UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 3, 2024

PROKIDNEY CORP.

(Exact name of Registrant as Specified in Its Charter)

Cayman Islands	**001-40560**	**98-1586514**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
2000 Frontis Plaza Blvd. Suite 250 Winston-Salem, North Carolina **(Address of Principal Executive Offices)**		**27103** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 336 999-7019

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Class A ordinary shares, $0.0001 par value per share	PROK	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

ProKidney Corp. (the "Company") has updated its investor presentation (the "Presentation"), which its senior management intends to use from time to time when interacting with investors and analysts, among others. The Presentation is available on the Company's website at https://investors.prokidney.com/news-events/events-and-presentations. The Presentation is also attached hereto as Exhibit 99.1.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in this Item 7.01 and Exhibit 99.1 of this report will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this Item 7.01 and Exhibit 99.1 is not intended to, and does not, constitute a determination or admission by the Company that the information in this report is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company or any of its affiliates.

Item 8.01 Other Events.

On September 3, 2024, the Company issued a press release announcing strategic updates to its Phase 3 program for rilparencel, an investigational treatment to potentially preserve kidney function in patients with type 2 diabetes and advanced chronic kidney disease. A copy of the press release is filed as Exhibit 99.2 hereto and incorporated herein by reference.

The disclosure in this report and the incorporated exhibits contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. The Company's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "continue," and similar expressions (or the negative versions of such words or expressions) are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, the Company's beliefs that (i) rilparencel is eligible for initial FDA approval under an expedited approval pathway based upon the successful completion of the Phase 3 REGEN-006 (PROACT 1) trial, (ii) the Phase 3 REGEN-016 (PROACT 2) trial is not required for initial U.S. registration, and (iii) the revised Phase 3 program will accelerate estimated topline data readout and deliver topline results by Q3 2027, expectations with respect to financial results and expected cash runway, including the Company's expectation that current cash will support operating plans into Q1 2027, future performance, development and commercialization of products, if approved, the potential benefits and impact of the Company's products, if approved, potential regulatory approvals, the size and potential growth of current or future markets for the Company's products, if approved, the advancement of the Company's development programs into and through the clinic and the expected timing for reporting data, the making of regulatory filings or achieving other milestones related to the Company's product candidates, and the advancement and funding of the Company's developmental programs generally. Most of these factors are outside of the Company's control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the inability to maintain the listing of the Company's Class A ordinary shares on the Nasdaq; the inability to implement business plans, forecasts, and other expectations or identify and realize additional opportunities, which may be affected by, among other things, competition and the ability of the Company to grow and manage growth profitably and retain its key employees; the risk of downturns and a changing regulatory landscape in the highly competitive biotechnology industry; the risk that results of the Company's clinical trials may not support approval; the risk that the FDA could require additional studies before approving the Company's drug candidates; the inability of the Company to raise financing in the future; the inability of the Company to obtain and maintain regulatory clearance or approval for its products, and any related restrictions and limitations of any cleared or approved product; the inability of the Company to identify, in-license or acquire additional technology; the inability of Company to compete with other companies currently marketing or engaged in the biologics market and in the area of treatment of kidney diseases; the size and growth potential of the markets for the Company's products, if approved, and its ability to serve those markets, either alone or in partnership with others; the Company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing; the Company's financial performance; the Company's intellectual property rights; uncertainties inherent in cell therapy research and development, including the actual time it takes to initiate and complete clinical studies and the timing and content of decisions made by regulatory authorities; the fact that interim results from our clinical programs may not be indicative of future results; the impact of geo-political conflict on the Company's business; and other risks and uncertainties included under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. The Company cautions readers that the foregoing list of factors is not exclusive and cautions readers not to place undue reliance upon any forward-looking statements, which speak only as of the date made. The Company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Investor Presentation
99.2	Press Release dated September 3, 2024
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROKIDNEY CORP.

Date: September 3, 2024

By: /s/ James Coulston

Name: James Coulston
Title: Chief Financial Officer

Exhibit 99.1

PROKIDNEY

Developing Solutions for Dialysis Prevention

Corporate Presentation

September 2024

Forward-looking Statements

This presentation includes “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. ProKidney’s actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as “expect,” “estimate,” “project,” “budget,” “forecast,” “anticipate,” “intend,” “plan,” “may,” “will,” “could,” “should,” “believes,” “predicts,” “potential,” “continue,” and similar expressions (or the negative versions of such words or expressions) are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, the Company’s expectations with respect to financial results, future performance, development and commercialization of products, if approved, the potential benefits and impact of the Company’s products, if approved, potential regulatory approvals, and the size and potential growth of current or future markets for the Company’s products, if approved. Most of these factors are outside of the Company’s control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the inability to maintain the listing of the Company’s Class A ordinary shares on the Nasdaq; the inability to implement business plans, forecasts, and other expectations or identify and realize additional opportunities, which may be affected by, among other things, competition and the ability of the Company to grow and manage growth profitably and retain its key employees; the risk of downturns and a changing regulatory landscape in the highly competitive biotechnology industry; the inability of the Company to raise financing in the future; the inability of the Company to obtain and maintain regulatory clearance or approval for its products, and any related restrictions and limitations of any cleared or approved product; the inability of the Company to identify, in-license or acquire additional technology; the inability of Company to compete with other companies currently marketing or engaged in the biologics market and in the area of treatment of kidney diseases; the size and growth potential of the markets for the Company’s products, if approved, and its ability to serve those markets, either alone or in partnership with others; the Company’s estimates regarding expenses, future revenue, capital requirements and needs for additional financing; the Company’s financial performance; the Company’s intellectual property rights; uncertainties inherent in cell therapy research and development, including the actual time it takes to initiate and complete clinical studies and the timing and content of decisions made by regulatory authorities; the impact of COVID-19 or geo-political conflict such as the war in Ukraine on the Company’s business; and other risks and uncertainties indicated from time to time in the Company’s filings with the Securities and Exchange Commission. The Company cautions readers that the foregoing list of factors is not exclusive and cautions readers not to place undue reliance upon any forward-looking statements, which speak only as of the date made. The Company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

ProKidney

Disrupting the CKD Treatment Landscape

Renal Autologous Cell Therapy:

Rilparencel (REACT®) proprietary autologous cellular therapy being evaluated to **preserve kidney function** in patients with diabetes and advanced chronic kidney disease

An Introduction to ProKidney

Goal

Preserve kidney function in advanced CKD patients

Preserve kidney function in patients with type 2 diabetes and advanced chronic kidney disease who are faced with limited options for care beyond transplantation or dialysis

Rilparencel

A proprietary autologous cellular therapy with RMAT designation

Currently in pivotal Phase 3 clinical development with REGEN-006 (PROACT 1)
Supported by three Phase 2 clinical trials in advanced CKD patient populations

Leadership

Leadership Team with Clinical Development & Regulatory Experience

Together the team brings over 150 years cumulative experience in the discovery, development, manufacturing and commercialization of biotechnology, pharmaceutical, and device products

Recent Developments

Meaningful Recent Developments

Refined the focus of the Phase 3 program in Sep 2024 to accelerate PROACT 1 and path to potential U.S. approval Completed an upsized common stock offering of $140 million in June 2024 extending cash runway into Q1 2027 Phase 2 REGEN-007 interim results published in June 2024

CKD = chronic kidney disease RMAT = regenerative medicine advanced therapy

What is Rilparencel and Why is it Relevant?

Unmet Needs

Over **35 million U.S. adults** have chronic kidney disease (CKD)[1]

More than **135,000 of these CKD patients progress to dialysis** every year[1]

Total annual costs to Medicare for patients with CKD (including ESRD) exceed $138B[2]

Our Goals

Preserve kidney function

Reduce or potentially eliminate time spent on dialysis

Return autonomy to patients and their families

Our Product

Rilparencel is a **proprietary** cell therapy using the patient's own kidney cells

Early clinical data demonstrate a potential to **preserve** kidney function

May provide greater benefit to **higher-risk** CKD patients

Our Plan

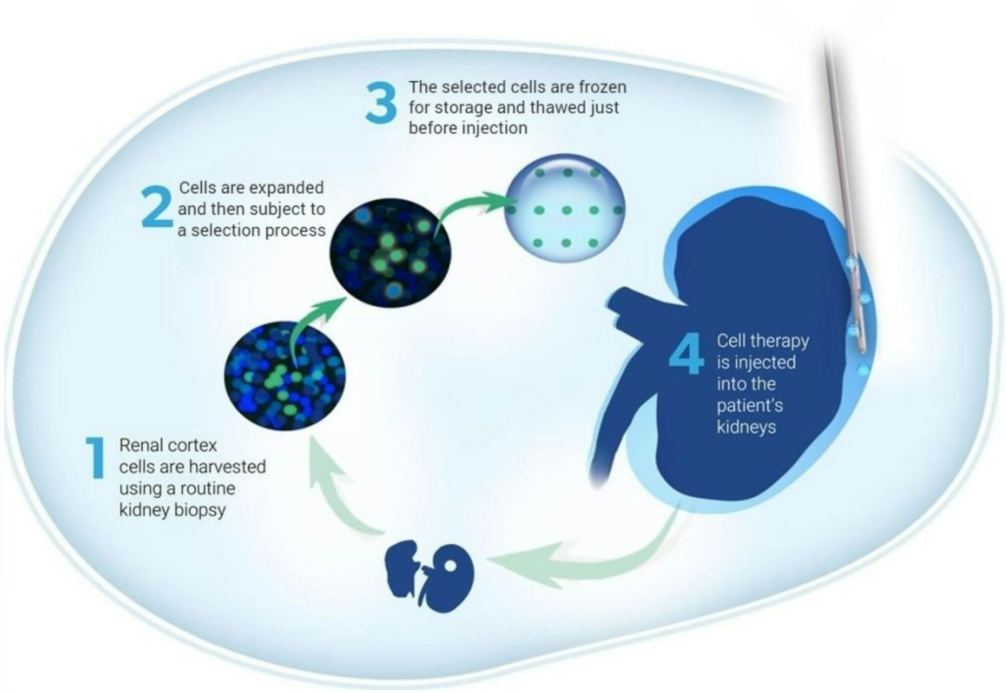
The **Phase 3 PROACT 1** clinical study is focused on patients with type 2 diabetes and late Stage 3b/4 CKD

Potential label expansion to re-dose rilparencel for **long-term dialysis prevention**

1. CDC Fact Sheet. https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html
2. USRDS 2023 Annual Report

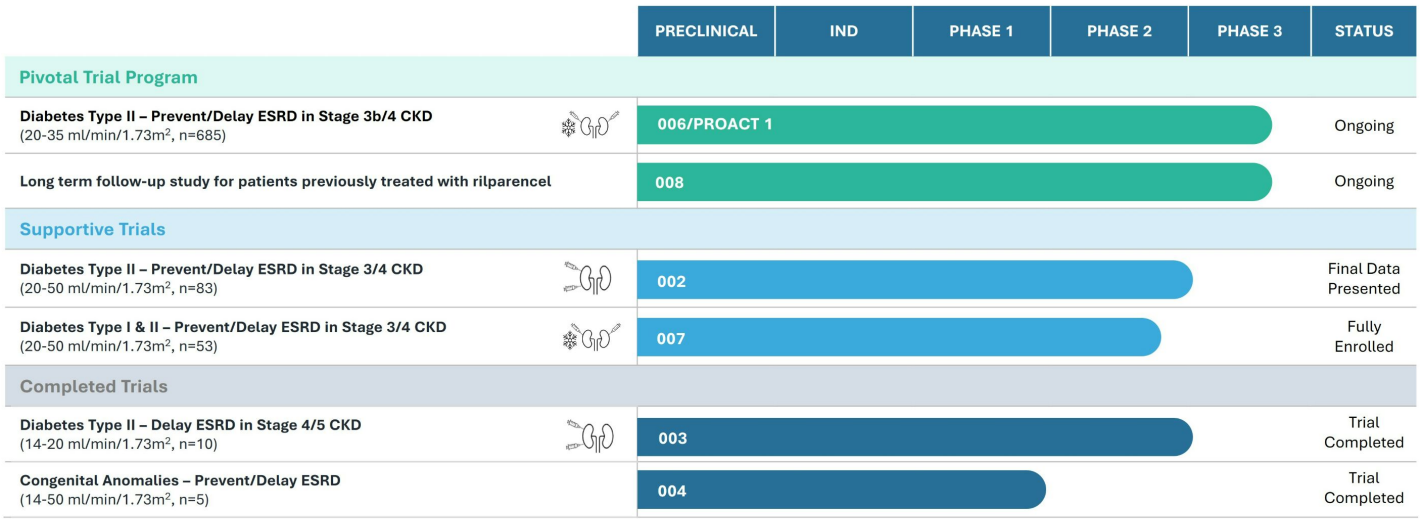
Rilparencel Goal: Preservation of Kidney Function

ProKidney's Autologous Cell Therapy



PROKIDNEY

Overview of the Rilparencel Clinical Program



As of August 2024

Advancing a Comprehensive Clinical Plan

2024

RMCL-002 Phase 2 Trial; Results published Q2 2024

- Open-label safety & efficacy of rilparencel in patients with type 2 diabetes and Stage 3/4 CKD (eGFR 20-50)
- Potential to preserve kidney function for up to 30 months in several patient groups

REGEN-007 Phase 2 Trial; Enrollment complete; Interim results published Q2 2024

- Open-label safety & efficacy of rilparencel in patients with diabetes and Stage 3/4 CKD (eGFR 20-50)
- Bilateral kidney injections & cryopreserved commercial formulation

Phase 3 Randomized Controlled Clinical Trial – type 2 diabetes and Stage 3b/4 CKD

- **PROACT 1** is enrolling patients

2025 and beyond

REGEN-007 Phase 2 Trial; Full 12 month data from Group 1 expected in 1H 2025

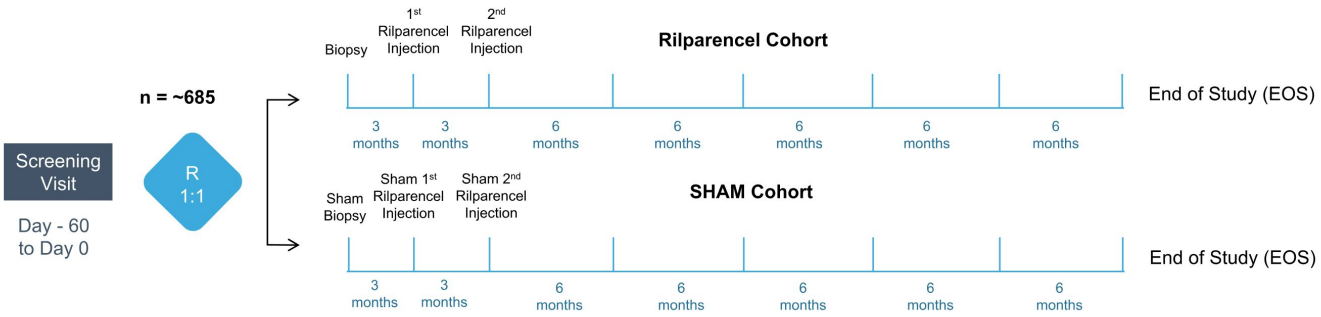
Update on rilparencel Mechanism of Action in 2H 2025

Phase 3 Randomized Controlled Clinical Trial – type 2 diabetes and Stage 3b/4 CKD

- Topline results for the **PROACT 1** study anticipated in Q3 2027

Rilparencel Registrational Program: proact 1 (REGEN-006)

PROACT 1 eGFR enrollment criteria range of ≥20 to ≤35 ml/min/1.73m^2 aligns with Phase 2 study results and payer / clinical feedback



Key Entry Criteria

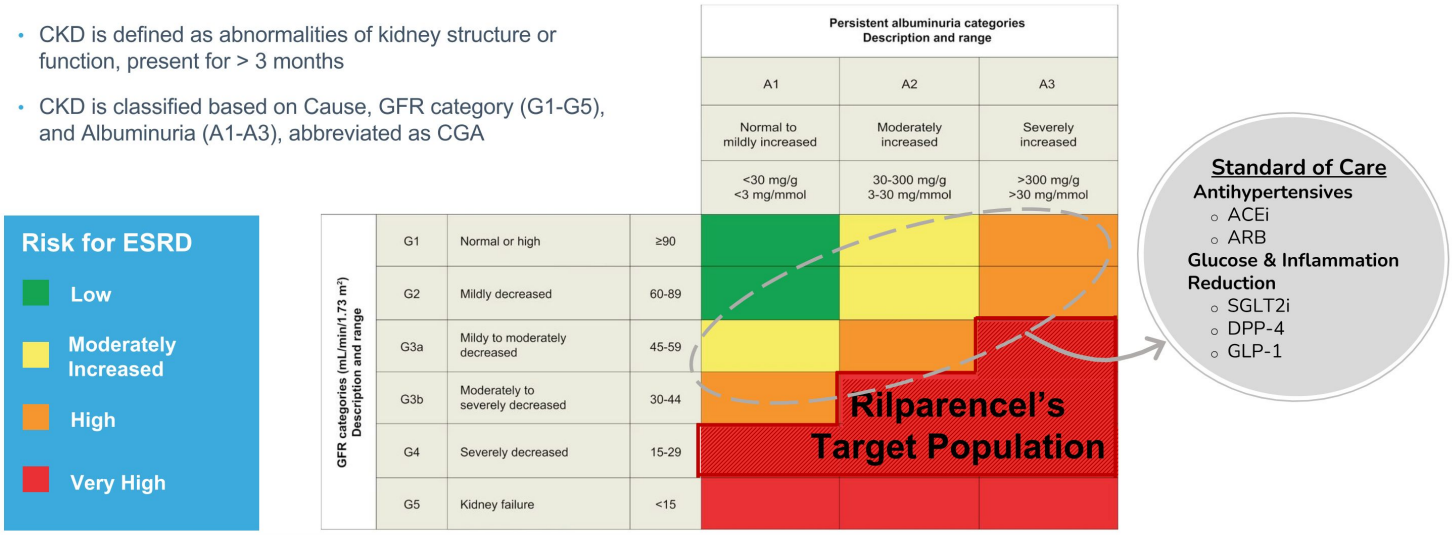
- Type 2 diabetes and CKD
- Male or Female 30-80 years of age
- eGFR ≥20 and ≤35 mL/min/1.73m^2
- UACR 300-5,000 mg/g for eGFR 30-35
- Not on renal dialysis, HbA1c <10%

Time-to-Event Primary Composite Endpoint

- At least 40% reduction in eGFR;
- eGFR <15mL/min/1.73m² sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
- Death from renal or cardiovascular causes

Unmet Clinical and Payer Need in High-Risk CKD Patients

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



Today, clinical priorities for patients with Stage 4 CKD (G4) are largely focused on treating co-morbidities and preparing patients for transplantation or dialysis

Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2020 clinical practice guideline for diabetes management in chronic kidney disease. *Kidney Int* 2020;98:S1–115.

Therapeutic Options that Delay the Need for Dialysis in Patients with Stage 4 Chronic Kidney Disease are Limited

Study	Active Product	Subjects with Stage 4 CKD
Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy[1]	Canagliflozin (SGLT2 inhibitor)	0%
Dapagliflozin in Patients with CKD[2]	Dapagliflozin (SGLT2 inhibitor)	14%
Empagliflozin in Patients with CKD[3]	Empagliflozin (SGLT2 inhibitor)	34%
Effect of Finerenone on Cardiovascular and Kidney Outcomes in Patients with Type 2 Diabetes and CKD[4]	Finerenone (Selective MRA)	7%
Effects of Semaglutide on Chronic Kidney Disease in Patients with Type 2 Diabetes[5]	Semaglutide (GLP-1RA)	11%

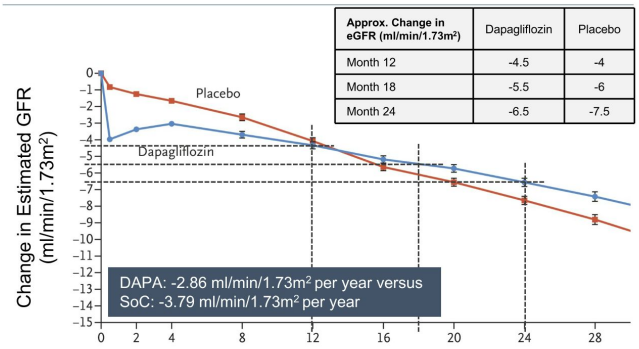
All recent landmark clinical trials in CKD primarily focus on Stage 2 and 3 CKD

1. Perkovic V et al. N Eng J Med 2019
2. Heerspink H et al. N Engl J Med 2020
3. Herrington et al. N Engl J Med 2023
4. Agarwal. R et al. Eur Heart J. 2022; Sarafidis. P et al. Clin J Am Soc Nephrol 2023
5. Perkovic V et al. N Engl J Medicine 2024

While New Therapies Are a Step Forward, Patients Still Lose Kidney Function and Experience Clinically Significant Events

SGLT2 inhibitors Do Not Prevent Progression of Advanced CKD

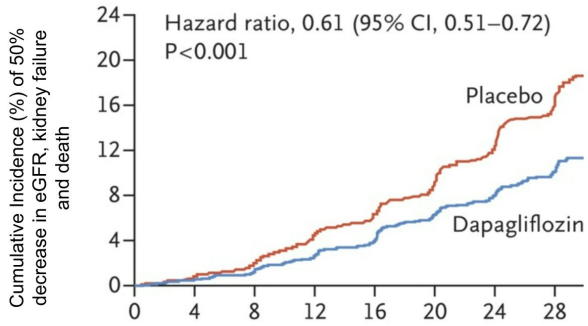
Patients continue to lose kidney function on SGLT2 inhibitors and progress to Stage 4/5 CKD



While dapagliflozin demonstrated <1.0 ml/min/yr difference in eGFR, it was able to achieve a reduction in clinically important events

Standard of Care has Limitations

Current standard of care[1] does not prevent events in ~50-75% of people with diabetic kidney disease[2]



Dapagliflozin: 19 patients required treatment to prevent one primary outcome event

1. Standard of care includes ACE inhibitors, angiotensin receptor blockers and SGLT2 inhibitors
2. Heerspink HJL et al. N Eng J Med 2020

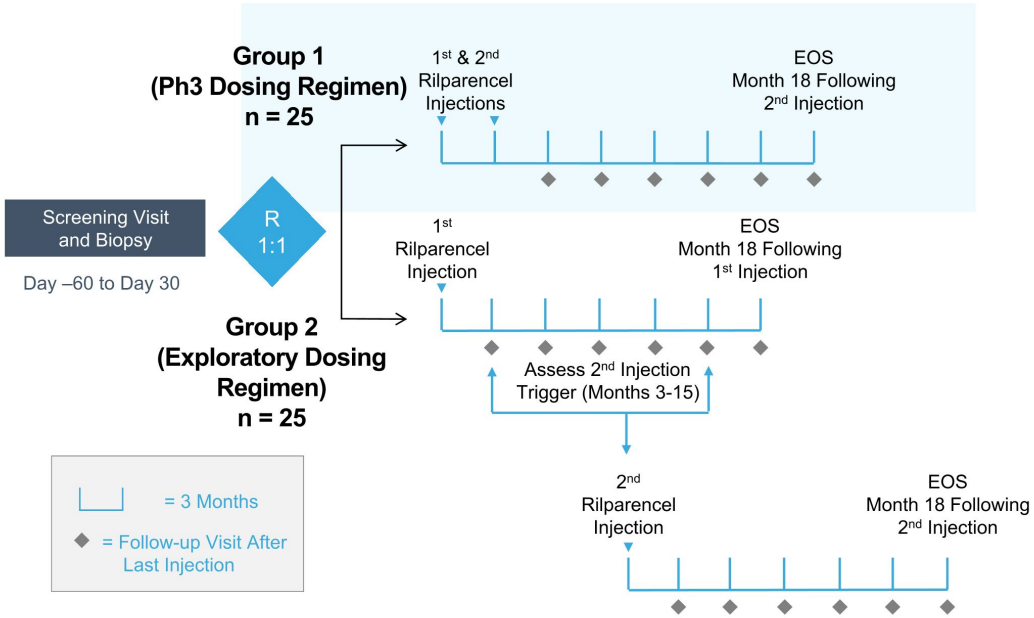
ProKidney

REGEN-007 Interim Analysis

Data as of May 7, 2024

REGEN-007 Trial Design

Group 1 Dosing Regimen and Use of Cryopreserved Product Mirrors Phase 3 Program



Key Entry Criteria

Type 1 or type 2 diabetes and CKD

Subjects 30-80 years of age

eGFR ≥20 and ≤50 mL/min/1.73m^2

UACR 30-5000 mg/g

HbA1c <10%

Group 2 Re-Dosing Trigger

Sustained 30-Day:

- Decline in eGFR of ≥20% from baseline, and/or
- Increase of ≥30% and ≥30 mg/g in UACR from baseline

eGFR = estimated glomerular filtration rate; UACR = urine albumin-to-creatinine ratio (a measure of albuminuria)

REGEN-007 Interim Analysis Objectives and Endpoints in Group 1

Objectives

- In subjects with at least 12 months follow-up after 2 injections, assess the safety and efficacy of cryopreserved rilparencel delivered into the biopsied and non-biopsied contralateral kidney using a percutaneous approach

Endpoints

- Procedural and investigational product-related adverse events
- Change in kidney function as measured by eGFR

Current Enrollment Status & Completion Expectations

53 Subjects were Randomized in REGEN-007 with 27 Subjects Randomized to Group 1
(1 Subject Withdrew Consent Pre-Biopsy)
26 Subjects in Group 1

Of the 26 Subjects who were Biopsied, 24 Subjects Received at-least 1 Injection (2 Subjects' Biopsies had Insufficient Cells for Injection)
24 Subjects

Of the 24 Subjects, 1 Subject had a Contra-indication (Bleeding Risk) for a 2nd Injection & 1 Subject Died before 12 Months Follow-up
22 Subjects Expected to Receive 2 Injections with 12 Months Follow-up

As of May 7, 2024: 13 Subjects Have Received 2 Injections with a Minimum of 12 Months Follow-up post 2nd Injection

Baseline Characteristics in Group 1 Subjects with a Minimum of 12 Months Follow-up after Two Rilparencel Injections

	SUBJECTS WITH MINIMUM 12 MONTHS FOLLOW-UP AFTER 2ND INJECTION (n=13)
Age, years *(mean +/- SD)*	62.8 +/- 8.2
Female : Male, %	54% : 46%
Hispanic or Latino, %	0%
Race, %	
Black or African American	0%
White	100%
Other	0%
Blood pressure, mm HG	135 / 72
eGFR, ml/min/1.73m^2 *(mean +/- SD)*	29.7 +/- 9.5
UACR mg/g *(median, min max)*	239 (4, 2392)
HbA1c, % *(mean +/- SD)*	7.3 % +/- 1.6
ACE/ARB Use, %	69%
SGLT2 Use, %	31%
GLP-1 Use, %	46%

HbA1c = hemoglobin A1c; SGLT2 = sodium glucose cotransporter 2 protein inhibitor; ACE = angiotensin converting enzyme; ARB = angiotensin II receptor blockers

Externally Developed Control Arm to Contextualize REGEN-007 Interim Data

Objective

- Explore how 18 month change in kidney function in subjects enrolled in REGEN-007 might compare against matched contemporaneous controls

Methods

- In partnership with Dr. Navdeep Tangri (University of Manitoba), 13 subjects from REGEN-007 were matched 10:1 with diabetic subjects from recent CKD clinical trials
- Matching was independently performed based upon 2-year risk of kidney failure using Klinrisk[1] software and comparable usage of SGLT2 inhibitors

1. https://www.klinrisk.com/

Klinrisk Founding Team

Navdeep Tangri

- ◊ Co-Founder and CEO
- ◊ Founder and Scientific Director, Chronic Disease Innovation Centre
- ◊ Professor of Medicine, University of Manitoba

Roche · TRICIDA · University of Manitoba · Chronic Disease Innovation Centre

- Global leader in risk prediction who developed the most widely used algorithms in nephrology worldwide
- Published more than 380 manuscripts
- Risk equations have been integrated in electronic health records (Epic), laboratory information systems, and national & international clinical practice guidelines
- Strong track record of leading international clinical trials, developing trial endpoints with FDA and participating FDA discussions on drug approval and labeling
- Relationships with large pharmaceutical companies – considered a key opinion leader internationally in the CKD space

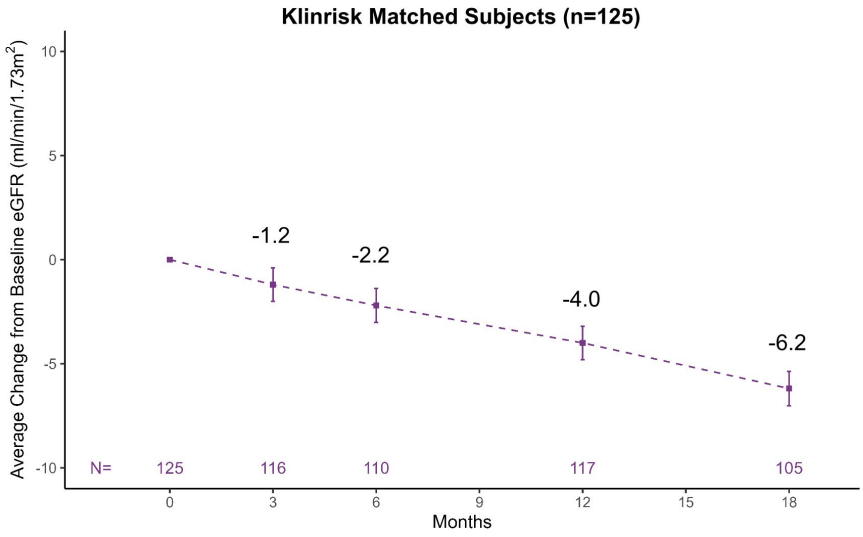
J.D. McCullough

- ◊ Chief Operating Officer
- ◊ Health tech executive specializing in regulated AI commercialization

Digital Diagnostics · AscendMed · Roche · MCRA · Lumanity

- First autonomous AI FDA clearance and SaMD reimbursement including CMS coverage at Digital Diagnostics
- Closed seven figure deals with health systems, payors, labs, and biopharma companies
- Led FDA strategy and engagement for 10+ SaMD products, including Breakthrough, PMA, De Novo, and 510(k)
- Licensed over 50M patient records globally to drive AI & drug development
- Strategic advisor to Top 20 Biopharma, regulatory & reimbursement firms, and venture-backed startups
- Previous Commercial & Product Executive positions at Aegis Ventures, Arcturis Data, Digital Diagnostics

Matched Controls Showed a Continuous Decline in Kidney Function over 18 Months



Average Change in eGFR from Baseline at 18 Months

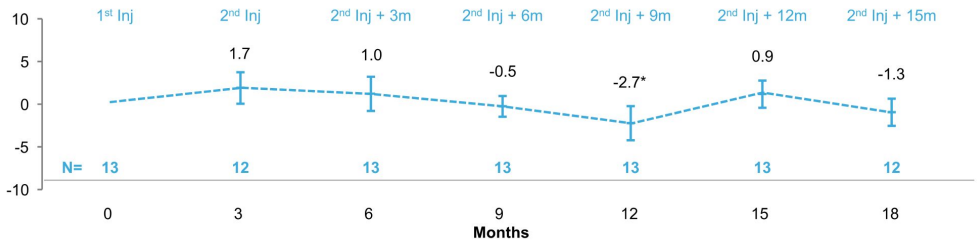
-6.2 ml/min/1.73m²
(95% CI -7.8, -4.6)

PROKIDNEY

Kidney Function Stabilizes for 18 Months After 1st Injection

Group 1 Subjects (n=13) with Minimum 12 Months Follow-up Data Post 2nd Injection

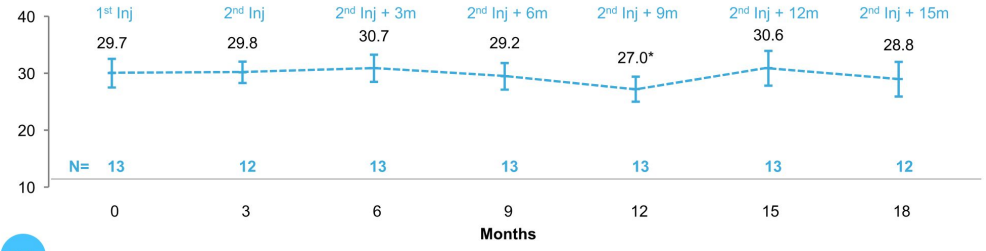
Average Change from Baseline eGFR (ml/min/1.73m²)



Average Change from Baseline with 18 Months Follow-up Post 1st Injection

-1.3 ml/min/1.73m²
(95% CI -5.1, 2.5)

Average eGFR (ml/min/1.73m²)



Average eGFR in Group 1 was 29.7 at Baseline vs 28.8 at 18 Months Post 1st Injection

[absolute difference -0.9 ml/min/1.73m² at 18-months]

Interim analysis; Data points are mean +/- SEM ; Data as of May 7, 2024 *eGFR highly influenced by 1 patient that recovered on measurements at month 15 and month18

ProKidney

No Rilparencel-related Serious Adverse Events have been Observed

ADVERSE EVENT	BIOPSY # of SAEs (n=51)	RILPARENCEL INJECTION # of SAEs (n=49)
Hematoma	2	1
Thrombosis	1	0
Hematuria	1	0
Hydronephrosis	1	0
Death	0	0
Acute Kidney Injury	2	0

Data as of May 7, 2024

REGEN-007 Interim Analysis Summary

Key Findings

- In Group 1 participants who had at least 12 months follow up after a second rilparencel injection, **kidney function was preserved for 18 months**
- Bilateral dosing of cryopreserved product showed safety profile consistent with prior studies and comparable to kidney biopsy

Next Steps

- We look forward to providing **full results for REGEN-007 in 1H 2025**
- We are focused on enrolling patients in our registrational **Phase 3 PROACT 1** study and expect topline results in Q3 2027

Financial Highlights

NASDAQ: PROK
289,675,217 shares outstanding*

$432M Cash** on hand expected to fund operations into Q1 2027

Headquarters:
Boston, MA
Winston-Salem, NC

Covering Research Analysts

Jason Gerberry	Bank of America Global Research
Justin Zelin	BTIG
Yigal Nochomovitz	Citigroup Inc.
Jonathan Miller	Evercore ISI
Judah Frommer	Morgan Stanley
Eliana Merle	UBS
Kelly Shi	Jefferies

*As of Aug 9, 2024
**Cash, cash equivalents and marketable securities as of June 30, 2024

ProKidney

ProKidney Announces Strategic Updates to its Phase 3 Program to Accelerate Rilparencel's Registrational Path to Potential Approval in the U.S.

- *Refined the focus of the Phase 3 program to accelerate path to potential U.S. approval and commercial launch in the Company's highest priority market*
- *Discontinued the ex-U.S.-based PROACT 2 trial and focused Company resources on PROACT 1 to expedite enrollment and accelerate estimated topline data readout to Q3 2027*

WINSTON-SALEM, N.C., September 3, 2024 – **ProKidney Corp. (Nasdaq: PROK)** ("ProKidney" or the "Company"), a late clinical-stage biotech company focused on the development of a first-in-class cell therapy candidate for chronic kidney disease (CKD), today announced strategic updates to its Phase 3 program for rilparencel, an investigational treatment to potentially preserve kidney function in patients with type 2 diabetes and advanced CKD.

ProKidney recently completed a comprehensive internal and external review, including engaging with ex-FDA officials and seasoned regulatory experts, to determine the optimal path to bring rilparencel to patients in the U.S. with type 2 diabetes and advanced CKD – a market where there is high unmet clinical and economic need. An important conclusion of this review is that under the provisions of the Regenerative Medicine Advanced Therapy (RMAT) designation, the Company believes rilparencel is eligible for initial FDA approval under an expedited approval pathway based upon successful completion of the ongoing Phase 3 REGEN-006 (PROACT 1) trial. ProKidney believes that the Phase 3 REGEN-016 (PROACT 2) trial is not required for initial U.S. registration. Thus, the Company will discontinue PROACT 2, which was focused on enrollment outside the U.S. With the discontinuation of PROACT 2, ProKidney now expects current cash to support operating plans into Q1 2027. The Company estimates the revised Phase 3 program will deliver topline results by Q3 2027 and reduce expenses by approximately $150 to $175 million.

"We decided to prioritize PROACT 1 to accelerate potential U.S. registration and commercial launch. We are confident that this strategic shift in our Phase 3 program is the most expeditious and resource efficient approach to bring rilparencel to market in the U.S., our highest priority market," said Bruce Culleton, M.D., Chief Executive Officer. "The recent positive REGEN-007 interim data update in June further supports the urgency to bring our innovation to patients with advanced CKD. We look forward to continuing our engagement with the FDA, under the RMAT designation, to bring rilparencel to market."

Today's update follows a transformational period for ProKidney over the past 10 months. In November 2023, Bruce Culleton, M.D., a nephrologist and seasoned leader of kidney care organizations, was appointed Chief Executive Officer. Under Dr. Culleton's leadership, ProKidney has made significant progress, including the implementation of improved quality management systems to ensure compliance with global standards for commercial manufacturing and the Phase 3 program, the refinement and restart of the Phase 3 program with a renewed focus on patients with advanced CKD in the U.S., and the appointment of several key executive leaders across clinical operations, manufacturing, human resources, and business operations. The Company also released final data from the Phase 2 RMCL-002 trial and interim data from the Phase 2 REGEN-007 trial. Data from these trials suggest that rilparencel's

greatest potential therapeutic impact is in advanced CKD patients at high risk of kidney failure. This patient population aligns with feedback from payors and providers who have emphasized the need for treatment options in this population.

Rilparencel was granted RMAT designation by the FDA in October 2021. RMAT designation can be granted to regenerative medicine therapies (including cell therapies) that are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and have preliminary clinical evidence that indicate the drug candidate has the potential to address unmet medical needs for such disease or condition. This designation is intended to facilitate an accelerated development and review process similar to the breakthrough therapy designation. With an RMAT designation for rilparencel, ProKidney will continue to work with the FDA to receive guidance on its registrational program, including guidance on clinical trial design, manufacturing, and long-term patient follow-up, as appropriate.

About the Phase 3 REGEN-006 (PROACT 1) Clinical Trial

REGEN-006 is an ongoing Phase 3, randomized, blinded, sham controlled safety and efficacy study of rilparencel in subjects with type 2 diabetes and advanced CKD. The study protocol was amended in 1H 2024 to focus on a subset of patients with stage 4 CKD (eGFR 20-30ml min/1.73m^2) and late stage 3b CKD (eGFR 30-35ml min/1.73m^2) with accompanying albuminuria (urine albumin-to-creatinine ratio, or UACR less than 5,000 mg/g for patients with eGFR 20-30ml min/1.73m^2 and 300-5,000 mg/g for patients with eGFR 30-35ml min/1.73m^2). The total planned enrollment is approximately 685 subjects. Subjects are randomized (1:1) to the treatment group and the sham control group prior to kidney biopsy or a sham biopsy procedure, respectively. Subjects in the treatment group are to receive the first rilparencel injection within 18 weeks of kidney biopsy. After three months it is intended that a second rilparencel injection be given into the contralateral kidney. Subjects in the control group, who previously underwent the sham biopsy procedure, are to receive two sham injections at similar time points as the treatment group. The primary objective is to assess the efficacy of up to two rilparencel injections using a minimally invasive percutaneous approach. The primary composite endpoint is the time from first injection to the earliest of: at least 40% reduction in eGFR; eGFR <15 mL/min/1.73m², and/or chronic dialysis, and/or renal transplant; or renal or cardiovascular death.

About ProKidney Corp.

ProKidney, a pioneer in the treatment of chronic kidney disease through innovations in cellular therapy, was founded in 2015 after a decade of research. ProKidney's lead product candidate, rilparencel (also known as REACT®), is a first-of-its-kind, patented, proprietary autologous cellular therapy being evaluated for its potential to preserve kidney function in diabetic patients at high risk of kidney failure.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. ProKidney's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "continue," and similar expressions (or the negative versions of such words or expressions) are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, the Company's beliefs that (i) rilparencel is eligible for initial FDA approval under an expedited approval pathway based upon the successful completion of the Phase 3 REGEN-006 (PROACT 1) trial, (ii) the Phase 3 REGEN-016 (PROACT 2) trial is not required for initial U.S.

registration, and (iii) the revised Phase 3 program will accelerate estimated topline data readout and deliver topline results by Q3 2027, expectations with respect to financial results and expected cash runway, including the Company's expectation that current cash will support operating plans into Q1 2027, future performance, development and commercialization of products, if approved, the potential benefits and impact of the Company's products, if approved, potential regulatory approvals, the size and potential growth of current or future markets for the Company's products, if approved, the advancement of the Company's development programs into and through the clinic and the expected timing for reporting data, the making of regulatory filings or achieving other milestones related to the Company's product candidates, and the advancement and funding of the Company's developmental programs generally. Most of these factors are outside of the Company's control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the inability to maintain the listing of the Company's Class A ordinary shares on the Nasdaq; the inability to implement business plans, forecasts, and other expectations or identify and realize additional opportunities, which may be affected by, among other things, competition and the ability of the Company to grow and manage growth profitably and retain its key employees; the risk of downturns and a changing regulatory landscape in the highly competitive biotechnology industry; the risk that results of the Company's clinical trials may not support approval; the risk that the FDA could require additional studies before approving the Company's drug candidates; the inability of the Company to raise financing in the future; the inability of the Company to obtain and maintain regulatory clearance or approval for its products, and any related restrictions and limitations of any cleared or approved product; the inability of the Company to identify, in-license or acquire additional technology; the inability of Company to compete with other companies currently marketing or engaged in the biologics market and in the area of treatment of kidney diseases; the size and growth potential of the markets for the Company's products, if approved, and its ability to serve those markets, either alone or in partnership with others; the Company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing; the Company's financial performance; the Company's intellectual property rights; uncertainties inherent in cell therapy research and development, including the actual time it takes to initiate and complete clinical studies and the timing and content of decisions made by regulatory authorities; the fact that interim results from our clinical programs may not be indicative of future results; the impact of geo-political conflict on the Company's business; and other risks and uncertainties included under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. The Company cautions readers that the foregoing list of factors is not exclusive and cautions readers not to place undue reliance upon any forward-looking statements, which speak only as of the date made. The Company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based.

Investor Contacts:

ProKidney
Ethan Holdaway
Ethan.Holdaway@prokidney.com

LifeSci Advisors, LLC
Daniel Ferry
Daniel@lifesciadvisors.com