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): November 10, 2023

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 **27103**
(Address of Principal Executive Offices) **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 336 999-7029

(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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Chief Executive Officer Transition

On November 10, 2023, the board of directors (the "Board") of ProKidney Corp. (the "Company") approved the termination, without cause, of Tim Bertram, Ph.D., Chief Executive Officer of the Company, effective November 15, 2023 (the "Effective Date"), following which Dr. Bertram is expected to continue to serve as a consultant of the Company and as a member of the Company's Scientific Advisory Board. On the Effective Date, and pursuant to the terms of Dr. Bertram's employment agreement, Dr. Bertram will resign from the Board of Directors (the "Board") of the Company. The Company expects to enter into a separation agreement and release and consulting agreement with Dr. Bertram, the terms of which will be disclosed once available.

In addition, on November 10, 2023, upon the recommendation of the Nominating and Corporate Governance Committee of the Board, the Board approved the appointment of Bruce Culleton, MD, as Chief Executive Officer and as a Class III director of the Company, effective as of the Effective Date. Dr. Culleton will serve as a director until his term expires at the 2025 annual meeting of stockholders. The Company expects to enter into an employment agreement with Dr. Culleton in connection with his appointment as Chief Executive Officer, the terms of which will be disclosed once available.

Dr. Culleton, age 56, has served as the Company's Executive Vice President, Clinical Development & Commercialization since July 2023. He has more than two decades of experience in industry and academia with a primary focus on kidney health. Prior to joining the Company, Dr. Culleton served as the Vice President and General Manager of CVS Kidney Care, LLC, a subsidiary of CVS Health Corporation (NYSE: CVS), a health solutions company, from June 2022 to July 2023. Previously, he served as Vice President and Chief Medical Officer at CVS Kidney Care from October 2017 to June 2022. Before joining CVS Health Corporation, he was Vice President, Global Clinical Development and World Wide Vice President, Medical Affairs, Medication and Procedural Solutions at Becton, Dickinson and Company (NYSE: BDX), a global medical technology company, from 2016 to 2017; and previously Vice President, Renal Therapeutic Area at Baxter International Inc. (NYSE: BAX), a healthcare company, from 2007 to 2016. Prior to beginning his industry career in 2007, Dr. Culleton was a Clinical Associate Professor, Department of Medicine at the University of Calgary. Dr. Culleton holds a Bachelor's degree in Medical Science and a Doctor of Medicine degree from Memorial University of Newfoundland, and a Master's degree in Business Administration from Northwestern University, Kellogg School of Management. He completed a specialization in Internal Medicine and Nephrology through the Royal College of Physicians and Surgeons of Canada, as well as a fellowship in Clinical Epidemiology at Boston University, Framingham Heart Study.

There are no arrangements or understandings between Dr. Culleton and any other person pursuant to which Dr. Culleton was appointed as Chief Executive Officer and as a director. There are no family relationships between Dr. Culleton and any director or executive officer of the Company, and there are no transactions between Dr. Culleton and the Company that would be reportable under Item 404(a) of Regulation S-K.

Dr. Culleton entered into an indemnification agreement in the form the Company has entered into with its other executive officers, which form is filed as Exhibit 10.13 to the Company's Current Report on Form 8-K, filed by the Company on July 15, 2022 and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

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 November 13, 2023, the Company issued a press release announcing updated Phase 2 data and the leadership transition described in Item 5.02 above. The Company also announced that the Company will host an investor conference call, with slides presented, on Tuesday, November 14, 2023, at 8:00 a.m. Eastern Time. 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. 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 and expected cash runway, 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, updating clinical trial protocols, 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 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 clearances or approvals 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 COVID-19 or geo-political conflict such as the war in Ukraine 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 of Exhibit
99.1	Investor Presentation
99.2	Press Release dated November 13, 2023.
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: November 13, 2023

By: /s/ Todd Girolamo
Name: Todd Girolamo
Title: Chief Legal Officer

Exhibit 99.1

PROKIDNEY

RMCL-002 Interim Results & Updates

November 14, 2023

Developing Solutions for Dialysis Prevention

REACT® [**RE**nal **A**utologous **C**ell **T**herapy]

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.

Agenda

01	Opening Remarks
02	REACT Phase 2 RMCL-002 Data
03	Plans for Phase 3 Program (Studies REGEN-006 and REGEN-016)
04	Advancing a Comprehensive Clinical Plan

Disrupting the CKD Treatment Landscape

Renal Autologous Cell Therapy:

REACT® (rilparencel) proprietary autologous cellular therapy being evaluated to **preserve kidney function** in diabetic patients at high risk of kidney failure

What is REACT® and Why is it Relevant?

Unmet Needs | **Our Goals** | **Our Product** | **Our Plan**

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[2]

Total annual costs to Medicare for patients with CKD (including ESRD) exceed $138B[1]

Preserve kidney function

Reduce or potentially eliminate time spent on dialysis

Return autonomy to patients and their families

REACT® 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

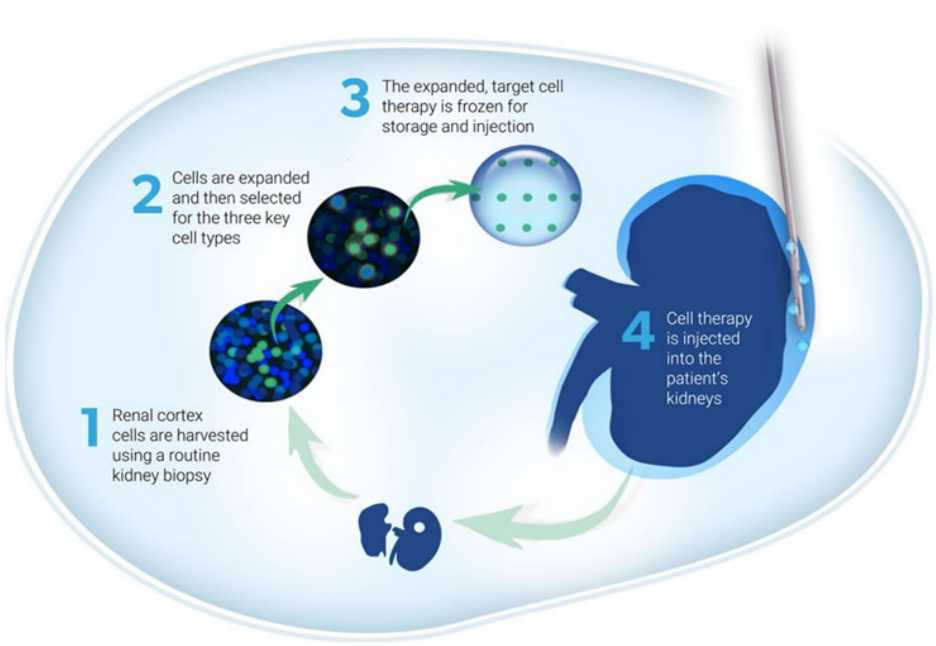
Phase 3 clinical program **proact 1 and proact 2 are underway** in patients with Stage 3b / 4 diabetic kidney disease

Potential label expansion to re-dose REACT 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*

REACT® Goal: Preservation of Kidney Function

ProKidney's REACT® Autologous Cell Therapy



PROKIDNEY

Overview of the REACT® Clinical Program

Lead Platform Programs*	PRECLINICAL	IND	PHASE 1	PHASE 2	PHASE 3	STATUS
Pivotal Trial Program						
Diabetes Type II – Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m^2, N = 600)				006/proact 1		Ongoing
Diabetes Type II – Prevent/Delay CKD 3/4 stratified for SGLT2i (20-44 ml/min/1.73m^2, N = 600)				016/proact 2		Enrollment Mid-2024
Long term follow-up study for patients previously treated with REACT				008		Enrollment 4Q 2023
Supportive Trials						
Diabetes Type II – Delay CKD 4/5 (14-20 ml/min/1.73m^2, N = 10)				003		Trial Completed
Diabetes Type II – Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m^2, N = 81)				002		Fully Enrolled
Diabetes Repeat Dose Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m^2, N= 50)				007		Fully Enrolled
Multi / extended-dosing for previously REACT-treated patients				015		Fully Enrolled
Congenital Anomalies – Prevent/Delay (14-50 ml/min/1.73m^2, N= 5)				004		Trial Completed

*As of October 2023

Frozen product

Unilateral injections

bilateral injections

Unmet Clinical and Payer Need in High-Risk CKD Patients

REACT® May Delay Need for Dialysis in Highest-Risk Progressors

- 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

Risk for ESRD

- Low
- Moderately Increased
- High
- Very High

GFR categories (mL/min/1.73 m²) Description and range			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
G1	Normal or high	≥90			
G2	Mildly decreased	60-89			
G3a	Mildy to moderately decreased	45-59			
G3b	Moderately to severely decreased	30-44			
G4	Severely decreased	15-29			
G5	Kidney failure	<15			

REACT's Target Population

Standard of Care

- **Antihypertensives**
  - ACEi
  - ARB
- **Glucose & Inflammation Reduction**
  - SGLT2i
  - DPP-4
  - GLP-1

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

Therapeutic Options to 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%
Dapaglifozin in Patients with CKD[2]	Dapaglifozin (SGLT2 inhibitor)	14%
Empaglifozin in Patients with CKD[3]	Empaglifozin (SGLT2 inhibitor)	34%
Effect of Finerenone on CKD Outcomes in Type 2 Diabetes[4]	Finerenone (Selective MRA)	< 10%
Rationale, Design, and Baseline Data of FLOW – a Kidney Outcomes Trial with Once Weekly Semaglutide in People with Type 2 Diabetes and CKD[5]	Semaglutide (GLP-1RA)	10%

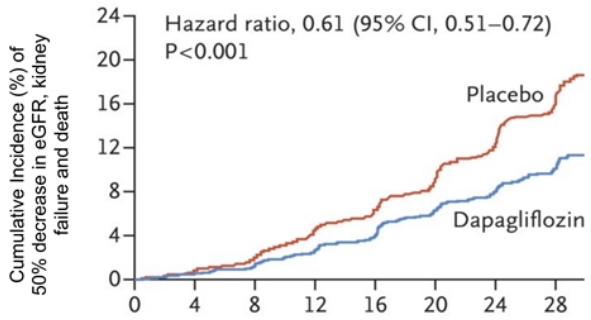
All recent landmark clinical trials in CKD focus on Stage 2/3 CKD

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. *Bakris G et al. N Engl J Med 2020*
5. *Rossing P et al. Nephrol Dial Transplant 2023*

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

Standard of Care has Limitations

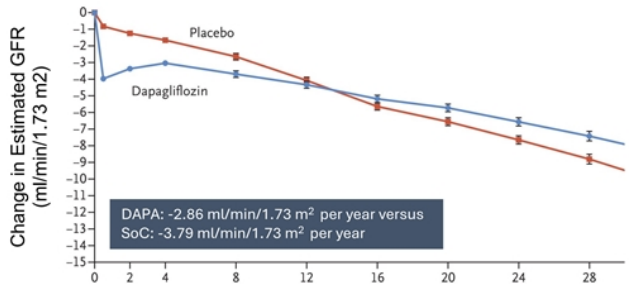
Current standard of care[1] does not prevent events in ~ 50-75% of people with diabetic kidney disease[2]



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

Current SGLT2 Inhibitors are Blockbusters

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

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

PROKIDNEY

RMCL-002 Interim Analysis

August 2023 Data Cut

ProKidney

In this Phase 2 Study, REACT® Demonstrates the Potential for Preservation of Kidney Function in Patients with Diabetes and Advanced Kidney Disease

Key Findings

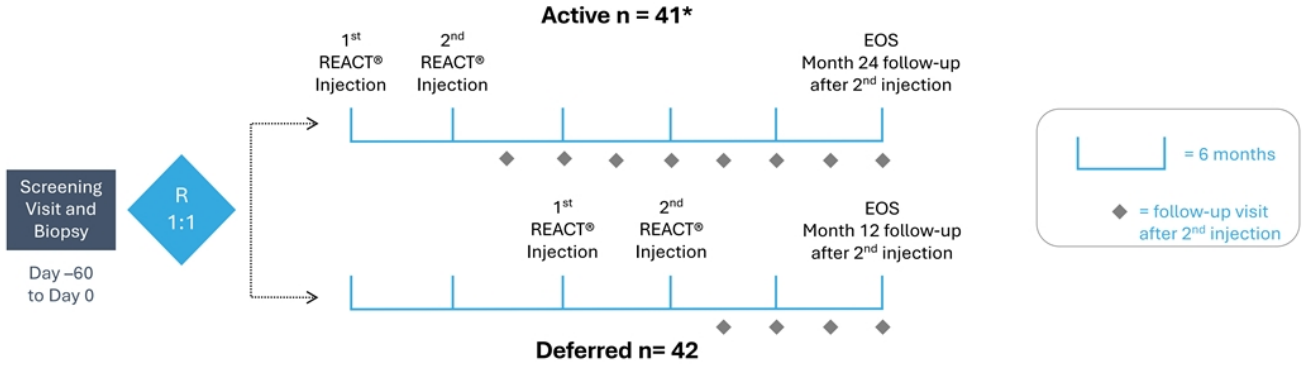
- REACT showed potential to preserve kidney function for up to 30 months in several patient groups
- REACT's benefit on kidney function was most notable in patients who had the highest risk of kidney failure (CKD 4 with high UACR[1])
- REACT injections were well tolerated with a consistent safety profile comparable to kidney biopsy

Next Steps

- We are enriching our Phase 3 Proact 1 Study to include more patients with the highest risk of kidney failure

1. *UACR = urine albumin-to-creatinine ratio (a measure of albuminuria)*

RMCL-002: Trial Design



Key Entry Criteria

- Type 2 Diabetes Mellitus (DKD)
- Male or female 30-80 years of age
- eGFR ≥20 and ≤50 mL/min/1.73m^2
- Not on kidney dialysis, HbA1c <10%

Study Endpoints

- **REACT and Procedure Related Adverse Events**
- **Change in kidney function (assessed by eGFR)**

Study Timeframe

- RMAT granted for Phase 3 program in January 2022
- 13 subjects remaining on study (n= 9 in Deferred arm) and will complete by YE 2023

Study Objectives and Endpoints

Study Objectives

- To assess the safety and efficacy of up to two REACT injections given 6 months apart and delivered into the biopsied kidney using a percutaneous approach

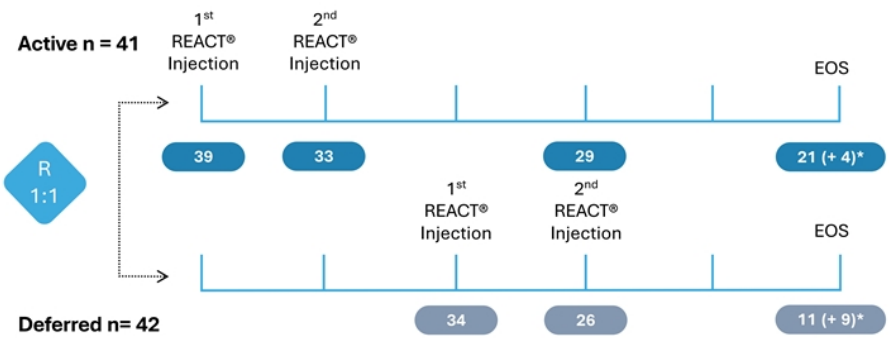
Study Endpoints

- Procedural- and investigational product-related adverse events
- Change in kidney function as measured by serial measurements of estimated glomerular filtration rate (eGFR)

Study Demographics are Balanced and Represent a High-Risk CKD Population

	ACTIVE (n=41)	DEFERRED (n=42)
Age, years *(mean +/- SD)*	66.1 +/- 9.9	64.6 +/- 8.9
Female : Male, %	29% : 71%	36% : 64%
Hispanic or Latino, %	17%	10%
Race, %		
Black or African American	2%	14%
White	93%	71%
Other	5%	14%
Blood pressure, mm HG	133 / 72	135 / 73
eGFR, ml/min/1.73m² *(mean +/- SD)*	33.9 +/- 8.6	31.8 +/- 7.4
Stage 3A CKD, n (%)	4 (10%)	3 (7%)
Stage 3B CKD, n (%)	21 (51%)	19 (45%)
Stage 4 CKD, n (%)	16 (39%)	20 (48%)
UACR mg/g *(median +/- interquartile range)*	740 (68, 1597)	598 (58, 1985)
Geometric Mean / Median of UACR mg/g	251 / 250	308 / 567
HbA1c, % *(mean +/- SD)*	7.2 +/- 1.0	7.1 +/- 1.0

Current Enrollment Status & Completion Expectations



- Rates of drop-out due to death or dialysis are typical for advanced CKD
- 13 patients remain on study (4 in Active cohort, 9 in Deferred cohort)
- All patients expected to complete the study by end of 2023
- Final study results anticipated in 1H 2024

ACTIVE COHORT

39	Before 1st Injection: 2 subjects withdrew
33	Before 2nd Injection: 4 subjects EOS** as per protocol, 1 subject expired, 1 started dialysis
29	Before 12-month follow-up after 2nd injection: 2 subjects expired, 2 subjects withdrew
21	Before 24-month follow-up after 2nd injection: 3 subjects EOS as per protocol, 1 subject started dialysis, 4 subjects remain enrolled but have not reached 24-month follow-up

DEFERRED COHORT

34	Before cross-over: 7 subjects EOS as per protocol, 1 subject started dialysis
26	Before 2nd injection: 4 subjects EOS as per protocol, 1 subject expired, 3 started dialysis
11	Before 12-month follow-up after 2nd injection: 2 subjects EOS as per protocol, 2 subjects expired, 2 subjects started dialysis, 9 subjects remain enrolled but have not reached 24-month follow-up

* Subjects pending last eGFR measurement. EOS = End of Study

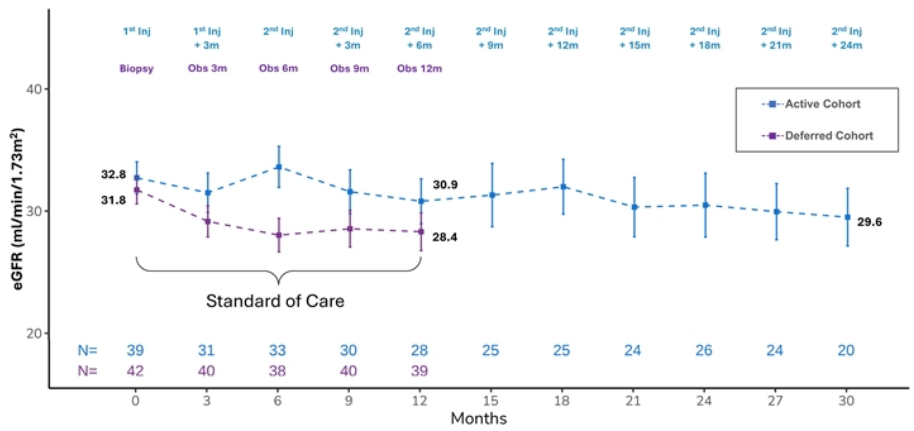
No REACT-related SAE's Identified in RMCL-002

ADVERSE EVENT	BIOPSY # of patients (%) (N=83)*	REACT INJECTION # of patients (%) (N=132)*
Hematoma	1(1.2)	1(0.8)
Pain	0	3(2.3)
Hematuria	0	0
Transfusion	0	1 (0.8)
Surgical Intervention	0	0
Death	0	0
Acute Kidney Injury	0	1(0.8)
CKD progression	0	1(0.8)
Renal vascular disorder	0	1(0.8)
Kidney fibrosis	0	1(0.8)

*All events are based on sponsor assessment of causality
No REACT-related serious adverse events were observed
Procedure-related serious adverse events were observed in 6/83 subjects including 1 participant who experienced a hematoma, transfusion, and acute kidney injury. A needle design change was implemented after this event

Active Cohort Patients Showed No Clinically Meaningful eGFR Decline Over 30 Months

Change in Average eGFR in Active Cohort vs Deferred Cohort on SOC



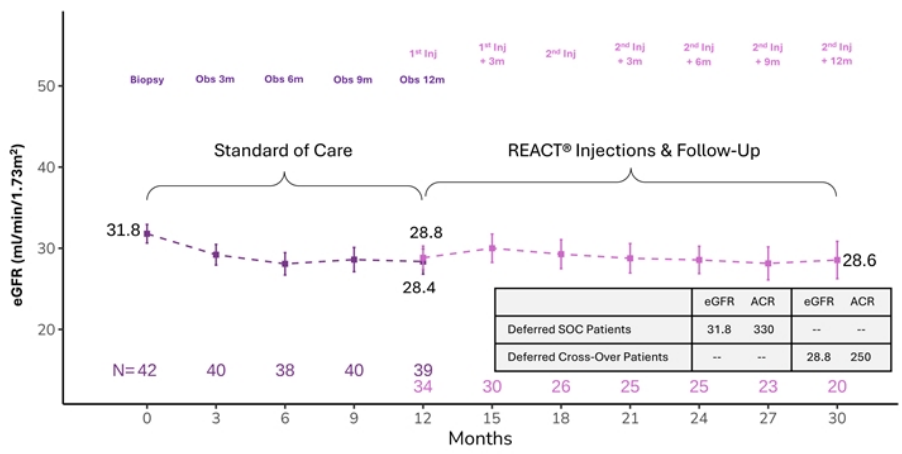
The Active Cohort showed a cumulative change in average eGFR of **-3.2 ml/min/1.73m^2 after 30-months**;

The Deferred Cohort, receiving standard of care, showed a cumulative change in average eGFR of **-3.4 ml/min/1.73m^2 after 12-months.**

Data points are mean +/- SEM ; Data as of August 1, 2023

Deferred to Cross-Over Patients Showed Preservation of eGFR after REACT Injection

Average eGFR in Deferred Cohort: SOC followed by REACT® Treatment



	eGFR	ACR	eGFR	ACR
Deferred SOC Patients	31.8	330	--	--
Deferred Cross-Over Patients	--	--	28.8	250

Average eGFR of the Deferred cohort was 31.8 at baseline vs 28.4 at 12 months

[absolute difference of -3.4 ml/min/1.73m² over 12 months]

Average eGFR at 1st injection after cross-over was 28.8 vs 28.6 at 18 months

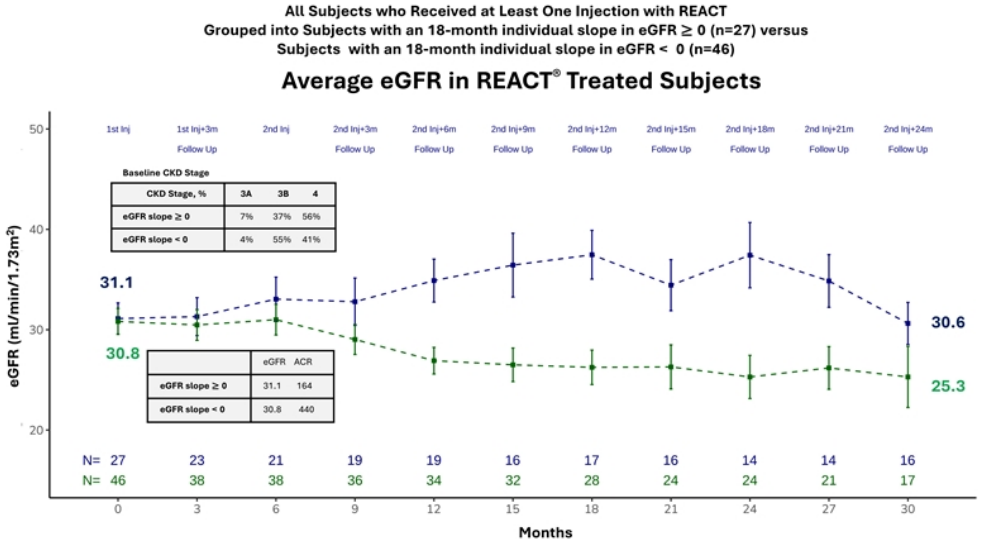
[absolute difference of -0.2 ml/min/1.73m² over 18 months]

Data as of August 1, 2023

PROKIDNEY

Post-Hoc Analysis of All Subjects who Received at Least One Injection

37% of subjects (27 / 73) had preservation of eGFR during 30 months of follow-up



Data as of August 1, 2023

REACT treated subjects with 18-month individual eGFR Slope ≥ 0 had a change in average eGFR of

-0.5 ml/min/1.73m²

[56% of these subjects had Stage 4 CKD]

REACT treated subjects with 18-month individual eGFR Slope < 0 had change in average eGFR of

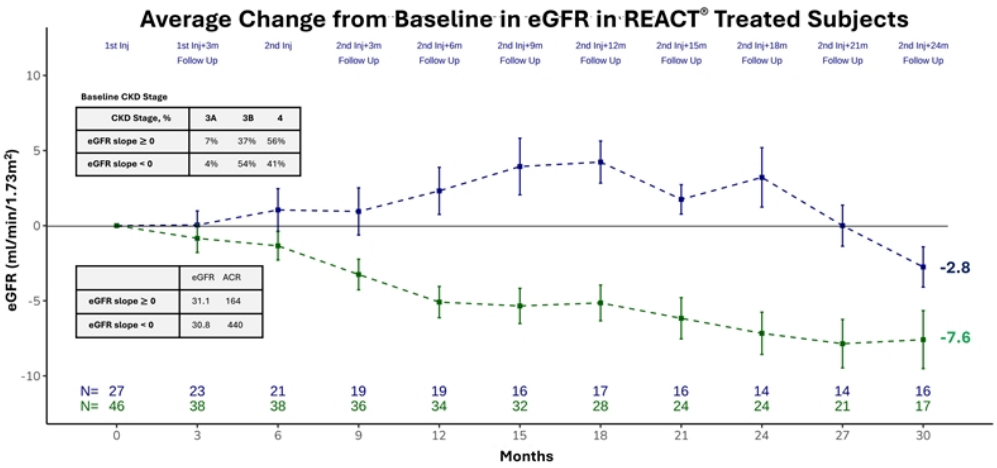
-5.5 ml/min/1.73m²

[41% of these subjects had Stage 4 CKD]

Post-Hoc Analysis of All Subjects who Received at Least One Injection

37% of subjects (27 / 73) had preservation of eGFR during 30 months of follow-up

All Subjects who Received at Least One Injection with REACT
Grouped into Subjects with an 18-month individual slope in eGFR ≥ 0 (n=27) versus
Subjects with an 18-month individual slope in eGFR < 0 (n=46)



Data as of August 1, 2023

REACT treated subjects with 18-month individual eGFR Slope ≥ 0 had an average change from baseline in eGFR of

-2.8 ml/min/1.73m²
at 30 months

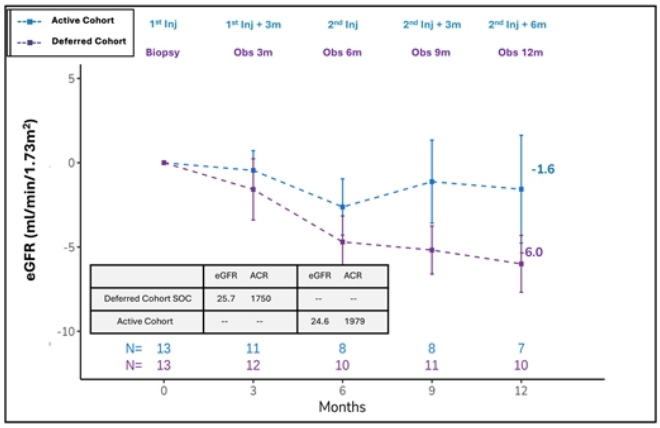
REACT treated subjects with 18-month individual eGFR Slope < 0 had an average change from baseline in eGFR of

-7.6 ml/min/1.73m²
at 30 months

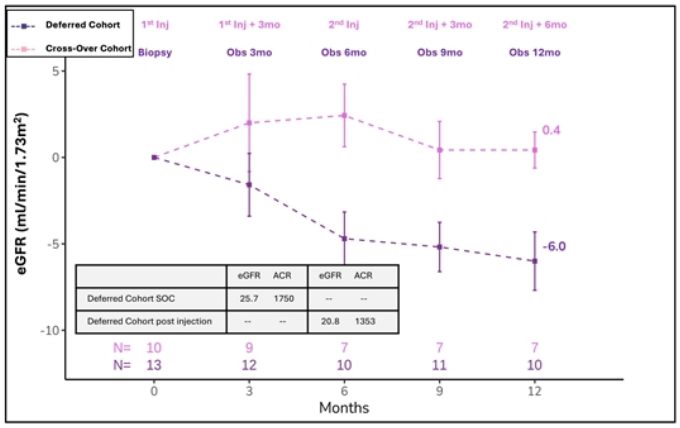
Subgroup Analysis of Diabetic Patients with CKD Stage 4 and Class A3 Albuminuria*

Stabilization of Kidney Function in Active (n=13) and Deferred (n=10) Patients at 12 months vs SOC

Avg Change in eGFR from Baseline In Active vs Deferred Patients on SOC



Avg Change in eGFR from Baseline in Cross-Over vs Deferred Patients on SOC



***Patients with Stage 4 CKD & Class A3 (Severe Albuminuria, >300 mg/g) are one of the fastest progressing patient populations[1]**

Data as of August 1, 2023

1. *Oshima M, Shimizu M, Yamanouchi M, et al. Trajectories of kidney function in diabetes: a clinicopathological update. Nat Rev Nephrol. 2021;17(11):740-750. doi:10.1038/s41581-021-00462-y*

In this Phase 2 Study, REACT® Demonstrates the Potential for Preservation of Kidney Function in Patients with Diabetes and Advanced Kidney Disease

Key Findings

- REACT showed potential to preserve kidney function for up to 30 months in several patient groups
- REACT's benefit on kidney function was most notable in patients who had the highest risk of kidney failure (CKD 4 with high UACR[1])
- REACT injections were well tolerated with a consistent safety profile comparable to kidney biopsy

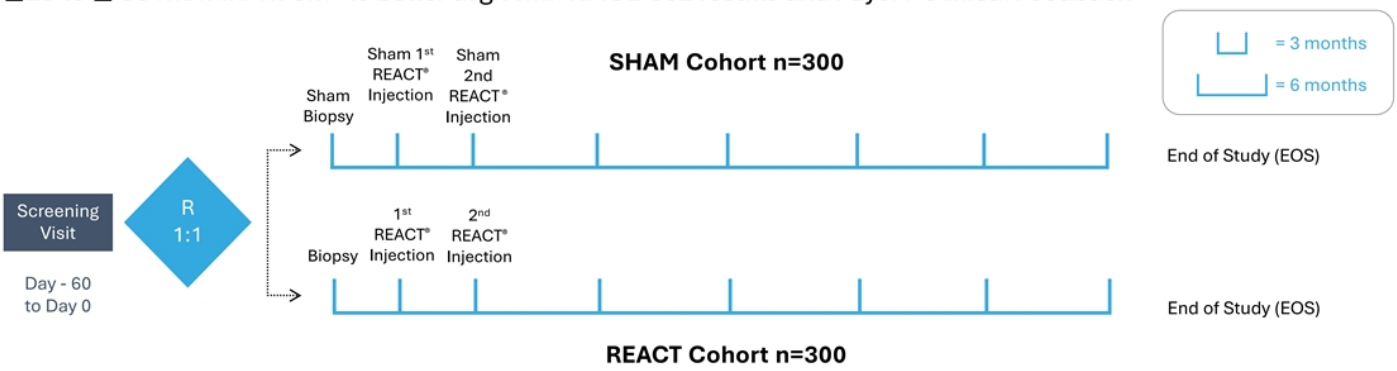
Next Steps

- We are enriching our Phase 3 Proact 1 Study to include more patients with the highest risk of kidney failure

1. *UACR = urine albumin-to-creatinine ratio (a measure of albuminuria)*

REACT® Registrational Program: proact 1 (REGEN-006)

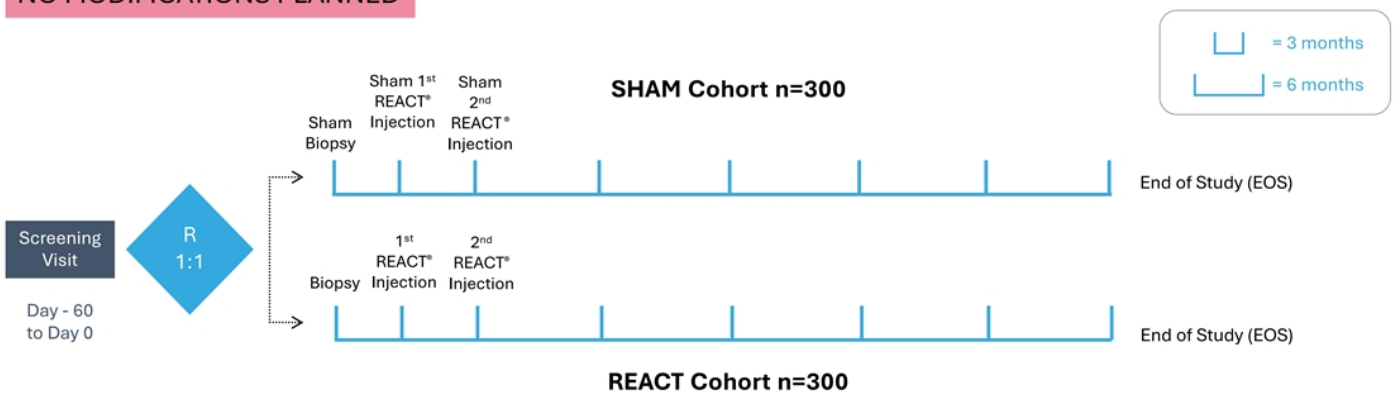
Modifying proact 1 eGFR enrollment criteria from current range of ≥20 to ≤ 50ml/min/1.73m² to new range of ≥20 to ≤ 35 ml/min/1.73m² to better align with RMCL-002 results and Payer / Clinical Feedback



Existing Key Entry Criteria	New Protocol Modifications	Time-to-Event Primary Composite Endpoint (Unchanged)
• CKD caused by Type II Diabetes • Male or Female 30-80 years of age • **eGFR ≥20 and ≤50 mL/min/1.73m²** • Not on renal dialysis, HbA1c <10% • UACR 300 - 5,000 mg/g	• **eGFR ≥20 and ≤ 35 ml/min/1.73m²** • UACR 300 - 5,000 mg/g for eGFR 30-35 • Updating standard of care expectations • 600 patients in addition to ~50 currently enrolled patients who meet new eGFR criteria	• 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

REACT® Registrational Program: proact2 (REGEN-016)

NO MODIFICATIONS PLANNED



Key Entry Criteria	Protocol	Time-to-Event Primary Composite Endpoint
• CKD caused by Type II Diabetes • Male or Female 30-80 years of age • eGFR ≥ 20 and ≤ 44 mL/min/1.73m^2 • Not on renal dialysis, HbA1c <10% • UACR 300 - 5,000 mg/g	• No protocol modifications planned	• At least 40% reduction in eGFR; • eGFR<15mL/min/1.73m^2 sustained for 30 days and/or chronic dialysis, and/or renal transplant; or • Death from renal or cardiovascular causes

Advancing a Comprehensive Clinical Plan

1H 2023	2H 2023	2024 and beyond	
☑ **REGEN-003 Phase 2 Trial; Results published 1Q23** • Safety & efficacy of REACT® • Stage 4/5 Diabetic CKD (eGFR 14-20) • Assess impact on progression and time to dialysis in patients with imminent risk of dialysis	☑ **RMCL-002 Phase 2 Enrollment complete Interim results 2H23** • Last patient last visit December 2023 • Stage 3b/4 Diabetic CKD (eGFR 20-50) • 2 injections into biopsied kidney • Open label safety & efficacy of REACT • **Full results in 1H 2024**	**REGEN-007 Phase 2 Enrollment complete** • Open-label trial Diabetic CKD Stage 3/4 (eGFR 20-50) • Bi-lateral kidney injections • Cryopreserved commercial formulation • **Interim Results mid-2024** • **Full results in 1H 2025**	**REACT® Phase 3 Diabetic CKD Trials** **proact 1 – Enrollment focused on U.S.** **proact 2 – Enrollment focused ex-U.S.** • Enriching proact 1 with high-risk patients to align with 002 data and meet clinical and payer needs • Manufacturing temporarily paused while company amends proact 1 protocol and concurrently, in response to QP audit, optimizes capabilities to meet EU and Global manufacturing and quality management system standards for Phase 3 studies, and prepares for transition to commercial manufacturing. NO SAFETY EVENTS are responsible for this pause • Expect proact 1 will resume, and proact 2 will commence, enrollment in mid-2024 • **Completion of both studies anticipated in 2027**

Cash Position (9/30/2023) $396M cash provides runway into 4Q 2025

Regulatory
- FDA / EMA agreement on pivotal study design
- RMAT designation in U.S.

PROKIDNEY

RMCL-002 Interim Results & Updates

November 14, 2023

Developing Solutions for Dialysis Prevention

REACT® [**RE**nal **A**utologous **C**ell **T**herapy]

Appendix

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Annualized eGFR Slopes using Linear Mixed Effects Modeling

Subject Group	Number of Subjects	Duration of Follow-up	Annualized eGFR Slope (ml/min/1.73m²)
Active Cohort	39	12-months after 1st injection	-3.6
Deferred Cohort during standard of care (SOC)	42	12-months after biopsy	-3.4
Deferred Cohort after Cross-over and injection with REACT	34	12-months after 2nd injection	-0.8
Active Cohort, Stage 4 and UACR > 300 mg/g	13	12-months after 1st injection	-2.4
Deferred Cohort during SOC, Stage 4 and UACR > 300 mg/g	13	12-months after biopsy	-5.8
Deferred Cohort after Cross-over, Stage 4 and UACR > 300mg/g	10	12 months after 1st injection	-0.4

ProKidney Announces Positive Interim Data from RMCL-002 Phase 2 Clinical Trial of Renal Autologous Cell Therapy (REACT®) for Diabetic CKD and Provides Corporate Updates

Updated positive interim Phase 2 data demonstrate potential efficacy of REACT® to preserve kidney function in moderate and high-risk diabetic CKD patients

Focusing Phase 3 development program on patients with Stage 3b and 4 diabetic CKD at highest risk of advancing to kidney failure and need for renal replacement therapy

Dr. Bruce Culleton appointed ProKidney CEO following Dr. Tim Bertram's transition to advisory role

Sufficient capital to fund operations into fourth quarter 2025

ProKidney to host conference call and webcast tomorrow at 8:00 a.m. ET

WINSTON-SALEM, N.C., November 13, 2023 — **ProKidney Corp. (Nasdaq: PROK)** ("ProKidney"), a leading late clinical-stage cellular therapeutics company focused on chronic kidney disease (CKD), today announced updated positive interim diabetic CKD data from its RMCL-002 Phase 2 study that support the Company's evolution into late-stage development and position the Company to change the treatment paradigm in high-risk diabetic CKD patients with its REACT® (rilparencel) renal autologous cell therapy.

Positive interim Phase 2 data demonstrate the potential of REACT® to preserve kidney function in moderate and high-risk diabetic CKD patients. Updated interim REACT RMCL-002 study data support continued investigation of REACT's potential to benefit patients with moderate and high-risk diabetic CKD. The updated data include information from 83 patients enrolled in the RMCL-002 study. All patients had Stage 3 or 4 CKD caused by type 2 diabetes. The ongoing Phase 2 clinical study assessed adverse events and changes in kidney function as measured by estimated glomerular filtration rate (eGFR), as primary study endpoints. The dataset revealed a safety profile in line with previous Phase 1 & 2 REACT trials, with REACT showing a safety profile similar to that of a kidney biopsy. Overall, the updated Phase 2 trial data showed preservation of kidney function in several patient groups with advanced CKD caused by type 2 diabetes, with the most notable potential benefit shown in patients who had the highest risk of kidney failure (CKD Stage 4 with severe albuminuria), where there remains a significant unmet clinical need.

Pablo Legorreta, Chairman of ProKidney's Board of Directors, said "We are excited to report more mature interim data for ProKidney's RMCL-002 Phase 2 study which suggests that REACT® was able to preserve kidney function for up to 30 months in a meaningful proportion of the patients treated in the study. When I got involved with ProKidney, I hoped that if REACT could slow the decline of kidney function in a meaningful proportion of patients, it could become an important and differentiated therapy. It is exciting to see that REACT appears to have exceeded my expectations of preservation of kidney function in this population that faces significant unmet medical needs."

Focusing ongoing Phase 3 development program on patients with Stage 3b and 4 diabetic CKD at highest risk of advancing to kidney failure and need for renal replacement therapy. Based on these emerging results, the Company plans to update its ongoing **proact 1** Phase 3 clinical study (REGEN-006) protocol to focus on patients with higher risk of kidney failure. In the **proact 1** Phase 3 clinical study we will modify the eGFR enrollment range from the **current range of ≥20 to ≤ 50 ml/min/1.73m^2** to **a new range of ≥20 to ≤ 35 ml/min/1.73m^2**, to focus on the most severe patients, to better align with RMCL-002 results and clinical feedback. The Company does not intend to modify the eGFR enrollment range for its second Phase 3 trial, **proact 2** (REGEN-016), which is currently **≥20 to ≤ 44 ml/min/1.73m^2**. Maintaining the eGFR enrollment range of **proact 2**, which includes the CKD Stage 3B population, will enable the Company to seek a broader

commercial label. The modification to the eGFR enrollment range to our **proact 1** Phase 3 clinical study will cause a delay in enrollment of this study, and we expect to resume enrollment during the first half of 2024.

ProKidney to temporarily pause manufacturing to address Qualified Person Audit - No safety events are responsible for this pause. A recent audit performed by the Company's contracted qualified person (QP) to evaluate its readiness for release and distribution of REACT to the EU, while still in process, identified certain deficiencies in the documentation of the quality management systems to be addressed prior to release and distribution of product for EU clinical sites. Many of these improvements to GMP systems and control activities were ongoing but had not yet been completed at the time of the audit.

The Company is temporarily pausing manufacturing until the first half of 2024, while the Company optimizes its capabilities to meet EU and global standards for its Phase 3 program and future commercial manufacturing. The Company will work to implement these manufacturing and documentation improvements concurrently with the 006 pause for protocol changes such that it expects proact 1 will resume, and proact 2 will commence enrollment in the first half of 2024.

Dr. Bruce Culleton, EVP Clinical Development and Commercialization, to be appointed ProKidney CEO upon Dr. Tim Bertram's transition to an advisory role. As the Company progresses into pivotal development and commercialization, ProKidney is pleased to announce the appointment of Dr. Bruce Culleton as the Company's CEO, effective November 15, 2023. Dr. Culleton will also join the ProKidney board of directors. Dr. Tim Bertram will transition from his current role as director and CEO to a scientific advisory role.

"We're leveraging a novel renal autologous cell therapy to improve care in a population of CKD patients with little to no options other than dialysis, and Dr. Culleton is uniquely qualified as a physician and business leader to guide ProKidney through the pivotal trials of REACT®, said Dr. Bertram. "I look forward to supporting the Company and helping ensure a smooth transition for the organization."

Commenting on his new role, Dr. Culleton stated, "I am honored to accept the role of CEO at ProKidney and to build upon the foundation laid by Dr. Bertram. I am excited by the opportunity to bring a life-changing solution to patients who are on a path to dialysis. ProKidney is well positioned to execute on a successful Phase 3 program, and I look forward to working with the team on this next phase while staying true to putting patients first in everything we do."

Mr. Legorreta added "We are thrilled to welcome Dr. Culleton into his new role as CEO, as he builds upon Dr. Betram's successes at ProKidney. Bruce's clinical, regulatory and commercial expertise will be invaluable as ProKidney navigates its Phase 3 studies towards completion, prepares for regulatory submission both in the U.S. and abroad, and prepares REACT for commercialization. We are thankful for Dr. Bertram's development of REACT and his decades-long perseverance and dedication to bringing the therapy forward to patients with kidney disease. Dr. Bertram's significant contribution has been instrumental in advancing ProKidney from its inception and into clinical development."

Dr. Culleton joined ProKidney in July 2023 as Executive Vice President of Clinical Development and Commercialization. Dr. Culleton has dedicated his 25-year professional career to improving the health and quality of life of patients with kidney disease. Over this time his responsibilities have included direct patient care, clinical research, product development, and executive leadership positions at Baxter Healthcare and CVS Kidney Care, a wholly owned subsidiary of CVS Health.

Dr. Culleton earned a Doctor of Medicine degree from Memorial University of Newfoundland, and a Master's Degree in Business Administration from Northwestern University, Kellogg School of Management. He completed specialization in Internal Medicine and Nephrology through the Royal College of Physicians and Surgeons of Canada, as well as a fellowship in Clinical Epidemiology at Boston University, Framingham Heart Study.

Sufficient capital to fund operations into fourth quarter 2025. ProKidney reported it has $396 million in cash, cash equivalents and marketable securities as of September 30, 2023. With the changes the Company announced today, including protocol modifications and manufacturing improvements, the Company expects to be able to fund operations into the fourth quarter of 2025.

The Company expects to provide full data of its RMCL-002 Phase 2 study in the first half of 2024 and interim results on its ongoing RMCL-007 Phase 2 study in mid- 2024 and full results in the first half of 2025. The Company will provide additional guidance regarding the timing of its Phase 3 programs during the conference call on November 14, 2023.

Investor Conference Call

ProKidney management will be hosting a webcast and investor conference call tomorrow, November 14, 2023, at 8:00 a.m. ET. The live webcast presentation may be accessed here. Further, you may listen to the presentation by dialing 1-877-407-0784 (US) or 1-201-689-8560 (International) and entering the Conference ID: 13742672. Following the completion of the presentation, a replay of the webcast will also be accessible on the investor relations section of ProKidney website here.

About ProKidney

ProKidney, a pioneer in the treatment of CKD through innovations in cellular therapy, was founded in 2015 after a decade of research. ProKidney's lead product candidate, REACT® (Renal Autologous Cell Therapy), is a first-of-its-kind, patented, proprietary autologous cellular therapy being evaluated to potentially preserve kidney function in diabetic patients at high risk of kidney failure. REACT® has received Regenerative Medicine Advanced Therapy (RMAT) designation, as well as FDA and EMA guidance, supporting its ongoing Phase 3 clinical program that launched in January 2022. For more information, please visit www.prokidney.com.

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 expectations with respect to financial results and expected cash runway, 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, updating clinical trial protocols, 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 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 clearances or approvals 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 COVID-19 or geo-political conflict such as the war in Ukraine 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.

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