability, even if any or all of the Parties have been advised of the possibility of such damages. Nothing in this Section 7.3 will limit a Party's liability pursuant to Sections 7.1 or 7.2.

7.4 Insurance

Sponsor represents and warrants that it maintains a policy or program of insurance or at levels sufficient to support the Sponsor's Indemnification and obligations and duties assumed under this Agreement. This includes:

- (1) General liability insurance for bodily injury, including death, and property damage;
- (2) Workers' compensation insurance in the amount required by the law of the state in which the Institution's employees are located; and
- (3) Clinical trial insurance policy or similar systems for compensation for any damage suffered by a subject resulting from participation in a clinical trial conducted in the EU.

Sponsor shall provide to Frenova, upon request, evidence of its insurance of the types specified in this Section or self-insurance.

Frenova represents and warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the Frenova's Indemnification and obligations and duties assumed under this Agreement. For Services performed within the United States of America, this includes:

- (1) General liability insurance for bodily injury, including death, and property damage;

- (2) Workers' compensation insurance in the amount required by the law of the state in which the Institution's employees are located;
- (3) Professional liability insurance.

For Services performed outside of the United States of America, this includes:

- (1) General and Product liability insurance for bodily injury, including death, and property damage.

Frenova shall provide to Sponsor, upon request, evidence of its insurance of the types specified in this Section or self-insurance.

8.0 MISCELLANEOUS CLAUSES

8.1 Independent contractor relationship

Frenova and Sponsor are independent contractors. Nothing in this Agreement will be construed to create the relationship of partners, joint venturers, or employer and employee between Frenova and Sponsor or Frenova's employees. Neither Party, nor its employees, or independent contractors will have authority to act on behalf of or bind the other Party in any manner whatsoever unless otherwise authorized in this Agreement or a specific Statement of Work or in a separate writing signed by both Parties.

8.2 Nonsolicitation of Employees

Neither Party, during the term of this Agreement and for twelve (12) months thereafter, will, without the prior written consent of the other Party, directly or indirectly solicit for employment or contract, attempt to employ or contract with or assist any other entity in employing, contracting with or soliciting for employment or contract any employee or executive who is at that time employed/contracted by the other Party or an Affiliate used in accordance with Section 8.8 and who had been employed/contracted by the other Party or an Affiliate used in accordance with Section 8.8 in connection with one or more Statements of Work issued hereunder. Provided, however, that the foregoing provision will not prevent either Party from conducting solicitation via a general advertisement for employment that is not specifically directed to any such employee or from employing any such person who responds to such solicitation.

8.3 Notices

Except as otherwise provided, all communications and notices required under this Agreement will be mailed by first class mail or sent via nationally recognized overnight courier to the addresses set forth below, or to such other addresses as the Parties from time to time specify in writing.

If to Sponsor:

inRegen
c/o Twin City Bio LLC
3929 WestPoint BLVD
Suite G
Winston-Salem, NC 27103
Attn: Tim Bertram

If to Frenova:

Frenova, LLC
920 Winter Street
Waltham, MA 02451
Attention: Business Operations

with a copy to:

Frenova, LLC
c/o FMCNA
920 Winter Street
Waltham, MA 02451
Attention: Corporate Law Department

8.4 Anti-Bribery; Anti-Corruption

As stated in the Fresenius Medical Care Code of Ethics and Business Conduct, Frenova upholds the values of quality, honesty and integrity, innovation and improvement, respect and dignity, as well as lawful conduct, especially with regard to anti-bribery and anti-corruption. Frenova upholds these values in its own operations, as well as in its relationships with business partners. Frenova's continued success and reputation depends on a common commitment to act accordingly. Together with Frenova, Sponsor is committed to uphold these fundamental values by adherence to applicable laws and regulations.

8.5 Force Majeure

If the performance of this Agreement by Frenova or Sponsor is prevented, restricted, interfered with or delayed (either totally or in part) by reason of any cause beyond the control of the Parties (including, but not limited to, acts of God, explosion, disease, weather, war, insurrection, terrorism, civil strike, riots or extensive power failure), the Party so affected will, upon giving notice to the other Party as soon as is practical, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party will use reasonable efforts to avoid or remove such causes of non-performance and will continue performance whenever such causes are removed.

8.6 Governing Law

This Agreement will be governed in all respects by the laws of New York, United States of America or the laws of Germany, as applicable to where the Services are performed, without regard to its conflict of laws principles.

8.7 Severability

If any of the provisions or a portion of any provision of this Agreement is held to be unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the enforceable portion of any such provision and/or the remaining provisions will not be affected thereby.

8.8 Assignment

Neither Party may assign this Agreement without the prior written consent of the other Party, which consent will not be unreasonably withheld; provided, however, that either Party may assign this Agreement without consent to a successor in interest to substantially all of the business of that Party to which the subject matter of this Agreement relates upon delivery to the other Party of notice of such assignment. Additionally, Frenova may use the services of its corporate Affiliates to fulfill its obligations under this Agreement and any Statement of Work provided that Frenova shall also remain fully responsible for such obligations regardless of whether Frenova or one of its Affiliates has signed the Statement of Work. Frenova shall ensure that any Affiliate so used shall be acts according to all of the terms and conditions applicable to Frenova under this Agreement or any Statement of Work, and the Affiliate shall be entitled to all rights and protections afforded Frenova under this Agreement and any Statement of Work. Any such Affiliate of Frenova may execute a Statement of Work directly.

8.9 Waiver

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances will be deemed to be construed as a further or continuing waiver of such term, provision or condition or of any other term, provision or condition of this Agreement.

8.10 Entire Agreement; Incorporation by Reference; Conflict

This Agreement and all Statements of Work (including any Protocols and Study Specifications) contains the full understanding of the Parties with respect to the Services and supersedes all existing agreements and all other oral, written or other communications between the Parties concerning the subject matter hereof. This Agreement will not be modified in any way except in writing and signed by a duly authorized representative of Sponsor and an authorized officer of Frenova. In the event of a conflict between the terms and conditions this Agreement or those of any Statement of Work, the terms of this Agreement will take precedence and control unless the provisions of a Statement of Work expressly provide otherwise.

8.11 English Language

The Parties hereto confirm that this Agreement as well as any other documents relating hereto, including notices, have been and shall be drawn up in the English language only.

8.12 Counterparts; Facsimile Signatures

This Agreement may be executed in any number of counterparts with the same effect as if all the parties had signed the same document. Such executions may be transmitted to the parties by facsimile, or in graphical-image form by email or other electronic transmission (collectively, "facsimile evidenced signature"), is to be deemed for all purposes to have been executed and delivered by that party to the other party and such facsimile evidenced signature shall have the full force and effect of an original signature. All fully executed counterparts, whether original or facsimile evidenced signature or a combination of both, shall be construed together and shall constitute one and the same agreement.

8.13 Dispute Resolution

In the event a dispute relating to this Agreement or any Statement of Work arises between the Parties, the Parties will use all reasonable efforts to resolve the dispute through direct discussions for a period of thirty (30) business days. The senior management of each Party is committed to respond to any such dispute. Should such effort to amicably settle the dispute fail, the Parties may proceed to file an action in court.

8.13 No Requirement for Referrals; Fair Market Value.

The Parties agree that the benefits to the parties hereunder do not require, are not payment for and are not in any way contingent upon the referral of patients or business or any other arrangement between the Parties. The Parties represent that the compensation negotiated and agreed upon is fair market value for the services rendered based upon arm's length bargaining. Furthermore, the parties represent that the compensation is not and has not been determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the Parties for which payment may be made in whole or in part under Medicare or any other federal health care program. The parties further represent that nothing contained in this Agreement and no amount paid hereunder is intended or shall be construed as an inducement for the Parties to refer or admit any patients to, or order any goods or services from any Parties, or any of their respective Affiliates.

8.14 Non-Exclusivity; Other Interests.

The Parties acknowledge and agree that this Agreement is non-exclusive. Additionally, nothing in this Agreement shall limit, restrict or prevent each Party from pursuing, developing, engaging, or providing products or services that are or may be competitive with the products or services of the other Party including, but not limited, providing products or services to a competitor; provided, however, that the confidentiality obligations hereunder remain in full force and effect with respect to each Party.

MASTER SERVICES AGREEMENT

THIS MASTER SERVICES AGREEMENT (the “**Agreement**”) is effective as of May 1, 2019 (the “**Effective Date**”) by and between **PPD DEVELOPMENT, L.P.**, a Delaware limited partnership, with its principal executive offices located at 929 North Front Street, Wilmington, North Carolina (“**PPD**”) and **inRegen**, a Cayman Islands exempted company with its principal executive offices located at 10 Market St., #688 Camana Bay, Grand Cayman KY1-9006 Cayman Islands (“**Sponsor**”).

WHEREAS, Sponsor is engaged in the development, manufacture, distribution and sale of pharmaceutical products; and

WHEREAS, PPD is a clinical research organization engaged in the business of managing clinical research programs and providing clinical development and other related services; and

WHEREAS, Sponsor may wish to retain the services of PPD from time to time to perform clinical development services in connection with certain clinical research programs Sponsor is conducting (individually, a “**Project**”), in which case the terms and conditions for each such Project shall be set forth in a project addendum to be attached to this Agreement and incorporated herein by reference (individually, a “**Project Addendum**” and collectively, the “**Project Addenda**”); and

WHEREAS, PPD is willing to provide such services to Sponsor in accordance with the terms and conditions of this Agreement and the attached Project Addenda.

NOW, THEREFORE, for good and valuable consideration contained herein, the exchange, receipt and sufficiency of which are acknowledged, the parties agree as follows:

1. SERVICES.

1.1 Services to be Provided by PPD. PPD hereby agrees to provide to Sponsor the services identified and described in the Services section of each Project Addendum attached to this Agreement (the “**Services**”). PPD shall perform the Services for each Project set forth in the applicable Project Addendum in compliance with (i) the protocol for the Project (“**Protocol**”), which may be attached to and made a part of the applicable Project Addendum, as amended or updated from time to time, (ii) the terms and conditions of this Agreement, (iii) the terms and conditions of the applicable Project Addendum, (iv) PPD’s standard operating procedures (“**SOPs**”), which will be available for Sponsor’s review upon written request, and (v) all applicable laws, rules and regulations. Sponsor agrees that PPD is responsible only for those Services set forth on a properly executed Project Addendum.

1.2 Project Addendum. In the event that the parties hereto shall reach agreement with respect to the provision of Services for a Project, PPD, or a PPD Affiliate, and Sponsor, or an affiliate of Sponsor, shall execute a Project Addendum evidencing such Services. Each Project Addendum shall be attached to this Agreement and incorporated into and made a part of this Agreement by reference, and each such Project Addendum and this Agreement shall constitute the entire agreement for the applicable Project. To the extent any terms set forth in a Project Addendum conflict with the terms set forth in this Agreement, the terms of the Project Addendum shall control.

1.3 Sponsor Cooperation. Sponsor will, and will cause its affiliates and their respective representatives, agents, employees and contractors (collectively referred to as “**Sponsor’s Representatives**”) to, cooperate with PPD and its Affiliates in providing accurate and up to date information, taking action and executing documents, as appropriate, to perform the Services or regulatory obligations delegated to PPD under a Project Addendum or achieve the objectives of this Agreement and any Project Addendum executed under this Agreement. Sponsor acknowledges and agrees that PPD’s performance under this Agreement is dependent on Sponsor’s and Sponsor’s Representatives’ timely and effective cooperation with PPD and its Affiliates. Accordingly, Sponsor acknowledges that any delay by

Sponsor or Sponsor's Representatives may result in PPD being released from an obligation or schedule deadline or in Sponsor having to pay extra fees in order for PPD to meet a specific obligation or deadline despite the delay. In the event of any such delays, the study timelines will be revised accordingly.

1.4 **Compliance with Law.** Sponsor shall comply with all Applicable Laws in its performance of its obligations under, and subject matter of, this Agreement. PPD will comply with all Applicable Laws in the performance of the Services and its obligations under this Agreement

1.5 **Operating Guideline, Safety Plan or Safety and Medical Management Plan.** Notwithstanding anything to the contrary herein, in the event PPD and Sponsor agree upon operating guidelines, safety plans or safety and medical management plans (each shall be referred to as a "**Project-Specific Plan**"), the parties shall comply with the terms and conditions of any such Project-Specific Plan. In the event of any conflict between the terms and conditions of a Project-Specific Plan and the relevant Project Addendum, the terms and conditions of the Project-Specific Plan shall control. Sponsor shall be responsible for any additional costs associated with compliance with the Project-Specific Plan, which will be captured in Contract Modification to the relevant Project Addendum.

1.6 **Patient Enrollment.** The parties agree that enrollment numbers are good faith estimates and that various factors outside of PPD's control can affect the rate of enrollment. PPD shall exercise all reasonable efforts to meet such enrollment estimates but cannot guarantee that enrollment numbers or enrollment timelines will be met.

1.7 **Final Protocol.** PPD shall not be liable or responsible for the final review, approval, adoption, and content of the Protocol, and, accordingly, Sponsor shall be solely liable and responsible in this regard.

1.8 **Definitions.** "**Affiliate**" means an entity which that controls, is controlled by or is under common control with a party or, with respect to PPD, PPD's parent company Pharmaceutical Product Development, LLC. "**Applicable Laws**" means any applicable federal, national (U.S. or foreign), supranational, state, provincial, territorial, local, municipal, regulatory, self-regulatory or similar statute, constitution, resolution, law, ordinance, regulation, rule or code, administrative order or requirement, judgment, decree or other restriction enacted, adopted, issued, implemented or promulgated or otherwise put into effect by or under the authority of any governmental entity or common law.

2. **COMPENSATION AND PAYMENT.**

2.1 **Charges for Services.** Sponsor shall pay PPD for all Services performed under this Agreement and any Project Addendum ("**Direct Fees**") in accordance with the rates for such Services set forth in such Project Addendum, CNF or Contract Modification thereto. Upon signature of a Project Addendum, PPD shall invoice Sponsor an initial amount equal to twelve percent (12%) of the total Direct Fees budget for that Project. Each Project Addendum will detail the payment schedule, inclusive of said advance, through which PPD shall be compensated for Services performed.

2.2 **Charges for Pass Through Costs.** Sponsor shall also reimburse PPD for all out-of-pocket expenses incurred in connection with the performance of the Services with respect to a Project, including, without limitation, investigator grants and fees, travel expenses, shipping and postage costs, copying and printing fees, copyright fees, third party drug storage and distribution fees, required Institutional Review Board or similar board or committee fees, and other "pass through" expenses, each as set forth in the Project Addendum or pre-approved in writing by Sponsor and incurred in connection with performing the Services (collectively, the "**Pass Through Costs**"). Upon signature of a Project Addendum, PPD shall invoice Sponsor a mutually pre-agreed initial amount of the total estimated Pass Through Costs, exclusive of investigator fees, which are addressed separately in Section 2.3 below. This initial payment will be used to offset PPD's payment of Pass Through Costs on Sponsor's behalf. After this initial payment, PPD will invoice Sponsor monthly in arrears reflecting all actual Pass Through Costs incurred by PPD.

Where PPD incurs Pass Through Costs in a currency other than the currency as stated in the contract (“Contract Currency”), PPD shall, for Sponsor invoicing and payment purposes, convert such costs to the Contract Currency based on an average exchange rate between the local currency and the Contract Currency for the month in which such costs were incurred. This average exchange rate will be based on the monthly average of the daily exchange rates as published in the Wall Street Journal.

2.3 Charges for Investigator Fees. At the beginning of each study Sponsor shall advance PPD a pre-agreed amount of the total investigator fee budget for the sole purpose of paying investigator fees. PPD will then invoice Sponsor monthly for reimbursement for all payments made to investigators during the invoice period using funds received in the advance payment, and Sponsor agrees to pay such invoices in accordance with the terms of this Section 2. For Sponsor invoicing and payment purposes, PPD shall convert all investigator fees that are to be paid in a currency other than the Contract Currency to the Contract Currency based on the average exchange rate between the currencies for the month prior to the month the invoice is raised. PPD shall have no obligation to pay vendor costs, or investigator payments to any vendor or investigator site for conduct of services related to a Project until PPD has received payment of such Pass-Through Costs from Sponsor. Notwithstanding anything to the contrary contained herein, Sponsor acknowledges and agrees that certain vendor contracts, including without limitation, contracts for investigator meetings, comparator drug purchase and patient recruitment services, must be advanced and paid up front by Sponsor.

2.4 Payment Terms. Sponsor shall pay (meaning PPD shall receive cleared funds into its account(s)) each invoice within forty-five (45) days of receipt of said invoice. In the event Sponsor disputes an invoice, or any portion of an invoice, such a dispute should be made, in writing (e-mail is sufficient) within forty-five (45) days of receipt of said invoice, together with documentation supporting Sponsor’s dispute. Notwithstanding the foregoing, all undisputed invoices and all undisputed portions of any invoice shall continue to be payable forty-five (45) days from receipt of said invoice. PPD and Sponsor shall use commercially reasonable efforts to resolve the dispute in good faith and as expeditiously as reasonably possible. Upon resolution of any such dispute, Sponsor shall make the agreed upon payment within fifteen (15) days of such resolution. If payment is not received within the timeframes set forth in this Section 2.4, in addition to any other rights and remedies available to PPD, such amounts shall be considered late and will be subject to interest at the rate of one per cent (1.0%) per month (or the maximum amount permitted by applicable law if less than 1.0% per month) from the due date of the applicable invoice and lasting until the date of actual and full payment of the outstanding amounts. Furthermore, in the event any undisputed amounts remain unpaid for ten (10) business days after Sponsor’s receipt of written notice from PPD of such amount, PPD shall have the right, in its sole discretion, to (i) suspend performance of the Services until PPD receives full payment of all outstanding and undisputed amounts. In no event will PPD have the right to withhold safety reports or patient data from Sponsor.

2.6 Purchase Orders. In the event Sponsor utilizes a purchase ordering system with its suppliers, Sponsor shall provide PPD the applicable purchase order number (“**PO**”) for the Project on or before the date on which the Project Addendum or any amendment, is executed (whichever is earlier in time). Should Sponsor fail to provide the PO within the above timeframe, PPD may invoice for Services performed and Pass Through Costs incurred. Sponsor will pay such invoices in accordance with the payment terms set forth in this Agreement irrespective of whether the invoice includes the Project PO.

2.7 Payment after Termination. Upon termination of any Project Addendum or this Agreement, Sponsor shall pay PPD: (i) all Direct Fees for all Services performed; (ii) all Pass Through Costs incurred; (iii) any other costs or expenses payable by Sponsor pursuant to the terms of this Agreement or the Project Addendum, including any costs specified for wind down activities; and (iv) all future non-cancelable obligations incurred (where such obligations were created as a result of a Project being authorized by Sponsor). If no sums are outstanding from Sponsor to PPD, any funds held by PPD, determined to be unearned (taking into account any wind down activities), shall be returned to Sponsor within sixty (60) days following completion of the final reconciliation Project budget.

2.9 Pre-Execution Services. In the event Sponsor requests in writing PPD to begin providing the Services for a Project prior to the execution by Sponsor of a Project Addendum, Sponsor agrees that PPD shall be compensated for Services performed pursuant to such written request in accordance with the payment terms contained herein and the PPD Proposal for Services.

2.10 Taxes. All fees stated in this Agreement or any Project Addendum are exclusive of Value Added Tax (“VAT”) or similar taxes. If any VAT or similar taxes are due, these will be payable by Sponsor in addition to the fees paid to PPD.

2.11 Payments. Unless otherwise set forth in a Project Addendum, all payments to PPD under this Agreement or any Project Addendum shall be made as follows:

payment wired to:

JPMorgan Chase
Acct: 500002360
R/T Number: 021000021 (ACH & Wire)
SWIFT/BIC: CHASUS33
Beneficiary: PPD Development, L.P.

Any changes to the payee information set forth above require a writing signed by PPD’s treasurer or chief financial officer.

3. TERM AND TERMINATION.

3.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue for a period of five (5) years unless extended by mutual written agreement by the parties. Each Project Addendum shall be effective upon the date set forth in such Project Addendum and shall terminate upon (i) the completion of the Services to be provided thereunder, and (ii) PPD’s receipt of all Direct Fees, Pass Through Costs, and any other payments due to PPD related to the Services provided thereunder, unless earlier terminated pursuant to the terms of this Agreement or the Project Addendum, as applicable.

3.2 Early Termination. Any Project Addendum may be terminated without cause by Sponsor upon thirty (30) days prior written notice. PPD or Sponsor may terminate any Project Addendum in the event of the other party’s breach of Agreement or Project Addendum upon thirty (30) days prior written notice, provided that such breach is not cured within such thirty (30) day period.

3.3 Insolvency. Either party hereto may terminate this Agreement or any Project Addendum hereunder immediately upon the occurrence of an “Insolvency Event” with respect to the other party. For purposes of this Agreement, “**Insolvency Event**” shall mean (1) a party, a party’s parent organisation or any of the party’s subsidiaries shall commence a voluntary proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency or other similar law or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, or shall consent to any such relief or to the appointment of or taking possession by any such official in an involuntary case or other proceeding commenced against it, or shall make a general assignment for the benefit of creditors, or ceases to be solvent, or suspends business, or shall fail generally to pay its debts as they become due, or shall take any action to authorize any of the foregoing; (2) an involuntary case or other proceeding shall be commenced against a party, a party’s parent organisation or any of the party’s subsidiaries seeking liquidation, reorganization or other relief with respect to it or its debts under bankruptcy, insolvency or other similar law or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, and such involuntary case or other proceeding shall remain undismissed and unstayed for a period of sixty (60) days; or (3) an order for relief shall be entered against a party, a party’s parent organisation or any of the party’s subsidiaries under the federal bankruptcy laws now or hereafter in effect.

3.4 Effect of Termination. The termination of this Agreement by either party shall not automatically terminate all Project Addenda, unless otherwise agreed in writing. In the event of termination or expiration of this Agreement, the terms and conditions of this Agreement shall continue to apply to all Project Addenda still in effect after such termination or expiration.

3.5 Wind Down. Upon the termination of this Agreement or a Project Addendum, PPD shall reasonably cooperate with Sponsor to provide for an orderly wind-down or transfer of the Services provided by PPD hereunder, which, shall include the prompt provision of all data and results belonging to Sponsor of any Project to Sponsor in a mutually acceptable format. Costs associated with such wind-down or transfer activities shall be billed to Sponsor on a time and materials basis, based on the then-current PPD rates.

3.6 Provisions Surviving Termination. The expiration, termination or cancellation of this Agreement will not extinguish the rights of either party that accrue prior to expiration, termination or cancellation or any obligations that extend beyond expiration, termination or cancellation, either by their inherent nature or by their express terms, including, without limitation, the obligations contained in Sections 2 (Compensation and Payment), 3.4 (Effect of Termination), 3.5 (Wind Down), 3.6 (Provisions Surviving Termination), 5 (Confidentiality), 6 (Data Privacy), 7 (Intellectual Property), 8 (Indemnification), 9 (Limitation of Liability), 10 (Insurance) 11.2 (Record Maintenance after Expiration or Termination), 13.2 (Publicity), 13.5 (Notices), 13.6 (Governing Law), 13.7 (Severability), 13.10 (Assignment), 13.11 (Subcontracting), 13.12 (Arbitration), 13.13 (Construction) and 13.18 (Clinical Trial Supply), hereof and herein shall survive termination of this Agreement.

4. PERSONNEL.

4.1 Project Management. The Services with respect to each Project shall be performed by PPD under the direction of the person identified as the operational lead in the applicable Project Addendum or such other person acceptable to Sponsor as PPD may from time to time designate as the Project Manager, such Sponsor acceptance of the designated Project Manager not to be unreasonably withheld or delayed in all instances.

4.2 Covenant Not to Interfere. During the term of a Project Addendum, neither party will knowingly solicit for employment any employee of the other party who is conducting the Project under that Project Addendum. As used in this section "**solicit**" means the initiation by a party or its agent of a contact with any of the other party's then current employees who are conducting the Project under that Project Addendum for the purpose of offering employment to such employees, but shall not include the circumstance where any such employee initiates a contact with the other party for the purpose of obtaining employment whether in response to a general advertisement of employment or where such contact is initiated by a third party who was not instructed to contact such employee by the hiring party.

4.3 Personnel Retention. In the event of delays in the performance of the Project, i.e., after PPD is authorized to commence work, which are beyond the control of PPD or caused by or are the responsibility of Sponsor, and where Sponsor desires for PPD to keep PPD Project personnel assigned to the Project, in addition to any other sums payable to PPD hereunder, Sponsor shall pay a personnel fee calculated on an FTE-day basis rate agreed upon by both parties. Said personnel fees shall be invoiced by PPD on a monthly basis and shall be due and payable by Sponsor within forty-five (45) days of receipt of invoice.

5 CONFIDENTIALITY.

5.1 Sponsor Confidential Information. PPD shall treat all of Sponsor's information, including information generated by or as a result of the Services or otherwise provided to PPD by or on behalf of Sponsor ("**Sponsor Confidential Information**") as the confidential and exclusive property of Sponsor.

5.2 PPD Confidential Information. Sponsor shall treat all information of PPD or any of PPD's Affiliates including, without limitation, any PPD bids or proposals, standard operating procedures, third party confidential information, personnel information, all PPD Property (as defined below) ("**PPD Confidential Information**") as the confidential and exclusive property of PPD. Further, with the exception of Sponsor Confidential Information, any information disclosed, obtained, or observed by Sponsor or any affiliate of Sponsor during an audit of PPD or an Affiliate of PPD, or the facilities of either shall be deemed to be PPD Confidential Information. Sponsor Confidential Information and PPD Confidential Information shall collectively be referred to as "**Confidential Information.**"

5.3 Use of Confidential Information. Each party shall use the other's Confidential Information solely for the purposes contemplated by this Agreement and for no other purpose without the prior written consent of the other party. Neither party shall publish, disseminate or otherwise disclose Confidential Information of the other to any third party without first obtaining the written consent of such other party; provided however that (i) each party may disseminate or otherwise disclose the other's Confidential Information within its organization to only those Affiliates, employees, agents, representatives and advisors (collectively "**Associates**") and Subcontractors who have a need to know; and (ii) PPD may disclose Sponsor's Confidential Information to investigator sites performing Services in respect of the applicable Project to the extent reasonably required to perform the Services or the Project. Furthermore, each party shall ensure that its Associates and Subcontractors are aware of this Agreement and bound by terms of confidentiality no less stringent than those stated herein. In addition, prior to providing any Confidential Information to a permitted third party other than an Associate, the receiving party will ensure that such third parties are bound to written obligations of confidentiality that are not less stringent than those contained herein. Each Party will remain responsible for the acts or omissions of its Associates and Subcontractors in connection with the Confidential Information.

5.4 Exceptions to Confidential Information. The above provisions of confidentiality shall not apply to that part of disclosing party's Confidential Information which the receiving party is able to demonstrate by documentary evidence: (i) was in the receiving party's possession prior to receipt from the disclosing party or is independently developed by or for the receiving party, as shown by the receiving party's contemporaneous written records; (ii) was in the public domain at the time of receipt from disclosing party; (iii) subsequently becomes a part of the public domain through no fault of the receiving party, its affiliates or its Associates and Subcontractors; or (iv) is lawfully received by the receiving party from a third party having a right of further disclosure.

5.5 Disclosure Required by Law. The receiving party may disclose Confidential Information to the extent required pursuant to any judicial action, order of the court or other governmental agency; provided, however, that the receiving party shall make all reasonable efforts to notify the disclosing party prior to the disclosure of Confidential Information and allow the disclosing party the opportunity to contest and avoid such disclosure, and further provided that the receiving party shall disclose only that portion of such Confidential Information that it is legally required to disclose. To the extent permitted by law the receiving party will request any disclosures made under this section be maintained confidential by the court or agency involved.

5.6 Return of Information. Upon termination or expiration of this Agreement and subject to the terms of Section 11.2 or at the disclosing party's earlier written request, the receiving party shall return, and shall cause its affiliates and Associates and Subcontractors to return, all documentary, electronic or other tangible forms of Confidential Information provided by the disclosing party including, without limitation, any and all copies thereof, or, at the disclosing party's request, destroy all or such parts of the disclosing party's Confidential Information as the disclosing party shall direct. Notwithstanding the foregoing, the receiving party may retain copies of such of the disclosing party's Confidential Information as is reasonably necessary for regulatory purposes and one copy for legal archival purposes, subject to the ongoing obligations of non-use and confidentiality.

5.7 Remedy. Each party agrees that its obligations hereunder are necessary and reasonable in order to protect the other party and the other party's business, and expressly agrees that monetary damages would be inadequate to compensate the other party for any breach of the terms of this Agreement or a Project Addendum. Accordingly, each party agrees and acknowledges that any such violation or threatened violation will cause irreparable injury to the other party, and that, in addition to any other remedies that may be available in law, in equity or otherwise, the other party shall be entitled to seek injunctive relief against the threatened breach of this Agreement or a Project Addendum or the continuation of any such breach, without the necessity of proving actual damages.

5.8 Survival. The obligations contained herein shall survive for a period of ten (10) years from the date of the disclosure of the Confidential Information.

6. **DATA PRIVACY.**

6.1 **Definitions.** “Data Protection and Privacy Laws” means all applicable laws, regulations and regulatory requirement and guidance relating to data protection and privacy globally, including: (a) the U.S. Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) Privacy and Security Rules, 45 C.F.R. Parts 160-164; (b) any other U.S. state or federal laws or regulations governing the privacy or security of personal data; (c) the EU Data Protection Directive 95/46/EC (“the Directive”), superseded by the General Data Protection Regulation (“Regulation”) on 25 May 2018, or any related legislation of any member state in the European Economic Area (“EEA”); or (d) any other law now in force or that may in future come into force governing the Processing of Personal Data applicable to any party to this Agreement, and including those relating to security breaches, identity theft, and unauthorized disclosures of Personal Data. “Personal Data”, “Process/Processing”, “Controller”, “Processor” and “Data Subject” shall have the same meaning as under the Regulation and shall also include these terms, or corresponding terms, as defined under any other Data Protection and Privacy Laws. In particular, “Personal Data” shall also include “personal information”, “health information”, and “protected health information” as defined by Data Protection and Privacy Laws, including HIPAA. “Data Subject” shall also include a “person” or “individual” as defined by Data Protection and Privacy Laws, including an “individual” as defined by HIPAA.

6.2 **Compliance.** Each party warrants to the other that it will Process Personal Data in compliance with all Data Protection and Privacy Laws, as well as applicable regulatory guidance, including the International Conference on Harmonisation Guideline for Good Clinical Practice (ICH-GCP) and Good Laboratory Practice (GLP).

6.3 **Respective Roles of the Parties.** Sponsor and PPD acknowledge that Sponsor is the Controller and PPD is the Processor with respect to the Processing of Personal Data on behalf of the Sponsor pursuant to Services provided by PPD under this Agreement. In the event that the Services are performed by any PPD Affiliate then such PPD Affiliate shall be a sub-Processor. Where Sponsor is the Controller, PPD shall Process the Personal Data only in accordance with instructions from Sponsor, unless restricted in doing so by a law to which PPD is subject. In such case, PPD shall inform the Sponsor of this legal restriction before the Processing begins, unless prevented from doing so by law. (The instructions referred to in this paragraph may be specific instructions or instructions of a general nature as set out in this Agreement, a Project Addendum, Protocol, SOP or Project-Specific Plan or as otherwise documented by Sponsor to PPD during the term of this Agreement).

6.4 **Representative.** If Sponsor needs to appoint a representative to comply with Data Protection and Privacy Laws in any EU Member State pursuant to Article 4 of the Directive or Article 27 of the Regulation, and PPD is willing to provide such services to Sponsor, Sponsor and PPD may enter into a mutually acceptable agreement for such representative purposes. Unless and until such an agreement is entered into, PPD shall not be deemed to be a representative under any Data Protection and Privacy Laws.

6.5 **Data Processing Obligations.** PPD shall implement appropriate technical and organisational measures to protect Personal Data as required by ICH-GCP and/or GLP and Data Protection and Privacy Laws, and in particular shall implement measures to assist Sponsor in meeting its information security obligations under Articles 32 to 36 of the Regulation. PPD shall in particular ensure that persons authorized to Process Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality. PPD shall make available to Sponsor all information necessary to demonstrate compliance with its data protection obligations pursuant to this Agreement and any Project Addendum and contribute to audits conducted by Sponsor or another auditor mandated by Sponsor, subject to the provisions of Section 11.3 of this Agreement regarding audits.

6.6 **Privacy and Security Incidents.** If PPD becomes aware of any unauthorized access, acquisition, use, disclosure, loss, destruction, or alteration of Personal Data resulting in a compromise of the confidentiality, integrity, or availability of the Personal Data, and a risk of harm to the Data Subjects (“Security Breach”), then it shall notify Sponsor without undue delay, and in any event within two (2)

business days, and, if requested, assist Sponsor in meeting its obligations to notify Data Subjects, regulatory authorities or other required parties. Such required notifications shall be at Sponsor's sole cost and expense, except to the extent PPD or its Associate or Subcontractor was responsible for such Security Breach.

6.7 Data Protection Requests. PPD shall promptly notify Sponsor in writing if, in the context of the Services, it receives any communication from a Data Subject (in particular where the Data Subject wishes to exercise their data protection rights), a privacy supervisory authority or other regulatory authority in each case in respect of data protection, and provide Sponsor with cooperation and assistance in relation to any such communication. PPD shall be entitled to charge Sponsor for such assistance at a mutually agreed upon hourly rate, unless the communication relates to a breach or violation by PPD or a PPD Affiliate of its obligations under this Section 6. However, PPD and Sponsor recognize that any fees charged to the requesting party must comply with Data Protection and Privacy Laws.

6.8 Processors and Data Transfers. In providing Services, it may be necessary to sub-contract certain Personal Data Processing tasks to one or more third party sub-Processors. An up-to-date list of appointed sub-Processors is available from the Sponsor's PPD business contact. It may also be necessary to transfer Personal Data to PPD Affiliates based outside the EEA (member states of the European Union plus, Norway, Iceland & Liechtenstein) and Switzerland or sub-contract certain tasks to one or more third party sub-Processors, including cloud-based service providers, whose servers may be located outside the EEA and Switzerland. Transfers of Personal Data to PPD Affiliates and sub-Processors outside the EEA and Switzerland shall be variously protected by EU Standard Contractual Clauses "Controller to Processor" 2010, or otherwise proceed on the basis of Data Subject consent. For the avoidance of doubt, Sponsor consents to the transfer of Personal Data to PPD's Affiliates and sub-Processors, including those outside the EEA and Switzerland using the above transfer mechanisms, where such transfers are necessary to perform the Services in accordance with this Agreement, any Project Addendum, Protocol, SOP or Project- Specific Plan.

6.9 Termination Obligations. On any termination or expiry of this Agreement or when instructed by Sponsor in writing, PPD shall cease all operations on Personal Data and shall promptly, at Sponsor's direction, cost and expense, return and/or irretrievably delete all Personal Data Processed by PPD under this Agreement and in a format agreed by the Parties and instruct its subcontractors to do the same. Should PPD be prevented by its national law or local regulator from destroying or returning all or part of such data, the data shall be kept confidential and not be actively processed for any purpose, and shall be deleted promptly upon the expiration or such legal or regulatory obligation.

7. INTELLECTUAL PROPERTY.

7.1 No License. Neither anything contained herein, nor the delivery of any information to a party hereto, shall be deemed to grant the receiving party any right or license under any patent or patent application or to any know-how, technology or invention of the disclosing party.

7.2 Sponsor Property. Subject to Section 7.3 below, PPD hereby assigns to Sponsor all rights PPD, PPD Affiliates or its Associates and Subcontractors may have in any invention, technology, know-how or other intellectual property relating to the drug or therapeutic product, which is the subject of the Project, or Protocol and which is either: (i) the result of PPD's provision of the Services and is contracted as part of the Services; (ii) incorporates, references, requires the use of, or is a derivative work of Sponsor's Confidential Information; or (ii) specifically set forth as a deliverable under a Project Addendum ("Sponsor Property"). PPD shall assist Sponsor, at Sponsor's sole cost and expense, in obtaining or extending protection therefor. PPD warrants that it has and will continue to have agreements with its Associates and Subcontractors to effect the terms of this Section 7.2.

7.3 PPD Property. PPD and PPD Affiliates possess, and in the future may possess certain processes, technology, know-how, methodologies trade secrets, improvements, and other intellectual property, which has been independently developed without the benefit of any information provided by Sponsor or in connection with the Services, does not incorporate, require the use of, or constitute derivative

works of any Sponsor Confidential Information (collectively, "PPD Inventions"). Sponsor and PPD agree that (i) any PPD Inventions; (ii) any literature reviews and analyses based on publicly available databases conducted by PPD in the performing the Services; and (iii) revisions, improvements, upgrades, or enhancements to each of (i)-(ii) set forth in this section (collectively, "PPD Property") shall, in each case, be the sole and exclusive property of PPD. PPD hereby grants to Sponsor a non-exclusive, royalty-free, worldwide, irrevocable (except in the event Sponsor breaches its licensing obligations herein), nontransferable (except in connection with the transfer of the product to which the Services or deliverable relate, and in no event to a competitor of PPD), sublicensable (except to a competitor of PPD), perpetual license to use and exploit any PPD Property that is incorporated in any deliverable or other material provided by PPD pursuant to this Agreement, but only to the extent necessary for Sponsor to use of the deliverables or the Services. In the event that Sponsor transfers its license or sublicenses as permitted in this Section 7.3, Sponsor agrees that it will (i) first have written confidentiality agreements in place with such third party in accordance with Section 5 above, (ii) have such third parties bound to licensing obligations that are no less stringent than the terms of this Section 7.3, with no further right to sublicense, and (iii) remain liable and responsible to PPD for any third party's breach of the confidentiality and licensing terms required herein.

7.4 Third Party Materials. In the event any Third Party Materials (as hereinafter defined) are used by PPD or its Affiliates to perform the Services, Sponsor acknowledges and agrees that any such Third Party Materials are the sole and exclusive property of the applicable third party providing such Third Party Materials. Sponsor shall obtain no right, title or interest in any Third Party Materials except as expressly provided herein. To the extent that a deliverable contains any Third Party Materials, PPD shall secure for Sponsor a fully paid up, royalty-free, non-exclusive license (PPD will use commercially reasonable efforts to secure a license that is sublicensable and transferable in connection with any license or transfer of the drug product to which the Services Relate) to use such Third Party Materials solely to the extent necessary to use such deliverable, provided that in no event may Sponsor use, offer, sell, commercialize or otherwise dispose of such Third Party Materials separate from such deliverable or on a stand-alone basis. "Third Party Materials" means any data or other materials obtained by PPD or its Associates and Subcontractors from third parties or proprietary databases maintained by third parties, scales, or copies of published articles.

8. INDEMNIFICATION.

8.1 Sponsor Indemnity. Sponsor shall indemnify, defend, and hold harmless PPD and its Associates ("**PPD Indemnitees**") from and against any and all damages, liabilities, losses, fines, penalties, settlement amounts, costs and expenses of any kind or nature whatsoever, including, without limitation, reasonable attorneys' fees, expert witness fees, court costs, and amounts (collectively, "**Losses**") incurred by PPD Indemnitees as a result of any third party claim, demand, action, proceeding, investigation or hearing (collectively, a "**Claim**") to the extent arising from this Agreement or any Services provided by PPD Indemnitees hereunder, including but not limited to, Project related services provided by PPD at the request of Sponsor yet prior to finalization of the relevant Project Addendum; provided however, that Sponsor shall have no obligation of indemnity hereunder with respect to any Claim to the extent such Claim arises from the negligence, intentional misconduct or breach of this Agreement on the part of PPD or its Associates.

8.2 PPD Indemnity. PPD shall indemnify, defend and hold harmless Sponsor and its Associates ("Sponsor Indemnitees") from and against any and all Losses incurred by Sponsor Indemnitees as a result of any Claim to the extent arising from the negligence, intentional misconduct, or breach of Agreement of PPD, PPD Affiliates or its Associates; provided however, that PPD shall have no obligation of indemnity hereunder with respect to any Claim which arose from the negligence, intentional misconduct or material breach of this Agreement on the part of Sponsor or its Associates.

8.3 Indemnification Procedure. Each indemnified party shall give the indemnifying party prompt notice of any Claim for which indemnification is sought hereunder. The indemnifying party shall have the right to control the defense and settlement of a Claim, at its sole expense, provided the indemnifying party shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of the Claim, and the indemnified party shall reasonably cooperate in the investigation,

defense and settlement of such Claim at the indemnifying party's expense. Neither party will enter into any settlement agreement that attributes fault or negligence to the other party, requires any payment by the other party, or restricts the future actions or activities of the other party, without the other party's prior written consent, which shall not be unreasonably withheld. Any indemnified party shall have the right to participate in, but not control, the defense and settlement of a Claim and to employ separate legal counsel of its own choice; provided, however, that such employment shall be at the indemnified party's own expense, unless the indemnifying party has failed to assume the defense and employ counsel (in which case the indemnified party shall control the defense and settlement of such Claim).

9. LIMITATION OF LIABILITY.

9.1 EXCEPT FOR LIABILITY ARISING FROM A PARTY'S BREACH OF SECTIONS 5, OR 6 OR A PARTY'S OBLIGATION OF INDEMNIFICATION UNDER SECTION 8, NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT (OR THE TERMINATION HEREOF) OR ANY PROJECT ADDENDUM, INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS OR ANTICIPATED SALES, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

9.2 TO THE FULLEST EXTENT PERMITTED BY LAW, AND EXCEPT FOR PPD'S LIABILITY FOR: (I) ITS BREACH OF SECTIONS 5 OR 6; (II) ITS INDEMNIFICATION OBLIGATIONS UNDER SECTION 8.2; OR (III) GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUD, THE TOTAL LIABILITY, IN THE AGGREGATE, OF PPD, PPD ASSOCIATES, AND ANY OF THEM, TO SPONSOR AND ANYONE CLAIMING BY OR THROUGH SPONSOR, FOR ANY AND ALL CLAIMS, LOSSES, COSTS OR DAMAGES, INCLUDING WITHOUT LIMITATION, ATTORNEYS' FEES AND COSTS AND EXPERT-WITNESS FEES AND COSTS OF ANY NATURE WHATSOEVER OR CLAIMS EXPENSES RESULTING FROM OR IN ANY WAY RELATED TO THIS AGREEMENT OR ANY PROJECT ADDENDUM FROM ANY CAUSE OR CAUSES SHALL NOT EXCEED ONE MILLION U.S. DOLLARS (\$1,000,000) OR THREE TIMES THE TOTAL DIRECT FEES, WHICHEVER IS GREATER, RECEIVED BY PPD UNDER THE APPLICABLE PROJECT ADDENDUM, WHICH IS THE SUBJECT OF THE CLAIM.

9.3 TO THE FULLEST EXTENT PERMITTED BY LAW, THE TOTAL LIABILITY, IN THE AGGREGATE, OF EACH PARTY, ITS ASSOCIATES, AND ANY OF THEM, TO THE OTHER PARTY AND ANYONE CLAIMING BY OR THROUGH THE OTHER PARTY, FOR ANY AND ALL SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES UNDER SECTION 9.1 ABOVE, AND RESULTING FROM ITS BREACH OF SECTIONS 5 OR 6 SHALL NOT EXCEED (I) EIGHT MILLION U.S. DOLLARS (\$8,000,000) IF THE DIRECT FEES PAYABLE UNDER THE PROJECT ADDENDUM GIVING RISE TO THE BREACH TOTAL TWO MILLION U.S. DOLLARS (\$2,000,000) OR LESS, OR (II) FOUR TIMES (4X) THE TOTAL DIRECTS FEES PAYABLE UNDER THE PROJECT ADDENDUM OR TWENTY- FIVE MILLION U.S. DOLLARS (\$25,000,000), WHICHEVER IS LESS, WHERE SUCH DIRECT FEES ARE GREATER THAN TWO MILLION US DOLLARS (\$2,000,000).

9.4 TO THE FULLEST EXTENT PERMITTED BY LAW, THE TOTAL LIABILITY, IN THE AGGREGATE, OF PPD, PPD ASSOCIATES, AND ANY OF THEM, TO SPONSOR AND ANYONE CLAIMING BY OR THROUGH SPONSOR, FOR ANY AND ALL CLAIMS, LOSSES, COSTS OR DAMAGES, INCLUDING WITHOUT LIMITATION, ATTORNEYS' FEES AND COSTS AND EXPERT-WITNESS FEES AND COSTS OF ANY NATURE WHATSOEVER OR CLAIMS EXPENSES RESULTING FROM ITS GROSS NEGLIGENCE SHALL NOT EXCEED (I) EIGHT MILLION U.S. DOLLARS (\$8,000,000) IF THE DIRECT FEES PAYABLE UNDER THE PROJECT ADDENDUM GIVING RISE TO THE BREACH TOTAL TWO MILLION U.S. DOLLARS (\$2,000,000) OR LESS, OR (II) FOUR TIMES (4X) THE TOTAL DIRECTS FEES PAYABLE UNDER THE PROJECT ADDENDUM OR TWENTY-FIVE MILLION U.S. DOLLARS (\$25,000,000), WHICHEVER IS LESS, WHERE SUCH DIRECT FEES ARE GREATER THAN TWO MILLION US DOLLARS (\$2,000,000).

10. INSURANCE.

10.1 Sponsor and PPD will each undertake to purchase and maintain insurance of such types and amounts reasonably adequate to cover any liabilities arising out of its obligations hereunder. Sponsor further undertakes to purchase and maintain insurance of such types and amounts and coverage reasonably adequate (including but not limited to that required by law) to cover any liabilities arising in relation to all clinical trials contracted to PPD pursuant to this Agreement. The following sets forth the minimum thresholds of insurance each party will maintain:

10.2 PPD Insurance. PPD shall, at its own cost and expense, obtain and thereafter maintain in full force and effect and with properly licensed and financially secure insurers (AM Best rating of A-VII in the United States and reasonably equivalent in countries outside the United States) the following insurance during the term of this Agreement and for a period of not less than three (3) years following termination of this Agreement:

- (i) Worker's Compensation. In amounts as required by applicable law;
- (ii) Automobile Liability Insurance. One Million US Dollars (\$1,000,000) per occurrence covering all owned, leased and hired vehicles;
- (iii) General Commercial Liability Insurance. One Million US Dollars (\$1,000,000) per occurrence and Three Million US Dollars (\$3,000,000) in the annual aggregate; and
- (iv) Professional Liability Insurance. Five Million US Dollars (\$5,000,000) per occurrence and Five Million US Dollars (\$5,000,000) in the annual aggregate.

10.3 Sponsor Insurance. Sponsor shall, at its own cost and expense, obtain and thereafter maintain in full force and effect, and with properly licensed and financially secure insurers (AM Best rating of A-VII in the United States and reasonably equivalent in countries outside the United States) the following insurance during the term of this Agreement and for a period of not less than three (3) years following termination of this Agreement:

- (i) Worker's Compensation. In amounts as required by applicable law;
- (ii) General Commercial Liability Insurance. One Million US Dollars (\$1,000,000) per occurrence and Three Million US Dollars (\$3,000,000) in the annual aggregate;
- (iii) Products Liability Insurance, including coverage for bodily injury suffered in the context of a clinical trial, with a minimum limit of Ten Million US Dollars (\$10,000,000) per occurrence and Ten Million US Dollars (\$10,000,000) in the annual aggregate; and
- (iv) Clinical Trials Insurance. In amounts as required by applicable law.

10.4 Sponsor and PPD will each undertake, upon request, to provide the other party a certificate (or certificates) of insurance setting forth the liability limits, exclusions and deductibles of the insurance such party is required to carry pursuant to this Agreement. Each party shall obtain the prior written consent of the other party before implementing any material change or cancellation of the insurance coverage agreed upon herein. Neither party will make any material changes to coverage thresholds that bring such party's required coverage below the minimum requirements stated in this Agreement. Unapproved reductions in any coverage threshold is a breach of this Agreement and at the non-breaching party's option, can result in termination of this Agreement.

11. RECORD STORAGE, AUDITS, AND INSPECTIONS.

11.1 Record Maintenance during Project. During the term of the applicable Project Addendum, PPD shall maintain all materials and all other data obtained or generated by PPD in the course of providing the Services thereunder, including all computerized records and files.

11.2 Record Maintenance after Expiration or Termination. Subject to the terms of this Section 11.2, upon the expiration or termination of the applicable Project Addendum, the continued retention of all materials and data directly relating to the Protocol and/or applicable drug product and obtained or generated by PPD in the course of providing the Services under the applicable Project Addendum (collectively, the “Records”) is the Sponsor’s responsibility. Upon completion of Sponsor’s payment obligations hereunder, PPD shall (at Sponsor’s risk, cost and expense), deliver the Records to Sponsor at its offices identified herein in such form as is then currently in the possession of PPD. Notwithstanding the foregoing, PPD shall be entitled at its expense to retain copies of the Records reasonably necessary for regulatory and business purposes and in accordance with PPD’s corporate records retention schedule, all subject to the confidentiality obligations set forth in Section 5 above. Upon the expiration of PPD’s retention period, PPD may dispose of all such copies; provided however that, prior to any such disposal, PPD shall provide Sponsor with ninety (90) days written notice and shall offer Sponsor, at Sponsor’s risk, cost and expense, the opportunity to request that PPD deliver such copies to Sponsor.

11.3 Sponsor conducted Services Audits. During the term of the applicable Project Addendum, at mutually agreeable dates and times and upon reasonable prior written notice to PPD, representatives of Sponsor (who shall not be competitors of PPD) shall be permitted to review, on site at PPD’s facilities, all documents, information, data and materials in the possession of PPD directly relating to the applicable Project conducted hereunder for the sole purpose of determining the compliance of the Services with the: (i) standard of performance and specifications set forth in the applicable Project Addendum; and (ii) applicable laws, regulations, guidelines and rules governing the Services. PPD and Sponsor agree to one (1) no-cost Services audit per year, to include no more than three (3) days on-site at PPD’s facilities. In instances where an audit is deemed necessary by Sponsor due to a significant quality concern or investigation (For Cause Audit), PPD and Sponsor agree to no-cost audits as needed. All other Services audits shall be charged according to PPD’s personnel billable rates. All Sponsor representatives shall, in advance of such audit, execute a mutually agreeable confidentiality and non-disclosure agreement with PPD. Notwithstanding the foregoing, Sponsor shall not be permitted to review information that is subject to third party confidentiality obligations, privileged, or not directly related to the performance of the applicable Services. Sponsor and its agents and consultants shall observe all confidentiality obligations concerning all documents, information, data or materials that it comes in contact with in connection with the audit.

11.4 Regulatory Inspections.

- a. Inspections of Investigator Sites. Both parties shall promptly notify the other party of any regulatory inspections of investigator sites of which it becomes aware. Where reasonably practicable and permitted by the relevant regulatory authority, Sponsor will have the right to be present at any inspections which are directly related to the Services. PPD shall reasonably act to secure the cooperation of investigators with respect to regulatory review.
- b. Inspections of PPD. PPD agrees to promptly notify Sponsor of a regulatory inspection of PPD in which Sponsor’s project is the scope of the inspection. Sponsor agrees to provide PPD support during the inspection as needed relative to the Services contracted and Project. PPD agrees to provide updates to Sponsor as to the progress of the inspection relative to the Services and Sponsor project.
- c. Inspection of Sponsor. Sponsor agrees to notify PPD of a regulatory inspection of Sponsor which are directly related to the Services. PPD agrees to provide Sponsor with support relative to the Services. Sponsor agrees to provide PPD with updates of inspection activities relative to the Services. The parties shall review costs associated with participation and shall agree to a reasonable rate of compensation in advance of the performance of any regulatory services.

11.5 Suspected Scientific Misconduct. Both parties agree to notify the other party of instances of suspected scientific misconduct as it relates to the Services.

11.6 Non-Compliance of Clinical Investigators and Related Parties. Notwithstanding anything to the contrary herein, in the event PPD or Sponsor identify continued non-compliance on the part of the clinical investigator/institution or related supporting staff, Sponsor agrees to support all actions required by PPD procedures/actions to secure compliance. Should the decision be made to terminate or suspend the trial as a result of serious and persistent non-compliance by these parties, Sponsor agrees to report the clinical investigator according to applicable regulatory requirement and authorizes PPD to report in the absence of such appropriate Sponsor action.

12. DEBARMENT.

PPD represents that, consistent with Section 306(a) and Section 306(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 335a (a) and 335a (b)), neither it nor any of its Associates and Subcontractors engaged in the performance of Services hereunder, is debarred and PPD will not knowingly hire any debarred individual to perform Services. PPD further warrants that neither it nor any of its Associates and Subcontractors engaged in the performance of Services hereunder, will use in any capacity in connection with the Services, any person who to its knowledge is the subject of a conviction described in 42 U.S.C. § 1320a-7(a) for which a person can be debarred, suspended, or excluded. PPD will Sponsor in writing promptly if it is debarred or it becomes aware of the fact that any of its Associates and Subcontractors performing Services is debarred or is the subject of a conviction described in 42 U.S.C. § 1320a-7(a), or if it is aware of any action, suit, claim, investigation or legal or administrative proceeding is pending, relating to the debarment, suspension, exclusion or conviction of PPD or its Associates and Subcontractors providing Services hereunder.

13. MISCELLANEOUS.

13.1 Independent Contractor Relationship. The parties hereto are independent contractors, and nothing contained in this Agreement is intended, and shall not be construed, to place the parties in the relationship of partners, principal and agent, employer/employee or joint venturer. Neither party shall have any right, power or authority to bind or obligate the other, nor shall either hold itself out as having such right, power or authority.

13.2 Publicity. Neither party shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of the other party in each instance. The restrictions imposed by this Section shall not prohibit a party from making any disclosure identifying the other party that is required by any Applicable Law.

13.3 Publication. PPD may not publish any articles or make any presentations relating to the Services provided to Sponsor hereunder with respect to a Project or referring to data, information or materials generated as part of the Services without the prior written consent of Sponsor.

13.4 Force Majeure. If either party shall be delayed, hindered, or prevented from the performance of any act required hereunder by reason of strike, lockouts, labor troubles, restrictive governmental or judicial orders or decrees, riots, insurrection, war, acts of God, inclement weather, or other cause beyond such party's reasonable control (each, a "**Disability**"), then performance of such act shall be excused for the length of time necessary to cure such Disability and resume performance. A party shall not be liable for any delays resulting from a Disability, and any affected timelines may be extended for a period at least equal to that of the Disability. The party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability and reasonably cooperate with the unaffected party to mitigate any potential delay.

13.5 Notices. Any notice required or permitted to be given hereunder by either party hereto shall be in writing and shall be deemed effectively given or delivered: (i) on the date delivered if delivered personally, (ii) on the first business day after the date sent if sent by recognized overnight courier, (iii) on the date transmitted if sent via facsimile (with confirmation of receipt generated by the transmitting machine), or (iv) on the second business day after the date deposited if mailed by certified mail, return receipt requested, postage prepaid. All notices to each party shall be sent to the address for said party set forth in the applicable Project Addendum. If no address is provided in the Project Addendum, then notices shall be sent to the following address:

If to PPD: PPD Development, L.P.
929 North Front Street
Wilmington, North Carolina 28401
Attention: CEO
Tel: (910) 251-0081
Fax: (910) 558-5820

If to Sponsor: inRegen
c/o Twin City Bio LLC
3929 WestPoint BLVD
Suite G
Winston-Salem, NC 27103
Attn: Tim Bertram

A party desiring to change its address for notice must give notice of the change to the other party hereto in the form and manner provided in this Section 13.5. Upon the failure of a party to notify the other Party of any change to or discontinuance of an address, any notices sent to the original or discontinued address shall be deemed to have been effectively given.

13.6 Governing Law. This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of the State of New York without reference to its conflicts of laws provisions.

13.7 Severability. If any provision of this Agreement or any Project Addendum is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of any party hereto under this Agreement or such Project Addendum will not be materially or adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement or such Project Addendum will be construed and enforced as if such illegal, invalid or unenforceable provision had never compromised a part hereof, (c) the remaining provisions of this Agreement or such Project Addendum will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a part of this Agreement or such Project Addendum, a legal, valid and enforceable provision as similar in terms as to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the parties herein.

13.8 Waiver. Any term or condition of this Agreement or a Project Addendum may be waived at any time by the party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the party waiving such term or condition. No waiver by any party hereto of any term or condition of this Agreement or a Project Addendum, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement or such Project Addendum on any future occasion.

13.9 Amendments. No amendment, change or modification to this Agreement or any Project Addendum shall be effective unless in writing and executed by the parties hereto.

13.10 Assignment. This Agreement and any Project Addendum may not be assigned by either party without the prior written consent of the other party; provided, however, that a party hereto may assign this Agreement or a Project Addendum hereunder to (i) a successor-in-interest to the party's business or (ii) an Affiliate.

13.11 Subcontracting. In the event that PPD subcontracts all or part of the Services under a Project Addendum to a third party Subcontractor, PPD shall be responsible and retain primary liability for the performance of all obligations of Subcontractors (as defined below). When used in this Agreement, the term "Subcontractor" shall mean and refer to any third party selected, managed and contracted by PPD or to whom PPD has subcontracted or delegated PPD's obligation to perform any portion of the Services hereunder, but shall exclude (i) investigators and investigative site personnel involved in the performance of a Project; (ii) a third party serving as a member on a data and safety monitoring board or data monitoring committee hereunder; and (iii) third party providers used by PPD at the written request of Sponsor despite the fact that PPD has the ability to perform the subcontracted service either itself or through a PPD Affiliate. Regarding Sponsor-requested subcontractors, PPD shall be liable to Sponsor only to the extent that PPD was negligent in fulfilling any contracting, validation, management and/or oversight responsibilities in respect to such third-party. Sponsor shall have the ability to approve PPD's use of any subcontractor prior to the assignment of any such Services by PPD.

13.12 Arbitration. Except for disputes regarding breaches of Section 5 and the right to pursue the remedies set forth in Section 5.7 above, the parties may submit any dispute arising hereunder to binding arbitration pursuant to the Commercial Arbitration Rules of the American Arbitration Association ("AAA"). The arbitration shall be conducted in Winston-Salem, North Carolina. The decision of the arbitrator or arbitration panel shall be final and binding upon the parties hereto and shall be enforceable by any court of competent jurisdiction. By agreeing to arbitration, the parties do not intend to deprive any competent court of such court's jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of the arbitration proceedings and the enforcement of any award or judgment. Without prejudice to such provisional remedies in aid of arbitration as may be available under the jurisdiction of a national court, the court of arbitration shall have full authority to grant provisional remedies and to award damages for failure of any party to respect the court of arbitration's order to that effect. The parties will keep the arbitration confidential and that the existence of the arbitration proceeding and any element of it (including but not limited to any pleadings, briefs or other documents submitted or exchanged, any testimony or other oral submissions, and any awards) shall not be disclosed beyond the tribunal, the AAA, the parties, their counsel, accountants and auditors, insurers and re-insurers, and any person or entity necessary to the conduct of the proceeding. The confidentiality obligations in this Section 13.12 shall not apply (i) if disclosure is required by law, or in judicial or administrative proceedings, or (ii) as far as disclosure is necessary to enforce the rights arising out of the arbitration award. Without otherwise limiting the requirements imposed by this Section 13.12, a party may seek from any court having jurisdiction any interim or provisional relief that may be necessary to protect its interests hereunder, pending the resolution of any dispute in accordance with this Section 13.12.

13.13 Construction. Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders, the word "or" is used in the inclusive sense, and "including" means including, without limitation. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the parties and no rule of strict construction shall be applied against either party hereto.

13.14 MedDRA and WHODrug Dictionary License. The parties acknowledge that MedDRA and Uppsala Monitoring Centre product licenses are required by all parties who wish to distribute or receive MedDRA or WHODrug dictionary terminology. Each party represents and warrants that it possesses a current MedDRA and/or Uppsala Monitoring Centre product license. In the event Sponsor requests that PPD perform services which require PPD to distribute MedDRA terminology or WHODrug dictionary to third parties, Sponsor shall be responsible for ensuring that all such third parties possess the necessary MedDRA and/or Uppsala Monitoring Centre product licenses.

13.15 Counterparts and Electronic Signatures. This Agreement, any Project Addendum hereunder, and all associated amendments may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument. Each party may execute this Agreement, any Project Addendum, and all amendments by electronic signature (whatever form the electronic signature takes) or in Portable Document Format (or other file format) sent by electronic means. Signatures of authorized signatories of the parties completed by electronic signature or sent by electronic means in Portable Document Format shall have the same force and effect as manual signatures, shall be valid and binding, and, upon delivery, shall constitute due execution of this Agreement, any Project Addendum, or any amendments hereunder.

13.16 Representative. With regard to any Project conducted under this Agreement, Sponsor shall not name any PPD employee, contractor, or other PPD representative on Line 16 of Form FDA 1571. Sponsor acknowledges and understands that if Sponsor desires that any PPD employee, contractor, or other PPD representative be named as the Senior Medical Officer in Canada on Line 89 of Form HC/SC 3011 or in any similar capacity for clinical trials conducted in other countries, Sponsor must first submit such a request to PPD in writing for the performance of services pursuant to such naming, including, without limitation, responsibility for review and evaluation of information relevant to the safety of the study drug. If PPD agrees to perform such services, the parties shall enter into good faith negotiations and enter into either a separate agreement or written amendment to the applicable Project Addendum prior to PPD initiating the services.

13.17 Economic Sanctions and Trade Embargoes. Sponsor represents and warrants that (i) neither Sponsor nor Sponsor's directors or officers are subject to economic sanctions and trade embargoes; (ii) Sponsor is not 50% or more owned, directly or indirectly, by individuals or entities that are subject to economic sanctions or trade embargoes; and (iii) Sponsor will not request PPD to provide any services that would cause PPD to violate any economic sanctions or trade embargoes. PPD represents and warrants that (i) neither PPD nor its Affiliates, nor its or their directors or officers are subject to economic sanctions and trade embargoes; (ii) PPD is not 50% or more owned, directly or indirectly, by individuals or entities that are subject to economic sanctions or trade embargoes; and (iii) PPD will not violate any economic sanctions or trade embargoes in connection with the Services.

13.18 Clinical Trial Supply. Sponsor acknowledges that in certain jurisdictions PPD may, at Sponsor's request, act as importer of record ("IoR") for the study by the operation of the laws or regulations or engaged by Sponsor to provide clinical trial supply management services. Where PPD acts as the IoR, clinical trial supply process shall follow PPD's guidelines and the Incoterms for the goods arriving into a jurisdiction shall be decided by PPD. If Sponsor uses its own logistics vendors for the study, Sponsor shall make sure its logistics vendors follow PPD's guidelines and adopt the Incoterms as designated by PPD. Sponsor shall bear or reimburse PPD for all the costs PPD may incur as IoR including without limitation all applicable customs duties, taxes, and government levies.

Where PPD recovers import VAT (or other tax) on behalf of Sponsor, fees shall be charged to Sponsor net of such VAT (or such other tax). Notwithstanding the foregoing, Sponsor agrees that if such import VAT (or other tax) is subsequently determined by a tax authority, during an audit or otherwise, to not be recoverable by PPD, Sponsor agrees that it will indemnify PPD and hold PPD harmless for all losses, claims and demands (including but not limited to such irrecoverable tax) in connection thereto, except to the extent arising out of PPD's negligence or willful misconduct or fraud. The indemnity under this clause shall survive the expiration or early termination of this Agreement.

13.19 Entire Agreement. This Agreement constitutes the entire agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, with respect to the subject matter hereof

IN WITNESS WHEREOF, this Agreement has been executed and delivered by the parties hereto by their duly authorized officers as of the date of last signature below.

PPD DEVELOPMENT, L.P.
BY: PPD GP, LLC
ITS: GENERAL PARTNER

INREGEN

By: /s/ William Sharbaugh
Name: William Sharbaugh
Title: Chief Operating Officer
Date: 01-May-2019

By: /s/ Timothy A Bertram
Name: Timothy A Bertram
Title: CEO
Date: 30 April 2019

MASTER SERVICES AGREEMENT

This Master Services Agreement (the “Agreement”) is made as of the 14th day of August, 2015 (“Effective Date”) by and between RegenMedTX, LLC, a Delaware limited liability company (“Sponsor”) with offices located at 3929 Westpoint Blvd., Suite G, Winston-Salem, NC 27103, and CTI Clinical Trial Services, Inc. & CTI Clinical Consulting Services, Inc., (“CTI”) with offices located at 10123 Alliance Road, Cincinnati, OH 45242.

Introduction

Sponsor may sponsor and/or conduct one or more clinical research studies from time to time, and CTI is knowledgeable and experienced in the design, management and conduct of such studies. Sponsor wishes to retain CTI to assist Sponsor in these studies on the terms and conditions set forth in this Agreement.

To that end, Sponsor and CTI now agree as follows:

1. Services. From time to time, CTI will provide Sponsor certain clinical research or design and development services pursuant to the terms of this Agreement. Prior to the commencement of such services, CTI and Sponsor shall enter into a Work Order that will describe the specific obligations transferred by Sponsor to CTI (the “Services”) in the performance of a particular clinical research study sponsored or conducted by Sponsor (each a “Study”). Each Work Order will be a separate agreement, and each Work Order will incorporate the terms of this Agreement by reference. A sample form of this Work Order is attached to this Agreement as Exhibit A.

CTI represents to Sponsor that it is not a party to any agreement which would prevent it from fulfilling its obligations under this Agreement and, that during the term, CTI agrees it will not enter into any agreement to provide services which would in any way prevent it from providing the Services as contemplated under this Agreement.

CTI will ensure that the Services are carried out by qualified and experienced staff. CTI covenants that it will render the Services in accordance with its applicable standard operating procedures and to the highest professional standards and will make all efforts to maintain consistently high levels of accuracy and expertise. CTI will comply with all applicable laws, rules, regulations and guidelines relating to the conduct of clinical investigations, including, without limitation, 21 C.F.R. Parts 50, 54, 56 and 312, the International Conference on Harmonization Guidelines for Good Clinical Practices (collectively, “Applicable Law”) and other good clinical practice requirements (collectively, “Applicable Requirements”). The parties agree to comply with the Health Insurance Portability and Accountability Act (45 C.F.R. Parts 160, 162 and 164, as well as the regulations thereunder) and any state, municipal or local law, ordinance or regulation protecting the privacy of individual health information (collectively “Privacy Laws and Regulations”).

2. **Personnel.** CTI shall ensure that appropriately trained and qualified employees and contractors of CTI deliver the Services outlined in each Work Order. CTI must obtain the prior written consent of Sponsor regarding any contractor which CTI proposes to engage to deliver the Services outlined in any Work Order. CTI also must obtain the prior written consent of Sponsor with respect to a decision by CTI to utilize any CTI employee that CTI proposes to have a substantive role in the delivery of the Services with respect to any Work Order that is not so engaged as of the Effective Date. However, such prior written consent shall not be required with respect to those employees whose involvement in the Study is limited to only non-substantive activities (e.g., monitors, etc.).

If CTI contracts with investigators or investigative sites (collectively, "Investigators"), any such contract shall be on a form mutually acceptable to CTI and Sponsor. If an Investigator requests any material changes to such form, CTI shall submit the proposed change to Sponsor, and Sponsor shall promptly review, comment on and/or approve such proposed changes. The parties acknowledge and agree that Investigators shall not be considered the employees, agents, or subcontractors of CTI or Sponsor, and that Investigators shall exercise their own independent medical judgment with respect to the applicable Study. CTI's responsibilities with respect to Investigators shall be limited to those responsibilities specifically set forth in this Agreement and any applicable Work Order.

If CTI will be paying Investigators on behalf of Sponsor, the parties will agree to a schedule of amounts to be paid to Investigators. Sponsor acknowledges and agrees CTI will only pay Investigators from advances or pre-payments received from Sponsor for Investigators' services, and that CTI will not make payments to Investigators prior to receipt of sufficient funds from Sponsor. Sponsor acknowledges and agrees that CTI will not be responsible for delays in a Study to the extent that such delays are caused by Sponsor's failure to make adequate pre-payment for Investigators' services. Sponsor further acknowledges and agrees that payments for Investigator's services are pass-through payments to third parties and are separate from payments for CTI Services. Sponsor agrees that it will not withhold Investigator payments except to the extent that it has reasonable questions about the services performed by a particular Investigator. CTI shall have Investigators complete and return to Sponsor such financial disclosure forms as may be required to comply with Applicable Regulations pertaining to financial disclosures of clinical investigators.

The parties agree that any payments to Investigators are not intended to encourage, and are not being given in exchange for any explicit or implicit agreement to:

(i) order, purchase, prescribe or recommend any Sponsor product; or (ii) influence or provide favorable formulary status for any Sponsor product. Payments have not been determined in a manner that would take into account the volume or value of referrals or business, if any, generated between Sponsor and any investigator, sub-investigator or their practice.

By entering into this Agreement, each party attests that it understands what is required of it for the Study under Applicable Law and Applicable Requirements, and commits to complying with such law and requirements. CTI hereby certifies to Sponsor that it is not, has not been, or has not used, nor will it use the services of any person, debarred under 21 U.S.C. 335a, as amended, or disqualified by any regulatory authority, or otherwise found by any regulatory authority to have violated any Applicable Law or Applicable Requirements concerning the conduct of clinical investigations or excluded from participation in any state or federal healthcare program (collectively, "Debarred" or "Debarment") in any capacity in connection with any of the services or work provided hereunder. In the event that during the term of this Agreement, CTI or any of its Investigators or any of their employees or agents (i) becomes Debarred or (ii) receives notice of an action or threat of an action with respect to its Debarment, CTI shall notify Sponsor immediately.

3. Transfer of Obligations. The specific obligations transferred by Sponsor to CTI in any particular Study will be detailed in the relevant Work Order. Sponsor will retain those responsibilities not specifically listed in that Work Order. Sponsor shall at all times be the "Sponsor" of each Study pursuant to the terms of the U.S. Food, Drug and Cosmetic Act, as from time to time amended (the "Act"). Sponsor will maintain all direct communication, whether oral, electronic or hard copy, with the U.S. Food and Drug Administration (the "FDA") at all times with respect to the Study, and CTI will only engage in limited preliminary communications with the FDA regarding the Study and shall give prompt notice of such communications to Sponsor. Sponsor will cooperate with CTI in taking any action that CTI reasonably believes is necessary to comply with the regulatory obligations that have been transferred to CTI.

Each party acknowledges that the other party may respond independently to any regulatory correspondence or inquiry in which such party or its affiliates is named and which does not relate to the Services provided under this Agreement. Each party however, shall: (a) notify the other party promptly of any FDA or other U.S. or non-U.S. governmental or regulatory inspection or inquiry relating to the Services provided by CTI under this Agreement including, but not limited to, inspections of investigational sites; (b) forward to the other party copies (within five (5) business days) of any correspondence from any regulatory or governmental agency relating to a Study, including, but not limited to, Form FD-483 notices, and FDA refusal to file, rejection or warning letters, even if they do not specifically mention the other party; (c) give the other party the opportunity to review and comment upon any response to a regulatory authority relative to the Services or a Study under this agreement before such response is submitted, such review and comment to be conducted promptly and without delay; and (d) obtain the written consent of the other party, which will not unreasonably be withheld, before referring to the other party or any of its affiliates in any regulatory correspondence relative to the Services or a Study under this Agreement. Where reasonably practicable, each party will be given the opportunity to have a representative present during a FDA or regulatory inspection. Each party however, acknowledges that it may not direct the manner in which the other party fulfills its obligations to permit inspection by

governmental entities. Notwithstanding the foregoing, CTI will promptly notify Sponsor of any FDA or other U.S. or non-U.S. governmental or regulatory inspection or inquiry with respect to CTI not relating to the Services or the Study but which is reasonably likely to have an impact on CTI's performance of the Services and/or its other obligations under this Agreement and, to the extent legally permissible, discuss with Sponsor such potential impact.

Each party agrees that, during an inspection by the FDA or other regulatory authority concerning any Study for which CTI is providing the Services, it will not disclose information and materials that are not required to be disclosed to such authority, without the prior written consent of the other party, which shall not unreasonably be withheld. Such information and materials includes, but are not limited to (i) financial data and pricing data (including, but not limited to, the Budget (as defined below)); (ii) sales data (other than shipment data); and (iii) personnel data (other than data as to qualification of technical and professional persons performing functions subject to regulatory requirements).

During the term of this Agreement, CTI will permit Sponsor's representatives (unless such representatives are competitors of CTI) to examine and review, without any additional cost to Sponsor, the work performed hereunder and any facilities at which the work is conducted, upon reasonable advance notice and at mutually agreeable times during regular business hours to determine that the Services are being performed in accordance with this Agreement and the Work Orders. In the event of a more formal audit, unless the costs of governmental or Sponsor audits are specifically included in the Budget, or a governmental "for cause" audit is conducted as a result of CTI activities, Sponsor shall reimburse CTI for its time and expenses, including reasonable attorney fees, associated with such audits, including the costs of responding to the findings of any such audit.

4. Scope of Work and Payment. The Work Order for each Study will include a scope of work statement that details CTI's Services for that Study. The Work Order will also include a budget and payment schedule for CTI's Services for each Study, and Sponsor will pay CTI for the Services accordingly ("Budget"). The aggregate fees and expenses set forth in that schedule will not change or be modified unless authorized by both parties in writing. CTI will invoice Sponsor in accordance with the relevant Work Order. Each invoice will describe the Services performed, and any expenses billed will be supported by appropriate documentation. Sponsor will pay all uncontested amounts reflected on each invoice within thirty (30) days of the date thereof. If all or any portion of an invoice is contested, Sponsor will provide written notice and a summary of the contested items to CTI within ten (10) days of Sponsor's receipt of invoice. The parties shall work in good faith toward resolution of such items.

If Sponsor requests CTI to perform services beyond those set out in the Work Order, CTI shall proceed as follows: consistent with the desire of both parties not to disrupt the ongoing progress of any Study, CTI shall (i) submit a proposed budget and payment schedule for such out-of-scope work and obtain Sponsor's written approval of that schedule before commencing that work, or (ii) obtain written authorization from Sponsor to proceed with such work prior to a final agreement on the proposed schedule. In either case, both parties will make good faith efforts to negotiate and agree upon a revised schedule as soon as possible and practicable.

5. **Term and Termination.** This Agreement and any Work Order will begin as of its stated Effective Date and will continue unless terminated under this Section 5. This Agreement or any Work Order may be terminated for any reason by any party upon ninety (90) days prior written notice to the other party. Further, this Agreement or any relevant Work Order may be terminated immediately by written notice from Sponsor, in the following circumstances:

- (1) The FDA withdraws authorization and approval to conduct a Study; or
- (2) Sponsor reasonably determines that for medical, clinical or patient safety reasons, a Study should terminate immediately.

In addition, either party may terminate this Agreement or any Work Order for material breach upon thirty (30) days written notice specifying the nature of the breach, if such breach has not been substantially cured within the thirty (30) day period.

For any termination of this Agreement or any Work Order, both parties recognize that such an event will require discussion, cooperation and coordination between them to ensure patient safety, compliance with all applicable regulations and continuity of treatment (if appropriate). To that end, upon any termination of this Agreement or any Work Order, CTI will cooperate with Sponsor to provide for an orderly cessation of CTI Services. Additionally, unless otherwise stipulated by Sponsor, CTI will perform such Services as are reasonably necessary for an orderly termination and shall transfer to Sponsor all Study data, reports, and all related Study documents prepared but not yet submitted to Sponsor after receiving full payment from Sponsor for all services and work related to such Study data, reports and Study documents. Similarly, upon any termination of this Agreement or any Work Order, Sponsor shall promptly pay CTI for Services performed under this Agreement or such Work Order prior to the effective date of termination or in connection with the process of an orderly termination; provided, however, that the total of such payments shall not exceed the total amount remaining under the Budget unless agreed to by Sponsor and CTI in writing. Sponsor's final payment to CTI will include reimbursement to CTI for all non-cancelable obligations and all pass-through expenses incurred prior to the effective date of termination or in connection with the process of an orderly termination. In the orderly cessation of activities, CTI will use its best efforts, consistent with good clinical practice, to minimize costs to be incurred by Sponsor for the Services.

6. Confidentiality. For this Agreement and its Work Orders, all materials, documents and information concerning a Study, including, without limitation, the protocol, case report forms, clinical data and other proprietary data provided to or developed by CTI for use in a Study, shall be considered "Confidential Information." All Confidential Information, except CTI Intellectual Property as defined in Section 7.D. below ("Records"), will be the exclusive property of Sponsor. CTI will maintain Confidential Information in confidence and shall not disclose it unless that disclosure is required for CTI's performance of its obligations under this Agreement or a Work Order. Unless otherwise agreed in a Work Order, CTI's confidentiality obligations shall survive for seven (7) years after the expiration or termination of the relevant Work Order. CTI is responsible for ensuring that all of its employees and contractors understand and maintain the confidentiality of such Confidential Information under this Agreement or its Work Orders.

Under this Agreement and its Work Orders, Confidential Information shall not include: (a) information which is known to CTI prior to disclosure by Sponsor; (b) information which is or becomes public through no improper act of CTI; (c) information which becomes available to CTI from a source other than Sponsor; or (d) information developed by or for CTI independent of the disclosure of Confidential Information by Sponsor.

The parties may disclose Confidential Information to the extent such disclosure is required to comply with applicable governmental regulations or to the extent ordered by a court exercising its right of authority over the disclosing party (subject to entry of an appropriate protective order), provided that if a party is required by such law, regulation or order to make any such disclosure of Confidential Information, such party shall give reasonable notice to the other party of such disclosure requirement and will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed.

CTI shall maintain all Records in a safe and secure manner and in compliance with all Applicable Laws and Applicable Requirements. CTI shall store all Records in compliance with the appropriate record retention regulations. Thereafter, prior to disposal of any Records, CTI shall give Sponsor not less than sixty (60) days written notice, and, if Sponsor so requests prior to such disposal, CTI shall transfer such Records to Sponsor at Sponsor's cost and expense. CTI shall make any and all Records available for inspection or duplication by Sponsor's authorized representatives during normal business hours at mutually agreed upon times. At any time and at Sponsor's cost and expense, Sponsor may request that CTI (i) deliver any or all Records to Sponsor or to a location specified by Sponsor, or (ii) dispose of Records as directed by Sponsor, unless such Records are required by Applicable Laws and Applicable Requirements to be stored or maintained. CTI shall be entitled to retain one (1) copy of any Confidential Information necessary for determining its ongoing obligations pursuant to this Agreement.

7. Intellectual Property.

- A. **Ownership.** All materials, documents and information obtained by, developed by or provided to CTI by or on behalf of Sponsor as part of CTI's Services under this Agreement or any Work Order will be the exclusive property of Sponsor.
- B. **Inventions.** CTI will disclose to Sponsor any and all inventions or discoveries that incorporate Confidential Information and that are made by CTI as part of its Services under this Agreement or any Work Order ("Intellectual Property"). Further, CTI will assign all rights it may have in any such Intellectual Property to Sponsor.
- C. **Assistance.** CTI will cooperate with Sponsor in executing any and all applications, assignments or other instruments reasonably necessary to apply for and obtain a patent in the United States or any foreign country, or to otherwise protect Sponsor's interest in such Intellectual Property. Sponsor shall compensate CTI for its time and reasonable expenses required by this assistance.
- D. Notwithstanding subsection A, B, and C above, all computer programs, software, applications, databases, proposals and other documentation generally used or developed by CTI, and any improvement, alteration or enhancement to these (unless specifically requested **and** paid for by Sponsor as part of CTI's Services under this Agreement and any Work Order), are the exclusive and confidential property of CTI or the third parties from whom CTI has secured the right of use ("CTI Intellectual Property").

8. Indemnification.

CTI will hold harmless and indemnify Sponsor, its employees, agents, representatives and assigns from and against all claims, costs, complaints, or lawsuits that arise as a result of the negligence or malfeasance of CTI or its employees, agents, representatives, and assigns in its performance under this Agreement or any Work Order. This CTI indemnification does not apply to any loss, damage, cost or expense to the extent such loss, damage, cost or expense is caused by or attributable to the negligence or malfeasance of Sponsor or any of its employees, agents, representatives or assigns.

Sponsor will hold harmless and indemnify CTI, its employees, agents, representatives and assigns from and against all claims, costs, complaints, or lawsuits that arise as a result of (i) the negligence or malfeasance of Sponsor or its employees, agents, representatives and assigns, or (ii) personal injury or death alleged to have been caused by or attributed to any Study substance provided by Sponsor and dispensed or administered in the Study pursuant to the provisions of the Study Protocol. CTI will promptly notify Sponsor of any such claim, complaint or lawsuit. Sponsor has the right, in its sole discretion, to defend, and/or settle any such claim, complaint, or lawsuit at its own expense and by its own counsel. CTI will cooperate fully in the investigation and defense of any such claim, complaint or lawsuit. This Sponsor indemnification does not apply to any loss, damage, cost or expense to the extent such loss, damage, cost or expense is caused by or attributable to the negligence or malfeasance of CTI or any of its employees, agents, representatives or assigns.

9. **Independent Contractor Relationship.** The parties to this Agreement and its Work Orders are independent contractors. Neither party can offer or agree to incur or assume any obligations or commitments in the name of or on behalf of the other, except as specifically stated in this Agreement or in a Work Order.

10. **Miscellaneous.**

- A. **Delegation and Subcontracts.** CTI may delegate part of its Services under a Work Order to its affiliated companies or other subcontractors as it may require, and with written notice to Sponsor of that delegation. However, CTI remains principally responsible to Sponsor for the performance of all its Services and obligations under this Agreement, whether delegated, subcontracted or otherwise.
- B. **Non-Solicitation.** During the term of this Master Agreement and for a period of twelve (12) months thereafter, neither Sponsor nor CTI shall recruit or otherwise induce any employee to terminate his/her employment or violate any agreement with, or duty to, Sponsor or CTI.
- C. **Force Majeure.** Either party shall be excused from performing its obligations under this Agreement or any Work Order if their performance is delayed or prevented by a cause beyond that party's control, including, but not limited to, acts of God, fire, explosion, weather, disease, war, insurrection, civil strife, riots, government action, or power failure. Performance will be excused only to the extent of and during the reasonable continuance of such disability. Any deadline or time for performance specified in a Work Order which falls due during or subsequent to the occurrence of any *force majeure* under this section will be extended for a period of time equal to the period of such disability. CTI will promptly notify Sponsor if, by reason of any *force majeure*, CTI is unable to meet any deadline or time for performance specified in a Work Order.
- D. **Binding Agreement.** This Agreement is binding on and inures to the benefit of its parties and their respective legal representatives, successors and assigns. However, neither party can transfer or assign this Agreement without the prior written consent of the other party.
- E. **Amendments.** This Agreement may be modified or amended only by a writing executed by the parties hereof.
- F. **Notices.** All notices shall be in writing and shall be personally delivered or sent by certified mail, return receipt requested to the parties at the addresses each party will furnish to the other.

- G. Waiver. The waiver or breach of any term or condition of this Agreement does not constitute a waiver of any other of its terms or conditions or any subsequent breach of the same term or condition.
- H. Entire Agreement. This Agreement and its Work Orders are the entire agreement between its parties as to its subject matter. There are no representations, warranties, covenants or undertakings as to that subject matter other than those expressly set forth in this Agreement and its Work Orders. This Agreement and Work Orders supersede all prior agreements between the parties as to its subject matter.
- I. Severability. The invalidity or unenforceability of any Agreement or Work Order provision shall in no way affect the validity or enforceability of any other provision.
- J. Governing Law. The laws of the State of Delaware (without regard to any provision or rule applying the law of another state or jurisdiction) shall govern this Agreement and its Work Orders.
- K. Counterparts. This Agreement and its Work Orders may be executed in two (2) counterparts and by facsimile or electronic means, each of which shall be considered an original, but are one and the same document.

[Signature page follows]

As witness to this Agreement, the authorized representatives of its parties have signed this Agreement below as of its Effective Date.

CTI Clinical Trial Services, Inc.

By: /s/ Timothy J. Schroeder
Name: Timothy J. Schroeder
Title: CEO

Date: 14 August 2015

RegenMedTX, LLC

By: /s/ Timothy A. Bertram
Name: Timothy A. Bertram
Title: Chief Executive Officer and Managing Director

Date: 17 August 2015

[Signature Page to Master Services Agreement]

This Laboratory Service Agreement ("Agreement") is made effective on 26 August 2016 by and between

- (1) **COVANCE CENTRAL LABORATORY SERVICES LP** an Indiana limited partnership, with its principal place of business at 8211 SciCor Drive, Indianapolis, Indiana 46214, USA; and **COVANCE CENTRAL LABORATORY SERVICES SÀRL**, with its principal place of business at Rue Moise-Marchines 7, 1217 Meyrin, Geneva Switzerland (collectively "**Covance**"); and
 - (2) **RegenMed (Cayman) Ltd.**, 10 Market Street, No. 774 Camana Bay, Grand Cayman KY1-9006, Cayman Islands ("**Sponsor**").
- (each a "**Party**" and collectively the "**Parties**").

WHEREAS

- (A) Covance is engaged in the business of providing laboratory testing, data management, protocol management and information management services for pharmaceutical clinical trials.
- (B) Sponsor desires for Covance to perform such services for one or more clinical trials, all in accordance with and subject to the terms and conditions of this Agreement.

IT IS AGREED

1. DEFINITIONS

1.1 In this Agreement, the following words and expressions shall have the following meanings:

"**Affiliate**" means any entity controlling, controlled by, or in common control with a Party. For the purposes of this definition, "**Control**" shall mean ownership or control, directly or indirectly of more than fifty percent (50%) of the common voting stock or ordinary shares in the entity or the right to appoint fifty percent (50%) or more of the directors of that entity. With respect to Covance, the term Affiliate shall include Laboratory Corporation of America Holdings and any business entity that is controlled by or is under common control with Laboratory Corporation of America Holdings.

"**Anti-Corruption Laws**" means any anti-bribery and anti-corruption laws, rules, regulations applicable to either Party (each as amended from time to time) including the United States Anti-Kickback Law, United States Foreign Corrupt Practices Act, the UK Bribery Act 2010 and the OECD Convention Against the Bribery of Foreign Government Officials in International Business Transactions, together with any applicable implementing legislation including any applicable local law addressing bribery or corruption.

"**Applicable Law**" means applicable federal, state and local laws, rules, regulations, including the regulations of the FDA and Data Protection Laws.

"**Background IP**" means all pre-existing intellectual property belonging to or licensed to a Party or other intellectual property created outside the scope of the Services.

“**Claim**” means any third party claims, demands, assessments, actions, suits, proceedings, or settlements.

“**Confidential Information**” means any and all non-public information or materials and derivatives thereof, in any and all forms, howsoever disclosed or obtained, including business plans, financial information, client lists, and requirements, techniques, designs, methods, processes and procedures, which: (i) is identified by a suitable legend or other marking as being confidential (or similar designation) in a prominent position or (ii) is described as being confidential at the time of disclosure or (iii) the disclosing Party regards or should reasonably be expected to regard as proprietary and confidential given the nature of the information and the circumstances of disclosure. Confidential Information shall not include information (a) that is or becomes publicly disclosed except to the extent such disclosure results from a violation hereof or any improper action or inaction by Recipient or any agent or representative of Recipient; (b) that was in Recipient’s possession prior to Recipient’s receipt of such material from Disclosing Party, as demonstrated by documentary evidence that itself was in Recipient’s possession at the time of Disclosing Party’s disclosure of such Confidential Information to Recipient; (c) that is lawfully acquired by Recipient from a third party not obligated to keep such information confidential; or (d) that is developed by the Recipient without the use of or reliance on the Disclosing Party’s Confidential Information, as demonstrated by Recipient’s written records. Information will not be deemed to be within the foregoing exceptions merely because such information is embraced by more general information that is within the foregoing exceptions. In addition, any combination of features will not be deemed to be within the foregoing exceptions merely because individual features are within the exceptions, but only if the combination itself and its principle of operation are within the exceptions.

“**Covance Property**” means inventions, proprietary processes, software (including codes) data, technology, know-how and other intellectual property that have been independently developed or discovered by Covance or its Affiliates without the use of Sponsor’s Confidential Information, including those that relate to the proprietary innovative testing procedures, laboratory testing data collection or data management procedures, procedural manuals, delta flags, nucleic acid based vectors, analytical procedures and approaches that are not specific for use with the Sponsor’s Background IP even if such are developed in the performance of the Services or are captured in documents pertaining to the Services (i.e. laboratory notebooks), techniques, skills, models, non-product specific components of questionnaires, management tools and any other materials, employed, developed or acquired by Covance or its Affiliates.

“**Data Protection Laws**” mean all applicable privacy, data protection or similar laws and regulations anywhere in the World, as the same may be amended from time to time, including to the extent applicable to the respective Services, the Data Protection Directive (95/46/EC), the Personal Data Protection Act 2012 of Singapore and any applicable implementing legislation or any amendment thereto.

“Deliverables” means as applicable to the Services, Results, or any other deliverable specified in this Agreement.

“Disclosing Party” means the Party disclosing or making available its Confidential Information to the other Party.

“FDA” means the United States Food and Drug Administration or any other government body or agency that succeeds it.

“Force Majeure Event” means circumstances or causes beyond the reasonable control of a Party, including war, threat of war or warlike conditions, blockade, embargo, fire, explosion, lightning, storm, drought, flood, earthquake or other natural disaster, pandemic or epidemic, power failure, acts of terrorism, riot, civil unrest, insurrection, acts of government or other international bodies, political subdivision and any other events which by their nature could not have been foreseen by the Parties, or, if it could have been foreseen were unavoidable by a reasonable prudent business.

“HBS Donor” means an individual, living or deceased, from whom the HBS was obtained.

“Human Biological Samples” or **“HBS”** means any human biological material, including, without limitation, human bodily parts and organs in whole or sub-samples, any tissue, skin, bone, muscle, connective tissue, blood, cerebrospinal fluid, cells, gametes, or sub-cellular structures such as DNA, or any derivative or product of such human biological materials including stem cells, cell lines, bodily fluids, blood derivatives and urine.

“IEC/IRB” means an independent ethics committee or institutional review board.

“Informed Consent” means an IEC/IRB approved informed consent form signed by the HBS Donor authorizing the Use of their HBS.

“Invention” means any patentable invention or other registerable intellectual property rights discovered, conceived of or made by Covance or its Affiliates specifically as result of the Services for the Sponsor and relating to the Test Materials. Covance Property is not included in Inventions.

“Loss” means any loss, cost, damage or expense (including reasonable legal expenses).

“Project” means a Study, project or assignment between Covance and Sponsor.

“Protocol” means the document which specifies the laboratory testing procedures as written by Sponsor as applicable for the performance of a Study and is provided to Covance.

“Recipient” means the Party receiving or having access to the Confidential Information from the other Party.

“Regulatory Authority” means any national or state (in the case of the US), or local agency, authority, department, inspectorate, minister, ministry official, parliament or public or statutory person (whether autonomous or not) of any government of any country having jurisdiction over either any of the activities contemplated by this Agreement or the Parties.

“Regulatory Requirements” means all laws, statutes, acts, rules, regulations, guidelines, codes, orders, directives or other legally binding requirements of any Regulatory Authority and industry standards or codes of conduct applicable to the Services.

“Results” mean materials, data, inventions, documents and information produced, conceived or developed by Covance specifically as a result of the Services and related to the Test Materials. Covance Property is not included in Results.

“Services” means the services provided by Covance to the Sponsor as more particularly described in this Agreement and the SOW.

“SOW” means the scope of work mutually agreed to in writing by the Parties, which will be attached hereto as an exhibit and will be governed by and is hereby made a part of this Agreement.

“Sponsor Information” means Test Materials, data, specification, or other materials or information supplied by the Sponsor to Covance in connection with the Services.

“Study” means a clinical trial or scientific evaluation of the Test Materials on the terms and conditions of the Protocol.

“Subcontractor” means a third party approved, reviewed and contracted by Covance for Services within the scope of this Agreement.

“System Data” means control data from laboratory tests or transactional, volume and performance data related to the Services, which does not contain any personally identifiable information or Sponsor Confidential Information.

“Test Materials” means compounds, materials or other substances as described in the Protocol to be tested or used in the performance of the Services and provided to Covance by the Sponsor.

“Use” (in the context of Section 13) means collection, storage, transfer (including import and export), use and return or disposal of HBS including by commercial organizations.

“Vendor” means third-party service providers other than a Subcontractor for which Covance may hold the contract with such service provider at Sponsor’s written request for the convenience or benefit of the Sponsor in connection with Services under this Agreement.

- 1.2 In this Agreement, unless the context otherwise requires, references to:
- (a) Schedule and Section headings are inserted for convenience only and do not affect the construction or interpretation of this Agreement;
 - (b) a particular law or statutory provision is a reference to it as it is in force for the time being taking account of any amendment, extension, or re-enactment and includes any subordinate legislation for the time being in force made under it;
 - (c) **writing** or **written** includes faxes and e-mail;
 - (d) a person includes a corporate or unincorporated body;
 - (e) any gender includes all genders;
 - (f) **including, include, in particular** or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;
 - (g) words in the singular include the plural and vice versa.
- 1.3 If this Agreement is translated, the English language text shall prevail.

2. SERVICES

- 2.1 Covance through itself and/or its Affiliates hereby agrees to perform Services for Sponsor's protocol RMCL-CL002, "A Phase 2, Prospective, Randomized, Double Arm, Deferred Treatment, Open Label, Repeat Dose, Safety and Efficacy Study of Autologous Neo-Kidney Augment (NKA) in Subjects with Type 2 Diabetes and Chronic Kidney Disease" as amended from time to time, a copy of which is attached hereto as Exhibit A. Such Services shall be performed pursuant to the terms and conditions contained herein.
- 2.2 Any changes or modifications to the Protocol and/or Services provided by Covance, or any Sponsor request for additional Services may commence upon Covance's receipt of Sponsors written approval of the revised SOW. Upon Sponsor's SOW signature, Covance shall provide such Services to the Sponsor and the Sponsor shall pay for costs associated with such Services at its current standard rates.
- 2.3 Should a kit be lost through no fault of Covance, or should a kit expire at the investigator site, Covance will supply replacement kits for those that are lost, expired, or otherwise rendered unusable, at an amount equal to the price listed in the Budget per kit for the same kit/visit that is being replaced.
- 2.4 After performing Services, Covance will store the remaining Study specimens for the length of time and under storage conditions as described in the applicable SOW. The remaining specimens may subsequently be shipped to Sponsor or another party as specified in the SOW or if not specified in the SOW, held as otherwise instructed by the Sponsor. In no event shall Covance's liability for any breach or default with regard to storage of an archival specimen exceed the fee it has been paid for storage of that specimen for the previous twelve (12) months.

3. TERM AND TERMINATION

- 3.1 The term of this Agreement shall be for **forty two (42) months** commencing on the date hereof or the conclusion of the study, whichever is earlier, and shall renew automatically for successive one (1) year periods unless a Party provides the other Party with written notice of its intention to not renew and extend this Agreement at least sixty (60) days prior to the commencement of any such renewal term.
- 3.2 Either Party may terminate this Agreement with immediate effect by notice in writing in the event that:
- (a) the other Party commits a material breach of any term of this Agreement which breach is irremediable or (if such breach is remediable) fails to remedy that breach within a period of thirty (30) days after being notified in writing to do so; or
 - (b) the other Party repeatedly breaches any of the terms of this Agreement in such a manner as to reasonably justify the opinion that its conduct is inconsistent with it having the intention or ability to give effect to the terms of this Agreement; or
 - (c) anyone commences an involuntary case against such other Party under title 11 of the United States Code or the corresponding provisions of any successor laws and either the case is not dismissed by midnight at the end of the sixtieth (60th) day after commencement;
 - (d) a court of competent jurisdiction appoints a custodian (as that term is defined in title 11 of the United States Code or the corresponding provisions of any successor laws) for such other Party or all or substantially all of its assets, or such other Party makes an assignment of all or substantially all of its assets to a custodian;
 - (e) the other Party fails generally to pay its debts as they become due (unless those debts are subject to a good-faith dispute as to liability or amount) or acknowledges in writing that it is unable to do so; or
 - (f) any event occurs, or proceeding is initiated, in any jurisdiction to which it is subject that has an effect equivalent or substantially similar to any of the events mentioned above.
- 3.3 Sponsor may terminate this Agreement for any reason upon ninety (90) days prior written notice to Covance.
- 3.4 In the event of such termination, Covance shall be entitled to full payment for work performed on the Study through the date work on such Study is concluded, including, without limitation, all fees and other out-of-pocket expenses incurred by Covance for such Study.
- 3.5 The termination of this Agreement shall not relieve either Party of its obligations to the other with respect to: (a) maintaining the confidentiality of Confidential Information; (b) obtaining consents for the use of names; (c) ownership of and assignment of inventions; (d) indemnification; (d) limitation

of liability; (e) compensation for Services performed; (f) publications; and (g) retention of records. The provisions of this Section together with any other section which is necessary for the interpretation or enforcement of this Agreement shall survive the expiry or termination of this Agreement howsoever arising.

4. REGULATORY COMPLIANCE

- 4.1 Covance will perform its Services in accordance with good laboratory practices and the applicable terms of this Agreement. All of Covance's tests, assays and other activities undertaken under this Agreement shall comply in all material respects with College of American Pathologists (**CAP**) rules. Covance represents that it has and shall maintain Clinical Laboratory Improvement Act (**CLIA**) certification. This Agreement shall contain all the conditions under which Covance will provide clinical laboratory Services. Covance makes no express or implied commitments or warranties concerning the performance of the Study except as set forth in this Agreement.
- 4.2 In the event that compliance with any regulatory requirements necessitates a change in this Agreement, Covance will submit to Sponsor a revised technical and cost proposal for Sponsor's acceptance prior to performing Services.
- 4.3 In the event of a conflict in government regulations, the Parties will discuss and designate which regulations shall be followed by Covance in its performance of the Services.

5. FEES, BILLING AND TAXES

- 5.1 Fees for the Project are set forth in the attached Budget. Sponsor acknowledges that SOW finalization, changes and/or modifications to the Project may result in a revised budget, which must be mutually agreed upon and the Agreement amended accordingly. The Budget contains all of the applicable discounts for Services that will be provided for that Project.
- 5.2 Upon execution, Covance will assess a fee equal to twenty percent (20%) of the value of the contract Budget ("**Project Initiation Fee**"). The Project Initiation Fee covers those value-added services rendered but unbilled, including developing the Scope of Work, quality control and loading of project databases, project management and shipping of kits. Sponsor will pay the Project Initiation Fee within thirty (30) days after receipt of invoice.
- 5.3 Each month, Covance will invoice Sponsor for all fees due and documented expenses incurred while providing Services during the previous month documentation for all expenses included on such invoice. Payment is due thirty (30) days from the date of the invoice.
- 5.4 The Project Initiation Fee will be retained until the first invoice has been paid. Covance will issue a credit on each month's invoices equal to one-sixth (1/6) of the Project Initiation Fee. Should the Study be terminated before the Project Initiation Fee is exhausted and assuming all prior invoices have been paid, Covance will apply Project Initiation Fee funds to the final invoice and refund any remaining Project Initiation Fee funds to Sponsor within thirty (30) days of termination.

- 5.5 For budgeting purposes, Covance creates the Budget using local unit pricing. The local unit pricing is then converted to the billing currency, as requested by Sponsor, using the Reuters exchange rate for the month the Budget is first created. Unless specified otherwise, this exchange rate remains unchanged during the course of the Study to simplify budget comparisons and enable Sponsor to track changes to the Study unrelated to changes in currency exchange rates.
- 5.6 For invoicing purposes, expenses are billed based on the contracted local unit prices. Each month, at the time of invoice creation, the local unit prices are converted to the billing currency using the Reuters exchange rate for the month in which the expenses were incurred.
- 5.7 Covance will hold prices unchanged for twelve (12) months from Project start up. Thereafter, a Project is subject to a fee increase every twelve (12) months from Project start-up. Any such increase shall not exceed the annual inflation rate during the previous twelve (12) month period, as measured by the increase in the U.S. Consumer Price Index. Fee increases apply only to Services not yet performed and invoiced on the Study.
- 5.8 Should the Sponsor disagree with the accuracy of an invoice, the Sponsor shall notify Covance of such inaccuracy within thirty (30) working days of receipt of the invoice. The Sponsor agrees to pay the amounts for any items not in dispute. The Sponsor agrees not to unreasonably withhold payment.
- 5.9 If Sponsor requests a material change to the Project at any time which would affect the Services, Covance will revise fees to reflect the change in the SOW and Budget.
- 5.10 Upon written notification by Sponsor that the Study has been concluded or upon completion of all Services required by Covance under this Agreement, Covance will issue a final invoice for Services rendered to identify amounts due to Covance or refund due to Sponsor.
- 5.11 Fees payable under this Agreement shall not include local, state, federal or foreign sales or use taxes, excise taxes, goods and services tax, value added tax or consumption taxes, as applicable. Any applicable taxes will be billed to and paid by Sponsor without deduction to amounts owed to Covance.

6. SITE VISITS

- 6.1 The Sponsor or its representative (which shall not be a competitor of Covance) may visit Covance's premises where the Services are being performed at reasonable times, on reasonable notice and with reasonable frequency during normal business hours to observe the progress of the Services. Covance will assist the Sponsor in scheduling such visits.
- 6.2 The Sponsor acknowledges that the Sponsor's representatives granted access to Covance facilities during any such visits may have access to confidential and proprietary information of Covance. The Sponsor agrees that all such confidential and proprietary information of Covance obtained or observed by the Sponsor during such visits shall remain the sole property of Covance and the Sponsor shall treat such information as Confidential Information in accordance with Section 8 of this Agreement

7. REGULATORY INSPECTIONS AND AUDITS

- 7.1** In the event of a Party receiving a notice from a Regulatory Authority which directly relates to the Services, the Party receiving such notice shall promptly notify the other Party or forward to the other Party a copy of such notice (or extract thereof). Each Party will cooperate with the other in responding to such notice before referring to the other Party in any regulatory correspondence or disclosing any Confidential Information to a Regulatory Authority. However, each Party acknowledges that it may not direct the manner in which the other Party fulfils its obligations to permit inspection by Regulatory Authorities.
- 7.2** Covance shall cooperate with any inspection or audit by a Regulatory Authority and shall notify the Sponsor promptly of any request by a Regulatory Authority.
- 7.3** Covance agrees that, during an inspection or audit by a Regulatory Authority concerning the Services, it will not disclose information and materials that are not required to be disclosed to such Regulatory Authority, without the prior written consent of the Sponsor.
- 7.4** If any inspections or audits conducted pursuant to this Section 7 that result in a finding that Covance has failed to comply with the terms of this Agreement, Covance shall promptly take such measures at its own cost and expense as are necessary to correct such defaults.
- 7.5** It is agreed that where any audit of Covance concerns or relates to referral laboratory testing or shipping methods of Covance, the Sponsor or its representative (which shall not be a competitor of Covance) may only confirm or not if Covance is properly billing such costs. The Sponsor expressly agrees that Sponsor's representatives may not directly or indirectly provide any details of the charges to the Sponsor, such as the actual amount of the referral laboratory testing or shipping costs incurred by Covance.

8. CONFIDENTIAL INFORMATION

- 8.1** Each Party agrees that all Confidential Information of the Disclosing Party is and shall be the sole property of the Disclosing Party.
- 8.2** Without prejudice to any Covance Property, all Results, information, data and records developed by Covance or its Affiliates in the performance of the Services shall be the Confidential Information of the Sponsor.
- 8.3** Each Party agrees to hold the Confidential Information of the other Party in confidence and in a manner consistent with the way in which it maintains the confidentiality of its own proprietary information, being at least a reasonable standard of care. Each Party shall disclose the Confidential Information only on a need to know basis, to its employees, officers, directors, representatives and third party investigators, in each case who are legally bound to treat the Confidential Information in the manner set forth in this Section 8.

- 8.4** Recipient agrees that, except as necessary to fulfil its obligations under this Agreement, it will not use any of the Confidential Information of the Disclosing Party.
- 8.5** Notwithstanding the non-disclosure obligations herein, Recipient shall not be in breach of this Section 8 if it discloses Confidential Information to the extent such disclosure is required by Applicable Law or a court or administrative subpoena or order; provided, however, that (a) any such disclosure shall not otherwise relieve Recipient of its continuing confidentiality and non-use obligations hereunder with respect to all of the Confidential Information, including the information disclosed by it to the court or agency under this Section 8 and (b) Recipient shall give Disclosing Party reasonable advance notice of any such disclosure and cooperate reasonably with Disclosing Party (and at Disclosing Party's expense) in Disclosing Party's efforts to object to such disclosure and to obtain the court's or administrative agency's agreement to maintain the confidentiality of the Confidential Information to be disclosed by Recipient under this Section 8.
- 8.6** The obligations in this Section 8 shall remain in full force and effect for a period of **seven (7) years** following termination of this Agreement except with respect to Confidential Information which is considered a trade secret under Applicable Law, which shall remain confidential as long as such Confidential Information retains its status as a trade secret.
- 8.7** Misuse or disclosure of the Confidential Information by Recipient may cause irreparable harm to Disclosing Party not adequately compensable by money damages. In the event of actual or threatened breach or violation of this Section 8, the disclosing Party shall have the right to seek injunctive relief in any court of competent jurisdiction, without the need to post any bond and without the need to demonstrate actual damages.

9. INTELLECTUAL PROPERTY RIGHTS

- 9.1** All Background IP is and shall remain the exclusive property of the Party owning it and except as expressly provided in this Agreement, no Party shall acquire any rights in or to the Background IP of the other Party.
- 9.2** The Sponsor acknowledges that Covance Property is owned or licensed by Covance or its Affiliates. Strategic insight and proposed Project design and scope provided in any quotation by Covance shall remain the property of Covance and may be used by the Sponsor only to assess whether it wishes to pursue such work with Covance.
- 9.3** The Sponsor will have title to the Deliverables and all intellectual property rights therein. Subject to RMCL's payment of amounts due to Covance hereunder, Covance assigns all rights in and to the Deliverables to the Sponsor, except that one (1) copy of the Results may be retained by Covance solely for regulatory or legal compliance purposes. The Sponsor hereby grants Covance an unrestricted, royalty-free license to aggregate and use System Data produced by or for Covance as part of the Services with other System Data owned or licensed by Covance only if Sponsor is not identifiable through Covance's aggregation and use.

9.4 Covance shall promptly disclose to the Sponsor (or its nominee) all Inventions. Covance assigns and agrees to assign to the Sponsor (or its nominee) all rights, title and interest in and to such Invention and shall do all acts that are reasonably necessary to vest the Invention in the name of the Sponsor (or its nominee), at Sponsor's expense.

10. REMEDIES AND LIMITATION OF LIABILITY

- 10.1** In the event of a material error by Covance that prevents proper performance under this Agreement or which renders the Services in whole or in part unacceptable to a Regulatory Authority to which the Sponsor intends to submit the Results, Covance's sole obligation to Sponsor (other than the obligations set forth in Section 11) shall be for Covance, at Sponsor's election, to either: (a) repeat the defective part of the Services at Covance's own cost; or (b) refund to the Sponsor the amount paid for the defective part of the Services.
- 10.2** Except for liability resulting from any breach of Sections 8 or 9 or liability pursuant to Section 11, Covance's total liability to the Sponsor, whether in contract, tort (including negligence) or otherwise, shall in no circumstances exceed the total price paid by the Sponsor for the Services that are the subject of this Agreement.
- 10.3** Nothing in this Agreement excludes or limits the liability of either Party where liability cannot be excluded or restricted as a matter of law.
- 10.4** Except for liability resulting from any breach of Sections 8 or 9 or liability pursuant to Section 11, Covance will not be liable to the Sponsor for any Loss in respect of any:
- (a) loss of profit, opportunity, business, or goodwill (in each case whether direct or indirect); or
 - (b) any indirect, consequential, punitive, exemplary or special damages or losses, arising under or in connection with this Agreement,
 - (c) and each type of loss arising under this Section 10.4 shall be severable in accordance with Section 22 of this Agreement. To the extent that Covance agrees to perform Services for Sponsor Affiliates, Covance shall only be liable to the entity named in this Agreement and not for multiple claims by Sponsor Affiliates.
- 10.5** Covance shall not be liable for any failure, error or delay in performing the Services if such failure, error or delay is directly caused by Sponsor, but Covance will cooperate with Sponsor to minimize any such delay and to correct any such failure or error.
- 10.6** Covance shall have no liability to Sponsor for loss, damage, delay or non-delivery/non-collection of any samples or shipment dispatched by Covance to Sponsor or to any third party designated by Sponsor in connection with the Services that are caused by the acts or omissions of any third party delivery services or carrier ("**Carrier**"). Notwithstanding the foregoing, to the extent permitted by law, Covance shall have the benefit of any right or remedy permitted under international or domestic law and any sums recoverable from a Carrier shall be paid to the Sponsor. For the avoidance of doubt, a Carrier is not considered a Subcontractor for the purposes of this Agreement.

11. INDEMNITIES

- 11.1** The Sponsor shall defend, indemnify, and hold harmless Covance and its respective Affiliates and their respective officers, directors, employees and agents (**Covance Group**) from any Loss resulting from any Claim arising from or related to:
- (a) personal injury to a participant in the Study directly or indirectly caused by the Test Material;
 - (b) Covance's proper execution and/or the proper performance of its obligations under this Agreement;
 - (c) the Sponsor's use of the Results or Deliverables or its use or marketing of any substance tested in association with the Study by Covance;
 - (d) the negligence or intentional misconduct of the Sponsor;
 - (e) the Test Material's harmful or otherwise unsafe effect, including, without limitation, a product liability claim based upon the Sponsor's or Sponsor's representatives' use, consumption, sale, distribution or marketing of the Sponsor's products tested under this Agreement; or
 - (f) the infringement, unlawful disclosure or misappropriation of copyright, patent, trade secret or other intellectual property of a third party by reason of Covance's use of the Sponsor Information in accordance with the terms of this Agreement,

provided that if such Loss or Claim arises in whole or in part from Covance's negligence or intentional misconduct, then the amount of such Loss that Sponsor shall indemnify the appropriate person or entity within the Covance Group pursuant to this Section 11 shall be reduced by an amount in proportion to the percentage of Covance's responsibilities for such Loss as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the Parties.

- 11.2** Covance shall defend, indemnify and hold harmless the Sponsor and its Affiliates and their respective officers, directors and employees (the "**Sponsor Group**") from any Loss resulting from any Claim arising from a breach of this Agreement by Covance, or the negligence or intentional misconduct of Covance, provided that if such Losses or Claims arise in whole, or in part, from the Sponsors Group's negligence or intentional misconduct, then the amount of such Losses that Covance shall be responsible for pursuant to this Section 11 shall be reduced by an amount in proportion to the percentage of the Sponsor Group's responsibilities for such Losses as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the Parties.

- 11.3** An indemnitee entitled to indemnification under Section 11 (the “**Indemnified Party**”) shall give written notice to the other Party (“**Indemnifying Party**”) of a claim or other circumstances likely to give rise to a request for indemnification, promptly after the Indemnified Party becomes aware of the same. The Indemnifying Party shall be afforded the opportunity to undertake the defense of, and, subject to Section 11.5, to settle by compromise, or otherwise, any claim for which indemnification is available under this Section.
- 11.4** If the Indemnifying Party assumes the defense of any claim, the Indemnified Party may participate in such defense with legal counsel of its selection and at its expense. If the Indemnifying Party fails to promptly assume the defense of a claim by the Indemnified Party under this Section 11.4, the Indemnified Party may thereupon undertake the defense on behalf of, at the risk and expense of the Indemnifying Party with all reasonable costs and expenses of such defense to be paid by the Indemnifying Party.
- 11.5** In the event that the Indemnifying Party assumes the defense of any claim, no compromise or settlement of any such claim may be made without the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld or delayed.

12. INSURANCE

- 12.1** Covance shall secure and maintain in full force and effect through the performance of the Services the necessary insurance coverage in amounts appropriate to the conduct of Covance’s business. Certificates evidencing such insurance will be made available for examination upon written request by Sponsor.
- 12.2** Sponsor hereby warrants and represents that it maintains and shall maintain adequate clinical trial and product liability insurance coverage consistent with industry standards and in compliance with all Applicable Laws. Certificates evidencing such insurance will be made available for examination upon written request by either Covance or Sponsor.

13. HUMAN BIOLOGICAL SAMPLES

- 13.1** Where the Sponsor supplies HBS to Covance, the Sponsor represents and warrants that:
- (a) all HBS supplied under this Agreement are or have been procured and reviewed by ethics committee and supplied to Covance in full compliance with any and all Applicable Laws and Regulatory Requirements relating to the Use of HBS providing protection for human subjects in the country of origin;
 - (b) the HBS Donor has given Informed Consent; and
 - (c) all HBS supplied to Covance: (i) may be Used for the Services; (ii) may be used to provide data in support of commercial product development; and (iii) were procured without inappropriate financial benefit to the HBS Donor.

- 13.2 The Sponsor shall: (a) upon request, provide a copy of the relevant Informed Consent template; and (b) ensure any HBS shall be de-identified or 'coded' according to applicable Regulatory Requirements to protect the identity and confidentiality of the HBS Donor. Full date of birth shall only be collected if medically relevant to the Services (unless legally restricted in the country of operation). In the event of a withdrawal of, or a material variation to the Informed Consent (including any material changes that may affect the Services provided by Covance) the Sponsor shall promptly notify all relevant Covance entities of such changes.
- 13.3 Covance agrees to Use the HBS in accordance with all applicable Regulatory Requirements.
- 13.4 Upon Sponsor's request, Covance shall retain, return or destroy all HBS in accordance with the Informed Consent, the Sponsor's instructions or any other specific requirements under Applicable Law and Regulatory Requirements.
- 13.5 The Sponsor acknowledges that where Covance enters into a material transfer agreement ("**MTA**") with the provider of any HBS, Covance shall act in accordance with the terms of the MTA and the disposition of the relevant HBS shall be as prescribed in the MTA. In the event of a conflict between the terms of the MTA, this Agreement, any Work Order and any instructions provided by the Sponsor, the terms of the MTA shall prevail.

14. DATA PROTECTION

- 14.1 Where Covance processes any personal data on behalf of the Sponsor, Covance shall process such personal data in accordance with all applicable Data Protection Laws in the territories in which the Services are performed ("**Protected Data**").
- 14.2 If Covance processes any Protected Data on behalf of the Sponsor, Covance and the Sponsor each agree and acknowledge that the Sponsor shall be the data controller and Covance shall be the data processor with respect to the processing of such Protected Data. Covance shall only process such Protected Data on behalf and upon the reasonable instructions of the Sponsor for purposes notified to it by the Sponsor for which consent from the relevant data subjects has been obtained in accordance with all applicable Regulatory Requirements. Covance shall follow such procedures, policies and reasonable instructions as may be agreed by the Parties from time to time.
- 14.3 Covance shall take reasonable technical and organizational measures that are necessary to protect against the unauthorized or unlawful processing of or the unauthorized or unlawful disclosure of such personal data. Covance shall promptly notify the Sponsor in the event of a security breach involving any personal data which Covance is processing on behalf of the Sponsor.
- 14.4 The Sponsor warrants that it has complied with any and all notification and information requirements under the applicable Data Protection Laws.

15. SUBCONTRACTORS

- 15.1** Notwithstanding Section 18, certain tasks, as may be agreed during the development of and specified in the Protocol, may be subcontracted by Covance to Subcontractors approved by Covance or subcontracted, or assigned and transferred to its Affiliates. Covance shall be responsible for the acts and performance of Subcontractors and Affiliates.
- 15.2** Covance shall not be responsible for the performance of third party Vendors. Liability of Covance to the Sponsor with respect to such Vendors shall be limited to the extent Covance is negligent in the performance of its obligations under this Agreement. Covance shall provide to the Sponsor any amounts that Covance may recover from such Vendors as a result of any error or service failure on the part of the Vendors in connection with this Agreement.

16. FORCE MAJEURE

- 16.1** Neither Party shall be in breach of this Agreement nor liable for delay in performing, or failure to perform, any of its obligations under this Agreement, if such delay or failure result from a Force Majeure Event. In such circumstances, any time specified for completion of performance in the Protocol falling due during or subsequent to the occurrence of a Force Majeure Event shall be automatically extended for a period of time equal to such event.
- 16.2** Should any part of the Services be rendered invalid as a result of a Force Majeure Event, Covance shall, upon written request from the Sponsor, and at the Sponsor's sole cost and expense, repeat the affected part of the Services.
- 16.3** If a Force Majeure Event prevents a Party from performing pursuant to this Agreement for a period of 180 days or more, the unaffected Party may terminate this Agreement upon written notice to the affected Party.

17. INDEPENDENT CONTRACTOR

- 17.1** The Parties agree that in performing the Services, Covance (including its employees, agents, subcontractors or other representatives) is acting as an independent contractor to Sponsor. The Parties further agree that Covance and its employees, agents, subcontractors or other representatives are not employees, agents or partners of Sponsor, and nothing in this Agreement and no actions of Sponsor in engaging Covance shall render Covance or any of its employees, agents, subcontractors or other representatives the employees, agents or partners of Sponsor. Neither Covance nor any of its employees, agents, subcontractors or other representatives will have power or authority to bind Sponsor. Neither the relationship between Covance and Sponsor nor any provision of this Agreement shall be construed to authorize Covance to take (or fail to take) any action or make (or fail to make) any decision, representation or commitment binding upon Sponsor or any of its affiliate companies. Sponsor shall at all times be free to engage other third parties to perform services in addition to or in lieu of those services being provided by the Covance. Subject to the provisions of this Agreement, Covance shall be free to devote such time that they do not spend providing Services under this Agreement to such person, firms or corporations as they may choose.

17.2 Nothing contained herein shall be construed (i) to create any association, partnership, joint venture, or relationship of principal and agent, or master and servant between the Parties or any of their affiliates or subsidiaries, employees and subcontractors, (ii) to provide any Party with the right, power or authority, either express or implied, to create any duty or obligation on behalf of another Party, (iii) to impose liability upon one Party for the act or failure to act of another Party, or (iv) to confer any right for Covance (or any of its employees, agents, subcontractors or other representatives) to participate in or be eligible to participate in any pension or welfare benefit plans, programs or arrangements of Sponsor or of its affiliate companies pertaining to any pension, stock, bonus, profit sharing or similar benefits or any employee health, life assurance, workers compensation insurance, disability, severance or any other benefit of any kind whatsoever which is associated with or customarily paid in connection with or in relation to an employment contractor.

18. ASSIGNMENT

18.1 Either Party may assign, transfer or subcontract any or all of its rights and obligations under this Agreement to its Affiliates.

18.2 Notwithstanding Section 18.1 and except in connection with an internal reorganization of the relevant Party's corporate structure, this Agreement shall not be assigned or transferred in whole or in part by either Party without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed.

19. NOTICES

19.1 All notices required to be given under this Agreement shall be in writing and shall be deemed to have been duly given if delivered personally or mailed first class, registered or certified mail, return receipt requested, postage paid:

If to Sponsor to:

RegenMed (Cayman) Ltd.
10 Market St.
#774 Camana Bay, Grand Cayman
KY 1-90006 Cayman Islands
Attention: _____

With a copy by email to:

If to Covance to:

Covance Central Laboratory Services LP
8211 SciCor Drive
Indianapolis, Indiana 46214-2985
UNITED STATES
Attention: VP, Finance

or at such other place as either Party shall hereafter furnish to the other Party in writing. Notices shall be deemed given on the date of personal delivery or deposit in the mail as specified above.

19.2 For the purposes of this Section 19, in relation to the purposes of any legal proceeding, “**writing**” shall not include email.

20. WAIVER

No waiver of any term, provision, or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver or estoppel of any such term, provision, or condition or of any other term, provision, or condition of this Agreement.

21. VARIATION

No provision of this Agreement may be amended, modified, varied, discharged, or terminated except by the express written agreement of both Parties and signed by an authorized representative of each Party.

22. SEVERABILITY

If any court or competent authority finds that any provision of this Agreement (or part of any provision) is invalid, illegal or unenforceable, that provision or part-provision shall, to the extent required, be deemed to be deleted, and the validity and enforceability of the other provisions of this Agreement shall not be affected. If any invalid, unenforceable or illegal provision of this Agreement would be valid, enforceable and legal if some part of it were deleted, the provision shall apply with the minimum modification necessary to make it legal, valid and enforceable.

23. PUBLICITY AND PUBLICATION

- 23.1** Neither Party will use the name, trademark or the name of any representative of the other, or the existence of this Agreement for any promotional or advertising purposes, or any other publication, without the prior written consent of the other.
- 23.2** Neither Party will state or imply that the other Party endorses or approves any service, material, product or compound of the other Party without the prior written consent of the other. Such restrictions shall not apply to internal communications and publications to a Party’s Affiliates.
- 23.3** Sponsor shall provide Covance with a pre-publication copy of any report, manuscript, publication or form of marketing material recognizing Covance’s participation in the Services or otherwise identifying Covance, for approval (which approval shall not be unreasonably withheld or delayed) in each case at least thirty (30) days before its submission for publication.

24. ENTIRE AGREEMENT

This Agreement represents the entire understanding between the Parties with respect to the subject matter hereof as of the Effective Date, and this Agreement supersedes all prior agreements, negotiations, understandings, representations, statements and writings between the Parties relating thereto, except that any written agreement entered into prior to the Effective Date with respect to a Study in process prior to the Effective Date shall remain effective and shall continue to govern such existing Study. The Parties agree that neither has relied upon prior representations made before executing this Agreement.

25. LEGAL TESTIMONY

Covance agrees to provide testimony or records regarding the Services for the Sponsor in any legal or administrative proceeding, provided that the Sponsor shall reimburse Covance for its out of pocket costs plus a reasonable hourly fee for the involvement of its employees or representatives in such proceedings.

26. THIRD PARTY RIGHTS

Except as expressly set forth in this Agreement in respect of Covance Affiliates, nothing in this Agreement is intended to confer any rights, benefits or remedies of any kind whatsoever, and a person who is not a party to this Agreement shall have no right to enforce any of its terms.

27. ANTI-BRIBERY

27.1 Both Parties agree that each has not and will not, either directly or indirectly, engage in bribery, or offer, or promise, or authorize to pay or make any improper payment of any monies or financial or other advantage, including cash, loan, gift, travel, entertainment, hospitality, facilitation payment, kickback, political or philanthropic contribution, anything of value, or any other perceived benefit to improperly obtain or retain a business advantage in violation of any Anti-Corruption Laws and further, each Party agrees that they shall not take any action that would cause the other Party to be in violation of such Anti-Corruption Laws.

27.2 Any breach of Section 27.1 by a Party shall allow the other Party to immediately terminate this Agreement.

28. TRADE CONTROL

28.1 Notwithstanding any other provision of this Agreement to the contrary, each Party shall comply with, and retain responsibility for its compliance with, all applicable export control laws (e.g., the U.S. Export Administration Regulations) and economic sanctions programs (e.g., economic sanctions maintained by the U.S. Treasury Department, as well as Specially Designated Nationals and Blocked Persons (SDNs)) relating to its respective business, facilities, and the provision of services to third parties (collectively, **Trade Control Laws**).

28.2 Nothing in this Agreement shall be construed to require Covance to be directly or indirectly involved in the provision of goods, software, services and/or technical data that may be prohibited by applicable Trade Control Laws, including sanctions currently in place against Cuba, Iran, North Korea, Sudan, Syria and SDNs.

29. COUNTERPARTS

This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original to this Agreement but all of which together shall constitute the same Agreement. Signatures upon this Agreement transmitted by facsimile, electronic mail or other electronic method shall have the same legal and binding effect as wet signatures.

30. CHOICE OF LAW AND DISPUTE RESOLUTION

30.1 This Agreement shall be governed and construed in accordance with the laws of the State of New York, U.S.A., without regard to conflicts of laws provisions.

30.2 Any dispute, controversy, or claim arising out of, relating to, or in connection with this Agreement, or the breach, termination, or validity thereof, shall be finally settled by arbitration. The arbitration shall be conducted in accordance with the Securities Arbitration Rules (the "Rules") of the American Arbitration Association ("AAA"), including the AAA's Procedures for Large, Complex Commercial Disputes, in effect at the time of the arbitration, except as they may be modified herein or by mutual agreement of the parties. The seat of the arbitration shall be New York, New York, and it shall be conducted in the English language. The arbitration and this clause shall be governed by Title 9 (Arbitration) of the United States Code. The Parties agree that irreparable damage may occur to a Party in the event that the other Party may fail or fails to comply with the provisions of Section 8. Accordingly and without otherwise limiting the requirement of mandatory arbitration imposed hereunder, a Party may seek from any court having jurisdiction any interim or provisional relief (without the necessity of posting bond) that may be necessary to protect its interests under Section 8, pending the arbitral tribunal's final determination of the merits of the controversy.

30.3 The arbitration shall be conducted by three arbitrators. The claimant shall appoint an arbitrator in its request for arbitration. The respondent shall appoint an arbitrator within twenty (20) days of the receipt of the request for arbitration. The two arbitrators shall appoint a third arbitrator, who shall act as chair of the tribunal, within twenty (20) days after the appointment of the second arbitrator. If any of the three arbitrators is not appointed within the time prescribed above, then the AAA shall appoint that arbitrator from its National Panel of Securities Arbitrators or its Large, Complex Commercial Case Panel, not including any such members affiliated with the securities industry. The chair of the tribunal shall be a citizen of the United States.

- 30.4** In addition to the authority conferred on the arbitration tribunal by the Rules, the arbitration tribunal shall have the authority to order such production of documents, generally consistent with the discovery permitted under the Federal Rules of Civil Procedure, as may reasonably be requested by any party or by the tribunal itself. In addition, any party may request a reasonable number of depositions of party witnesses.
- 30.5** The Parties agree that the arbitration shall be kept confidential and that the existence of the proceeding and any element of it (including but not limited to any pleadings, briefs or other documents submitted or exchanged, any testimony or other oral submissions, and any awards) shall not be disclosed beyond the tribunal, the AAA, the Parties, their counsel, accountants and auditors, insurers and re-insurers, and any person or entity necessary to the conduct of the proceeding. The confidentiality obligations in this Section 28.5 shall not apply (i) if disclosure is required by Applicable Law, or in judicial or administrative proceedings, or (ii) as far as disclosure is necessary to enforce the rights arising out of the award.
- 30.6** The arbitration award shall be final and binding on the Parties. Judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party or its assets.
- 30.7** In order to facilitate the comprehensive resolution of related disputes, and upon request of any party to the arbitration proceeding, the arbitration tribunal may consolidate the arbitration proceeding with any other arbitration proceeding involving any of the Parties hereto relating to this Agreement. The arbitration tribunal shall not consolidate such arbitrations unless it determines that (i) there are issues of fact or law common to the related proceedings so that a consolidated proceeding would be more efficient than separate proceedings, and (ii) no party would be prejudiced as a result of such consolidation through undue delay or otherwise.
- 30.8** The Parties agree that any dispute arising from or in connection with this Agreement (including any non-contractual obligations) shall be referred to and finally resolved by arbitration under the Rules of the International Chamber of Commerce which Rules shall be deemed incorporated by reference to the Agreement. The number of arbitrators shall be three (3), the seat or legal place of arbitration shall be New York and the language used in the arbitration shall be English.

[signature page follows]

IN WITNESS WHEREOF, the Parties by their duly authorized officers have executed this Agreement on the dates set forth below, to be effective on the Effective Date set forth on the first page of this Agreement.

RegenMed (Cayman) Ltd.

Signature: /s/ Alasdair Foster
Name: Alasdair Foster
Title: Director
Date: 29 August 2016

**COVANCE CENTRAL LABORATORY SERVICES LP
COVANCE CENTRAL LABORATORY SERVICES
SÀRL**

Signature: /s/ Cheryl Helton
Name: Cheryl Helton
Title: VP, Covance CLS
Date: 8/29/2016

This **Laboratory Service Agreement** ("**Agreement**") is made effective on 1 August 2017 by and between

- (1) **COVANCE CENTRAL LABORATORY SERVICES LP** an Indiana limited partnership, with its principal place of business at 8211 SciCor Drive, Indianapolis, Indiana 46214, USA; and **COVANCE CENTRAL LABORATORY SERVICES SÀRL**, with its principal place of business at Rue Moise-Marchines 7, 1217 Meyrin, Geneva Switzerland (collectively "**Covance**"); and
 - (2) **inRegen**, 10 Market Street, No. 774 Camana Bay, Grand Cayman KY1-9006, Cayman Islands ("**Sponsor**").
- (each a "**Party**" and collectively the "**Parties**").

WHEREAS

- (A) Covance is engaged in the business of providing laboratory testing, data management, protocol management and information management services for pharmaceutical clinical trials.
- (B) Sponsor desires for Covance to perform such services for one or more clinical trials, all in accordance with and subject to the terms and conditions of this Agreement.

IT IS AGREED

1. DEFINITIONS

1.1 In this Agreement, the following words and expressions shall have the following meanings:

"**Affiliate**" means any entity controlling, controlled by, or in common control with a Party. For the purposes of this definition, "**Control**" shall mean ownership or control, directly or indirectly of more than fifty percent (50%) of the common voting stock or ordinary shares in the entity or the right to appoint fifty percent (50%) or more of the directors of that entity. With respect to Covance, the term Affiliate shall include Laboratory Corporation of America Holdings and any business entity that is controlled by or is under common control with Laboratory Corporation of America Holdings.

"**Anti-Corruption Laws**" means any anti-bribery and anti-corruption laws, rules, regulations applicable to either Party (each as amended from time to time) including the United States Anti-Kickback Law, United States Foreign Corrupt Practices Act, the UK Bribery Act 2010 and the OECD Convention Against the Bribery of Foreign Government Officials in International Business Transactions, together with any applicable implementing legislation including any applicable local law addressing bribery or corruption.

"**Applicable Law**" means applicable federal, state and local laws, rules, regulations, including the regulations of the FDA and Data Protection Laws.

"**Background IP**" means all pre-existing intellectual property belonging to or licensed to a Party or other intellectual property created outside the scope of the Services.

"**Claim**" means any third party claims, demands, assessments, actions, suits, proceedings, or settlements.

“Confidential Information” means any and all non-public information or materials and derivatives thereof, in any and all forms, howsoever disclosed or obtained, including business plans, financial information, client lists, and requirements, techniques, designs, methods, processes and procedures, which:

(i) is identified by a suitable legend or other marking as being confidential (or similar designation) in a prominent position or (ii) is described as being confidential at the time of disclosure or (iii) the disclosing Party regards or should reasonably be expected to regard as proprietary and confidential given the nature of the information and the circumstances of disclosure. Confidential Information shall not include information (a) that is or becomes publicly disclosed except to the extent such disclosure results from a violation hereof or any improper action or inaction by Recipient or any agent or representative of Recipient; (b) that was in Recipient’s possession prior to Recipient’s receipt of such material from Disclosing Party, as demonstrated by documentary evidence that itself was in Recipient’s possession at the time of Disclosing Party’s disclosure of such Confidential Information to Recipient;

(c) that is lawfully acquired by Recipient from a third party not obligated to keep such information confidential; or (d) that is developed by the Recipient without the use of or reliance on the Disclosing Party’s Confidential Information, as demonstrated by Recipient’s written records. Information will not be deemed to be within the foregoing exceptions merely because such information is embraced by more general information that is within the foregoing exceptions. In addition, any combination of features will not be deemed to be within the foregoing exceptions merely because individual features are within the exceptions, but only if the combination itself and its principle of operation are within the exceptions.

“Covance Property” means inventions, proprietary processes, software (including codes) data, technology, know-how and other intellectual property that have been independently developed or discovered by Covance or its Affiliates without the use of Sponsor’s Confidential Information, including those that relate to the proprietary innovative testing procedures, laboratory testing data collection or data management procedures, procedural manuals, delta flags, nucleic acid based vectors, analytical procedures and approaches that are not specific for use with the Sponsor’s Background IP even if such are developed in the performance of the Services or are captured in documents pertaining to the Services (i.e. laboratory notebooks), techniques, skills, models, non-product specific components of questionnaires, management tools and any other materials, employed, developed or acquired by Covance or its Affiliates.

“Data Protection Laws” mean all applicable privacy, data protection or similar laws and regulations anywhere in the World, as the same may be amended from time to time, including to the extent applicable to the respective Services, the Data Protection Directive (95/46/EC), the Personal Data Protection Act 2012 of Singapore and any applicable implementing legislation or any amendment thereto.

“Deliverables” means as applicable to the Services, Results, or any other deliverable specified in this Agreement.

“Disclosing Party” means the Party disclosing or making available its Confidential Information to the other Party.

“FDA” means the United States Food and Drug Administration or any other government body or agency that succeeds it.

“Force Majeure Event” means circumstances or causes beyond the reasonable control of a Party, including war, threat of war or warlike conditions, blockade, embargo, fire, explosion, lightning, storm, drought, flood, earthquake or other natural disaster, pandemic or epidemic, power failure, acts of terrorism, riot, civil unrest, insurrection, acts of government or other international bodies, political subdivision and any other events which by their nature could not have been foreseen by the Parties, or, if it could have been foreseen were unavoidable by a reasonable prudent business.

“HBS Donor” means an individual, living or deceased, from whom the HBS was obtained.

“Human Biological Samples” or **“HBS”** means any human biological material, including, without limitation, human bodily parts and organs in whole or sub-samples, any tissue, skin, bone, muscle, connective tissue, blood, cerebrospinal fluid, cells, gametes, or sub-cellular structures such as DNA, or any derivative or product of such human biological materials including stem cells, cell lines, bodily fluids, blood derivatives and urine.

“IEC/IRB” means an independent ethics committee or institutional review board.

“Informed Consent” means an IEC/IRB approved informed consent form signed by the HBS Donor authorizing the Use of their HBS.

“Invention” means any patentable invention or other registerable intellectual property rights discovered, conceived of or made by Covance or its Affiliates specifically as result of the Services for the Sponsor and relating to the Test Materials. Covance Property is not included in Inventions.

“Loss” means any loss, cost, damage or expense (including reasonable legal expenses).

“Project” means a Study, project or assignment between Covance and Sponsor.

“Protocol” means the document which specifies the laboratory testing procedures as written by Sponsor as applicable for the performance of a Study and is provided to Covance.

“Recipient” means the Party receiving or having access to the Confidential Information from the other Party.

“Regulatory Authority” means any national or state (in the case of the US), or local agency, authority, department, inspectorate, minister, ministry official, parliament or public or statutory person (whether autonomous or not) of any government of any country having jurisdiction over either any of the activities contemplated by this Agreement or the Parties.

“Regulatory Requirements” means all laws, statutes, acts, rules, regulations, guidelines, codes, orders, directives or other legally binding requirements of any Regulatory Authority and industry standards or codes of conduct applicable to the Services.

“Results” mean materials, data, inventions, documents and information produced, conceived or developed by Covance specifically as a result of the Services and related to the Test Materials. Covance Property is not included in Results.

“Services” means the services provided by Covance to the Sponsor as more particularly described in this Agreement and the SOW.

“SOW” means the scope of work mutually agreed to in writing by the Parties, which will be attached hereto as an exhibit and will be governed by and is hereby made a part of this Agreement.

“Sponsor Information” means Test Materials, data, specification, or other materials or information supplied by the Sponsor to Covance in connection with the Services.

“Study” means a clinical trial or scientific evaluation of the Test Materials on the terms and conditions of the Protocol.

“Subcontractor” means a third party approved, reviewed and contracted by Covance for Services within the scope of this Agreement.

“System Data” means control data from laboratory tests or transactional, volume and performance data related to the Services, which does not contain any personally identifiable information or Sponsor Confidential Information.

“Test Materials” means compounds, materials or other substances as described in the Protocol to be tested or used in the performance of the Services and provided to Covance by the Sponsor.

“Use” (in the context of Section 13) means collection, storage, transfer (including import and export), use and return or disposal of HBS including by commercial organizations.

“Vendor” means third-party service providers other than a Subcontractor for which Covance may hold the contract with such service provider at Sponsor’s written request for the convenience or benefit of the Sponsor in connection with Services under this Agreement.

- 1.2 In this Agreement, unless the context otherwise requires, references to:
- (a) Schedule and Section headings are inserted for convenience only and do not affect the construction or interpretation of this Agreement;
 - (b) a particular law or statutory provision is a reference to it as it is in force for the time being taking account of any amendment, extension, or re-enactment and includes any subordinate legislation for the time being in force made under it;
 - (c) **writing** or **written** includes faxes and e-mail;
 - (d) a person includes a corporate or unincorporated body;
 - (e) any gender includes all genders;
 - (f) **including, include, in particular** or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;
 - (g) words in the singular include the plural and vice versa.
- 1.3 If this Agreement is translated, the English language text shall prevail.

2. SERVICES

- 2.1 Covance through itself and/or its Affiliates hereby agrees to perform Services for Sponsor's protocol REGEN003, "PHASE II, OPEN-LABEL SAFETY AND TOLERABILITY STUDY OF AN AUTOLOGOUS NEO-KIDNEY AUGMENT (NKA) IN PATIENTS WITH TYPE 2 DIABETES AND CHRONIC KIDNEY DISEASE." as amended from time to time, a copy of which is attached hereto as Exhibit A. Such Services shall be performed pursuant to the terms and conditions contained herein.
- 2.2 Any changes or modifications to the Protocol and/or Services provided by Covance, or any Sponsor request for additional Services may commence upon Covance's receipt of Sponsors written approval of the revised SOW. Upon Sponsor's SOW signature, Covance shall provide such Services to the Sponsor and the Sponsor shall pay for costs associated with such Services at its current standard rates.
- 2.3 Should a kit be lost through no fault of Covance, or should a kit expire at the investigator site, Covance will supply replacement kits for those that are lost, expired, or otherwise rendered unusable, at an amount equal to the price listed in the Budget per kit for the same kit/visit that is being replaced.
- 2.4 After performing Services, Covance will store the remaining Study specimens for the length of time and under storage conditions as described in the applicable SOW. The remaining specimens may subsequently be shipped to Sponsor or another party as specified in the SOW or if not specified in the SOW, held as otherwise instructed by the Sponsor. In no event shall Covance's liability for any breach or default with regard to storage of an archival specimen exceed the fee it has been paid for storage of that specimen for the previous twelve (12) months.

3. TERM AND TERMINATION

- 3.1 The term of this Agreement shall be for **forty two (42) months** commencing on the date hereof or the conclusion of the study, whichever is earlier, and shall renew automatically for successive one (1) year periods unless a Party provides the other Party with written notice of its intention to not renew and extend this Agreement at least sixty (60) days prior to the commencement of any such renewal term.
- 3.2 Either Party may terminate this Agreement with immediate effect by notice in writing in the event that:
- (a) the other Party commits a material breach of any term of this Agreement which breach is irremediable or (if such breach is remediable) fails to remedy that breach within a period of thirty (30) days after being notified in writing to do so; or
 - (b) the other Party repeatedly breaches any of the terms of this Agreement in such a manner as to reasonably justify the opinion that its conduct is inconsistent with it having the intention or ability to give effect to the terms of this Agreement; or
 - (c) anyone commences an involuntary case against such other Party under title 11 of the United States Code or the corresponding provisions of any successor laws and either the case is not dismissed by midnight at the end of the sixtieth (60th) day after commencement;
 - (d) a court of competent jurisdiction appoints a custodian (as that term is defined in title 11 of the United States Code or the corresponding provisions of any successor laws) for such other Party or all or substantially all of its assets, or such other Party makes an assignment of all or substantially all of its assets to a custodian;
 - (e) the other Party fails generally to pay its debts as they become due (unless those debts are subject to a good-faith dispute as to liability or amount) or acknowledges in writing that it is unable to do so; or
 - (f) any event occurs, or proceeding is initiated, in any jurisdiction to which it is subject that has an effect equivalent or substantially similar to any of the events mentioned above.
- 3.3 Sponsor may terminate this Agreement for any reason upon ninety (90) days prior written notice to Covance.
- 3.4 In the event of such termination, Covance shall be entitled to full payment for work performed on the Study through the date work on such Study is concluded, including, without limitation, all fees and other out-of-pocket expenses incurred by Covance for such Study.
- 3.5 The termination of this Agreement shall not relieve either Party of its obligations to the other with respect to: (a) maintaining the confidentiality of Confidential Information; (b) obtaining consents for the use of names; (c) ownership of and assignment of inventions; (d) indemnification; (d) limitation

of liability; (e) compensation for Services performed; (f) publications; and (g) retention of records. The provisions of this Section together with any other section which is necessary for the interpretation or enforcement of this Agreement shall survive the expiry or termination of this Agreement howsoever arising.

4. REGULATORY COMPLIANCE

- 4.1 Covance will perform its Services in accordance with good laboratory practices and the applicable terms of this Agreement. All of Covance's tests, assays and other activities undertaken under this Agreement shall comply in all material respects with College of American Pathologists (**CAP**) rules. Covance represents that it has and shall maintain Clinical Laboratory Improvement Act (**CLIA**) certification. This Agreement shall contain all the conditions under which Covance will provide clinical laboratory Services. Covance makes no express or implied commitments or warranties concerning the performance of the Study except as set forth in this Agreement.
- 4.2 In the event that compliance with any regulatory requirements necessitates a change in this Agreement, Covance will submit to Sponsor a revised technical and cost proposal for Sponsor's acceptance prior to performing Services.
- 4.3 In the event of a conflict in government regulations, the Parties will discuss and designate which regulations shall be followed by Covance in its performance of the Services.

5. FEES, BILLING AND TAXES

- 5.1 Fees for the Project are set forth in the attached Budget. Sponsor acknowledges that SOW finalization, changes and/or modifications to the Project may result in a revised budget, which must be mutually agreed upon and the Agreement amended accordingly. The Budget contains all of the applicable discounts for Services that will be provided for that Project.
- 5.2 Upon execution, Covance will assess a fee equal to twenty percent (20%) of the value of the contract Budget ("**Project Initiation Fee**"). The Project Initiation Fee covers those value-added services rendered but unbilled, including developing the Scope of Work, quality control and loading of project databases, project management and shipping of kits. Sponsor will pay the Project Initiation Fee within thirty (30) days after receipt of invoice.
- 5.3 Each month, Covance will invoice Sponsor for all fees due and documented expenses incurred while providing Services during the previous month documentation for all expenses included on such invoice. Payment is due thirty (30) days from the date of the invoice.
- 5.4 The Project Initiation Fee will be retained until the first invoice has been paid. Covance will issue a credit on each month's invoices equal to one-sixth (1/6) of the Project Initiation Fee. Should the Study be terminated before the Project Initiation Fee is exhausted and assuming all prior invoices have been paid, Covance will apply Project Initiation Fee funds to the final invoice and refund any remaining Project Initiation Fee funds to Sponsor within thirty (30) days of termination.

- 5.5 For budgeting purposes, Covance creates the Budget using local unit pricing. The local unit pricing is then converted to the billing currency, as requested by Sponsor, using the Reuters exchange rate for the month the Budget is first created. Unless specified otherwise, this exchange rate remains unchanged during the course of the Study to simplify budget comparisons and enable Sponsor to track changes to the Study unrelated to changes in currency exchange rates.
- 5.6 For invoicing purposes, expenses are billed based on the contracted local unit prices. Each month, at the time of invoice creation, the local unit prices are converted to the billing currency using the Reuters exchange rate for the month in which the expenses were incurred.
- 5.7 Covance will hold prices unchanged for twelve (12) months from Project start up. Thereafter, a Project is subject to a fee increase every twelve (12) months from Project start-up. Any such increase shall not exceed the annual inflation rate during the previous twelve (12) month period, as measured by the increase in the U.S. Consumer Price Index. Fee increases apply only to Services not yet performed and invoiced on the Study.
- 5.8 Should the Sponsor disagree with the accuracy of an invoice, the Sponsor shall notify Covance of such inaccuracy within thirty (30) working days of receipt of the invoice. The Sponsor agrees to pay the amounts for any items not in dispute. The Sponsor agrees not to unreasonably withhold payment.
- 5.9 If Sponsor requests a material change to the Project at any time which would affect the Services, Covance will revise fees to reflect the change in the SOW and Budget.
- 5.10 Upon written notification by Sponsor that the Study has been concluded or upon completion of all Services required by Covance under this Agreement, Covance will issue a final invoice for Services rendered to identify amounts due to Covance or refund due to Sponsor.
- 5.11 Fees payable under this Agreement shall not include local, state, federal or foreign sales or use taxes, excise taxes, goods and services tax, value added tax or consumption taxes, as applicable. Any applicable taxes will be billed to and paid by Sponsor without deduction to amounts owed to Covance.

6. SITE VISITS

- 6.1 The Sponsor or its representative (which shall not be a competitor of Covance) may visit Covance's premises where the Services are being performed at reasonable times, on reasonable notice and with reasonable frequency during normal business hours to observe the progress of the Services. Covance will assist the Sponsor in scheduling such visits.
- 6.2 The Sponsor acknowledges that the Sponsor's representatives granted access to Covance facilities during any such visits may have access to confidential and proprietary information of Covance. The Sponsor agrees that all such confidential and proprietary information of Covance obtained or observed by the Sponsor during such visits shall remain the sole property of Covance and the Sponsor shall treat such information as Confidential Information in accordance with Section 8 of this Agreement

7. REGULATORY INSPECTIONS AND AUDITS

- 7.1 In the event of a Party receiving a notice from a Regulatory Authority which directly relates to the Services, the Party receiving such notice shall promptly notify the other Party or forward to the other Party a copy of such notice (or extract thereof). Each Party will cooperate with the other in responding to such notice before referring to the other Party in any regulatory correspondence or disclosing any Confidential Information to a Regulatory Authority. However, each Party acknowledges that it may not direct the manner in which the other Party fulfils its obligations to permit inspection by Regulatory Authorities.
- 7.2 Covance shall cooperate with any inspection or audit by a Regulatory Authority and shall notify the Sponsor promptly of any request by a Regulatory Authority.
- 7.3 Covance agrees that, during an inspection or audit by a Regulatory Authority concerning the Services, it will not disclose information and materials that are not required to be disclosed to such Regulatory Authority, without the prior written consent of the Sponsor.
- 7.4 If any inspections or audits conducted pursuant to this Section 7 that result in a finding that Covance has failed to comply with the terms of this Agreement, Covance shall promptly take such measures at its own cost and expense as are necessary to correct such defaults.
- 7.5 It is agreed that where any audit of Covance concerns or relates to referral laboratory testing or shipping methods of Covance, the Sponsor or its representative (which shall not be a competitor of Covance) may only confirm or not if Covance is properly billing such costs. The Sponsor expressly agrees that Sponsor's representatives may not directly or indirectly provide any details of the charges to the Sponsor, such as the actual amount of the referral laboratory testing or shipping costs incurred by Covance.

8. CONFIDENTIAL INFORMATION

- 8.1 Each Party agrees that all Confidential Information of the Disclosing Party is and shall be the sole property of the Disclosing Party.
- 8.2 Without prejudice to any Covance Property, all Results, information, data and records developed by Covance or its Affiliates in the performance of the Services shall be the Confidential Information of the Sponsor.
- 8.3 Each Party agrees to hold the Confidential Information of the other Party in confidence and in a manner consistent with the way in which it maintains the confidentiality of its own proprietary information, being at least a reasonable standard of care. Each Party shall disclose the Confidential Information only on a need to know basis, to its employees, officers, directors, representatives and third party investigators, in each case who are legally bound to treat the Confidential Information in the manner set forth in this Section 8.

- 8.4** Recipient agrees that, except as necessary to fulfil its obligations under this Agreement, it will not use any of the Confidential Information of the Disclosing Party.
- 8.5** Notwithstanding the non-disclosure obligations herein, Recipient shall not be in breach of this Section 8 if it discloses Confidential Information to the extent such disclosure is required by Applicable Law or a court or administrative subpoena or order; provided, however, that (a) any such disclosure shall not otherwise relieve Recipient of its continuing confidentiality and non-use obligations hereunder with respect to all of the Confidential Information, including the information disclosed by it to the court or agency under this Section 8 and (b) Recipient shall give Disclosing Party reasonable advance notice of any such disclosure and cooperate reasonably with Disclosing Party (and at Disclosing Party's expense) in Disclosing Party's efforts to object to such disclosure and to obtain the court's or administrative agency's agreement to maintain the confidentiality of the Confidential Information to be disclosed by Recipient under this Section 8.
- 8.6** The obligations in this Section 8 shall remain in full force and effect for a period of **seven (7) years** following termination of this Agreement except with respect to Confidential Information which is considered a trade secret under Applicable Law, which shall remain confidential as long as such Confidential Information retains its status as a trade secret.
- 8.7** Misuse or disclosure of the Confidential Information by Recipient may cause irreparable harm to Disclosing Party not adequately compensable by money damages. In the event of actual or threatened breach or violation of this Section 8, the disclosing Party shall have the right to seek injunctive relief in any court of competent jurisdiction, without the need to post any bond and without the need to demonstrate actual damages.

9. INTELLECTUAL PROPERTY RIGHTS

- 9.1** All Background IP is and shall remain the exclusive property of the Party owning it and except as expressly provided in this Agreement, no Party shall acquire any rights in or to the Background IP of the other Party.
- 9.2** The Sponsor acknowledges that Covance Property is owned or licensed by Covance or its Affiliates. Strategic insight and proposed Project design and scope provided in any quotation by Covance shall remain the property of Covance and may be used by the Sponsor only to assess whether it wishes to pursue such work with Covance.
- 9.3** The Sponsor will have title to the Deliverables and all intellectual property rights therein. Subject to RMCL's payment of amounts due to Covance hereunder, Covance assigns all rights in and to the Deliverables to the Sponsor, except that one (1) copy of the Results may be retained by Covance solely for regulatory or legal compliance purposes. The Sponsor hereby grants Covance an unrestricted, royalty-free license to aggregate and use System Data produced by or for Covance as part of the Services with other System Data owned or licensed by Covance only if Sponsor is not identifiable through Covance's aggregation and use.

9.4 Covance shall promptly disclose to the Sponsor (or its nominee) all Inventions. Covance assigns and agrees to assign to the Sponsor (or its nominee) all rights, title and interest in and to such Invention and shall do all acts that are reasonably necessary to vest the Invention in the name of the Sponsor (or its nominee), at Sponsor's expense.

10. REMEDIES AND LIMITATION OF LIABILITY

- 10.1** In the event of a material error by Covance that prevents proper performance under this Agreement or which renders the Services in whole or in part unacceptable to a Regulatory Authority to which the Sponsor intends to submit the Results, Covance's sole obligation to Sponsor (other than the obligations set forth in Section 11) shall be for Covance, at Sponsor's election, to either: (a) repeat the defective part of the Services at Covance's own cost; or (b) refund to the Sponsor the amount paid for the defective part of the Services.
- 10.2** Except for liability resulting from any breach of Sections 8 or 9 or liability pursuant to Section 11, Covance's total liability to the Sponsor, whether in contract, tort (including negligence) or otherwise, shall in no circumstances exceed the total price paid by the Sponsor for the Services that are the subject of this Agreement.
- 10.3** Nothing in this Agreement excludes or limits the liability of either Party where liability cannot be excluded or restricted as a matter of law.
- 10.4** Except for liability resulting from any breach of Sections 8 or 9 or liability pursuant to Section 11, Covance will not be liable to the Sponsor for any Loss in respect of any:
- (a) loss of profit, opportunity, business, or goodwill (in each case whether direct or indirect); or
 - (b) any indirect, consequential, punitive, exemplary or special damages or losses, arising under or in connection with this Agreement,
 - (c) and each type of loss arising under this Section 10.4 shall be severable in accordance with Section 22 of this Agreement. To the extent that Covance agrees to perform Services for Sponsor Affiliates, Covance shall only be liable to the entity named in this Agreement and not for multiple claims by Sponsor Affiliates.
- 10.5** Covance shall not be liable for any failure, error or delay in performing the Services if such failure, error or delay is directly caused by Sponsor, but Covance will cooperate with Sponsor to minimize any such delay and to correct any such failure or error.
- 10.6** Covance shall have no liability to Sponsor for loss, damage, delay or non- delivery/non-collection of any samples or shipment dispatched by Covance to Sponsor or to any third party designated by Sponsor in connection with the Services that are caused by the acts or omissions of any third party delivery services or carrier ("**Carrier**"). Notwithstanding the foregoing, to the extent permitted by law, Covance shall have the benefit of any right or remedy permitted under international or domestic law and any sums recoverable from a Carrier shall be paid to the Sponsor. For the avoidance of doubt, a Carrier is not considered a Subcontractor for the purposes of this Agreement.

11. INDEMNITIES

- 11.1** The Sponsor shall defend, indemnify, and hold harmless Covance and its respective Affiliates and their respective officers, directors, employees and agents (**Covance Group**) from any Loss resulting from any Claim arising from or related to:
- (a) personal injury to a participant in the Study directly or indirectly caused by the Test Material;
 - (b) Covance's proper execution and/or the proper performance of its obligations under this Agreement;
 - (c) the Sponsor's use of the Results or Deliverables or its use or marketing of any substance tested in association with the Study by Covance;
 - (d) the negligence or intentional misconduct of the Sponsor;
 - (e) the Test Material's harmful or otherwise unsafe effect, including, without limitation, a product liability claim based upon the Sponsor's or Sponsor's representatives' use, consumption, sale, distribution or marketing of the Sponsor's products tested under this Agreement; or
 - (f) the infringement, unlawful disclosure or misappropriation of copyright, patent, trade secret or other intellectual property of a third party by reason of Covance's use of the Sponsor Information in accordance with the terms of this Agreement,

provided that if such Loss or Claim arises in whole or in part from Covance's negligence or intentional misconduct, then the amount of such Loss that Sponsor shall indemnify the appropriate person or entity within the Covance Group pursuant to this Section 11 shall be reduced by an amount in proportion to the percentage of Covance's responsibilities for such Loss as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the Parties.

- 11.2** Covance shall defend, indemnify and hold harmless the Sponsor and its Affiliates and their respective officers, directors and employees (the "**Sponsor Group**") from any Loss resulting from any Claim arising from a breach of this Agreement by Covance, or the negligence or intentional misconduct of Covance, provided that if such Losses or Claims arise in whole, or in part, from the Sponsors Group's negligence or intentional misconduct, then the amount of such Losses that Covance shall be responsible for pursuant to this Section 11 shall be reduced by an amount in proportion to the percentage of the Sponsor Group's responsibilities for such Losses as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the Parties.

- 11.3** An indemnitee entitled to indemnification under Section 11 (the “**Indemnified Party**”) shall give written notice to the other Party (“**Indemnifying Party**”) of a claim or other circumstances likely to give rise to a request for indemnification, promptly after the Indemnified Party becomes aware of the same. The Indemnifying Party shall be afforded the opportunity to undertake the defense of, and, subject to Section 11.5, to settle by compromise, or otherwise, any claim for which indemnification is available under this Section.
- 11.4** If the Indemnifying Party assumes the defense of any claim, the Indemnified Party may participate in such defense with legal counsel of its selection and at its expense. If the Indemnifying Party fails to promptly assume the defense of a claim by the Indemnified Party under this Section 11.4, the Indemnified Party may thereupon undertake the defense on behalf of, at the risk and expense of the Indemnifying Party with all reasonable costs and expenses of such defense to be paid by the Indemnifying Party.
- 11.5** In the event that the Indemnifying Party assumes the defense of any claim, no compromise or settlement of any such claim may be made without the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld or delayed.

12. INSURANCE

- 12.1** Covance shall secure and maintain in full force and effect through the performance of the Services the necessary insurance coverage in amounts appropriate to the conduct of Covance’s business. Certificates evidencing such insurance will be made available for examination upon written request by Sponsor.
- 12.2** Sponsor hereby warrants and represents that it maintains and shall maintain adequate clinical trial and product liability insurance coverage consistent with industry standards and in compliance with all Applicable Laws. Certificates evidencing such insurance will be made available for examination upon written request by either Covance or Sponsor.

13. HUMAN BIOLOGICAL SAMPLES

- 13.1** Where the Sponsor supplies HBS to Covance, the Sponsor represents and warrants that:
- (a) all HBS supplied under this Agreement are or have been procured and reviewed by ethics committee and supplied to Covance in full compliance with any and all Applicable Laws and Regulatory Requirements relating to the Use of HBS providing protection for human subjects in the country of origin;
 - (b) the HBS Donor has given Informed Consent; and
 - (c) all HBS supplied to Covance: (i) may be Used for the Services; (ii) may be used to provide data in support of commercial product development; and (iii) were procured without inappropriate financial benefit to the HBS Donor.

- 13.2 The Sponsor shall: (a) upon request, provide a copy of the relevant Informed Consent template; and (b) ensure any HBS shall be de-identified or 'coded' according to applicable Regulatory Requirements to protect the identity and confidentiality of the HBS Donor. Full date of birth shall only be collected if medically relevant to the Services (unless legally restricted in the country of operation). In the event of a withdrawal of, or a material variation to the Informed Consent (including any material changes that may affect the Services provided by Covance) the Sponsor shall promptly notify all relevant Covance entities of such changes.
- 13.3 Covance agrees to Use the HBS in accordance with all applicable Regulatory Requirements.
- 13.4 Upon Sponsor's request, Covance shall retain, return or destroy all HBS in accordance with the Informed Consent, the Sponsor's instructions or any other specific requirements under Applicable Law and Regulatory Requirements.
- 13.5 The Sponsor acknowledges that where Covance enters into a material transfer agreement ("**MTA**") with the provider of any HBS, Covance shall act in accordance with the terms of the MTA and the disposition of the relevant HBS shall be as prescribed in the MTA. In the event of a conflict between the terms of the MTA, this Agreement, any Work Order and any instructions provided by the Sponsor, the terms of the MTA shall prevail.

14. DATA PROTECTION

- 14.1 Where Covance processes any personal data on behalf of the Sponsor, Covance shall process such personal data in accordance with all applicable Data Protection Laws in the territories in which the Services are performed ("**Protected Data**").
- 14.2 If Covance processes any Protected Data on behalf of the Sponsor, Covance and the Sponsor each agree and acknowledge that the Sponsor shall be the data controller and Covance shall be the data processor with respect to the processing of such Protected Data. Covance shall only process such Protected Data on behalf and upon the reasonable instructions of the Sponsor for purposes notified to it by the Sponsor for which consent from the relevant data subjects has been obtained in accordance with all applicable Regulatory Requirements. Covance shall follow such procedures, policies and reasonable instructions as may be agreed by the Parties from time to time.
- 14.3 Covance shall take reasonable technical and organizational measures that are necessary to protect against the unauthorized or unlawful processing of or the unauthorized or unlawful disclosure of such personal data. Covance shall promptly notify the Sponsor in the event of a security breach involving any personal data which Covance is processing on behalf of the Sponsor.
- 14.4 The Sponsor warrants that it has complied with any and all notification and information requirements under the applicable Data Protection Laws.

15. SUBCONTRACTORS

- 15.1** Notwithstanding Section 18, certain tasks, as may be agreed during the development of and specified in the Protocol, may be subcontracted by Covance to Subcontractors approved by Covance or subcontracted, or assigned and transferred to its Affiliates. Covance shall be responsible for the acts and performance of Subcontractors and Affiliates.
- 15.2** Covance shall not be responsible for the performance of third party Vendors. Liability of Covance to the Sponsor with respect to such Vendors shall be limited to the extent Covance is negligent in the performance of its obligations under this Agreement. Covance shall provide to the Sponsor any amounts that Covance may recover from such Vendors as a result of any error or service failure on the part of the Vendors in connection with this Agreement.

16. FORCE MAJEURE

- 16.1** Neither Party shall be in breach of this Agreement nor liable for delay in performing, or failure to perform, any of its obligations under this Agreement, if such delay or failure result from a Force Majeure Event. In such circumstances, any time specified for completion of performance in the Protocol falling due during or subsequent to the occurrence of a Force Majeure Event shall be automatically extended for a period of time equal to such event.
- 16.2** Should any part of the Services be rendered invalid as a result of a Force Majeure Event, Covance shall, upon written request from the Sponsor, and at the Sponsor's sole cost and expense, repeat the affected part of the Services.
- 16.3** If a Force Majeure Event prevents a Party from performing pursuant to this Agreement for a period of 180 days or more, the unaffected Party may terminate this Agreement upon written notice to the affected Party.

17. INDEPENDENT CONTRACTOR

- 17.1** The Parties agree that in performing the Services, Covance (including its employees, agents, subcontractors or other representatives) is acting as an independent contractor to Sponsor. The Parties further agree that Covance and its employees, agents, subcontractors or other representatives are not employees, agents or partners of Sponsor, and nothing in this Agreement and no actions of Sponsor in engaging Covance shall render Covance or any of its employees, agents, subcontractors or other representatives the employees, agents or partners of Sponsor. Neither Covance nor any of its employees, agents, subcontractors or other representatives will have power or authority to bind Sponsor. Neither the relationship between Covance and Sponsor nor any provision of this Agreement shall be construed to authorize Covance to take (or fail to take) any action or make (or fail to make) any decision, representation or commitment binding upon Sponsor or any of its affiliate companies. Sponsor shall at all times be free to engage other third parties to perform services in addition to or in lieu of those services being provided by the Covance. Subject to the provisions of this Agreement, Covance shall be free to devote such time that they do not spend providing Services under this Agreement to such person, firms or corporations as they may choose.

17.2 Nothing contained herein shall be construed (i) to create any association, partnership, joint venture, or relationship of principal and agent, or master and servant between the Parties or any of their affiliates or subsidiaries, employees and subcontractors, (ii) to provide any Party with the right, power or authority, either express or implied, to create any duty or obligation on behalf of another Party, (iii) to impose liability upon one Party for the act or failure to act of another Party, or (iv) to confer any right for Covance (or any of its employees, agents, subcontractors or other representatives) to participate in or be eligible to participate in any pension or welfare benefit plans, programs or arrangements of Sponsor or of its affiliate companies pertaining to any pension, stock, bonus, profit sharing or similar benefits or any employee health, life assurance, workers compensation insurance, disability, severance or any other benefit of any kind whatsoever which is associated with or customarily paid in connection with or in relation to an employment contractor.

18. ASSIGNMENT

18.1 Either Party may assign, transfer or subcontract any or all of its rights and obligations under this Agreement to its Affiliates.

18.2 Notwithstanding Section 18.1 and except in connection with an internal reorganization of the relevant Party's corporate structure, this Agreement shall not be assigned or transferred in whole or in part by either Party without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed.

19. NOTICES

19.1 All notices required to be given under this Agreement shall be in writing and shall be deemed to have been duly given if delivered personally or mailed first class, registered or certified mail, return receipt requested, postage paid:

If to Sponsor to:

inRegen
10 Market St.
#774 Camana Bay, Grand Cayman
KY 1-90006 Cayman Islands

With a copy by email to:

If to Covance to:

Covance Central Laboratory Services LP
8211 SciCor Drive
Indianapolis, Indiana 46214-2985
UNITED STATES
Attention: VP, Finance

or at such other place as either Party shall hereafter furnish to the other Party in writing. Notices shall be deemed given on the date of personal delivery or deposit in the mail as specified above.

19.2 For the purposes of this Section 19, in relation to the purposes of any legal proceeding, “writing” shall not include email.

20. WAIVER

No waiver of any term, provision, or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver or estoppel of any such term, provision, or condition or of any other term, provision, or condition of this Agreement.

21. VARIATION

No provision of this Agreement may be amended, modified, varied, discharged, or terminated except by the express written agreement of both Parties and signed by an authorized representative of each Party.

22. SEVERABILITY

If any court or competent authority finds that any provision of this Agreement (or part of any provision) is invalid, illegal or unenforceable, that provision or part-provision shall, to the extent required, be deemed to be deleted, and the validity and enforceability of the other provisions of this Agreement shall not be affected. If any invalid, unenforceable or illegal provision of this Agreement would be valid, enforceable and legal if some part of it were deleted, the provision shall apply with the minimum modification necessary to make it legal, valid and enforceable.

23. PUBLICITY AND PUBLICATION

- 23.1 Neither Party will use the name, trademark or the name of any representative of the other, or the existence of this Agreement for any promotional or advertising purposes, or any other publication, without the prior written consent of the other.
- 23.2 Neither Party will state or imply that the other Party endorses or approves any service, material, product or compound of the other Party without the prior written consent of the other. Such restrictions shall not apply to internal communications and publications to a Party’s Affiliates.
- 23.3 Sponsor shall provide Covance with a pre-publication copy of any report, manuscript, publication or form of marketing material recognizing Covance’s participation in the Services or otherwise identifying Covance, for approval (which approval shall not be unreasonably withheld or delayed) in each case at least thirty (30) days before its submission for publication.

24. ENTIRE AGREEMENT

This Agreement represents the entire understanding between the Parties with respect to the subject matter hereof as of the Effective Date, and this Agreement supersedes all prior agreements, negotiations, understandings, representations, statements and writings between the Parties relating thereto, except that any written agreement entered into prior to the Effective Date with respect to a Study in process prior to the Effective Date shall remain effective and shall continue to govern such existing Study. The Parties agree that neither has relied upon prior representations made before executing this Agreement.

25. LEGAL TESTIMONY

Covance agrees to provide testimony or records regarding the Services for the Sponsor in any legal or administrative proceeding, provided that the Sponsor shall reimburse Covance for its out of pocket costs plus a reasonable hourly fee for the involvement of its employees or representatives in such proceedings.

26. THIRD PARTY RIGHTS

Except as expressly set forth in this Agreement in respect of Covance Affiliates, nothing in this Agreement is intended to confer any rights, benefits or remedies of any kind whatsoever, and a person who is not a party to this Agreement shall have no right to enforce any of its terms.

27. ANTI-BRIBERY

27.1 Both Parties agree that each has not and will not, either directly or indirectly, engage in bribery, or offer, or promise, or authorize to pay or make any improper payment of any monies or financial or other advantage, including cash, loan, gift, travel, entertainment, hospitality, facilitation payment, kickback, political or philanthropic contribution, anything of value, or any other perceived benefit to improperly obtain or retain a business advantage in violation of any Anti-Corruption Laws and further, each Party agrees that they shall not take any action that would cause the other Party to be in violation of such Anti-Corruption Laws.

27.2 Any breach of Section 27.1 by a Party shall allow the other Party to immediately terminate this Agreement.

28. TRADE CONTROL

28.1 Notwithstanding any other provision of this Agreement to the contrary, each Party shall comply with, and retain responsibility for its compliance with, all applicable export control laws (e.g., the U.S. Export Administration Regulations) and economic sanctions programs (e.g., economic sanctions maintained by the U.S. Treasury Department, as well as Specially Designated Nationals and Blocked Persons (SDNs)) relating to its respective business, facilities, and the provision of services to third parties (collectively, **Trade Control Laws**).

28.2 Nothing in this Agreement shall be construed to require Covance to be directly or indirectly involved in the provision of goods, software, services and/or technical data that may be prohibited by applicable Trade Control Laws, including sanctions currently in place against Cuba, Iran, North Korea, Sudan, Syria and SDNs.

29. COUNTERPARTS

This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original to this Agreement but all of which together shall constitute the same Agreement. Signatures upon this Agreement transmitted by facsimile, electronic mail or other electronic method shall have the same legal and binding effect as wet signatures.

30. CHOICE OF LAW AND DISPUTE RESOLUTION

30.1 This Agreement shall be governed and construed in accordance with the laws of the State of New York, U.S.A., without regard to conflicts of laws provisions.

30.2 Any dispute, controversy, or claim arising out of, relating to, or in connection with this Agreement, or the breach, termination, or validity thereof, shall be finally settled by arbitration. The arbitration shall be conducted in accordance with the Securities Arbitration Rules (the "Rules") of the American Arbitration Association ("AAA"), including the AAA's Procedures for Large, Complex Commercial Disputes, in effect at the time of the arbitration, except as they may be modified herein or by mutual agreement of the parties. The seat of the arbitration shall be New York, New York, and it shall be conducted in the English language. The arbitration and this clause shall be governed by Title 9 (Arbitration) of the United States Code. The Parties agree that irreparable damage may occur to a Party in the event that the other Party may fail or fails to comply with the provisions of Section 8. Accordingly and without otherwise limiting the requirement of mandatory arbitration imposed hereunder, a Party may seek from any court having jurisdiction any interim or provisional relief (without the necessity of posting bond) that may be necessary to protect its interests under Section 8, pending the arbitral tribunal's final determination of the merits of the controversy.

30.3 The arbitration shall be conducted by three arbitrators. The claimant shall appoint an arbitrator in its request for arbitration. The respondent shall appoint an arbitrator within twenty (20) days of the receipt of the request for arbitration. The two arbitrators shall appoint a third arbitrator, who shall act as chair of the tribunal, within twenty (20) days after the appointment of the second arbitrator. If any of the three arbitrators is not appointed within the time prescribed above, then the AAA shall appoint that arbitrator from its National Panel of Securities Arbitrators or its Large, Complex Commercial Case Panel, not including any such members affiliated with the securities industry. The chair of the tribunal shall be a citizen of the United States.

- 30.4** In addition to the authority conferred on the arbitration tribunal by the Rules, the arbitration tribunal shall have the authority to order such production of documents, generally consistent with the discovery permitted under the Federal Rules of Civil Procedure, as may reasonably be requested by any party or by the tribunal itself. In addition, any party may request a reasonable number of depositions of party witnesses.
- 30.5** The Parties agree that the arbitration shall be kept confidential and that the existence of the proceeding and any element of it (including but not limited to any pleadings, briefs or other documents submitted or exchanged, any testimony or other oral submissions, and any awards) shall not be disclosed beyond the tribunal, the AAA, the Parties, their counsel, accountants and auditors, insurers and re-insurers, and any person or entity necessary to the conduct of the proceeding. The confidentiality obligations in this Section 28.5 shall not apply (i) if disclosure is required by Applicable Law, or in judicial or administrative proceedings, or (ii) as far as disclosure is necessary to enforce the rights arising out of the award.
- 30.6** The arbitration award shall be final and binding on the Parties. Judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party or its assets.
- 30.7** In order to facilitate the comprehensive resolution of related disputes, and upon request of any party to the arbitration proceeding, the arbitration tribunal may consolidate the arbitration proceeding with any other arbitration proceeding involving any of the Parties hereto relating to this Agreement. The arbitration tribunal shall not consolidate such arbitrations unless it determines that (i) there are issues of fact or law common to the related proceedings so that a consolidated proceeding would be more efficient than separate proceedings, and (ii) no party would be prejudiced as a result of such consolidation through undue delay or otherwise.
- 30.8** The Parties agree that any dispute arising from or in connection with this Agreement (including any non-contractual obligations) shall be referred to and finally resolved by arbitration under the Rules of the International Chamber of Commerce which Rules shall be deemed incorporated by reference to the Agreement. The number of arbitrators shall be three (3), the seat or legal place of arbitration shall be New York and the language used in the arbitration shall be English.

[signature page follows]

IN WITNESS WHEREOF, the Parties by their duly authorized officers have executed this Agreement on the dates set forth below, to be effective on the Effective Date set forth on the first page of this Agreement.

INREGEN

Signature: /s/ Alasdair Foster
Name: Alasdair Foster
Title: Director
Date: 10th August 2017

**COVANCE CENTRAL LABORATORY SERVICES LP
COVANCE CENTRAL LABORATORY SERVICES
SÀRL**

Signature: /s/ Cheryl Helton
Name: Cheryl Helton
Title: VP, Covance Central Laboratories
Date: 8/12/2017

This Laboratory Service Agreement (“Agreement”) is made effective on 21 June 2019 by and between

- (1) **COVANCE CENTRAL LABORATORY SERVICES LP** an Indiana limited partnership, with its principal place of business at 8211 SciCor Drive, Indianapolis, Indiana 46214, USA; and **COVANCE CENTRAL LABORATORY SERVICES SÀRL**, with its principal place of business at Rue Moise-Marchines 7, 1217 Meyrin, Geneva Switzerland (collectively “**Covance**”); and
 - (2) **inRegen**, 10 Market Street, No. 774 Camana Bay, Grand Cayman KY1-9006, Cayman Islands (“**Sponsor**”).
- (each a “**Party**” and collectively the “**Parties**”).

WHEREAS

- (A) Covance is engaged in the business of providing laboratory testing, data management, protocol management and information management services for pharmaceutical clinical trials.
- (B) Sponsor desires for Covance to perform such services for one or more clinical trials, all in accordance with and subject to the terms and conditions of this Agreement.

IT IS AGREED

1. DEFINITIONS

1.1 In this Agreement, the following words and expressions shall have the following meanings:

“**Affiliate**” means any entity controlling, controlled by, or in common control with a Party. For the purposes of this definition, “**Control**” shall mean ownership or control, directly or indirectly of more than fifty percent (50%) of the common voting stock or ordinary shares in the entity or the right to appoint fifty percent (50%) or more of the directors of that entity. With respect to Covance, the term Affiliate shall include Laboratory Corporation of America Holdings and any business entity that is controlled by or is under common control with Laboratory Corporation of America Holdings.

“**Anti-Corruption Laws**” means any anti-bribery and anti-corruption laws, rules, regulations applicable to either Party (each as amended from time to time) including the United States Anti-Kickback Law, United States Foreign Corrupt Practices Act, the UK Bribery Act 2010 and the OECD Convention Against the Bribery of Foreign Government Officials in International Business Transactions, together with any applicable implementing legislation including any applicable local law addressing bribery or corruption.

“**Applicable Law**” means applicable federal, state and local laws, rules, regulations, including the regulations of the FDA and Data Protection Laws.

“**Background IP**” means all pre-existing intellectual property belonging to or licensed to a Party or other intellectual property created outside the scope of the Services.

“**Claim**” means any third party claims, demands, assessments, actions, suits, proceedings, or settlements.

“**Confidential Information**” means any and all non-public information or materials and derivatives thereof, in any and all forms, howsoever disclosed or obtained, including business plans, financial information, client lists, and requirements, techniques, designs, methods, processes and procedures, which: (i) is identified by a suitable legend or other marking as being confidential (or similar designation) in a prominent position or (ii) is described as being confidential at the time of disclosure or (iii) the disclosing Party regards or should reasonably be expected to regard as proprietary and confidential given the nature of the information and the circumstances of disclosure. Confidential Information shall not include information (a) that is or becomes publicly disclosed except to the extent such disclosure results from a violation hereof or any improper action or inaction by Recipient or any agent or representative of Recipient; (b) that was in Recipient’s possession prior to Recipient’s receipt of such material from Disclosing Party, as demonstrated by documentary evidence that itself was in Recipient’s possession at the time of Disclosing Party’s disclosure of such Confidential Information to Recipient; (c) that is lawfully acquired by Recipient from a third party not obligated to keep such information confidential; or (d) that is developed by the Recipient without the use of or reliance on the Disclosing Party’s Confidential Information, as demonstrated by Recipient’s written records. Information will not be deemed to be within the foregoing exceptions merely because such information is embraced by more general information that is within the foregoing exceptions. In addition, any combination of features will not be deemed to be within the foregoing exceptions merely because individual features are within the exceptions, but only if the combination itself and its principle of operation are within the exceptions.

“**Covance Property**” means inventions, proprietary processes, software (including codes) data, technology, know-how and other intellectual property that have been independently developed or discovered by Covance or its Affiliates without the use of Sponsor’s Confidential Information, including those that relate to the proprietary innovative testing procedures, laboratory testing data collection or data management procedures, procedural manuals, delta flags, nucleic acid based vectors, analytical procedures and approaches that are not specific for use with the Sponsor’s Background IP even if such are developed in the performance of the Services or are captured in documents pertaining to the Services (i.e. laboratory notebooks), techniques, skills, models, non-product specific components of questionnaires, management tools and any other materials, employed, developed or acquired by Covance or its Affiliates.

“**Data Protection Laws**” mean all applicable privacy, data protection or similar laws and regulations anywhere in the World, as the same may be amended from time to time, including to the extent applicable to the respective Services, the Data Protection Directive (95/46/EC), the Personal Data Protection Act 2012 of Singapore and any applicable implementing legislation or any amendment thereto.

“Deliverables” means as applicable to the Services, Results, or any other deliverable specified in this Agreement.

“Disclosing Party” means the Party disclosing or making available its Confidential Information to the other Party.

“FDA” means the United States Food and Drug Administration or any other government body or agency that succeeds it.

“Force Majeure Event” means circumstances or causes beyond the reasonable control of a Party, including war, threat of war or warlike conditions, blockade, embargo, fire, explosion, lightning, storm, drought, flood, earthquake or other natural disaster, pandemic or epidemic, power failure, acts of terrorism, riot, civil unrest, insurrection, acts of government or other international bodies, political subdivision and any other events which by their nature could not have been foreseen by the Parties, or, if it could have been foreseen were unavoidable by a reasonable prudent business.

“HBS Donor” means an individual, living or deceased, from whom the HBS was obtained.

“Human Biological Samples” or **“HBS”** means any human biological material, including, without limitation, human bodily parts and organs in whole or sub-samples, any tissue, skin, bone, muscle, connective tissue, blood, cerebrospinal fluid, cells, gametes, or sub-cellular structures such as DNA, or any derivative or product of such human biological materials including stem cells, cell lines, bodily fluids, blood derivatives and urine.

“IEC/IRB” means an independent ethics committee or institutional review board.

“Informed Consent” means an IEC/IRB approved informed consent form signed by the HBS Donor authorizing the Use of their HBS.

“Invention” means any patentable invention or other registerable intellectual property rights discovered, conceived of or made by Covance or its Affiliates specifically as result of the Services for the Sponsor and relating to the Test Materials. Covance Property is not included in Inventions.

“Loss” means any loss, cost, damage or expense (including reasonable legal expenses).

“Project” means a Study, project or assignment between Covance and Sponsor.

“Protocol” means the document which specifies the laboratory testing procedures as written by Sponsor as applicable for the performance of a Study and is provided to Covance.

“Recipient” means the Party receiving or having access to the Confidential Information from the other Party.

“Regulatory Authority” means any national or state (in the case of the US), or local agency, authority, department, inspectorate, minister, ministry official, parliament or public or statutory person (whether autonomous or not) of any government of any country having jurisdiction over either any of the activities contemplated by this Agreement or the Parties.

“Regulatory Requirements” means all laws, statutes, acts, rules, regulations, guidelines, codes, orders, directives or other legally binding requirements of any Regulatory Authority and industry standards or codes of conduct applicable to the Services.

“Results” mean materials, data, inventions, documents and information produced, conceived or developed by Covance specifically as a result of the Services and related to the Test Materials. Covance Property is not included in Results.

“Services” means the services provided by Covance to the Sponsor as more particularly described in this Agreement and the SOW.

“SOW” means the scope of work mutually agreed to in writing by the Parties, which will be attached hereto as an exhibit and will be governed by and is hereby made a part of this Agreement.

“Sponsor Information” means Test Materials, data, specification, or other materials or information supplied by the Sponsor to Covance in connection with the Services.

“Study” means a clinical trial or scientific evaluation of the Test Materials on the terms and conditions of the Protocol.

“Subcontractor” means a third party approved, reviewed and contracted by Covance for Services within the scope of this Agreement.

“System Data” means control data from laboratory tests or transactional, volume and performance data related to the Services, which does not contain any personally identifiable information or Sponsor Confidential Information.

“Test Materials” means compounds, materials or other substances as described in the Protocol to be tested or used in the performance of the Services and provided to Covance by the Sponsor.

“Use” (in the context of Section 13) means collection, storage, transfer (including import and export), use and return or disposal of HBS including by commercial organizations.

“Vendor” means third-party service providers other than a Subcontractor for which Covance may hold the contract with such service provider at Sponsor’s written request for the convenience or benefit of the Sponsor in connection with Services under this Agreement.

- 1.2 In this Agreement, unless the context otherwise requires, references to:
- (a) Schedule and Section headings are inserted for convenience only and do not affect the construction or interpretation of this Agreement;
 - (b) a particular law or statutory provision is a reference to it as it is in force for the time being taking account of any amendment, extension, or re-enactment and includes any subordinate legislation for the time being in force made under it;
 - (c) **writing** or **written** includes faxes and e-mail;
 - (d) a person includes a corporate or unincorporated body;
 - (e) any gender includes all genders;
 - (f) **including, include, in particular** or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;
 - (g) words in the singular include the plural and vice versa.
- 1.3 If this Agreement is translated, the English language text shall prevail.

2. SERVICES

- 2.1 Covance through itself and/or its Affiliates hereby agrees to perform Services for Sponsor's protocol REGEN004, "A PHASE 1, OPEN-LABEL SAFETY, TOLERABILITY, AND EARLY EFFICACY STUDY OF A RENAL AUTOLOGOUS CELL THERAPY (REACT) IN PATIENTS WITH CHRONIC KIDNEY DISEASE FROM CONGENITAL ANOMALIES OF THE KIDNEY AND URINARY TRACT (CAKUT)" as amended from time to time, a copy of which is attached hereto as Exhibit A. Such Services shall be performed pursuant to the terms and conditions contained herein.
- 2.2 Any changes or modifications to the Protocol and/or Services provided by Covance, or any Sponsor request for additional Services may commence upon Covance's receipt of Sponsors written approval of the revised SOW. Upon Sponsor's SOW signature, Covance shall provide such Services to the Sponsor and the Sponsor shall pay for costs associated with such Services at its current standard rates.
- 2.3 Should a kit be lost through no fault of Covance, or should a kit expire at the investigator site, Covance will supply replacement kits for those that are lost, expired, or otherwise rendered unusable, at an amount equal to the price listed in the Budget per kit for the same kit/visit that is being replaced.
- 2.4 After performing Services, Covance will store the remaining Study specimens for the length of time and under storage conditions as described in the applicable SOW. The remaining specimens may subsequently be shipped to Sponsor or another party as specified in the SOW or if not specified in the SOW, held as otherwise instructed by the Sponsor. In no event shall Covance's liability for any breach or default with regard to storage of an archival specimen exceed the fee it has been paid for storage of that specimen for the previous twelve (12) months.

3. TERM AND TERMINATION

- 3.1** The term of this Agreement shall be for fifty (50) months, commencing on the date hereof, or the conclusion of the study, whichever is earlier, and shall renew automatically for successive one (1) year periods unless a Party provides the other Party with written notice of its intention to not renew and extend this Agreement at least sixty (60) days prior to the commencement of any such renewal term.
- 3.2** Either Party may terminate this Agreement with immediate effect by notice in writing in the event that:
- (a) the other Party commits a material breach of any term of this Agreement which breach is irremediable or (if such breach is remediable) fails to remedy that breach within a period of thirty (30) days after being notified in writing to do so; or
 - (b) the other Party repeatedly breaches any of the terms of this Agreement in such a manner as to reasonably justify the opinion that its conduct is inconsistent with it having the intention or ability to give effect to the terms of this Agreement; or
 - (c) anyone commences an involuntary case against such other Party under title 11 of the United States Code or the corresponding provisions of any successor laws and either the case is not dismissed by midnight at the end of the sixtieth (60th) day after commencement;
 - (d) a court of competent jurisdiction appoints a custodian (as that term is defined in title 11 of the United States Code or the corresponding provisions of any successor laws) for such other Party or all or substantially all of its assets, or such other Party makes an assignment of all or substantially all of its assets to a custodian;
 - (e) the other Party fails generally to pay its debts as they become due (unless those debts are subject to a good-faith dispute as to liability or amount) or acknowledges in writing that it is unable to do so; or
 - (f) any event occurs, or proceeding is initiated, in any jurisdiction to which it is subject that has an effect equivalent or substantially similar to any of the events mentioned above.
- 3.3** Sponsor may terminate this Agreement for any reason upon ninety (90) days prior written notice to Covance.
- 3.4** In the event of such termination, Covance shall be entitled to full payment for work performed on the Study through the date work on such Study is concluded, including, without limitation, all fees and other out-of-pocket expenses incurred by Covance for such Study.
- 3.5** The termination of this Agreement shall not relieve either Party of its obligations to the other with respect to: (a) maintaining the confidentiality of Confidential Information; (b) obtaining consents for the use of names; (c) ownership of and assignment of inventions; (d) indemnification; (d) limitation

of liability; (e) compensation for Services performed; (f) publications; and (g) retention of records. The provisions of this Section together with any other section which is necessary for the interpretation or enforcement of this Agreement shall survive the expiry or termination of this Agreement howsoever arising.

4. REGULATORY COMPLIANCE

- 4.1 Covance will perform its Services in accordance with good laboratory practices and the applicable terms of this Agreement. All of Covance's tests, assays and other activities undertaken under this Agreement shall comply in all material respects with College of American Pathologists (**CAP**) rules. Covance represents that it has and shall maintain Clinical Laboratory Improvement Act (**CLIA**) certification. This Agreement shall contain all the conditions under which Covance will provide clinical laboratory Services. Covance makes no express or implied commitments or warranties concerning the performance of the Study except as set forth in this Agreement.
- 4.2 In the event that compliance with any regulatory requirements necessitates a change in this Agreement, Covance will submit to Sponsor a revised technical and cost proposal for Sponsor's acceptance prior to performing Services.
- 4.3 In the event of a conflict in government regulations, the Parties will discuss and designate which regulations shall be followed by Covance in its performance of the Services.

5. FEES, BILLING AND TAXES

- 5.1 Fees for the Project are set forth in the attached Budget. Sponsor acknowledges that SOW finalization, changes and/or modifications to the Project may result in a revised budget, which must be mutually agreed upon and the Agreement amended accordingly. The Budget contains all of the applicable discounts for Services that will be provided for that Project.
- 5.2 Upon execution, Covance will assess a fee equal to twenty percent (20%) of the value of the contract Budget ("**Project Initiation Fee**"). The Project Initiation Fee covers those value-added services rendered but unbilled, including developing the Scope of Work, quality control and loading of project databases, project management and shipping of kits. Sponsor will pay the Project Initiation Fee within thirty (30) days after receipt of invoice.
- 5.3 Each month, Covance will invoice Sponsor for all fees due and documented expenses incurred while providing Services during the previous month documentation for all expenses included on such invoice. Payment is due thirty (30) days from the date of the invoice.
- 5.4 The Project Initiation Fee will be retained until the first invoice has been paid. Covance will issue a credit on each month's invoices equal to one-sixth (1/6) of the Project Initiation Fee. Should the Study be terminated before the Project Initiation Fee is exhausted and assuming all prior invoices have been paid, Covance will apply Project Initiation Fee funds to the final invoice and refund any remaining Project Initiation Fee funds to Sponsor within thirty (30) days of termination.

- 5.5 For budgeting purposes, Covance creates the Budget using local unit pricing. The local unit pricing is then converted to the billing currency, as requested by Sponsor, using the Reuters exchange rate for the month the Budget is first created. Unless specified otherwise, this exchange rate remains unchanged during the course of the Study to simplify budget comparisons and enable Sponsor to track changes to the Study unrelated to changes in currency exchange rates.
- 5.6 For invoicing purposes, expenses are billed based on the contracted local unit prices. Each month, at the time of invoice creation, the local unit prices are converted to the billing currency using the Reuters exchange rate for the month in which the expenses were incurred.
- 5.7 Covance will hold prices unchanged for twelve (12) months from Project start up. Thereafter, a Project is subject to a fee increase every twelve (12) months from Project start-up. Any such increase shall not exceed the annual inflation rate during the previous twelve (12) month period, as measured by the increase in the U.S. Consumer Price Index. Fee increases apply only to Services not yet performed and invoiced on the Study.
- 5.8 Should the Sponsor disagree with the accuracy of an invoice, the Sponsor shall notify Covance of such inaccuracy within thirty (30) working days of receipt of the invoice. The Sponsor agrees to pay the amounts for any items not in dispute. The Sponsor agrees not to unreasonably withhold payment.
- 5.9 If Sponsor requests a material change to the Project at any time which would affect the Services, Covance will revise fees to reflect the change in the SOW and Budget.
- 5.10 Upon written notification by Sponsor that the Study has been concluded or upon completion of all Services required by Covance under this Agreement, Covance will issue a final invoice for Services rendered to identify amounts due to Covance or refund due to Sponsor.
- 5.11 Fees payable under this Agreement shall not include local, state, federal or foreign sales or use taxes, excise taxes, goods and services tax, value added tax or consumption taxes, as applicable. Any applicable taxes will be billed to and paid by Sponsor without deduction to amounts owed to Covance.

6. SITE VISITS

- 6.1 The Sponsor or its representative (which shall not be a competitor of Covance) may visit Covance's premises where the Services are being performed at reasonable times, on reasonable notice and with reasonable frequency during normal business hours to observe the progress of the Services. Covance will assist the Sponsor in scheduling such visits.
- 6.2 The Sponsor acknowledges that the Sponsor's representatives granted access to Covance facilities during any such visits may have access to confidential and proprietary information of Covance. The Sponsor agrees that all such confidential and proprietary information of Covance obtained or observed by the Sponsor during such visits shall remain the sole property of Covance and the Sponsor shall treat such information as Confidential Information in accordance with Section 8 of this Agreement

7. REGULATORY INSPECTIONS AND AUDITS

- 7.1 In the event of a Party receiving a notice from a Regulatory Authority which directly relates to the Services, the Party receiving such notice shall promptly notify the other Party or forward to the other Party a copy of such notice (or extract thereof). Each Party will cooperate with the other in responding to such notice before referring to the other Party in any regulatory correspondence or disclosing any Confidential Information to a Regulatory Authority. However, each Party acknowledges that it may not direct the manner in which the other Party fulfils its obligations to permit inspection by Regulatory Authorities.
- 7.2 Covance shall cooperate with any inspection or audit by a Regulatory Authority and shall notify the Sponsor promptly of any request by a Regulatory Authority.
- 7.3 Covance agrees that, during an inspection or audit by a Regulatory Authority concerning the Services, it will not disclose information and materials that are not required to be disclosed to such Regulatory Authority, without the prior written consent of the Sponsor.
- 7.4 If any inspections or audits conducted pursuant to this Section 7 that result in a finding that Covance has failed to comply with the terms of this Agreement, Covance shall promptly take such measures at its own cost and expense as are necessary to correct such defaults.
- 7.5 It is agreed that where any audit of Covance concerns or relates to referral laboratory testing or shipping methods of Covance, the Sponsor or its representative (which shall not be a competitor of Covance) may only confirm or not if Covance is properly billing such costs. The Sponsor expressly agrees that Sponsor's representatives may not directly or indirectly provide any details of the charges to the Sponsor, such as the actual amount of the referral laboratory testing or shipping costs incurred by Covance.

8. CONFIDENTIAL INFORMATION

- 8.1 Each Party agrees that all Confidential Information of the Disclosing Party is and shall be the sole property of the Disclosing Party.
- 8.2 Without prejudice to any Covance Property, all Results, information, data and records developed by Covance or its Affiliates in the performance of the Services shall be the Confidential Information of the Sponsor.
- 8.3 Each Party agrees to hold the Confidential Information of the other Party in confidence and in a manner consistent with the way in which it maintains the confidentiality of its own proprietary information, being at least a reasonable standard of care. Each Party shall disclose the Confidential Information only on a need to know basis, to its employees, officers, directors, representatives and third party investigators, in each case who are legally bound to treat the Confidential Information in the manner set forth in this Section 8.

- 8.4** Recipient agrees that, except as necessary to fulfil its obligations under this Agreement, it will not use any of the Confidential Information of the Disclosing Party.
- 8.5** Notwithstanding the non-disclosure obligations herein, Recipient shall not be in breach of this Section 8 if it discloses Confidential Information to the extent such disclosure is required by Applicable Law or a court or administrative subpoena or order; provided, however, that (a) any such disclosure shall not otherwise relieve Recipient of its continuing confidentiality and non-use obligations hereunder with respect to all of the Confidential Information, including the information disclosed by it to the court or agency under this Section 8 and (b) Recipient shall give Disclosing Party reasonable advance notice of any such disclosure and cooperate reasonably with Disclosing Party (and at Disclosing Party's expense) in Disclosing Party's efforts to object to such disclosure and to obtain the court's or administrative agency's agreement to maintain the confidentiality of the Confidential Information to be disclosed by Recipient under this Section 8.
- 8.6** The obligations in this Section 8 shall remain in full force and effect for a period of **seven (7) years** following termination of this Agreement except with respect to Confidential Information which is considered a trade secret under Applicable Law, which shall remain confidential as long as such Confidential Information retains its status as a trade secret.
- 8.7** Misuse or disclosure of the Confidential Information by Recipient may cause irreparable harm to Disclosing Party not adequately compensable by money damages. In the event of actual or threatened breach or violation of this Section 8, the disclosing Party shall have the right to seek injunctive relief in any court of competent jurisdiction, without the need to post any bond and without the need to demonstrate actual damages.

9. INTELLECTUAL PROPERTY RIGHTS

- 9.1** All Background IP is and shall remain the exclusive property of the Party owning it and except as expressly provided in this Agreement, no Party shall acquire any rights in or to the Background IP of the other Party.
- 9.2** The Sponsor acknowledges that Covance Property is owned or licensed by Covance or its Affiliates. Strategic insight and proposed Project design and scope provided in any quotation by Covance shall remain the property of Covance and may be used by the Sponsor only to assess whether it wishes to pursue such work with Covance.
- 9.3** The Sponsor will have title to the Deliverables and all intellectual property rights therein. Subject to RMCL's payment of amounts due to Covance hereunder, Covance assigns all rights in and to the Deliverables to the Sponsor, except that one (1) copy of the Results may be retained by Covance solely for regulatory or legal compliance purposes. The Sponsor hereby grants Covance an unrestricted, royalty-free license to aggregate and use System Data produced by or for Covance as part of the Services with other System Data owned or licensed by Covance only if Sponsor is not identifiable through Covance's aggregation and use.

9.4 Covance shall promptly disclose to the Sponsor (or its nominee) all Inventions. Covance assigns and agrees to assign to the Sponsor (or its nominee) all rights, title and interest in and to such Invention and shall do all acts that are reasonably necessary to vest the Invention in the name of the Sponsor (or its nominee), at Sponsor's expense.

10. REMEDIES AND LIMITATION OF LIABILITY

- 10.1** In the event of a material error by Covance that prevents proper performance under this Agreement or which renders the Services in whole or in part unacceptable to a Regulatory Authority to which the Sponsor intends to submit the Results, Covance's sole obligation to Sponsor (other than the obligations set forth in Section 11) shall be for Covance, at Sponsor's election, to either: (a) repeat the defective part of the Services at Covance's own cost; or (b) refund to the Sponsor the amount paid for the defective part of the Services.
- 10.2** Except for liability resulting from any breach of Sections 8 or 9 or liability pursuant to Section 11, Covance's total liability to the Sponsor, whether in contract, tort (including negligence) or otherwise, shall in no circumstances exceed the total price paid by the Sponsor for the Services that are the subject of this Agreement.
- 10.3** Nothing in this Agreement excludes or limits the liability of either Party where liability cannot be excluded or restricted as a matter of law.
- 10.4** Except for liability resulting from any breach of Sections 8 or 9 or liability pursuant to Section 11, Covance will not be liable to the Sponsor for any Loss in respect of any:
- (a) loss of profit, opportunity, business, or goodwill (in each case whether direct or indirect); or
 - (b) any indirect, consequential, punitive, exemplary or special damages or losses, arising under or in connection with this Agreement,
 - (c) and each type of loss arising under this Section 10.4 shall be severable in accordance with Section 22 of this Agreement. To the extent that Covance agrees to perform Services for Sponsor Affiliates, Covance shall only be liable to the entity named in this Agreement and not for multiple claims by Sponsor Affiliates.
- 10.5** Covance shall not be liable for any failure, error or delay in performing the Services if such failure, error or delay is directly caused by Sponsor, but Covance will cooperate with Sponsor to minimize any such delay and to correct any such failure or error.
- 10.6** Covance shall have no liability to Sponsor for loss, damage, delay or non-delivery/non-collection of any samples or shipment dispatched by Covance to Sponsor or to any third party designated by Sponsor in connection with the Services that are caused by the acts or omissions of any third party delivery services or carrier ("**Carrier**"). Notwithstanding the foregoing, to the extent permitted by law, Covance shall have the benefit of any right or remedy permitted under international or domestic law and any sums recoverable from a Carrier shall be paid to the Sponsor. For the avoidance of doubt, a Carrier is not considered a Subcontractor for the purposes of this Agreement.

11. INDEMNITIES

- 11.1** The Sponsor shall defend, indemnify, and hold harmless Covance and its respective Affiliates and their respective officers, directors, employees and agents (**Covance Group**) from any Loss resulting from any Claim arising from or related to:
- (a) personal injury to a participant in the Study directly or indirectly caused by the Test Material;
 - (b) Covance's proper execution and/or the proper performance of its obligations under this Agreement;
 - (c) the Sponsor's use of the Results or Deliverables or its use or marketing of any substance tested in association with the Study by Covance;
 - (d) the negligence or intentional misconduct of the Sponsor;
 - (e) the Test Material's harmful or otherwise unsafe effect, including, without limitation, a product liability claim based upon the Sponsor's or Sponsor's representatives' use, consumption, sale, distribution or marketing of the Sponsor's products tested under this Agreement; or
 - (f) the infringement, unlawful disclosure or misappropriation of copyright, patent, trade secret or other intellectual property of a third party by reason of Covance's use of the Sponsor Information in accordance with the terms of this Agreement,

provided that if such Loss or Claim arises in whole or in part from Covance's negligence or intentional misconduct, then the amount of such Loss that Sponsor shall indemnify the appropriate person or entity within the Covance Group pursuant to this Section 11 shall be reduced by an amount in proportion to the percentage of Covance's responsibilities for such Loss as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the Parties.

- 11.2** Covance shall defend, indemnify and hold harmless the Sponsor and its Affiliates and their respective officers, directors and employees (the "**Sponsor Group**") from any Loss resulting from any Claim arising from a breach of this Agreement by Covance, or the negligence or intentional misconduct of Covance, provided that if such Losses or Claims arise in whole, or in part, from the Sponsors Group's negligence or intentional misconduct, then the amount of such Losses that Covance shall be responsible for pursuant to this Section 11 shall be reduced by an amount in proportion to the percentage of the Sponsor Group's responsibilities for such Losses as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the Parties.

- 11.3** An indemnitee entitled to indemnification under Section 11 (the “**Indemnified Party**”) shall give written notice to the other Party (“**Indemnifying Party**”) of a claim or other circumstances likely to give rise to a request for indemnification, promptly after the Indemnified Party becomes aware of the same. The Indemnifying Party shall be afforded the opportunity to undertake the defense of, and, subject to Section 11.5, to settle by compromise, or otherwise, any claim for which indemnification is available under this Section.
- 11.4** If the Indemnifying Party assumes the defense of any claim, the Indemnified Party may participate in such defense with legal counsel of its selection and at its expense. If the Indemnifying Party fails to promptly assume the defense of a claim by the Indemnified Party under this Section 11.4, the Indemnified Party may thereupon undertake the defense on behalf of, at the risk and expense of the Indemnifying Party with all reasonable costs and expenses of such defense to be paid by the Indemnifying Party.
- 11.5** In the event that the Indemnifying Party assumes the defense of any claim, no compromise or settlement of any such claim may be made without the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld or delayed.

12. INSURANCE

- 12.1** Covance shall secure and maintain in full force and effect through the performance of the Services the necessary insurance coverage in amounts appropriate to the conduct of Covance’s business. Certificates evidencing such insurance will be made available for examination upon written request by Sponsor.
- 12.2** Sponsor hereby warrants and represents that it maintains and shall maintain adequate clinical trial and product liability insurance coverage consistent with industry standards and in compliance with all Applicable Laws. Certificates evidencing such insurance will be made available for examination upon written request by either Covance or Sponsor.

13. HUMAN BIOLOGICAL SAMPLES

- 13.1** Where the Sponsor supplies HBS to Covance, the Sponsor represents and warrants that:
- (a) all HBS supplied under this Agreement are or have been procured and reviewed by ethics committee and supplied to Covance in full compliance with any and all Applicable Laws and Regulatory Requirements relating to the Use of HBS providing protection for human subjects in the country of origin;
 - (b) the HBS Donor has given Informed Consent; and
 - (c) all HBS supplied to Covance: (i) may be Used for the Services; (ii) may be used to provide data in support of commercial product development; and (iii) were procured without inappropriate financial benefit to the HBS Donor.

- 13.2 The Sponsor shall: (a) upon request, provide a copy of the relevant Informed Consent template; and (b) ensure any HBS shall be de-identified or ‘coded’ according to applicable Regulatory Requirements to protect the identity and confidentiality of the HBS Donor. Full date of birth shall only be collected if medically relevant to the Services (unless legally restricted in the country of operation). In the event of a withdrawal of, or a material variation to the Informed Consent (including any material changes that may affect the Services provided by Covance) the Sponsor shall promptly notify all relevant Covance entities of such changes.
- 13.3 Covance agrees to Use the HBS in accordance with all applicable Regulatory Requirements.
- 13.4 Upon Sponsor’s request, Covance shall retain, return or destroy all HBS in accordance with the Informed Consent, the Sponsor’s instructions or any other specific requirements under Applicable Law and Regulatory Requirements.
- 13.5 The Sponsor acknowledges that where Covance enters into a material transfer agreement (“MTA”) with the provider of any HBS, Covance shall act in accordance with the terms of the MTA and the disposition of the relevant HBS shall be as prescribed in the MTA. In the event of a conflict between the terms of the MTA, this Agreement, any Work Order and any instructions provided by the Sponsor, the terms of the MTA shall prevail.

14. DATA PROTECTION

- 14.1 Where Covance processes any personal data on behalf of the Sponsor, Covance shall process such personal data in accordance with all applicable Data Protection Laws in the territories in which the Services are performed (“**Protected Data**”).
- 14.2 If Covance processes any Protected Data on behalf of the Sponsor, Covance and the Sponsor each agree and acknowledge that the Sponsor shall be the data controller and Covance shall be the data processor with respect to the processing of such Protected Data. Covance shall only process such Protected Data on behalf and upon the reasonable instructions of the Sponsor for purposes notified to it by the Sponsor for which consent from the relevant data subjects has been obtained in accordance with all applicable Regulatory Requirements. Covance shall follow such procedures, policies and reasonable instructions as may be agreed by the Parties from time to time.
- 14.3 Covance shall take reasonable technical and organizational measures that are necessary to protect against the unauthorized or unlawful processing of or the unauthorized or unlawful disclosure of such personal data. Covance shall promptly notify the Sponsor in the event of a security breach involving any personal data which Covance is processing on behalf of the Sponsor.
- 14.4 The Sponsor warrants that it has complied with any and all notification and information requirements under the applicable Data Protection Laws.

15. SUBCONTRACTORS

- 15.1 Notwithstanding Section 18, certain tasks, as may be agreed during the development of and specified in the Protocol, may be subcontracted by Covance to Subcontractors approved by Covance or subcontracted, or assigned and transferred to its Affiliates. Covance shall be responsible for the acts and performance of Subcontractors and Affiliates.
- 15.2 Covance shall not be responsible for the performance of third party Vendors. Liability of Covance to the Sponsor with respect to such Vendors shall be limited to the extent Covance is negligent in the performance of its obligations under this Agreement. Covance shall provide to the Sponsor any amounts that Covance may recover from such Vendors as a result of any error or service failure on the part of the Vendors in connection with this Agreement.

16. FORCE MAJEURE

- 16.1 Neither Party shall be in breach of this Agreement nor liable for delay in performing, or failure to perform, any of its obligations under this Agreement, if such delay or failure result from a Force Majeure Event. In such circumstances, any time specified for completion of performance in the Protocol falling due during or subsequent to the occurrence of a Force Majeure Event shall be automatically extended for a period of time equal to such event.
- 16.2 Should any part of the Services be rendered invalid as a result of a Force Majeure Event, Covance shall, upon written request from the Sponsor, and at the Sponsor's sole cost and expense, repeat the affected part of the Services.
- 16.3 If a Force Majeure Event prevents a Party from performing pursuant to this Agreement for a period of 180 days or more, the unaffected Party may terminate this Agreement upon written notice to the affected Party.

17. INDEPENDENT CONTRACTOR

- 17.1 The Parties agree that in performing the Services, Covance (including its employees, agents, subcontractors or other representatives) is acting as an independent contractor to Sponsor. The Parties further agree that Covance and its employees, agents, subcontractors or other representatives are not employees, agents or partners of Sponsor, and nothing in this Agreement and no actions of Sponsor in engaging Covance shall render Covance or any of its employees, agents, subcontractors or other representatives the employees, agents or partners of Sponsor. Neither Covance nor any of its employees, agents, subcontractors or other representatives will have power or authority to bind Sponsor. Neither the relationship between Covance and Sponsor nor any provision of this Agreement shall be construed to authorize Covance to take (or fail to take) any action or make (or fail to make) any decision, representation or commitment binding upon Sponsor or any of its affiliate companies. Sponsor shall at all times be free to engage other third parties to perform services in addition to or in lieu of those services being provided by the Covance. Subject to the provisions of this Agreement, Covance shall be free to devote such time that they do not spend providing Services under this Agreement to such person, firms or corporations as they may choose.

17.2 Nothing contained herein shall be construed (i) to create any association, partnership, joint venture, or relationship of principal and agent, or master and servant between the Parties or any of their affiliates or subsidiaries, employees and subcontractors, (ii) to provide any Party with the right, power or authority, either express or implied, to create any duty or obligation on behalf of another Party, (iii) to impose liability upon one Party for the act or failure to act of another Party, or (iv) to confer any right for Covance (or any of its employees, agents, subcontractors or other representatives) to participate in or be eligible to participate in any pension or welfare benefit plans, programs or arrangements of Sponsor or of its affiliate companies pertaining to any pension, stock, bonus, profit sharing or similar benefits or any employee health, life assurance, workers compensation insurance, disability, severance or any other benefit of any kind whatsoever which is associated with or customarily paid in connection with or in relation to an employment contractor.

18. ASSIGNMENT

18.1 Either Party may assign, transfer or subcontract any or all of its rights and obligations under this Agreement to its Affiliates.

18.2 Notwithstanding Section 18.1 and except in connection with an internal reorganization of the relevant Party's corporate structure, this Agreement shall not be assigned or transferred in whole or in part by either Party without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed.

19. NOTICES

19.1 All notices required to be given under this Agreement shall be in writing and shall be deemed to have been duly given if delivered personally or mailed first class, registered or certified mail, return receipt requested, postage paid:

If to Sponsor to:

inRegen
10 Market St.
#774 Camana Bay, Grand Cayman
KY 1-90006 Cayman Islands

If to Covance to:

Covance Central Laboratory Services LP
8211 SciCor Drive
Indianapolis, Indiana 46214-2985
UNITED STATES
Attention: VP, Finance

or at such other place as either Party shall hereafter furnish to the other Party in writing. Notices shall be deemed given on the date of personal delivery or deposit in the mail as specified above.

19.2 For the purposes of this Section 19, in relation to the purposes of any legal proceeding, “writing” shall not include email.

20. WAIVER

No waiver of any term, provision, or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver or estoppel of any such term, provision, or condition or of any other term, provision, or condition of this Agreement.

21. VARIATION

No provision of this Agreement may be amended, modified, varied, discharged, or terminated except by the express written agreement of both Parties and signed by an authorized representative of each Party.

22. SEVERABILITY

If any court or competent authority finds that any provision of this Agreement (or part of any provision) is invalid, illegal or unenforceable, that provision or part-provision shall, to the extent required, be deemed to be deleted, and the validity and enforceability of the other provisions of this Agreement shall not be affected. If any invalid, unenforceable or illegal provision of this Agreement would be valid, enforceable and legal if some part of it were deleted, the provision shall apply with the minimum modification necessary to make it legal, valid and enforceable.

23. PUBLICITY AND PUBLICATION

23.1 Neither Party will use the name, trademark or the name of any representative of the other, or the existence of this Agreement for any promotional or advertising purposes, or any other publication, without the prior written consent of the other.

23.2 Neither Party will state or imply that the other Party endorses or approves any service, material, product or compound of the other Party without the prior written consent of the other. Such restrictions shall not apply to internal communications and publications to a Party’s Affiliates.

23.3 Sponsor shall provide Covance with a pre-publication copy of any report, manuscript, publication or form of marketing material recognizing Covance’s participation in the Services or otherwise identifying Covance, for approval (which approval shall not be unreasonably withheld or delayed) in each case at least thirty (30) days before its submission for publication.

24. ENTIRE AGREEMENT

This Agreement represents the entire understanding between the Parties with respect to the subject matter hereof as of the Effective Date, and this Agreement supersedes all prior agreements, negotiations, understandings, representations, statements and writings between the Parties relating thereto, except that any written agreement entered into prior to the Effective Date with respect to a Study in process prior to the Effective Date shall remain effective and shall continue to govern such existing Study. The Parties agree that neither has relied upon prior representations made before executing this Agreement.

25. **LEGAL TESTIMONY**

Covance agrees to provide testimony or records regarding the Services for the Sponsor in any legal or administrative proceeding, provided that the Sponsor shall reimburse Covance for its out of pocket costs plus a reasonable hourly fee for the involvement of its employees or representatives in such proceedings.

26. **THIRD PARTY RIGHTS**

Except as expressly set forth in this Agreement in respect of Covance Affiliates, nothing in this Agreement is intended to confer any rights, benefits or remedies of any kind whatsoever, and a person who is not a party to this Agreement shall have no right to enforce any of its terms.

27. **ANTI-BRIBERY**

27.1 Both Parties agree that each has not and will not, either directly or indirectly, engage in bribery, or offer, or promise, or authorize to pay or make any improper payment of any monies or financial or other advantage, including cash, loan, gift, travel, entertainment, hospitality, facilitation payment, kickback, political or philanthropic contribution, anything of value, or any other perceived benefit to improperly obtain or retain a business advantage in violation of any Anti-Corruption Laws and further, each Party agrees that they shall not take any action that would cause the other Party to be in violation of such Anti-Corruption Laws.

27.2 Any breach of Section 27.1 by a Party shall allow the other Party to immediately terminate this Agreement.

28. **TRADE CONTROL**

28.1 Notwithstanding any other provision of this Agreement to the contrary, each Party shall comply with, and retain responsibility for its compliance with, all applicable export control laws (e.g., the U.S. Export Administration Regulations) and economic sanctions programs (e.g., economic sanctions maintained by the U.S. Treasury Department, as well as Specially Designated Nationals and Blocked Persons (SDNs)) relating to its respective business, facilities, and the provision of services to third parties (collectively, **Trade Control Laws**).

28.2 Nothing in this Agreement shall be construed to require Covance to be directly or indirectly involved in the provision of goods, software, services and/or technical data that may be prohibited by applicable Trade Control Laws, including sanctions currently in place against Cuba, Iran, North Korea, Sudan, Syria and SDNs.

29. COUNTERPARTS

This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original to this Agreement but all of which together shall constitute the same Agreement. Signatures upon this Agreement transmitted by facsimile, electronic mail or other electronic method shall have the same legal and binding effect as wet signatures.

30. CHOICE OF LAW AND DISPUTE RESOLUTION

- 30.1** This Agreement shall be governed and construed in accordance with the laws of the State of New York, U.S.A., without regard to conflicts of laws provisions.
- 30.2** Any dispute, controversy, or claim arising out of, relating to, or in connection with this Agreement, or the breach, termination, or validity thereof, shall be finally settled by arbitration. The arbitration shall be conducted in accordance with the Securities Arbitration Rules (the "Rules") of the American Arbitration Association ("AAA"), including the AAA's Procedures for Large, Complex Commercial Disputes, in effect at the time of the arbitration, except as they may be modified herein or by mutual agreement of the parties. The seat of the arbitration shall be New York, New York, and it shall be conducted in the English language. The arbitration and this clause shall be governed by Title 9 (Arbitration) of the United States Code. The Parties agree that irreparable damage may occur to a Party in the event that the other Party may fail or fails to comply with the provisions of Section 8. Accordingly, and without otherwise limiting the requirement of mandatory arbitration imposed hereunder, a Party may seek from any court having jurisdiction any interim or provisional relief (without the necessity of posting bond) that may be necessary to protect its interests under Section 8, pending the arbitral tribunal's final determination of the merits of the controversy.
- 30.3** The arbitration shall be conducted by three arbitrators. The claimant shall appoint an arbitrator in its request for arbitration. The respondent shall appoint an arbitrator within twenty (20) days of the receipt of the request for arbitration. The two arbitrators shall appoint a third arbitrator, who shall act as chair of the tribunal, within twenty (20) days after the appointment of the second arbitrator. If any of the three arbitrators is not appointed within the time prescribed above, then the AAA shall appoint that arbitrator from its National Panel of Securities Arbitrators or its Large, Complex Commercial Case Panel, not including any such members affiliated with the securities industry. The chair of the tribunal shall be a citizen of the United States.
- 30.4** In addition to the authority conferred on the arbitration tribunal by the Rules, the arbitration tribunal shall have the authority to order such production of documents, generally consistent with the discovery permitted under the Federal Rules of Civil Procedure, as may reasonably be requested by any party or by the tribunal itself. In addition, any party may request a reasonable number of depositions of party witnesses.

- 30.5** The Parties agree that the arbitration shall be kept confidential and that the existence of the proceeding and any element of it (including but not limited to any pleadings, briefs or other documents submitted or exchanged, any testimony or other oral submissions, and any awards) shall not be disclosed beyond the tribunal, the AAA, the Parties, their counsel, accountants and auditors, insurers and re-insurers, and any person or entity necessary to the conduct of the proceeding. The confidentiality obligations in this Section 28.5 shall not apply (i) if disclosure is required by Applicable Law, or in judicial or administrative proceedings, or (ii) as far as disclosure is necessary to enforce the rights arising out of the award.
- 30.6** The arbitration award shall be final and binding on the Parties. Judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party or its assets.
- 30.7** In order to facilitate the comprehensive resolution of related disputes, and upon request of any party to the arbitration proceeding, the arbitration tribunal may consolidate the arbitration proceeding with any other arbitration proceeding involving any of the Parties hereto relating to this Agreement. The arbitration tribunal shall not consolidate such arbitrations unless it determines that (i) there are issues of fact or law common to the related proceedings so that a consolidated proceeding would be more efficient than separate proceedings, and (ii) no party would be prejudiced as a result of such consolidation through undue delay or otherwise.
- 30.8** The Parties agree that any dispute arising from or in connection with this Agreement (including any non-contractual obligations) shall be referred to and finally resolved by arbitration under the Rules of the International Chamber of Commerce, which Rules shall be deemed incorporated by reference to the Agreement. The number of arbitrators shall be three (3), the seat or legal place of arbitration shall be New York and the language used in the arbitration shall be English.

[signature page follows]

IN WITNESS WHEREOF, the Parties by their duly authorized officers have executed this Agreement on the dates set forth below, to be effective on the Effective Date set forth on the first page of this Agreement.

INREGEN

Signature: /s/ Timothy A Bertram
Name: Timothy A Bertram
Title: CEO
Date: 26 June 2019

COVANCE CENTRAL LABORATORY SERVICES LP

Signature: /s/ Annabel Bower
Name: Annabel Bower
Title: Dir, Contract Mgt
Date: June 21, 2019

COVANCE CENTRAL LABORATORY SERVICES SÀRL

Signature: /s/ Monica Malcarne
Title: Geneva Site Lead and Senior Director Operations
Date: June 22, 2019

This Laboratory Service Agreement (“**Agreement**”) is made effective on the date of the last signature below (“**Effective Date**”) by and between

LABCORP CENTRAL LABORATORY SERVICES LP (formerly known as Covance Central Laboratory Services LP) an Indiana limited partnership, with its principal place of business at 8211 SciCor Drive, Indianapolis, Indiana 46214, USA; and **LABCORP CENTRAL LABORATORY SERVICES SÀRL** (formerly known as Covance Central Laboratory Services SÀRL), with its principal place of business at Rue Moise-Marchines 7, 1217 Meyrin, Geneva Switzerland (collectively “**Labcorp**”); and

ProKidney with its principal place of business located at 10 Market St., #688 Camana Bay, Grand Cayman KY1-9006 Cayman Islands (“**Sponsor**”).

(each a “**Party**” and collectively the “**Parties**”).

IT IS AGREED

1 DEFINITIONS

1.1 In this Agreement, unless the context otherwise requires, the following words and expressions shall have the following meanings:

“**Affiliate**” means any entity controlling, controlled by, or in common control with a Party. For the purposes of this definition, “**Control**” shall mean ownership or control, directly or indirectly of more than fifty percent (50%) of the common voting stock or ordinary shares in the entity or the right to appoint fifty percent (50%) or more of the directors of that entity. With respect to Labcorp, the term Affiliate shall include Laboratory Corporation of America Holdings and any business entity that is controlled by or is under common control with Laboratory Corporation of America Holdings.

“**Anti-Corruption Laws**” means any anti-bribery and anti-corruption laws, rules, regulations applicable to either Party (each as amended from time to time) together with any applicable implementing legislation including any applicable local law addressing bribery or corruption.

“**Background IP**” means all pre-existing intellectual property belonging to or licensed to a Party or other intellectual property created outside the scope of the Services.

“**Claim**” means any third party claims, demands, assessments, actions, suits, proceedings, settlements or investigations.

“**Confidential Information**” means any and all non-public information or materials and all derivatives thereof, in any and all forms, howsoever disclosed or obtained, including business plans, financial information, client lists, and requirements, techniques, designs, methods, processes and procedures, which: (i) is identified by a suitable legend or other marking as being confidential (or similar designation) in a prominent position or (ii) is described as being confidential at the time of disclosure or (iii) the disclosing Party regards or should reasonably be expected to regard as proprietary and confidential given the nature of the information.

“**Labcorp Property**” means inventions, proprietary processes, software (including codes), data, technology, know-how and other intellectual property that have been independently developed or discovered by Labcorp or its Affiliates without the use of Sponsor’s Confidential Information, including those that relate to the proprietary innovative testing procedures, laboratory testing, data collection or data management, procedural manuals, delta flags, nucleic acid based vectors, analytical procedures and approaches that are not specific for use with the Sponsor’s Background IP even if such are developed in the performance

of the Services or are captured in documents pertaining to the Services (i.e. laboratory notebooks), techniques, models, non-product specific components of questionnaires, management tools and any other materials, employed, developed or acquired by Labcorp or its Affiliates which are not specifically part of the Services.

“**Data Protection Laws**” mean all applicable privacy, data protection or similar laws and regulations anywhere in the World, as the same may be amended from time to time, including to the extent applicable to the respective Services and any applicable implementing legislation or any amendment thereto.

“**Deliverables**” means as applicable to the Services, Results, or any other deliverable specified in this Agreement.

“**Force Majeure Event**” means circumstances or causes beyond the reasonable control of a Party, including war, threat of war or warlike conditions, blockade, embargo, fire, explosion, lightning, storm, drought, flood, earthquake or other natural disaster, pandemic or epidemic, power failure, acts of terrorism, riot, civil unrest, insurrection, acts of government or other international bodies, political subdivision and any other events which by their nature could not have been foreseen by the Parties, or, if it could have been foreseen were unavoidable by a reasonable prudent business.

“**HBS Donor**” means an individual, living or deceased, from whom the HBS was obtained.

“**Human Biological Samples**” or “**HBS**” means any human biological material, including human bodily parts and organs in whole or sub-samples, any tissue, skin, bone, muscle, connective tissue, blood, cerebrospinal fluid, gametes, or sub-cellular structures such as DNA, or any derivative or product of such human biological materials, cell lines, bodily fluids, blood derivatives and urine.

“**IEC/IRB**” means an independent ethics committee or institutional review board.

“**Informed Consent**” means an IEC/IRB approved informed consent form signed by the HBS Donor authorizing the Use of their HBS.

“**Invention**” means any invention (whether or not patentable), proprietary processes, software (including codes), data, technology, know-how or other intellectual property discovered, conceived or made by Labcorp or its Affiliates specifically as a part of the Services for the Sponsor and directly relating to the Test Materials.

“**Loss**” means any loss, cost, damage or expense (including reasonable legal expenses).

“**Project**” means a Study, project or assignment between Labcorp and Sponsor.

“**Protocol**” means the document which specifies the laboratory testing procedures as written by Sponsor as applicable for the performance of a Study and is provided to Labcorp.

“**Regulatory Authority**” means any national or state or local agency, authority, department, inspectorate, minister, ministry official, parliament or public or statutory person of any government of any country having jurisdiction over either any of the activities contemplated by this Agreement or the Parties.

“**Regulatory Requirements**” means all laws, statutes, acts, rules, regulations, guidelines, codes, orders, directives or other legally binding requirements of any Regulatory Authority and industry standards or codes of conduct applicable to the Services.

“**Results**” mean materials, data, Inventions, documents and information produced or developed by Labcorp exclusively in the course of the Services and directly related to the Test Materials.

“**Services**” means the services provided by Labcorp to the Sponsor as more particularly described in this Agreement.

“**SOW**” means the scope of work, which is the primary Labcorp laboratory specification document and defines all study specific Services to be provided for a Protocol.

“**Sponsor Information**” means Test Materials, data, specification, or other materials or information supplied by the Sponsor to Labcorp in connection with the Services.

“**Study**” means a clinical trial or scientific evaluation of the Test Materials on the terms and conditions of the Protocol.

“**Subcontractor**” means a third party approved, reviewed and contracted by Labcorp for Services within the scope of this Agreement.

“**System Data**” means control data from laboratory tests or transactional, volume and performance data related to the Services, which does not contain any personally identifiable information or Sponsor Confidential Information.

“**Test Materials**” means compounds, materials or other substances as described in the Protocol to be tested or used in the performance of the Services and provided to Labcorp by the Sponsor.

“**Use**” (in the context of Section 13) means collection, storage, transfer (including import and export), use and return or disposal of HBS including by commercial organizations.

“**Vendor**” means third-party service providers other than a Subcontractor for which Labcorp may hold the contract with such service provider for the convenience or benefit of the Sponsor in connection with Services under this Agreement and as set forth in the applicable SOW.

1.2 In this Agreement, unless the context otherwise requires, references to:

(a) Schedule and Section headings are inserted for convenience only and do not affect the construction or interpretation of this Agreement;

(b) **writing** or **written** includes faxes and e-mail;

(c) a particular law or statutory provision is a reference to it as it is in force for the time being taking account of any amendments, extensions, or re-enactments and includes any subordinate legislation for the time being in force made under it;

(d) a person includes a corporate or unincorporated body;

(e) any gender includes all genders;

(f) **including, include, in particular** or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;

(g) words in the singular include the plural and vice versa.

1.3 If this Agreement is translated, the English language text shall prevail.

2 SERVICES

2.1 Labcorp through itself and/or its Affiliates hereby agrees to perform Services for Sponsor’s protocol REGEN006. Such Services shall be performed pursuant to the terms and conditions contained herein and the terms of the Protocol.

2.2 Any changes or modifications to the Protocol and/or Services provided by Labcorp, or any Sponsor request for additional Services may commence upon Labcorp’s receipt of Sponsor’s written approval of the revised SOW. Upon Sponsor’s SOW signature, Labcorp shall provide such Services to the Sponsor and the Sponsor shall pay for costs associated with such Services at its current standard rates. Labcorp reserves the right to refuse to perform any Services of Test Materials that are hazardous in nature when performed in accordance with relevant instructions and specifications, but only where such hazard was not known prior to signing the SOW.

2.3 Labcorp shall provide each investigator site with Project-related materials and documentation, including the relevant Protocol, as well as Project- and visit-specific specimen collection supplies needed to collect and ship specimens. The specimen collection kits shall also have a test requisition form or other electronic method to capture such data, for the particular Project.

2.4 Should a kit be lost through no fault of Labcorp, or should a kit expire at the investigator site, Labcorp will supply replacement kits for those that are lost, expired, or otherwise rendered unusable, at an amount equal to the price listed in the quote for Services attached hereto (“**Budget**”) per kit for the same kit/visit that is being replaced.

2.5 After performing Services, Labcorp will store the remaining Study specimens for the length of time and under storage conditions as described in the applicable SOW. The remaining specimens may subsequently be shipped to Sponsor or another party as specified in the SOW or if not specified in the SOW, held as otherwise instructed by the Sponsor. In no event shall Labcorp’s liability for any breach or default with regard to storage of an archival specimen exceed the fee it has been paid for storage of that specimen for the previous twelve (12) months.

3 TERM AND TERMINATION

3.1 The term of this Agreement shall commence on the date hereof and continue until the conclusion of the Study.

3.2 Either Party may terminate this Agreement with immediate effect by notice in writing in the event that the other Party:

(a) commits a material breach of any term of this Agreement which breach is irremediable or (if such breach is remediable) fails to remedy that breach within a period of thirty (30) days after being notified in writing to do so; or

(b) repeatedly breaches any of the terms of this Agreement in such a manner as to reasonably justify the opinion that its conduct is inconsistent with it having the intention or ability to give effect to the terms of this Agreement; or

(c) suspends, or threatens to suspend, payment of all or substantially all of its debts or is unable to pay all or substantially all of its debts as they fall due or admits in writing its inability to pay its debts or is deemed by a court of competent jurisdiction to be unable to pay its debts; or

(d) suspends, or threatens to suspend, or ceases or threatens to cease to carry on, all or substantially the whole of its business; or

(e) presents a petition or has a petition presented for its winding-up or has a receiver or an administrative receiver appointed of all or substantially all of its assets; or

(f) any event occurs, or proceeding is initiated, in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events mentioned above.

3.3 Sponsor may terminate this Agreement for any reason upon ninety (90) days prior written notice to Labcorp.

3.4 In the event of such termination, Labcorp shall be entitled to full payment for work properly performed on the Study through the date work on such Study is concluded, including, without limitation, all non-cancelable fees and other out-of-pocket expenses of Labcorp for such Study.

3.5 The termination of this Agreement shall not relieve either Party of its obligations to the other with respect to: (a) maintaining the confidentiality of Confidential Information; (b) obtaining consents for the use of names; (c) ownership of and assignment of inventions; (d) indemnification; (d) limitation of liability; (e) compensation for Services performed; (f) publications; and (g) retention of records. The provisions of this Section together with any other section which is necessary for the interpretation or enforcement of this Agreement shall survive the expiry or termination of this Agreement howsoever arising.

4 REGULATORY COMPLIANCE

4.1 Labcorp will perform its Services in accordance with the terms of this Agreement, the applicable Protocol, and all Regulatory Requirements applicable to the Project. All activities undertaken under this Agreement by Labcorp shall comply in all material respects with College of American Pathologists (CAP) rules. Labcorp represents that it has and shall maintain Clinical Laboratory Improvement Act (CLIA) certification. This Agreement shall contain all the conditions under which Labcorp will provide clinical laboratory Services. Labcorp makes no other express or implied commitments or warranties concerning the performance of the Study.

4.2 In the event that compliance with any new Regulatory Requirements necessitates a change in this Agreement, Labcorp will submit to Sponsor a revised technical and cost proposal for Sponsor's acceptance prior to performing Services.

4.3 In the event of a material conflict in applicable Regulatory Requirements, the Sponsor will designate which regulations shall be followed by Labcorp in its performance of the Services and the Sponsor shall be fully responsible, to the extent permitted by law, for the outcome of such a decision.

5 FEES, BILLING AND TAXES

5.1 Fees for the Project are set forth in the attached Budget. Sponsor acknowledges that SOW finalization, changes and/or modifications to the Project may result in a revised Budget. The Budget contains all the applicable discounts and Services that will be provided for that Project.

5.2 During performance of Services, Labcorp may be required to provide certain items including but not limited to ancillary supplies, logistics and minor modifications to database design ("**Items**"). Items may not appear in Sponsor's Budget and will require written approval from Sponsor prior to the commencement of work on said items. Total fees for these items will be capped at \$150,000. Sponsor agrees to remit payment for Items invoiced in accordance with payment terms provided in Section 5.4.

5.3 Upon execution, Labcorp will assess a fee equal to five per cent (5%) of the value of the contract Budget (**Deposit**). Sponsor will pay the Deposit within thirty (30) calendar days after receipt of invoice.

5.4 Each month, Labcorp will invoice Sponsor for all fees due and expenses incurred while providing Services during the previous month. Payment is due thirty (30) calendar days from invoice receipt. Payments not received within five business days of Labcorp's notice to Sponsor of non-payment may be subject to a fifteen per cent (15%) per annum late payment fee.

5.5 Labcorp shall retain the Deposit until the Study invoices have reached ninety-five percent (95%) of the total Study Budget at which point the Deposit will be applied to monthly invoices. At the end of each Study, Labcorp shall conduct a final account reconciliation and will refund to Sponsor any remaining amounts of the Deposit within sixty (60) days after the date of the final invoice.

5.6 For budgeting purposes, Labcorp creates the Budget using local unit pricing. The local unit pricing is then converted to the billing currency, as requested by Sponsor, using the Reuters exchange rate for the month the Budget is first created. Unless specified otherwise, this exchange rate remains unchanged during the course of the Study to simplify budget comparisons and enable Sponsor to track changes to the Study unrelated to changes in currency exchange rates.

5.7 For invoicing purposes, Services are billed based on the contracted local unit prices. Each month, at the time of invoice creation, the local unit prices are converted to the billing currency using the Reuters exchange rate for the month in which the Services were performed.

5.8 Labcorp will hold prices unchanged for twelve (12) months from Project start up. Thereafter, fees may be adjusted annually by Labcorp upon thirty (30) days written notice to Sponsor.

5.9 Invoices will be provided by Labcorp to: ProKidney Accounts Payable payables@ProKidney.com

5.10 Payment shall be made from Sponsor to Labcorp as follows:

Payment by Check:

Labcorp Central Laboratory Services, Inc.
P.O. Box 2484
Burlington, NC 27216

Payment by Bank Transfer:

Labcorp Central Laboratory Services, Inc.
Wells Fargo Bank, N.A
420 Montgomery, San Francisco, CA 94104
Routing Transit Number/ABA: 121000248
Account Number: 4244842191
SWIFT: WFBIUS6S

5.11 If a dispute arises between the Parties in respect of any part of an invoice, and unless otherwise agreed in a Work Order, Sponsor (i) must pay all undisputed parts of the invoice when due; (ii) must notify Labcorp in writing of the particulars of the dispute within fifteen (15) business days of receipt of the invoice; and (iii) may withhold payment of the disputed part of the invoice, provided that Sponsor endeavors promptly and in good faith to resolve the dispute pursuant to Section 30. If Sponsor fails to pay the amount of any undisputed invoice or part of an invoice within the time prescribed in Section 5.4, five (5) business days after giving Sponsor written notice after providing Sponsor, Labcorp may charge interest on any such amount at the rate of one and one half percent (1.5%) per month, or the maximum rate allowed by Applicable Law if lower, will accrue from the date the payment was originally due until the date of payment, and (b) five (5) business days after giving Sponsor written notice that undisputed amounts are due, Labcorp may elect to suspend work on a Study or to withhold Deliverables, reports or other material in respect of a Study for so long as Sponsor fails to pay such undisputed amounts until such undisputed amounts are paid. If Sponsor requests a material change to the Project at any time which would affect the Services, Labcorp will notify Sponsor of the new proposed budget amount and, if approved and agreed to by Sponsor, Labcorp will revise fees to reflect the change in the SOW and Budget.

5.12 Upon written notification by Sponsor that the Study has been concluded or upon completion of all Services required by Labcorp under this Agreement, Labcorp will issue a final invoice for Services rendered to identify amounts due to Labcorp or refund due to Sponsor.

5.13 Fees payable under this Agreement shall not include local, state, federal or foreign sales or use taxes, excise taxes, goods and services tax, value added tax or consumption taxes, as applicable. Any applicable taxes will be billed to and paid by Sponsor without deduction to amounts owed to Labcorp.

6 SITE VISITS

6.1 The Sponsor or its representative (which shall not be a competitor of Labcorp) may visit Labcorp's premises where the Services are being performed at reasonable times, on reasonable notice and with reasonable frequency during normal business hours to observe the progress of the Services. Labcorp will assist the Sponsor in scheduling such visits.

6.2 The Sponsor acknowledges that the Sponsor's representatives granted access to Labcorp facilities during any such visits may have access to confidential and proprietary information of Labcorp. The Sponsor agrees that all such confidential and proprietary information of Labcorp obtained

or observed by the Sponsor during such visits shall remain the sole property of Labcorp and the Sponsor shall treat such information as Confidential Information in accordance with Section 8 of this Agreement.

7 REGULATORY INSPECTIONS AND AUDITS

7.1 In the event of a Party receiving a notice from a Regulatory Authority which directly relates to the Services, the Party receiving such notice shall promptly notify the other Party or forward to the other Party a copy of such notice (or extract thereof). Each Party will cooperate with the other in responding to such notice before referring to the other Party in any regulatory correspondence or disclosing any Confidential Information to a Regulatory Authority. However, each Party acknowledges that it may not direct the manner in which the other Party fulfils its obligations to permit inspection by Regulatory Authorities.

7.2 Labcorp shall cooperate with any inspection or audit by a Regulatory Authority and shall notify the Sponsor promptly of any request by a Regulatory Authority.

7.3 Labcorp agrees that, during an inspection or audit by a Regulatory Authority concerning the Services, it will not disclose information and materials that are not required to be disclosed to such Regulatory Authority, without the prior written consent of the Sponsor.

7.4 If any inspections or audits conducted pursuant to this Section 7 that result in a finding that Labcorp has failed to comply with the terms of this Agreement, Labcorp shall promptly take such measures at its own cost and expense as are necessary to correct such defaults.

7.5 It is agreed that where any audit of Labcorp concerns or relates to referral laboratory testing or shipping methods of Labcorp, the Sponsor or its representative (which shall not be a competitor of Labcorp) may only confirm or not if Labcorp is properly billing such costs. The Sponsor expressly agrees that Sponsor's representatives may not directly or indirectly provide any details of the charges to the Sponsor, such as the actual amount of the referral laboratory testing or shipping costs incurred by Labcorp.

8 CONFIDENTIAL INFORMATION

8.1 Each Party agrees that all Confidential Information of the disclosing Party is and shall be the sole property of the disclosing Party.

8.2 Without prejudice to any Labcorp Property, all Results, Inventions, data and records developed by Labcorp or its Affiliates specifically from the performance of the Services shall be the Confidential Information of the Sponsor.

8.3 Each Party agrees to hold the Confidential Information of the other Party in confidence and in a manner consistent with the way in which it maintains the confidentiality of its own proprietary information, being at least a reasonable standard of care. Each Party shall disclose the Confidential Information only on a need-to-know basis, to its employees, officers, directors, representatives and third-party investigators and who are bound to retain the Confidential Information in confidence.

8.4 Each Party agrees that, except as necessary to fulfil its obligations under this Agreement, it will not use or disclose to any third party any of the Confidential Information.

8.5 The obligations of non-use and non-disclosure shall not apply to Confidential Information that the receiving Party can show:

(a) was, or becomes, publicly known through no fault of the receiving Party; or

(b) was lawfully obtained from a third party without restriction as to its use or disclosure; or

(c) was already in the possession of the receiving Party prior to disclosure as shown by the receiving Party's written records; or

(d) was independently developed by the receiving Party without the benefit of the Confidential Information as shown by the receiving Party's contemporaneous written records; or

(e) is required for Sponsor's pursuit of registration of a product connected with the Services with a government agency.

8.6 The receiving Party shall be entitled to disclose Confidential Information to the extent required by any law, rule, regulation, order, decree or subpoena, except that the receiving Party shall, unless restricted by law or where not practicable, promptly notify the other Party of such requirement prior to the disclosure and shall cooperate with the disclosing Party to seek to oppose, minimize or obtain the confidential treatment of the requested disclosure to the extent of such order.

8.7 The obligations in this Section 8 shall remain in full force and effect for a period of **seven (7) years** following termination of this Agreement except with respect to Confidential Information which is considered a trade secret under applicable law, which shall remain confidential as long as such Confidential Information retains its status as a trade secret. Labcorp shall not disclose any trade secret to Sponsor.

8.8 In the event of actual or threatened breach or violation of this Section 8, the disclosing Party shall have the right to seek injunctive relief in any court of competent jurisdiction.

9 INTELLECTUAL PROPERTY RIGHTS

9.1 All Background IP is and shall remain the exclusive property of the Party owning it and except as expressly provided in this Agreement, no Party shall acquire any rights in or to the Background IP of the other Party.

9.2 The Sponsor acknowledges that Labcorp Property is owned or licensed by Labcorp or its Affiliates. The Parties agree that any improvement, enhancement or modification made, conceived or developed by Labcorp to any Labcorp Property in the performance of the Services which is not (i) specific or related directly to the Test Materials, or (ii) an Invention, shall be deemed Labcorp Property and shall vest absolutely and exclusively in Labcorp. In addition, subject to Sections 8 and 9 of this Agreement, Labcorp and its Affiliates shall be entitled to use and exploit any skills, techniques or know-how acquired, developed or used in the course of the Services. Strategic insight and proposed Project design and scope provided in any quotation by Labcorp shall remain the property of Labcorp and may be used by the Sponsor only to assess whether it wishes to pursue such work with Labcorp.

9.3 Without prejudice to Sections 9.1 and 9.2, and upon receipt by Labcorp of payment in full of all amounts due and payable under this Agreement, the Sponsor will have title to the Deliverables and all intellectual property rights arising

therefrom. Labcorp agrees to assign such rights to the Sponsor except that one (1) copy of the Results may be retained by Labcorp for regulatory or legal compliance purposes. Labcorp hereby grants to Sponsor a non-exclusive, worldwide, transferrable, perpetual, royalty-free license to use any Labcorp Background IP incorporated or included in the Deliverables for the sole purpose of and to the extent necessary to use, incorporate or explain any Deliverable (without modification), and for obtaining regulatory approvals in connection with such Deliverable. In no event shall Sponsor use or distribute Labcorp Background IP on a stand-alone basis, separate from the Deliverables. Notwithstanding the foregoing, the Sponsor hereby grants Labcorp an unrestricted, royalty-free license to aggregate and use any System Data produced by or for Labcorp as part of the Services with other System Data owned or licensed by Labcorp provided that Labcorp shall not identify such data as belonging to the Sponsor and Sponsor is not identifiable through such aggregated data.

9.4 Without prejudice to Sections 9.1 and 9.2, Labcorp shall promptly disclose to the Sponsor (or its nominee) all Inventions and hereby assigns and agrees to assign to the Sponsor (or its nominee) the rights to such Inventions and shall do all acts that are reasonably necessary to vest the Inventions in the name of the Sponsor (or its nominee).

Where an Invention is a laboratory testing method, or other laboratory processes used by Labcorp in the performance of its laboratory testing services, the Sponsor hereby agrees to grant to Labcorp and its Affiliates a non-exclusive, non-transferable, irrevocable, perpetual, royalty-free, worldwide license to use the Invention solely to perform its laboratory testing services, in each case subject to Section 8.

10 REMEDIES AND LIMITATION OF LIABILITY

10.1 In the event of a material error by Labcorp that prevents proper performance under this Agreement or which renders the Services in whole or in part unacceptable to a Regulatory Authority to which the Sponsor intends to submit the Results, Labcorp's sole obligation to Sponsor shall be for Labcorp, in agreement with the Sponsor, to either: (a) repeat the defective part of the Services at Labcorp's own cost; or (b) refund to the Sponsor the amount paid for the defective part of the Services.

10.2 Labcorp's total liability to the Sponsor, whether in contract, tort (including negligence) or otherwise, shall in no circumstances exceed the total price paid by the Sponsor for the Services that are the subject of this Agreement.

10.3 Nothing in this Agreement excludes or limits the liability of either Party where liability cannot be excluded or restricted as a matter of law.

10.4 Except for any liability resulting from any breach of Section 8 or indemnification obligation pursuant to Section 11, Labcorp will not be liable to the Sponsor for any Loss in respect of any (a) loss of profit, opportunity, business, or goodwill (in each case whether direct or indirect); or (b) any indirect, consequential, punitive, exemplary or special damages or losses, arising under or in connection with this Agreement, and each type of loss arising under this Section 10.4 shall be severable in accordance with Section 22 of this Agreement. To the extent that Labcorp agrees to perform Services for Sponsor Affiliates, Labcorp shall only be liable to the entity named in this Agreement and not for multiple claims by Sponsor Affiliates.

10.5 Labcorp shall not be liable for any failure, error or delay in performing the Services if such failure, error or delay is caused by Sponsor, or is a result of an express instruction from Sponsor or a change in Sponsor Information.

10.6 Labcorp shall have no liability to Sponsor for loss, damage, delay or non-delivery/non-collection of any samples or shipment dispatched by Labcorp to Sponsor or to any third party designated by Sponsor in connection with the Services that are caused by the acts or omissions of any third party delivery services or carrier (“**Carrier**”). Notwithstanding the foregoing, to the extent permitted by law, Labcorp shall have the benefit of any right or remedy permitted under international or domestic law and any sums recoverable from a Carrier shall be paid to the Sponsor. For the avoidance of doubt, a Carrier is not considered a Subcontractor for the purposes of this Agreement.

11 INDEMNITIES

11.1 The Sponsor shall defend, indemnify, and hold harmless Labcorp and its respective Affiliates and their respective officers, directors, employees and agents (“**Labcorp Group**”) from any Loss resulting from any Claim arising from or related to, directly or indirectly:

(a) personal injury to a participant in the Study or personal injury to any employee within the Labcorp Group directly or indirectly caused by the Test Material;

(b) Labcorp’s proper execution and/or proper performance of its obligations under this Agreement;

(c) the Sponsor’s use of the Results or Deliverables or its use or marketing of any substance tested in association with the Study by Labcorp;

(d) the negligence or intentional misconduct of the Sponsor;

(e) the Test Material’s harmful or otherwise unsafe effects, including, without limitation, a Claim based upon Sponsors or any other person’s use, consumption, sale, distribution or marketing of any substance tested in association with the Study; or

(f) the infringement, unlawful disclosure or misappropriation of copyright, patent, trade secret or other intellectual property of a third party by reason of the proper performance of the Services using the Sponsor Information, provided that if such Loss or Claim arises in whole or in part from Labcorp’s negligence or intentional misconduct, then the amount of such Loss that Sponsor shall indemnify the appropriate person or entity within the Labcorp Group pursuant to this Section 11 shall be reduced by an amount in proportion to the percentage of Labcorp’s responsibilities for such Loss as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the Parties.

11.2 Labcorp shall defend, indemnify and hold harmless the Sponsor and its Affiliates and their respective officers, directors and employees (the “**Sponsor Group**”) from any Loss resulting from any Claim arising from or associated directly with, a breach of this Agreement by Labcorp, or the negligence or intentional misconduct of Labcorp, provided that if such Losses or Claims arise in whole, or in part, from the Sponsors Group’s negligence or intentional misconduct, then the amount of such Losses that Labcorp shall be responsible for pursuant to this Section 11 shall be reduced by an amount in proportion to the percentage of the Sponsor

Group’s responsibilities for such Losses as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the Parties.

11.3 An indemnitee entitled to indemnification under Section 11 (“**Indemnified Party**”) shall give written notice to the other Party (“**Indemnifying Party**”) of a claim or other circumstances likely to give rise to a request for indemnification, promptly after the Indemnified Party becomes aware of the same. The Indemnifying Party shall be afforded the opportunity to undertake the defense of, and, subject to Section 11.5, to settle by compromise, or otherwise, any claim for which indemnification is available under this Section.

11.4 If the Indemnifying Party assumes the defense of any claim, the Indemnified Party may participate in such defense with legal counsel of its selection and at its expense. If the Indemnifying Party fails to promptly assume the defense of a claim by the Indemnified Party under this Section 11, the Indemnified Party may thereupon undertake the defense on behalf of, at the risk and expense of the Indemnifying Party with all reasonable costs and expenses of such defense to be paid by the Indemnifying Party.

11.5 In the event that the Indemnified Party assumes the defense of any claim, no compromise or settlement of any such claim shall be made without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld or delayed.

12 INSURANCE

12.1 Labcorp shall secure and maintain in full force and effect through the performance of the Services the necessary insurance coverage in amounts appropriate to the conduct of Labcorp’s business. Certificates evidencing such insurance will be made available for examination upon written request by Sponsor.

12.2 Sponsor hereby represents and warrants that it maintains or shall maintain adequate clinical trial and product liability insurance coverage consistent with industry standards and in compliance with all applicable laws, rules and regulations. Certificates evidencing such insurance will be made available for examination upon written request by Labcorp.

13 HUMAN BIOLOGICAL SAMPLES

13.1 Where the Sponsor supplies HBS to Labcorp, the Sponsor represents and warrants that:

(a) all HBS supplied under this Agreement are or have been procured and supplied to Labcorp ethically in full compliance with any and all applicable national laws, regulations, or codes of practice relating to the Use of HBS providing protection for human subjects in the country of origin;

(b) the HBS Donor has given Informed Consent;

(c) all HBS will be supplied to Labcorp without any information or data that identifies the HBS Donor; and

(d) all HBS supplied to Labcorp: (i) may be Used for the Services; (ii) may be used to provide data in support of commercial product development; and (iii) were procured without inappropriate financial benefit to the HBS Donor.

13.2 The Sponsor shall: (a) upon request, provide a copy of the relevant Informed Consent template; (b) upon request, provide adequate evidence that the HBS provided to Labcorp has completed the necessary submissions, approvals and

registrations required to be made to any applicable Regulatory Authority and (c) ensure any HBS shall be de-identified or 'coded' according to applicable Regulatory Requirements to protect the identity and confidentiality of the HBS Donor. Full date of birth of the HBS Donor shall only be collected if medically relevant to the Services (unless legally restricted in the country of operation). In the event of a withdrawal of, or a material variation to the Informed Consent that is likely to affect the Services provided by Labcorp, the Sponsor shall promptly notify all relevant Labcorp entities of such changes.

13.3 Upon Sponsor's request, Labcorp shall retain, return or destroy all HBS in accordance with the Informed Consent, the Sponsor's instructions or any other specific requirements under applicable national law.

13.4 The Sponsor acknowledges that where Labcorp enters into a material transfer agreement ("MTA") with the provider of any HBS, Labcorp shall act in accordance with the terms of the MTA and the disposition of the relevant HBS shall be as prescribed in the MTA. In the event of a conflict between the terms of the MTA, this Agreement and any instructions provided by the Sponsor with regard to handling HBS, the terms of the MTA shall prevail.

14 DATA PROTECTION

14.1 Where Labcorp processes any personal data on behalf of the Sponsor, Labcorp shall process such personal data in accordance with all applicable Data Protection Laws in the territories in which the Services are performed ("Protected Data").

14.2 If Labcorp processes any Protected Data of Data Subject(s) who are in the European Union ("EU") on behalf of the Sponsor, Labcorp and the Sponsor each agree and acknowledge that the Sponsor shall be the data controller and Labcorp shall be the data processor, as defined by the General Data Protection Regulation (Regulation (EU) 2016/679) ("GDPR"), with respect to the processing of such Protected Data. Labcorp shall only process such Protected Data on behalf and upon the reasonable instructions of the Sponsor for purposes notified to it by the Sponsor under this Agreement, including the Data Processing Agreement annexed to it as Appendix A.

15 SUBCONTRACTORS

15.1 Notwithstanding Section 18, certain tasks, as may be agreed during the development of and specified in the Protocol, may be subcontracted by Labcorp to Subcontractors approved by Labcorp or subcontracted, or assigned and transferred to its Affiliates. Labcorp shall be responsible for the performance of Subcontractors and Affiliates.

15.2 Labcorp shall not be responsible for the performance of third-party Vendors. Liability of Labcorp to the Sponsor with respect to such Vendors shall be limited to the extent Labcorp is negligent in the performance of its obligations under this Agreement. Labcorp shall provide to the Sponsor any amounts that Labcorp may recover from such Vendors as a result of any error or service failure on the part of the Vendors in connection with this Agreement.

16 FORCE MAJEURE

16.1 Neither Party shall be in breach of this Agreement nor liable for delay in performing, or failure to perform, any of its obligations under this Agreement, if such delay or failure result from a Force Majeure Event. In such circumstances, any

time specified for completion of performance in the Protocol falling due during or subsequent to the occurrence of a Force Majeure Event shall be automatically extended for a period of time equal to such event.

16.2 Should any part of the Services be rendered invalid as a result of a Force Majeure Event, Labcorp shall, upon written request from the Sponsor, and at the Sponsor's sole cost and expense, repeat the affected part of the Services, or if Labcorp is unable to re-perform, Sponsor will not be obligated to pay for the affected Services.

17 INDEPENDENT CONTRACTOR

Labcorp and/or its Affiliates shall perform their duties as an independent contractor and shall have complete and exclusive control over its employees and agents. Labcorp will have no authority to bind or commit the Sponsor in any manner whatsoever and will not, at any time, hold itself out to third parties as having authority to enter into or incur any commitments, expenses, liabilities or obligations or any nature on behalf of the Sponsor, except pursuant to this Agreement.

18 ASSIGNMENT

18.1 Labcorp may subcontract any or all of its obligations under this Agreement to its Affiliates as indicated in the Budget.

18.2 Notwithstanding Section 18.1 and except in connection with an internal reorganization of the relevant Party's corporate structure, this Agreement shall not be assigned in whole or in part by either Party without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed.

19 NOTICES

19.1 All notices required to be given under this Agreement shall be in writing and shall be deemed to have been duly given if delivered personally or mailed first class, registered or certified mail, return receipt requested, postage paid:

If to Sponsor to:

ProKidney
8020 Arco Corporate Drive, Ste 118
Raleigh, NC 27617
Attention: Ashley Johns, VP, Clinical Operations

If to Labcorp to:

Labcorp Central Laboratory Services LP
8211 SciCor Drive
Indianapolis, Indiana 46214-2985
UNITED STATES
Attention: VP, Finance

or at such other place as either Party shall hereafter furnish to the other Party in writing. Notices shall be deemed given on the date of personal delivery or deposit in the mail as specified above.

19.2 For the purposes of this Section 19, in relation to the purposes of any legal proceeding, "writing" shall not include email.

20 WAIVER

No waiver of any term, provision, or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver or estoppel of any such term, provision, or condition or of any other term, provision, or condition of this Agreement.

21 VARIATION

No provision of this Agreement may be amended, modified, varied, discharged, or terminated except by the express written agreement of both Parties and signed by an authorized representative of each Party.

22 SEVERABILITY

If any court or competent authority finds that any provision of this Agreement (or part of any provision) is invalid, illegal or unenforceable, that provision or part-provision shall, to the extent required, be deemed to be deleted, and the validity and enforceability of the other provisions of this Agreement shall not be affected. If any invalid, unenforceable or illegal provision of this Agreement would be valid, enforceable and legal if some part of it were deleted, the provision shall apply with the minimum modification necessary to make it legal, valid and enforceable.

23 PUBLICITY AND PUBLICATION

23.1 Neither Party will use the name, trademark or the name of any representative of the other, or the existence of this Agreement for any promotional or advertising purposes, or any other publication, without the prior written consent of the other.

23.2 Neither Party will state or imply that the other Party endorses or approves any service, material, product or compound of the other Party without the prior written consent of the other. Such restrictions shall not apply to internal communications and publications to a Party's Affiliates.

23.3 Sponsor shall provide Labcorp with a pre-publication copy of any report, manuscript, publication or form of marketing material recognizing Labcorp's participation in the Services or otherwise identifying Labcorp, for approval (which approval shall not be unreasonably withheld or delayed) in each case at least thirty (30) days before its submission for publication.

24 ENTIRE AGREEMENT

This Agreement represents the entire understanding between the Parties with respect to the subject matter hereof as of the Effective Date, and this Agreement supersedes all prior agreements, negotiations, understandings, representations, statements and writings between the Parties relating thereto, except that any written agreement entered into prior to the Effective Date with respect to a Study in process prior to the Effective Date shall remain effective and shall continue to govern such existing Study. The Parties agree that neither has relied upon prior representations made before executing this Agreement.

25 LEGAL TESTIMONY

If Labcorp is obliged to provide testimony or records regarding the Services for the Sponsor in any legal or administrative proceeding, then the Sponsor shall reimburse Labcorp for its out of pocket costs plus a reasonable hourly fee for the involvement of its employees or representatives in such proceedings.

26 THIRD PARTY RIGHTS

Except as expressly set forth in this Agreement in respect of Labcorp Affiliates, nothing in this Agreement is intended to confer any rights, benefits or remedies of any kind whatsoever, and a person who is not a party to this Agreement shall have no right to enforce any of its terms.

27 ANTI-BRIBERY

27.1 Both Parties agree that each has not and will not, either directly or indirectly, engage in bribery, or offer, or promise, or authorize to pay or make any improper payment of any monies or financial or other advantage, including cash, loan, gift, travel, entertainment, hospitality, facilitation payment, kickback, political or philanthropic contribution, anything of value, or any other perceived benefit to improperly obtain or retain a business advantage in violation of any Anti-Corruption Laws and further, each Party agrees that they shall not take any action that would cause the other Party to be in violation of such Anti-Corruption Laws.

27.2 Any breach of Section 27.1 by a Party shall allow the other Party to immediately terminate this Agreement.

28 TRADE CONTROL

28.1 Notwithstanding any other provision of this Agreement to the contrary, each Party shall comply with, and retain responsibility for its compliance with, all applicable export control laws (e.g., the U.S. Export Administration Regulations) and economic sanctions programs (e.g., economic sanctions maintained by the U.S. Treasury Department, as well as Specially Designated Nationals and Blocked Persons ("SDNs")) relating to its respective business, facilities, and the provision of services to third parties (collectively, "Trade Control Laws").

28.2 It shall be in the sole discretion of Labcorp to refrain from being directly or indirectly involved in the provision of goods, software, services and/or technical data that may be prohibited by applicable Trade Control Laws, including sanctions currently in place against Cuba, Iran, North Korea, Sudan, Syria and SDNs.

29 COUNTERPARTS

This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original to this Agreement but all of which together shall constitute the same Agreement. Signatures upon this Agreement transmitted by facsimile, electronic mail or other electronic method shall have the same legal and binding effect as wet signatures.

30 CHOICE OF LAW AND JURISDICTION

30.1 This Agreement will be governed by the laws of Delaware excluding its conflict of law provisions. The application of the United Nations Convention on Contracts for the International Sale of Goods is expressly excluded from this Agreement. The Parties irrevocably agree that any dispute or claim arising out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims) shall be governed by the exclusive jurisdiction of the courts of the state of Delaware.

30.2 The Parties agree that any dispute arising from or in connection with this Agreement (including any non-contractual obligations) shall be referred to and finally resolved by arbitration under the Rules of the New York which Rules shall be deemed incorporated by reference to the Agreement. The number of arbitrators shall be three (3), the seat or legal place of arbitration shall be New York and the language used in the arbitration shall be English.

IN WITNESS WHEREOF, the Parties by their duly authorized officers have executed this Agreement on the dates set forth below, to be effective on the Effective Date set forth on the first page of this Agreement.

PROKIDNEY

Signature: /s/ Pablo Legorreta

Name: Pablo Legorreta

Date: September 15, 2021

LABCORP CENTRAL LABORATORY SERVICES LP

Signature: /s/ Kristine Needle

Name: Kristine Needle

Date: September 16, 2021

LABCORP CENTRAL LABORATORY SERVICES SÀRL

Signature: /s/ Kristine Needle

Name: Kristine Needle

Date: September 16, 2021

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the inclusion in this Registration Statement of ProKidney Corp. (f/k/a Social Capital Suvretta Holdings Corp. III) on Form S-1 of our report dated March 23, 2022, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the financial statements of ProKidney Corp. (f/k/a Social Capital Suvretta Holdings Corp. III) as of December 31, 2021 and for the period from February 25, 2021 (inception) through December 31, 2021, which report appears in the Prospectus, which is part of this Registration Statement. We were dismissed as auditors on July 15, 2022 and, accordingly, we have not performed any audit or review procedures with respect to any financial statements appearing in such Prospectus for the periods after the date of our dismissal. We also consent to the reference to our Firm under the heading "Experts" in such Prospectus.

/s/ Marcum LLP

Marcum LLP
New York, NY
August 8, 2022

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated April 11, 2022, with respect to the consolidated financial statements of ProKidney LP included in the Registration Statement (Form S-1) and related Prospectus of ProKidney Corp. for the registration of up to 232,530,000 shares of its Class A ordinary shares.

/s/ Ernst & Young LLP

Raleigh, North Carolina
August 8, 2022

Calculation of Filing Fee Table

Form S-1
(Form Type)

ProKidney Corp.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

Title of Each Class of Security to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price per Security	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Class A ordinary shares, par value \$0.0001 per share	232,530,000(2)	\$8.68(3)	\$2,018,360,400.00	\$187,102.01

- (1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), the registrant is also registering an indeterminate number of additional Class A common ordinary shares that may become issuable as a result of any stock dividend, stock split, recapitalization or other similar transaction.
- (2) Consists of (i) 50,000 Class A ordinary shares, par value \$0.0001 per share, of the Registrant, collectively held by certain holders of the Registrant's securities (the "Holders") party to that certain Amended and Restated Registration Rights Agreement, dated as of July 11, 2022, by and among the Registrant, SCS Sponsor III LLC, and the Holders (the "Amended and Restated Registration Rights Agreement"), their permitted transferees and certain Additional Holders (as defined in the Amended and Restated Registration Rights Agreement); (ii) 180,000,000 Class A ordinary shares issued or issuable pursuant to that certain Exchange Agreement, dated as of July 11, 2022, by and among the Registrant, ProKidney LP, and certain holders of the Company's securities party thereto; and (iii) 52,480,000 Class A ordinary shares purchased by certain investors at a purchase price of \$10.00 per share, pursuant to subscription agreements with the Registrant.
- (3) Pursuant to Rule 457(c) under the Securities Act, and solely for the purpose of calculating the registration fee, the proposed maximum offering price per share is \$8.68, which is the average of the high and low prices of the Class A ordinary shares on August 3, 2022 on the Nasdaq Capital Market.