# 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): January 25, 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** **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 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 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description of Exhibit |
|---|---|
| 99.1 | Investor Presentation |
| 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: January 25, 2024

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

Exhibit 99.1

PROKIDNEY

# Corporate Presentation

January 2024

*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

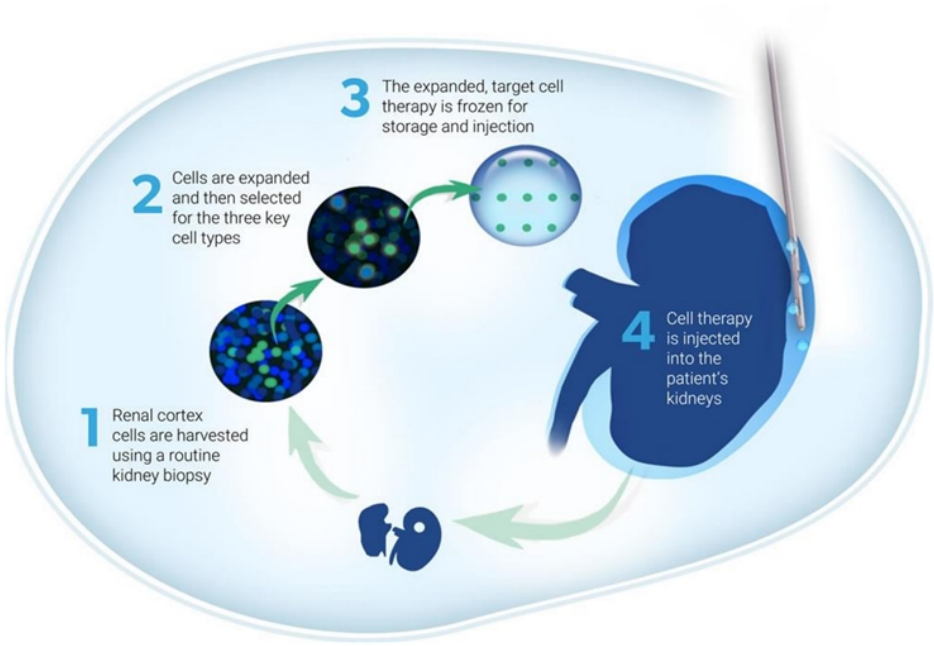
Potential label expansion to re-dose REACT for **long-term dialysis prevention**



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

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# 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/1.73m², N = 600) | | | | 006/proact 1 | | Ongoing |
| **Diabetes Type II – Prevent/Delay CKD 3/4 stratified for SGLT2i** (20-44 ml/min/1.73m², 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/1.73m², N = 10) | | | | 003 | | Trial Completed |
| **Diabetes Type II – Prevent/Delay CKD 3/4** (20-50 ml/min/1.73m², N = 81) | | | | 002 | | Fully Enrolled |
| **Diabetes Repeat Dose Prevent/Delay CKD 3/4** (20-50 ml/min/1.73m², N= 50) | | | | 007 | | Fully Enrolled |
| **Multi / extended-dosing for previously REACT-treated patients** | | | | 015 | | Fully Enrolled |
| **Congenital Anomalies – Prevent/Delay** (14-50 ml/min/1.73m², 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

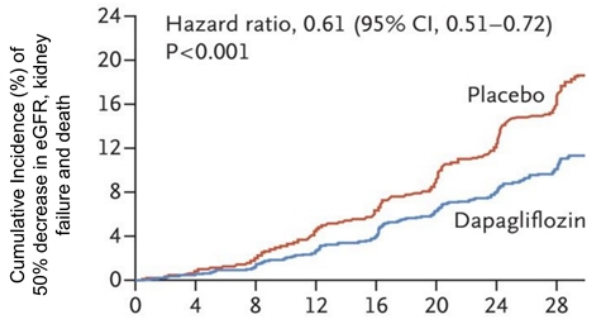



1. *Perkovic V et al. N Eng J Med 2019*
2. *Heerspink H et al. N Engl J Med 2020*
3. *Herrington et al. N Engl J Med 2023*
4. *Bakris G et al. N Engl J Med 2020*
5. *Rossing P et al. Nephrol Dial Transplant 2023*

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

## Standard of Care has Limitations

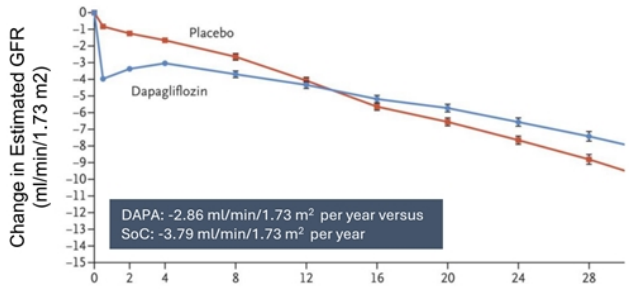
**Current standard of care[1] does not prevent events in ~ 50-75% of people with diabetic kidney disease[2]**




**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

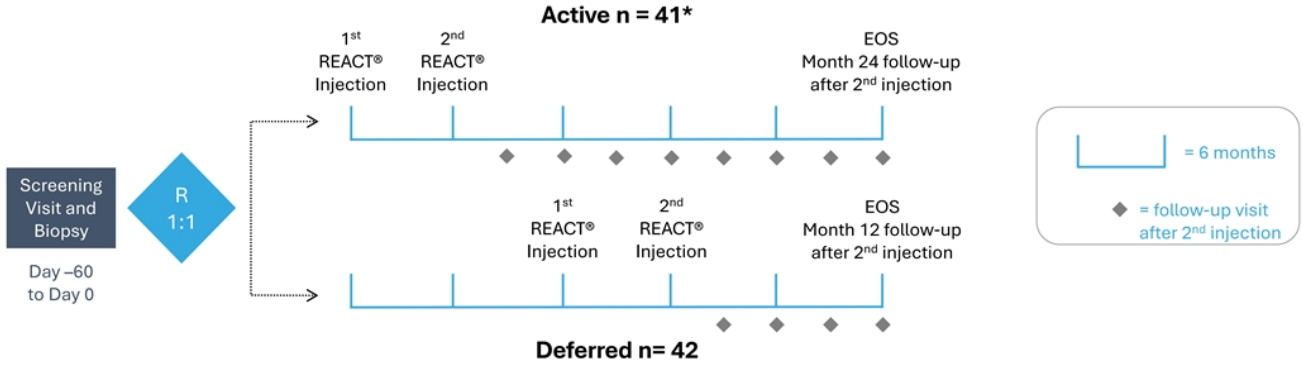
**Next Steps**

- 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

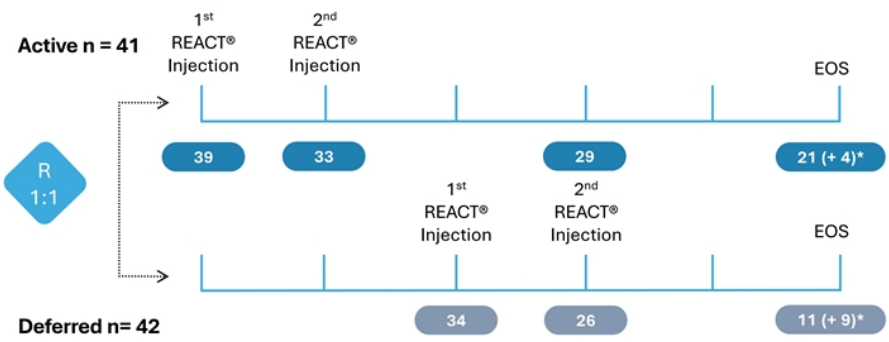
**Study Endpoints**

- 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/1.73m$^2$ *(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 |

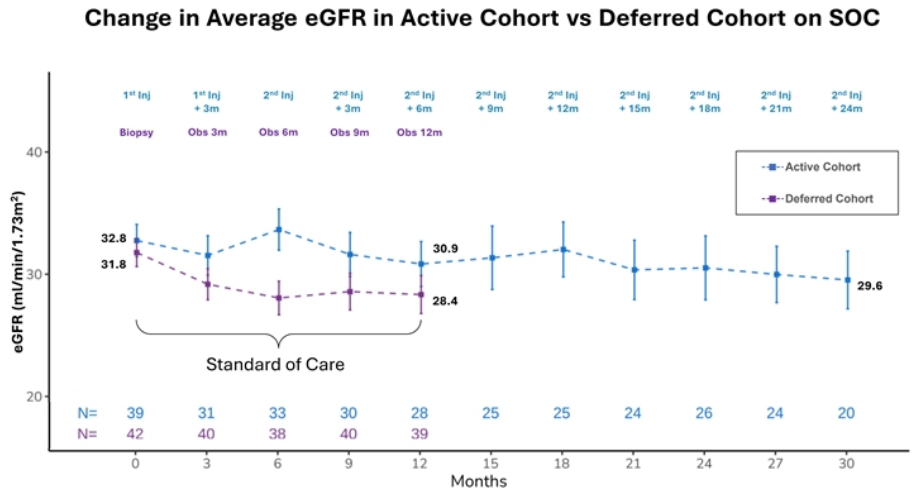
* Subjects pending last eGFR measurement. EOS = End of Study

# 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



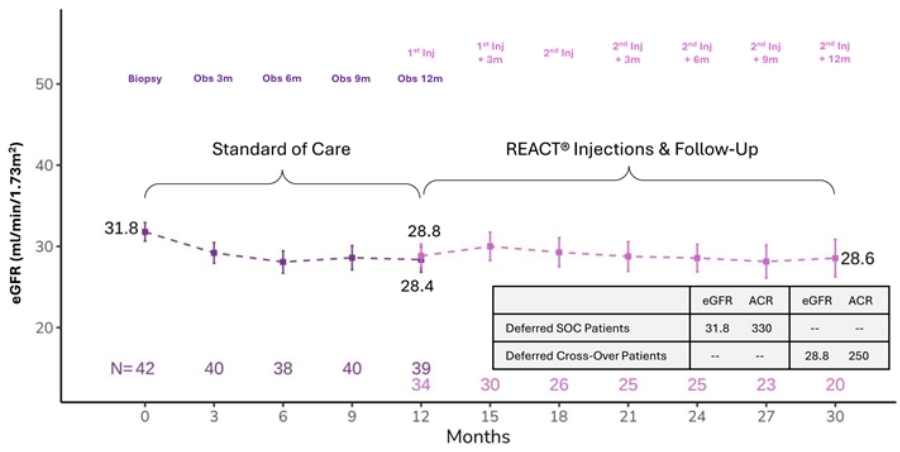

The Active Cohort showed a cumulative change in average eGFR of **-3.2 ml/min/1.73m² after 30-months**;

The Deferred Cohort, receiving standard of care, showed a cumulative change in average eGFR of **-3.4 ml/min/1.73m² 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**




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]**

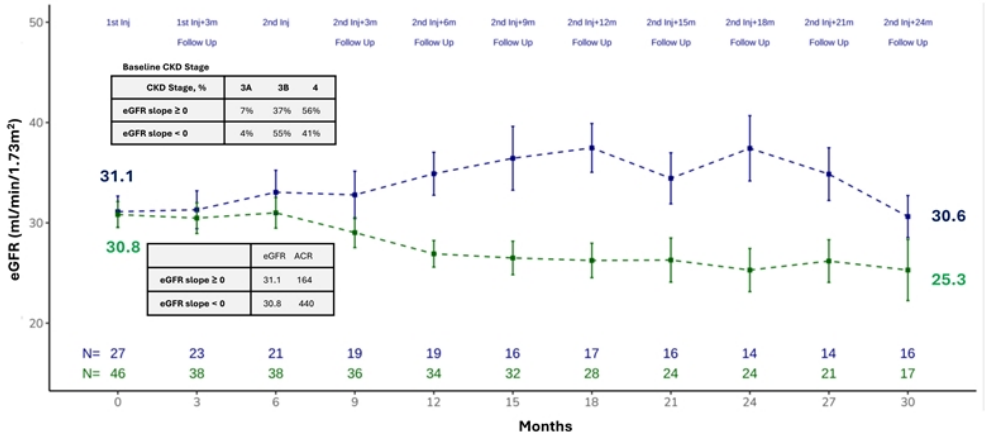
Data as of August 1, 2023

# 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)**

### Average eGFR in REACT® Treated Subjects




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

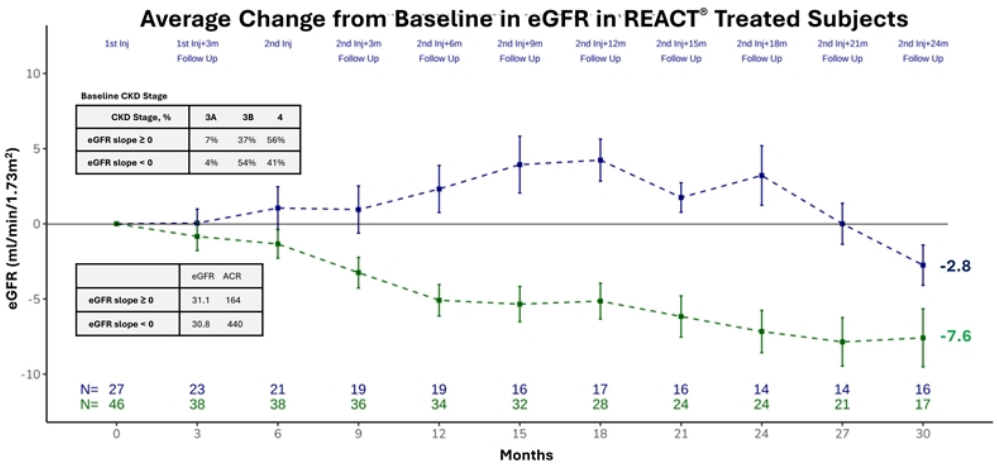
**-5.5 ml/min/1.73m²**

**[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

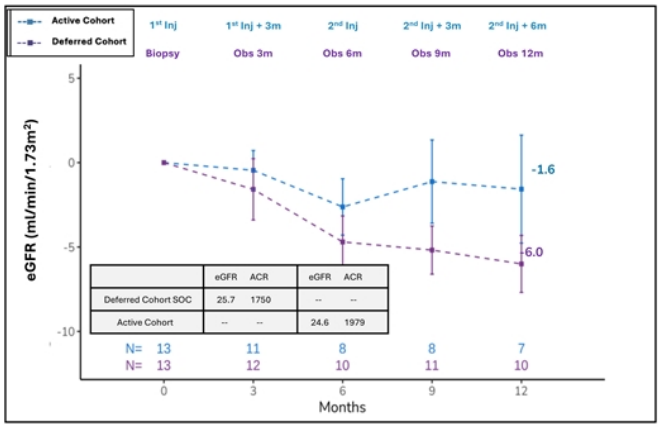
REACT treated subjects with 18-month individual eGFR Slope < 0 had an average change from baseline in eGFR of

**-7.6 ml/min/1.73m²**
at 30 months

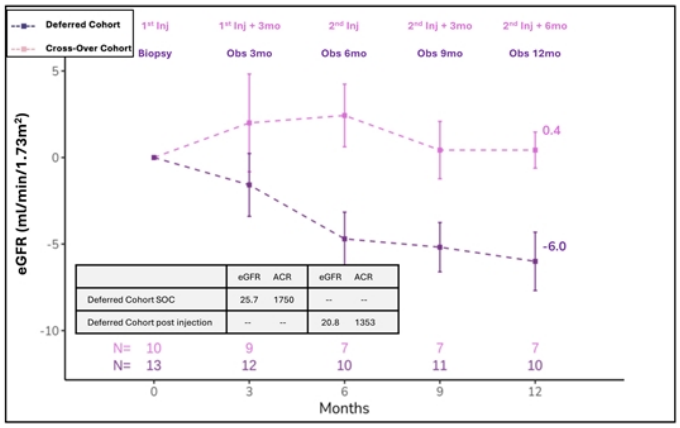
# Subgroup Analysis of Diabetic Patients with CKD Stage 4 and Class A3 Albuminuria*

## 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**

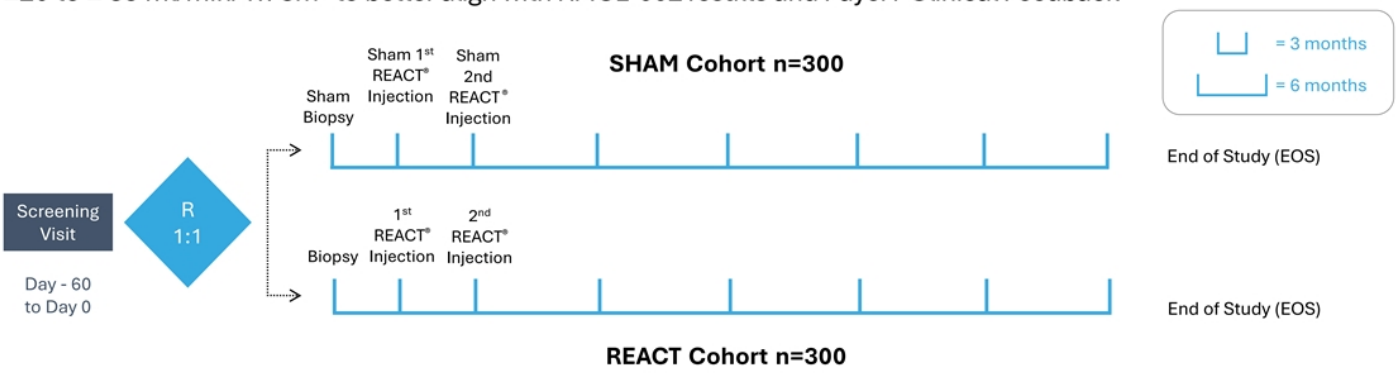
- We are enriching our Phase 3 Proact 1 Study to include more patients with the highest risk of kidney failure



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/1.73m$^2$ to new range of ≥20 to ≤ 35 ml/min/1.73m$^2$ to better align with RMCL-002 results and Payer / Clinical Feedback



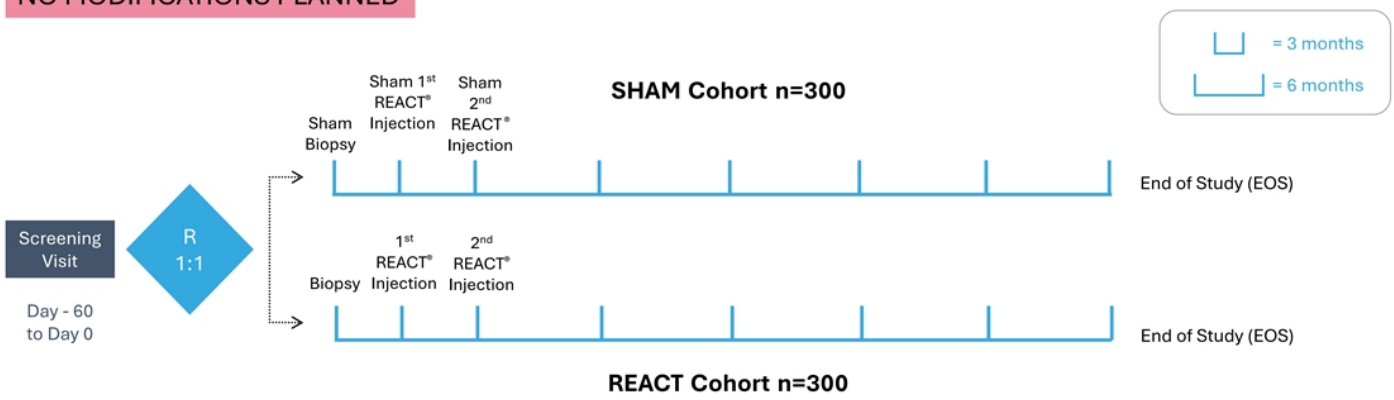

| Existing Key Entry Criteria | New Protocol Modifications | Time-to-Event Primary Composite Endpoint (Unchanged) |
|---|---|---|
| • CKD caused by Type II Diabetes<br>• Male or Female 30-80 years of age<br>• **eGFR ≥20 and ≤50 mL/min/1.73m$^2$**<br>• Not on renal dialysis, HbA1c <10%<br>• UACR 300 - 5,000 mg/g | • **eGFR ≥20 and ≤ 35 ml/min/1.73m$^2$**<br>• UACR 300 - 5,000 mg/g for eGFR 30-35<br>• Updating standard of care expectations<br>• 600 patients in addition to ~50 currently enrolled patients who meet new eGFR criteria | • At least 40% reduction in eGFR;<br>• eGFR<15mL/min/1.73m$^2$ sustained for 30 days and/or chronic dialysis, and/or renal transplant; or<br>• Death from renal or cardiovascular causes |



ProKidney

# 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<br>• Male or Female 30-80 years of age<br>• eGFR ≥ 20 and ≤ 44 mL/min/1.73m$^2$<br>• Not on renal dialysis, HbA1c <10%<br>• UACR 300 - 5,000 mg/g | • No protocol modifications planned | • At least 40% reduction in eGFR;<br>• eGFR<15mL/min/1.73m$^2$ sustained for 30 days and/or chronic dialysis, and/or renal transplant; or<br>• 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**<br>• Safety & efficacy of REACT®<br>• Stage 4/5 Diabetic CKD (eGFR 14-20)<br>• Assess impact on progression and time to dialysis in patients with imminent risk of dialysis | ☑ **RMCL-002 Phase 2 Enrollment complete Interim results 2H23**<br>• Last patient last visit December 2023<br>• Stage 3b/4 Diabetic CKD (eGFR 20-50)<br>• 2 injections into biopsied kidney<br>• Open label safety & efficacy of REACT<br>• **Full results in 1H 2024** | **REGEN-007 Phase 2 Enrollment complete**<br>• Open-label trial Diabetic CKD Stage 3/4 (eGFR 20-50)<br>• Bi-lateral kidney injections<br>• Cryopreserved commercial formulation<br>• **Interim Results mid-2024**<br>• **Full results in 1H 2025** | **REACT® Phase 3 Diabetic CKD Trials**<br>**proact 1 – Enrollment focused on U.S.**<br>**proact 2 – Enrollment focused ex-U.S.**<br>• Enriching proact 1 with high-risk patients to align with 002 data and meet clinical and payer needs<br>• 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<br>• Expect proact 1 will resume, and proact 2 will commence, enrollment in mid-2024<br>• **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.

# World-class Leadership and Board of Directors

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PROKIDNEY

# Corporate Presentation

January 2024

*Developing Solutions for Dialysis Prevention*

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

# Appendix

PROKIDNEY

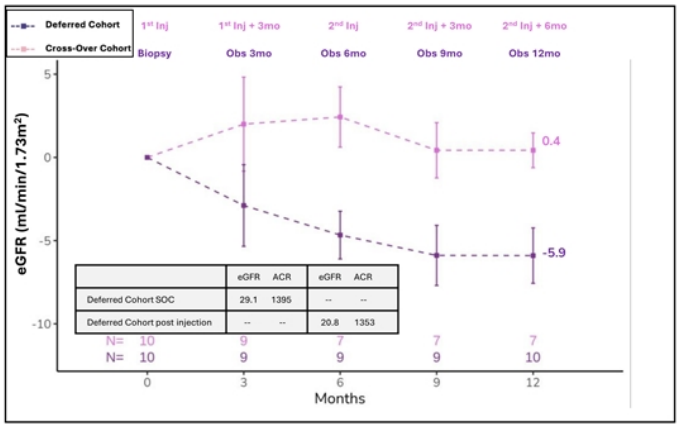
# Annualized eGFR Slopes using Linear Mixed Effects Modeling

| Subject Group | Number of Subjects | Duration of Follow-up | Annualized eGFR Slope (ml/min/1.73m$^2$) |
|---|---|---|---|
| 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 2$^{nd}$ injection | -0.8 |
| Active Cohort, Stage 4 and UACR > 300 mg/g | 13 | 12-months after 1$^{st}$ 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 1$^{st}$ injection | -0.4 |

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

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

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




Includes subjects in the Standard-of-Care (SOC) cohort who received REACT after cross-over (n=10). 3 subjects excluded due to attrition during 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*