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): July 08, 2025

PROKIDNEY CORP.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**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: 336 999-7019

(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 common stock, $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.

On July 8, 2025, ProKidney Corp. (the "Company") issued a press release to announce topline results for its REGEN-007 study. REGEN-007 is an ongoing Phase 2, prospective, randomized, open-label, repeat dose, two group, safety and efficacy study of rilparencel in subjects with type 1 or 2 diabetes and CKD. A copy of the press release is furnished as Exhibit 99.1

In addition, 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 99.2.

The information in this Current Report on Form 8-K (including Exhibits 99.1 and 99.2) is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in Items 7.01 and 9.01 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 report 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
99.1	Press Release dated July 8, 2025
99.2	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: July 8, 2025

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

ProKidney Reports Statistically and Clinically Significant Topline Results for the Phase 2 REGEN-007 Trial Evaluating Rilparencel in Patients with Chronic Kidney Disease and Diabetes

- *Full results from REGEN-007 are being held and will be submitted to the American Society of Nephrology 2025 Kidney Week as a late-breaking clinical trial*
- *In Group 1 (n=24), kidney function stabilized in patients randomized to receive two rilparencel injections (one in each kidney). The annual decline in eGFR slope improved by 78% from -5.8 mL/min/1.73m^2 in the pre-injection period to -1.3 mL/min/1.73m^2 in the period following the last rilparencel injection. This 4.6 mL/min/1.73m^2 per year difference was statistically significant (p<0.001) and clinically meaningful*
- *In Group 2 (n=25), patients were randomized to receive a single rilparencel injection followed by a second injection only if kidney function worsened and a re-dosing trigger was met. The annual decline in eGFR slope improved by 50% from -3.4 mL/min/1.73m^2 in the pre-injection period to -1.7 mL/min/1.73m^2 in the period following the last rilparencel injection. This 1.7 mL/min/1.73m^2 per year difference was not statistically significant (p=0.085) but suggests evidence of a dose response*
- *No rilparencel-related serious adverse events were observed; the safety profile was consistent with previously reported study results and comparable to a kidney biopsy*
- *FDA Type B meeting set for this summer to confirm ProKidney's approach to using eGFR slope as the surrogate endpoint in the ongoing Phase 3 PROACT 1 study for accelerated approval*

WINSTON-SALEM, N.C., July 8, 2025 – **ProKidney Corp. (Nasdaq: PROK)** ("ProKidney" or the "Company"), a leading late clinical-stage cellular therapeutics company focused on chronic kidney disease (CKD), today reported statistically significant and clinically meaningful positive topline results from the full Group 1 modified intent-to-treat (mITT) population of the Phase 2 REGEN-007 trial evaluating rilparencel in patients with CKD and diabetes. Rilparencel is an autologous cellular therapy that has received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food & Drug Administration (FDA) and is currently being evaluated in the ongoing Phase 3 REGEN-006 (PROACT 1) trial to demonstrate the therapy's potential to preserve kidney function in patients with advanced CKD and type 2 diabetes.

"We are very encouraged by the REGEN-007 topline results that demonstrated a robust improvement in eGFR slope following treatment with rilparencel in Group 1 as well as evidence of a dose response in Group 2. These data bolster our confidence in the design of our ongoing Phase 3 PROACT 1 study given the similarity between the dosing regimen in REGEN-007 Group 1 and PROACT 1. It is also worth noting that 15 of the 24 patients in Group 1 (63%) met key Phase 3 PROACT 1 inclusion criteria, and similar efficacy results were observed in this subgroup compared to the full Group 1 results. We plan to submit the full results from REGEN-007 to ASN's 2025 Kidney Week as a late-breaking clinical trial and are excited to share more details at that time with investors and the medical community," said Bruce Culleton, M.D., CEO of ProKidney. "We also look forward to our upcoming FDA Type B meeting in the coming weeks to confirm our approach to eGFR slope as a surrogate endpoint for accelerated approval. This meeting

represents an important step toward our goal of expediting rilparencel's potential path to market in the U.S. where there remains a significant unmet clinical need in patients with advanced CKD and diabetes."

Phase 2 REGEN-007 Overview and Topline Results
REGEN-007 is a multi-center Phase 2 open-label 1:1 randomized two-arm trial in patients with diabetes, CKD, and an estimated glomerular filtration rate (eGFR) of 20-50 mL/min/1.73m². At randomization, patients were assigned to one of two treatment groups using different dosing regimens. Group 1 replicated the dosing schedule of the ongoing Phase 3 PROACT 1 study in which patients received two scheduled rilparencel injections (one in each kidney), approximately three months apart. Group 2 tested an exploratory dosing regimen to investigate whether disease progression triggers, rather than a time-based trigger, could optimize multiple administrations of rilparencel. In Group 2, patients received a single rilparencel injection in one kidney and a second injection in the contralateral kidney only if triggered by a sustained eGFR decline from baseline of ≥ 20%, and/or an increase in the urine albumin to creatinine ratio (UACR) from baseline of ≥ 30% and ≥ 30 mg/g.

The prespecified primary endpoint for REGEN-007 is the difference in annual eGFR slope (calculated using a linear mixed effects model) in the pre-injection period versus the period following the last rilparencel injection. The pre-injection period included all historical eGFR values collected up to 24 months before the screening visit as well as the on-study central laboratory eGFR results prior to first rilparencel injection. The period following the last injection included eGFR values from the last rilparencel injection to the end of study (EOS) visit. Median follow-up after the last injection was approximately 18 months in both Group 1 and Group 2.

Fifty-three patients were randomized in the study, of whom 49 patients (mITT population) received at least one rilparencel injection. Four patients did not receive any rilparencel injections. The majority of patients were male (69%), and the mean age was 60 years. At baseline, 38 of 49 patients (78%) had type 2 diabetes mellitus and 11 (22%) had type 1 diabetes. Thirty-nine (80%) patients were receiving an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB), and 18 (37%) were receiving a sodium-glucose cotransporter-2 inhibitor (SGLT2i). At baseline, the mean (SD) eGFR was 33±10 mL/min/1.73m². Notably, the median UACR was higher in Group 1 (792 mg/g) compared to Group 2 (229 mg/g).

		Annual eGFR Slope (mL/ min/ 1.73m²)			
Group	**N (mITT)**	**Pre inj**	**Post last inj**	**Absolute benefit**	**Relative benefit**
1	24	-5.8	-1.3	**4.6**	**78%**
2	25	-3.4	-1.7	**1.7**	**50%**

In Group 1 (n=24), kidney function stabilized after receiving rilparencel. The annual decline in eGFR slope improved by 78% from -5.8 mL/min/1.73m² in the pre-injection period to -1.3 mL/min/1.73m² in the period following the last rilparencel injection. This 4.6 mL/min/1.73m² per year difference[1] was statistically significant ($p<0.001$) and clinically meaningful. Of the 24 patients in Group 1, 15 (63%) met key Phase 3 PROACT 1 inclusion criteria, and similar efficacy results were observed in this subgroup compared to the full Group 1 results. As a reminder, the Phase 3 PROACT 1 protocol was amended in 1H 2024 after a similar eGFR efficacy signal was observed in the Phase 2 RMCL-002 study subgroup analysis (n=23) of high-UACR, Stage 4 CKD patients with type 2 diabetes.

[1] Difference in values is due to rounding.

In Group 2 (n=25), the annual change in kidney function as measured by eGFR slope was -3.4 mL/min/1.73m^2 in the pre-injection period versus -1.7 mL/min/1.73m^2 in the period following the last rilparencel injection, resulting in an improvement of 50%, or 1.7 mL/min/1.73m^2 per year. This difference was not statistically significant (p=0.085) but suggests evidence of a dose response. Out of the 25 patients in Group 2, 15 (60%) met the re-dosing trigger and received a second rilparencel injection. The median time between the first and second injections in these 15 patients was approximately 11 months.

No rilparencel-related serious adverse events were observed across all patients in the study who received at least one rilparencel injection (n=49). The safety profile was consistent with previously reported study results and comparable to a kidney biopsy.

Full results from REGEN-007 are being held and will be submitted to the American Society of Nephrology (ASN) 2025 Kidney Week as a late-breaking clinical trial.

Phase 3 PROACT 1 Regulatory Progress
As previously communicated, the FDA confirmed during a Type B meeting in Q4 2024 that the accelerated approval pathway is available for rilparencel if an acceptable surrogate endpoint, such as eGFR slope, is used. ProKidney has an upcoming FDA Type B meeting this summer to confirm the approach to using eGFR slope as the surrogate endpoint for accelerated approval. Additional details are expected in mid-2025.

About Chronic Kidney Disease
CKD is a progressive condition characterized by the gradual decline of kidney function, which can ultimately lead to end-stage kidney disease (ESKD) requiring dialysis or transplantation. An estimated 37 million adults in the U.S. have CKD, though many remain undiagnosed in the early stages. Diabetes is the leading cause of CKD, and individuals with both conditions face significantly elevated risks of cardiovascular events, hospitalization, and mortality. ProKidney is developing rilparencel for patients with Stage 3b/4 CKD and diabetes, a population that includes 1 to 2 million people in the U.S. While current treatment options aim to slow disease progression, there remains a substantial unmet need for therapies that can stabilize kidney function and delay or prevent the need for dialysis in patients with advanced CKD.

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 advanced CKD and type 2 diabetes. 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 (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. The primary objective is to assess the efficacy of up to two rilparencel injections (one in each kidney) 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-in-class, patented, proprietary autologous cellular therapy being evaluated for its potential to preserve kidney function in diabetic patients at high risk of kidney failure. Rilparencel has received RMAT designation from the FDA. 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 beliefs that the FDA agrees that the Company's Phase 3 REGEN-006 (PROACT 1) trial could be sufficient to support a potential BLA submission and full regulatory approval and that the Company could consider using eGFR slope as a surrogate endpoint on an accelerated approval pathway for rilparencel, expectations with respect to financial results and expected cash runway, including the Company's expectation that current cash will support operating plans into 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: disruptions to our business or that may otherwise materially harm our results of operations or financial condition as a result of our recent domestication to the United States; the inability to maintain the listing of the Company's Class A common stock on Nasdaq; the inability of the Company's Class A common stock to remain included in various indices and the potential negative impact on the trading price of the Class A common stock if excluded from such indices; 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

Exhibit 99.2

Corporate Presentation

July 2025

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 beliefs that the FDA agrees that the Company’s Phase 3 REGEN-006 (PROACT 1) trial could be sufficient to support a potential BLA submission and full regulatory approval and that the Company could consider using eGFR slope as a surrogate endpoint on an accelerated approval pathway for rilparencel, expectations with respect to financial results and expected cash runway, including the Company’s expectation that current cash will support operating plans into mid-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: disruptions to our business that may otherwise materially harm our results of operations or financial condition as a result of our recent domestication to the United States; the inability to maintain the listing of the Company’s Class A common stock on Nasdaq; the inability of the Company’s Class A common stock to remain included in various indices and the potential negative impact on the trading price of the Class A common stock if excluded from such indices; 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. 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:

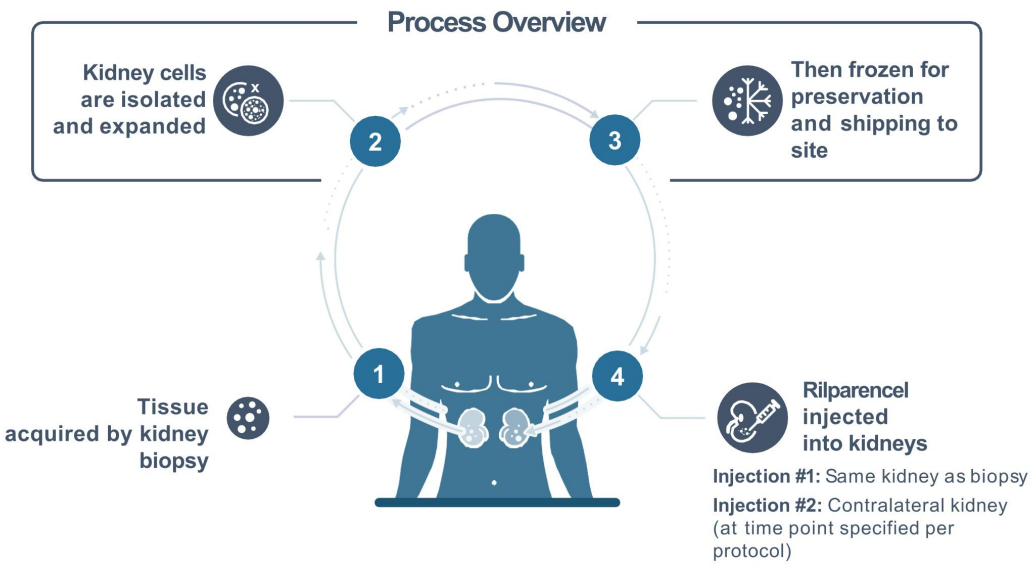
Rilparencel (REACT®) proprietary autologous cellular therapy being evaluated to **preserve kidney function** in patients with diabetes and advanced chronic kidney disease

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	**Key Developments Across Clinical and Regulatory Objectives** In July 2025, announced positive topline results for the Phase 2 REGEN-007 trial In a Q4 2024 Type B meeting, the FDA confirmed the accelerated approval pathway is available for rilparencel if an acceptable surrogate endpoint, such as eGFR slope, is used; additional details expected in mid-2025

CKD = chronic kidney disease RMAT = regenerative medicine advanced therapy

Rilparencel Tissue Acquisition-to-Injection Process Overview



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

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			

Rilparencel'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

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%

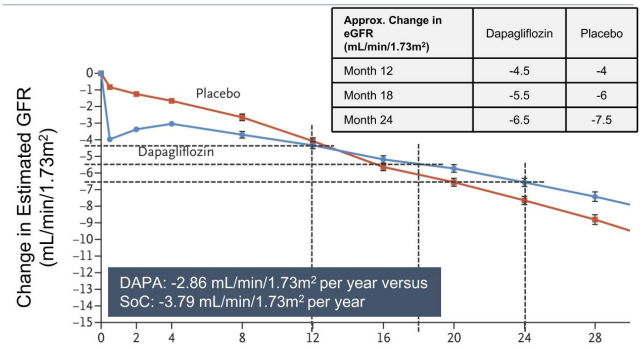
All recent landmark clinical trials in CKD primarily focus on Stage 2 and 3 CKD

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

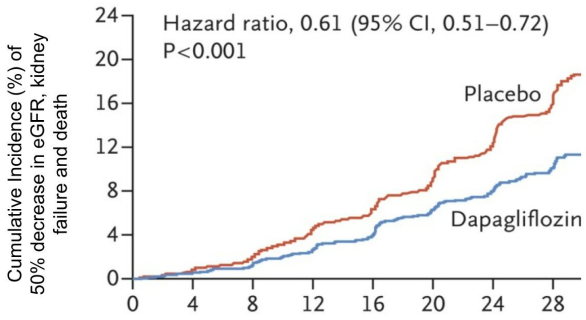
Patients continue to lose kidney function on SGLT2 inhibitors and progress to Stage 4/5 CKD



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

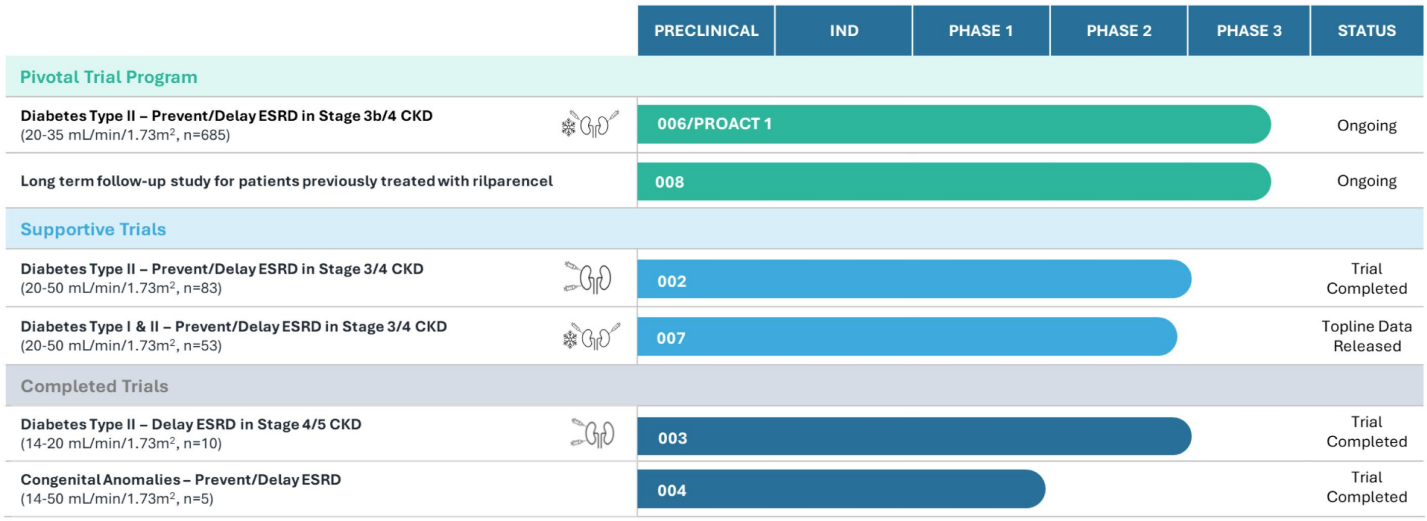
Current standard of care[1] does not prevent events in ~50-75% of people with diabetic kidney disease[2]



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

Overview of the Rilparencel Clinical Program



Frozen product Unilateral injections Bilateral injections ESRD = End-Stage Renal Disease

Advancing a Comprehensive Clinical Plan

2024

RMCL-002 Phase 2 Trial; full results published in May 2024

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

REGEN-006 (PROACT 1) Phase 3 Trial in patients with Stage 3b/4 CKD and type 2 diabetes

- In a Q4 2024 Type B meeting, FDA confirmed that PROACT 1 could be sufficient to support a full U.S. rilparencel approval
- FDA also confirmed that the **accelerated approval pathway** is available for rilparencel if an acceptable surrogate endpoint, such as eGFR slope, is used

2025 and beyond

REGEN-007 Phase 2 Trial; positive topline results announced in July 2025

- Open-label safety & efficacy trial of rilparencel in patients with Stage 3/4 CKD (eGFR 20-50) and diabetes
- Patients in Group 1 (n=24) met the primary endpoint demonstrating kidney function stabilization
- Safety profile was consistent with previously reported study results and comparable to a kidney biopsy
- Full results will be submitted as a late-breaking clinical trial to the American Society of Nephrology (ASN) Kidney Week

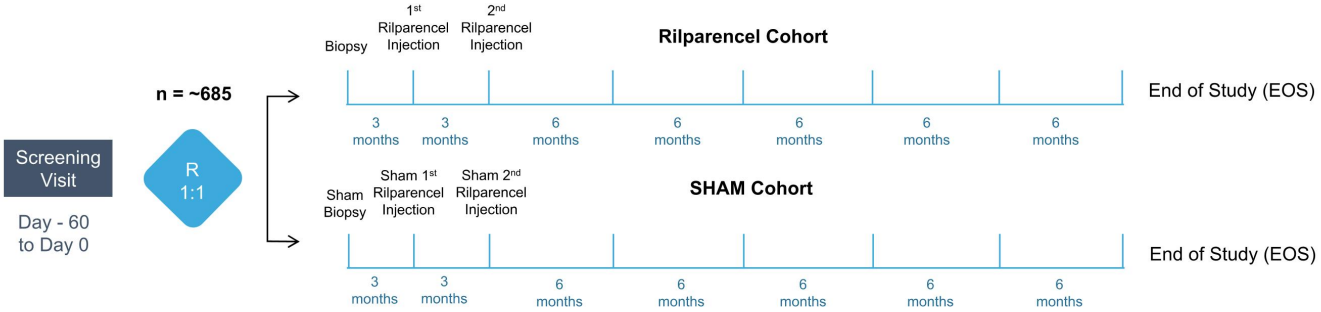
REGEN-006 (PROACT 1) Phase 3 Trial in patients with Stage 3b/4 CKD and type 2 diabetes

- Upcoming FDA Type B meeting in summer 2025 to confirm the approach using eGFR slope as the surrogate endpoint for the **accelerated approval** path for rilparencel
- Additional details expected in mid-2025

Update on rilparencel mechanism of action in 2H 2025

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 <9.5%

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

Accelerated Approval Pathway

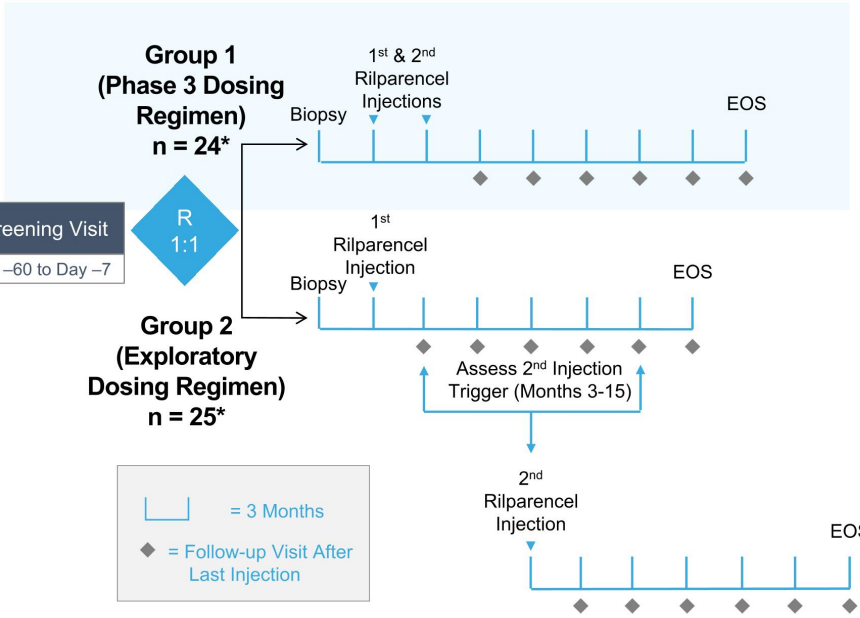
- FDA confirmed that the accelerated approval pathway is available for rilparencel if an acceptable surrogate endpoint, such as eGFR slope, is used
- Additional details expected in mid-2025

ProKidney

REGEN-007 Topline Results

REGEN-007 Trial Design

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



Pre-Injection Period

Includes all historical eGFR values collected up to 24 months before the Screening Visit as well as the on-study central laboratory eGFR results prior to first rilparencel injection.

Screening Visit

Day –60 to Day –7

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

*Modified intent-to-treat population (mITT) including all patients who received at least one rilparencel injection
eGFR = estimated glomerular filtration rate; UACR = urine albumin-to-creatinine ratio (a measure of albuminuria); EOS = end of study

REGEN-007 Objectives and Endpoints

Study Objective	Evaluate the efficacy, safety, and durability of up to two rilparencel injections on progression of kidney disease in two patient groups using different dosing regimens
Primary Efficacy Endpoint	Difference in annual eGFR slope in the pre-injection period versus the period following the last rilparencel injection*
Primary Safety Endpoint	Frequency of procedural and investigational product-related adverse events

*Pre-injection period included all historical eGFR values collected up to 24 months before the screening visit as well as the on-study central laboratory eGFR results prior to first rilparencel injection. Period following the last injection included visits from the last rilparencel injection to the EOS visit. Annual eGFR slope calculated using a linear mixed effects model.

REGEN-007 Baseline Characteristics

	Group 1 (n=24)	**Group 2** (n=25)
Age, years ***(mean +/- SD)***	62 +/- 11	58 +/- 11
Female : Male, %	33% : 67%	28% : 72%
Hispanic or Latino, %	0%	4%
Race, %		
Black or African American	8%	16%
White	92%	84%
Other	0%	0%
Blood pressure, mm HG ***(mean)***	137 / 76	132 / 77
eGFR, ml/min/1.73m² ***(mean +/- SD)***	31 +/- 8	34 +/- 12
UACR mg/g, ***(median (IQR))***	792 (71, 1955)	229 (77, 780)
HbA1c, % ***(mean (SD))***	7.2% (1.3)	7.8% (1.4)
ACE/ARB Use, %	75%	84%
SGLT2i Use, %	42%	32%
GLP-1 Use, %	33%	44%

HbA1c = hemoglobin A1c; ACE = angiotensin converting enzyme; ARB = angiotensin II receptor blockers; SGLT2i = sodium-glucose cotransporter-2 protein inhibitor; GLP-1 = glucagon-like peptide-1

REGEN-007 Topline Results

Group 1 *(Phase 3 Dosing Regimen; n=24)*

Annual decline in eGFR slope* improved by 78% from -5.8 in the pre-injection period to -1.3 in the period following the last rilparencel injection.

This 4.6 mL/min/1.73m^2 per year difference was statistically significant (p<0.001) and clinically meaningful.**

Median follow-up after the last injection was approximately 18 months.

Group 2 *(Exploratory Dosing Regimen; n=25)*

Annual decline in eGFR slope* improved by 50% from -3.4 in the pre-injection period to -1.7 in the period following the last rilparencel injection.

This 1.7 mL/min/1.73m^2 per year difference was not statistically significant (p=0.085) but suggests evidence of a dose response.

Median follow-up after the last injection was approximately 18 months.

Safety *(n=49)*

No rilparencel-related serious adverse events were observed across all patients in the study who received at least one rilparencel injection. The safety profile was consistent with previously reported study results and comparable to a kidney biopsy.

*Annual eGFR slope calculated in mL/min/1.73m^2 using a linear mixed effects model
**Difference in values is due to rounding

Key Findings and Next Steps

Key Findings

- Bilateral dosing of cryopreserved product (which mirrors the Phase 3 study dosing regimen) resulted in **stabilized kidney function** in Group 1 patients after treatment with rilparencel
- Overall **safety profile** was consistent with prior studies and comparable to kidney biopsy

Next Steps

- Submit **full REGEN-007 results** as a late-breaking clinical trial to **ASN Kidney Week**
- Focus on the continued enrollment of patients in our registrational **Phase 3 PROACT 1** study
- Provide an update on the **accelerated approval** pathway for **PROACT 1** in mid-2025

Financial Highlights

NASDAQ: PROK
292,703,024 shares outstanding*

$328M Cash** on hand expected to fund operations into mid-2027

Headquarters:
Boston, MA
Winston-Salem, NC

Covering Research Analysts

Jason Gerberry	Bank of America
Yigal Nochomovitz	Citi
Jonathan Miller	Evercore
Vamil Divan	Guggenheim
Kelly Shi	Jefferies
Anupam Rama	JP Morgan
Judah Frommer	Morgan Stanley
Eliana Merle	UBS

*As of May 12, 2025
**Cash, cash equivalents and marketable securities as of March 31, 2025

ProKidney