

**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): May 15, 2026

PROKIDNEY CORP.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40560
(Commission File Number)

98-1586514
(IRS Employer
Identification No.)

**2000 Frontis Plaza Blvd.
Suite 250
Winston-Salem, North Carolina**
(Address of Principal Executive Offices)

27103
(Zip Code)

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

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A 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 2.02 Results of Operations and Financial Condition.

On May 15, 2026, ProKidney Corp. (the "Company") issued a press release to announce its financial results for the quarter ended March 31, 2026. A copy of the press release is furnished as Exhibit 99.1.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that section, and shall not be deemed to be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

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 99.2.

The Company is on track to complete enrollment for the Phase 3 PROACT 1 accelerated approval analysis in mid-2026, with pivotal topline results anticipated in Q2 2027. The PROACT 1 study is expected to have 90% power to detect an effect size in annualized eGFR slope of 1.75 mL/min/1.73m², and 80% power to detect an effect size in annualized eGFR slope of 1.5 mL/min/1.73m². Under rilparencel's regenerative medicine advanced therapy (RMAT) designation, the U.S. Food and Drug Administration (FDA) agreed that an effect size in annualized eGFR slope of 1.5 mL/min/1.73m² would be an acceptable demonstration of efficacy in the setting of patients receiving appropriate standard of care therapies. For context, in Group 1 of the Phase 2 REGEN-007 study, bilateral kidney injections with rilparencel were associated with a 4.6 mL/min/1.73m² improvement in the annual decline in eGFR slope.

The information in this Item 7.01, including Exhibit 99.2 attached hereto, is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in this Item 7.01 and Exhibit 99.2 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 99.2 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.

The statistical powering assumption for the surrogate endpoint (eGFR slope) analysis in the PROACT 1 study has been updated to 80%, while the statistical powering assumption for the confirmatory endpoint analysis remains at 80%.

Forward-Looking Statements

The disclosure in this Current Report on Form 8-K and the attached exhibits include "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 achievement and timing of the topline data readout of the Company's PROACT 1 trial and other milestones provided, the Company's beliefs that its Phase 3 REGEN-006 (PROACT 1) trial could be sufficient to support a potential BLA submission and full regulatory approval, eGFR slope can be used 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 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 15, 2026
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: May 15, 2026

By: /s/ James Coulston
James Coulston
Chief Financial Officer



ProKidney Reports First Quarter 2026 Financial Results and Business Highlights

- *On track to complete enrollment for the Phase 3 PROACT 1 accelerated approval analysis of rilparencel in mid-2026; anticipate pivotal topline results in Q2 2027*
- *Peer-reviewed results from the Phase 2 REGEN-007 study were published in the Clinical Journal of the American Society of Nephrology (CJASN) in January 2026*
- *Ended Q1 2026 with \$224.9 million in cash and cash equivalents and marketable securities, supporting operations into mid-2027*

WINSTON-SALEM, N.C., May 15, 2026 – **ProKidney Corp. (Nasdaq: PROK)** (“ProKidney” or the “Company”), a leading late clinical-stage cell therapy company focused on chronic kidney disease (CKD), today reported financial results for the first quarter ended March 31, 2026, and provided business highlights.

“As we progress through 2026, we continue to build on the momentum established last year through positive Phase 2 REGEN-007 results, alignment with the FDA on the accelerated approval pathway, and meaningful progress on Phase 3 PROACT 1 study enrollment,” said Bruce Culleton, M.D., CEO of ProKidney. “We expect to complete enrollment in PROACT 1 this year, positioning us to deliver pivotal eGFR slope topline results in the second quarter of 2027. Our mission remains highly focused on advancing a potential new treatment option for patients with advanced CKD and diabetes at high risk of kidney failure, an area of significant unmet medical need.”

Business Highlights

Phase 3 REGEN-006 (PROACT 1) — Pivotal Study

- **Enrollment:** On track to complete enrollment for the surrogate (eGFR slope) endpoint in mid-2026
 - **Topline readout:** Pivotal results expected in Q2 2027
 - **Study Power**
 - 90% power to detect an effect size of 1.75 mL/min/1.73m² in annualized eGFR slope
 - 80% power to detect an effect size of 1.5 mL/min/1.73m² in annualized eGFR slope
 - **FDA Alignment:** Under rilparencel’s regenerative medicine advanced therapy (RMAT) designation, the U.S. Food and Drug Administration (FDA) confirmed in a prior Type B meeting that a rilparencel effect size of 1.5 mL/min/1.73m² per year would be an acceptable demonstration of efficacy in patients receiving appropriate standard of care
 - **Phase 2 REGEN-007 Data:** In Group 1, bilateral kidney injections with rilparencel were associated with a 4.6 mL/min/1.73m² improvement in the annual decline in eGFR slope in the pre-injection period versus the period after the last rilparencel injection
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Regulatory Position

- **July 2025 Type B meeting:** FDA confirmed that eGFR slope in patients from the ongoing PROACT 1 study can serve as the surrogate endpoint and primary basis for a Biologics License Application (BLA) submission under the accelerated approval pathway
- FDA also confirmed that PROACT 1 may be used to support both accelerated and confirmatory approval of rilparencel
- ProKidney continues to maintain its ongoing dialogue with the FDA under rilparencel's RMAT designation

Publications & Presentations

- **January 2026:** Phase 2 REGEN-007 results published in the *Clinical Journal of the American Society of Nephrology (CJASN)*
- **November 2025:** Phase 2 REGEN-007 results presented as a late-breaking clinical trial at ASN Kidney Week

Key Clinical Takeaway

The Company has achieved FDA alignment on the accelerated and confirmatory approval pathways for rilparencel. Completion of PROACT 1 enrollment this year is a key 2026 milestone. The positive Phase 2 REGEN-007 results provide confidence heading into the expected pivotal topline results (eGFR slope) in the second quarter of 2027.

First Quarter 2026 Financial Highlights

Liquidity: Cash, cash equivalents and marketable securities as of March 31, 2026, totaled \$224.9 million, compared to \$270.0 million as of December 31, 2025. We expect that our existing cash, cash equivalents and marketable securities held at March 31, 2026, will enable us to fund our operating expenses and capital expenditure requirements into mid-2027.

R&D Expenses: Research and development expenses were \$33.8 million for the three months ended March 31, 2026, compared to \$27.3 million for the same period in 2025. The increase of \$6.6 million was driven primarily by increases in clinical study and related manufacturing costs of \$6.5 million related to our ongoing PROACT 1 study. Additionally, compensation costs increased \$1.2 million related to the hiring of additional personnel to support our operations. These increases have been offset by decreases in costs of \$1.6 million related to clinical study costs for trials that have been completed or terminated.

G&A Expenses: General and administrative expenses were \$11.3 million for the three months ended March 31, 2026 compared to \$14.4 million for the same period in 2025. The decrease of \$3.1 million was driven primarily by decreases in compensation costs of approximately \$1.7 million due to vesting of awards issued prior to the business combination coupled with forfeitures of equity-based awards and reductions in severance costs. Additionally, professional fees and other operating costs have decreased \$1.4 million driven by ongoing initiatives, including the domestication and restructuring transactions in 2025.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was \$42.6 million and \$38.0 million for the three months ended March 31, 2026, and 2025, respectively.

Shares Outstanding: Class A and Class B common stock outstanding at March 31, 2026, totaled 301,953,977.

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 over 1 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 2 REGEN-007 Clinical Trial

REGEN-007 was a multi-center Phase 2 open-label 1:1 randomized two-armed trial in patients with diabetes and CKD who have an 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 $\geq 20\%$, and/or an increase of $\geq 30\%$ and ≥ 30 mg/g in the urine albumin to creatinine ratio (UACR) from baseline. The purpose of this study was to assess the safety, efficacy, and durability of up to two rilparencel injections on renal function progression.

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 20-30 mL/min/1.73m²) and late Stage 3b CKD (eGFR 30-35 mL/min/1.73m²) with accompanying albuminuria (UACR less than 5,000 mg/g for patients with eGFR 20-30 mL/min/1.73m² and 300-5,000 mg/g for patients with eGFR 30-35 mL/min/1.73m²). The total planned enrollment is approximately 470 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 surrogate endpoint for accelerated approval is eGFR slope, and 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 CKD through innovations in cell 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 cell therapy with regenerative medicine advanced therapy designation that is being evaluated in the ongoing Phase 3 REGEN-006 (PROACT 1) study for its potential to preserve kidney function in patients with advanced CKD and type 2 diabetes. For more information, please visit www.prokidney.com.

Forward-Looking Statements

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ProKidney Corp. and Subsidiaries
Consolidated Balance Sheets
(in thousands, except for share data)

	March 31, 2026 (Unaudited)	December 31, 2025
Assets		
Cash and cash equivalents	\$ 101,895	\$ 108,537
Marketable securities	123,049	161,480
Interest receivable	1,032	1,127
Prepaid assets	3,083	2,808
Prepaid clinical	4,049	3,923
Other current assets	1,794	2,804
Total current assets	<u>234,902</u>	<u>280,679</u>
Fixed assets, net	54,441	51,231
Right of use assets, net	3,441	3,664
Total assets	<u>\$ 292,784</u>	<u>\$ 335,574</u>
Liabilities and Stockholders' Deficit		
Accounts payable	\$ 2,592	\$ 940
Lease liabilities	1,108	1,071
Accrued expenses and other	22,231	28,731
Income taxes payable	—	—
Total current liabilities	<u>25,931</u>	<u>30,742</u>
Income tax payable, net of current portion	1,074	1,074
Lease liabilities, net of current portion	2,675	2,965
Total liabilities	<u>29,680</u>	<u>34,781</u>
Commitments and contingencies		
Redeemable noncontrolling interest	1,286,887	1,311,990
Stockholders' deficit		
Class A common stock, \$0.0001 par value; 700,000,000 shares authorized as of March 31, 2026 and December 31, 2025; 141,980,643 and 141,807,277 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	14	14
Class B common stock, \$0.0001 par value; 500,000,000 shares authorized; 159,973,334 and 159,262,779 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	16	16
Additional paid-in capital	266,112	258,552
Accumulated other comprehensive (loss) gain	(53)	56
Accumulated deficit	(1,289,872)	(1,269,835)
Total stockholders' deficit	<u>(1,023,783)</u>	<u>(1,011,197)</u>
Total liabilities and stockholders' deficit	<u>\$ 292,784</u>	<u>\$ 335,574</u>

ProKidney Corp. and Subsidiaries
Consolidated Statements of Operations - Unaudited
(in thousands, except for share and per share data)

	Three Months Ended March 31,	
	2026	2025
Revenue	\$ 226	\$ 230
Operating expenses		
Research and development	33,842	27,263
General and administrative	11,317	14,355
Total operating expenses	<u>45,159</u>	<u>41,618</u>
Operating loss	(44,933)	(41,388)
Other income (expense):		
Interest income	2,327	4,027
Interest expense	(15)	—
Net loss before income taxes	<u>(42,621)</u>	<u>(37,361)</u>
Income tax expense	—	591
Net loss before noncontrolling interest	<u>(42,621)</u>	<u>(37,952)</u>
Net loss attributable to noncontrolling interest	<u>(22,584)</u>	<u>(21,218)</u>
Net loss available to Class A common stockholders	<u>\$ (20,037)</u>	<u>\$ (16,734)</u>
Weighted average shares of Class A common stock outstanding:		
Basic and diluted	141,925,099	126,976,366
Net loss per share attributable to Class A common stock:		
Basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.13)</u>

ProKidney Corp. and Subsidiaries
Consolidated Statements of Cash Flows – Unaudited
(in thousands)

	Three Months Ended March 31,	
	2026	2025
Cash flows from operating activities		
Net loss before noncontrolling interest	\$ (42,621)	\$ (37,952)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:		
Depreciation and amortization	1,658	1,600
Equity-based compensation	4,945	6,416
Gain on marketable securities, net	(413)	(1,069)
Loss on disposal of equipment	–	300
Changes in operating assets and liabilities		
Interest receivable	95	695
Prepaid and other assets	609	5,729
Accounts payable and accrued expenses	(5,957)	(5,902)
Income taxes payable	–	591
Net cash flows used in operating activities	(41,684)	(29,592)
Cash flows from investing activities		
Purchases of marketable securities	(44,754)	(55,449)
Sales and maturities of marketable securities	83,366	84,873
Purchase of equipment and facility expansion	(3,785)	(1,135)
Net cash flows provided by investing activities	34,827	28,289
Cash flows from financing activities		
Proceeds from sales of Class A common stock, net of offering costs	7	–
Payments on finance leases	(3)	(12)
Exercise of stock options	211	–
Net cash flows provided by (used in) financing activities	215	(12)
Net change in cash and cash equivalents	(6,642)	(1,315)
Cash, beginning of period	108,537	99,120
Cash, end of period	<u>\$ 101,895</u>	<u>\$ 97,805</u>
Supplemental disclosure of non-cash investing and financing activities:		
Right of use assets obtained in exchange for lease obligations	<u>\$ –</u>	<u>\$ 322</u>
Exchange of Class B common stock	<u>\$ 26</u>	<u>\$ 2,418</u>
Impact of equity transactions and compensation on redeemable noncontrolling interest	<u>\$ 2,366</u>	<u>\$ 4,426</u>
Equipment and facility expansion included in accounts payable and accrued expenses	<u>\$ 859</u>	<u>\$ 1,653</u>



Transforming the Future of Chronic Kidney Disease Treatment

Preserving Kidney Function in Patients
at High Risk of Kidney Failure

Corporate Presentation

May 2026

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Forward-looking Statements

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These forward-looking statements include, without limitation, the achievement and timing of the topline data readout of the Company’s PROACT 1 trial and other milestones provided, the Company’s beliefs that its Phase 3 REGEN-006 (PROACT 1) trial could be sufficient to support a potential BLA submission and full regulatory approval, eGFR slope can be used 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 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.

Advanced CKD Patients Want More Time

- More time before dialysis
- More time for life's moments
- More time and flexibility with the people who matter most

• **Time for Hope**



PROKIDNEY 

Rilparencel: Buying Meaningful Time

- **NOVEL** autologous cell therapy made from a patient's own kidney cells
- **CLINICAL DATA** shows kidney function stabilization in multiple Phase 2 studies
- **WELL-TOLERATED** with no preconditioning or immunosuppression required
- **PHASE 3 STUDY** is ongoing with pivotal topline results expected in Q2 2027

**For CKD
Patients**



PROKIDNEY 

Transforming Chronic Kidney Disease (CKD) Care with Innovation and Execution



Rilparencel

First-in-class autologous cell therapy (RMAT designation)



Advancing Pipeline in Stage 3/4 CKD

Pivotal Phase 3 trial in Stage 3b/4 CKD (Type 2 Diabetes)

ONGOING

Three Phase 2 trials in Stage 3/4 CKD

✓ COMPLETED



Market Opportunity

Over 1 million people in the U.S. with Stage 3b/4 CKD and diabetes



Key Value Drivers

- ✓ Robust Clinical Data
- ✓ Experienced Leadership
- ✓ Established Manufacturing
- ✓ Cash Runway into Mid-2027

Building a future where advanced CKD treatment means more options and more hope

2025 Was a Pivotal Year at ProKidney



Aligned with FDA on an **accelerated approval pathway** for rilparencel using eGFR slope as the surrogate endpoint in the Phase 3 PROACT 1 study



Presented **positive Phase 2 REGEN-007 data** as a late-breaking clinical trial at American Society of Nephrology (ASN) Kidney Week

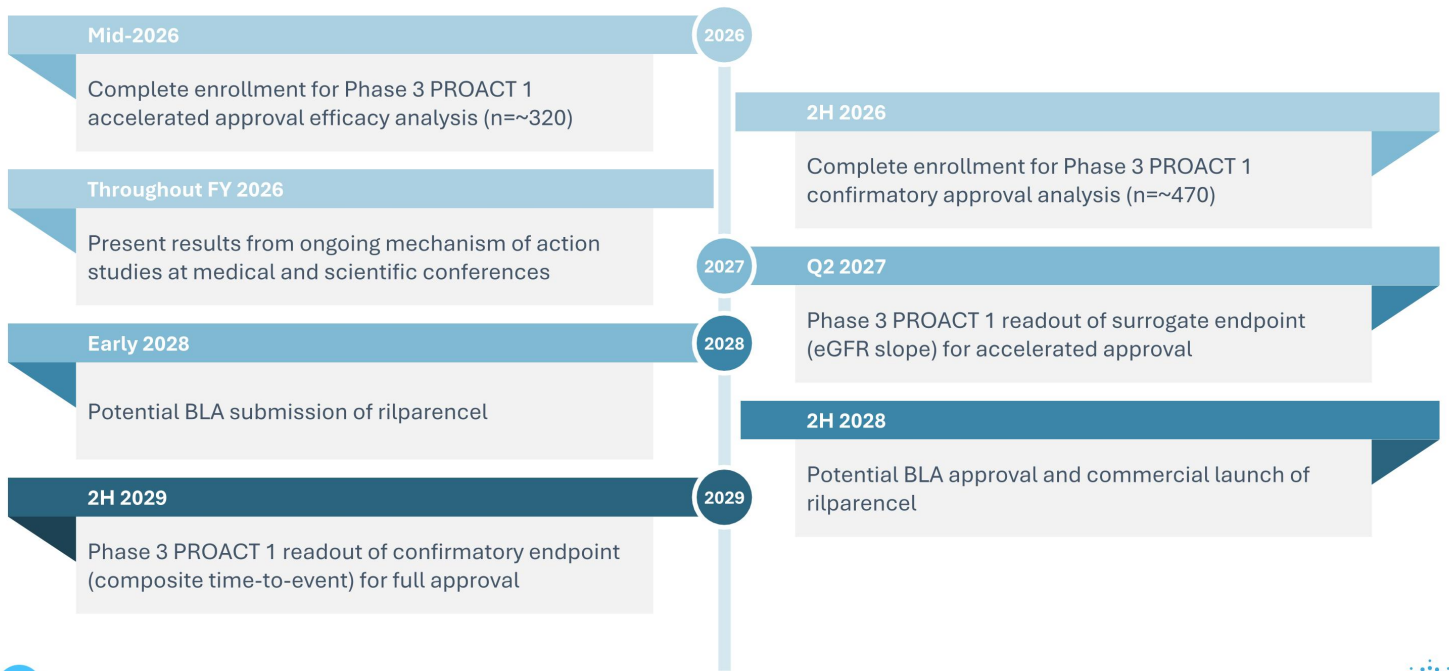


Generated significant **enrollment momentum** in the Phase 3 PROACT 1 study



Initiated expansion of ProKidney's **in-house manufacturing footprint** in two adjacent, company-owned facilities totaling 180,000 SF in Winston-Salem, NC

Well Positioned to Deliver on Milestones in 2026 and Beyond





CHRONIC KIDNEY DISEASE

Significant Unmet Need and Limitations with Standard-of-Care

PROKIDNEY 

Addressing Unmet Need in Advanced Kidney Disease

Stage 4 CKD (G4):
Today, clinical priorities are largely focused on treating comorbidities and preparing patients for transplantation or dialysis

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

STANDARD OF CARE

- Blood pressure and glucose control
- RAAS blockade
- SGLT2i +/- GLP-1 RA

RILPARENCEL
Highest risk of kidney failure

Risk for End-Stage Kidney Disease (ESKD) ■ Low ■ Moderately increased ■ High ■ Very High

Rilporenzel aims to preserve kidney function and delay or prevent dialysis for patients at highest risk

Limited Therapeutic Options that Delay Dialysis in Patients with Stage 4 CKD

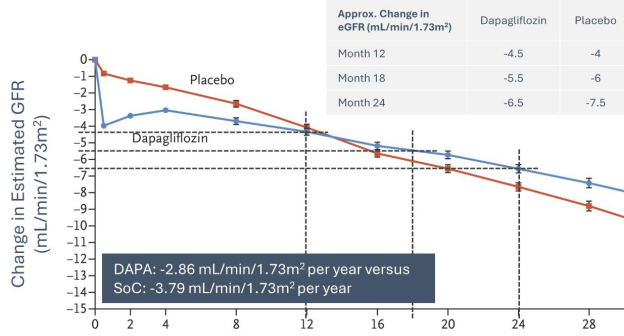
Study	Active Product	Subjects with Stage 4 CKD
Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy ¹	Canagliflozin (SGLT2 inhibitor)	0%
Dapagliflozin in Patients with CKD ²	Dapagliflozin (SGLT2 inhibitor)	14%
Empagliflozin in Patients with CKD ³	Empagliflozin (SGLT2 inhibitor)	34%
Effect of Finerenone on Cardiovascular and Kidney Outcomes in Patients with Type 2 Diabetes and CKD ^{4,5}	Finerenone (Selective MRA)	7%
Effects of Semaglutide on Chronic Kidney Disease in Patients with Type 2 Diabetes ⁶	Semaglutide (GLP-1RA)	11%

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

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

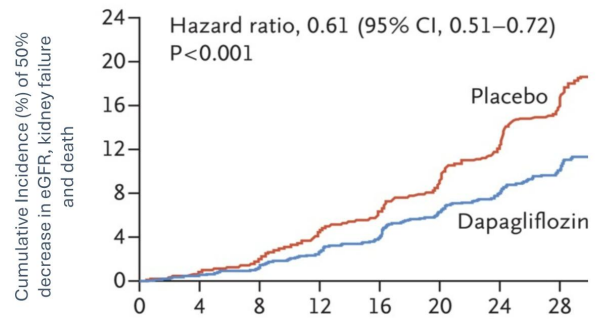
Patients continue to lose kidney function on SGLT2 inhibitors and progress to Stage 4/5 CKD²



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 care¹ does not prevent events in ~50-75% of people with diabetic kidney disease²



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



RILPARENCEL RENAL AUTOLOGOUS CELL THERAPY

Transforming the Chronic Kidney Disease Treatment Landscape

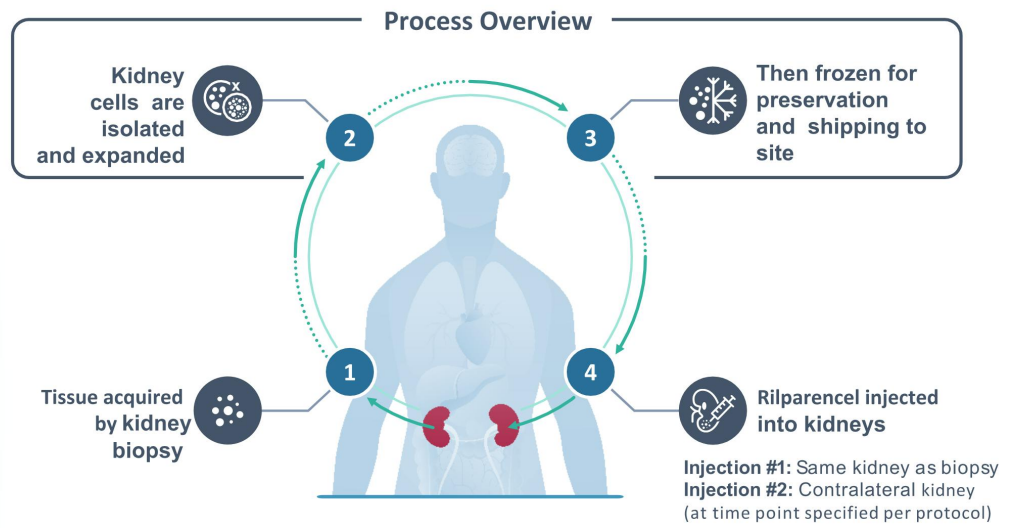
PROKIDNEY 

Rilparencel: A Patient's Own Cells—From Biopsy to Kidney Therapy

NOT ALL CELL THERAPIES ARE CREATED EQUAL

Rilparencel:

- Made from a patient's own kidney cells
- No genetic modification
- No preconditioning
- No lifelong immunosuppression
- Well-tolerated with favorable safety profile



Continued Expansion of In-House Manufacturing Facilities

Purpose-built, scalable manufacturing infrastructure supporting Phase 3 study execution and longer-term commercialization

- Purchased two adjacent buildings in Winston-Salem, NC in November 2024, totaling approximately 180,000 square feet
- Currently supports Phase 3 PROACT 1 clinical manufacturing, with capacity to accommodate future commercial supply
- Ongoing capital investment in manufacturing infrastructure and systems to support process readiness for BLA submission and commercial launch
- Facilities support office, research, and cGMP manufacturing operations for ProKidney's autologous cell therapy platform



PROKIDNEY

Advancing Kidney Care: Rilparencel Trials at a Glance

	PRECLINICAL	IND	PHASE 1	PHASE 2	PHASE 3	STATUS
Pivotal Trial Program						
Diabetes Type II – Prevent/Delay ESKD in Stage 3b/4 CKD (20-35 mL/min/1.73m ² , n=470)						Ongoing
Long term follow-up study for patients previously treated with rilparencel						Ongoing
Supportive Trials						
Diabetes Type II – Prevent/Delay ESKD in Stage 3/4 CKD (20-50 mL/min/1.73m ² , n=83)						Trial Completed
Diabetes Type I & II – Prevent/Delay ESKD in Stage 3/4 CKD (20-50 mL/min/1.73m ² , n=53)						Trial Completed
Other Completed Trials						
Diabetes Type II – Delay ESKD in Stage 4/5 CKD (14-20 mL/min/1.73m ² , n=10)						Trial Completed
Congenital Anomalies – Prevent/Delay ESKD (14-50 mL/min/1.73m ² , n=5)						Trial Completed



Frozen product



Unilateral injections

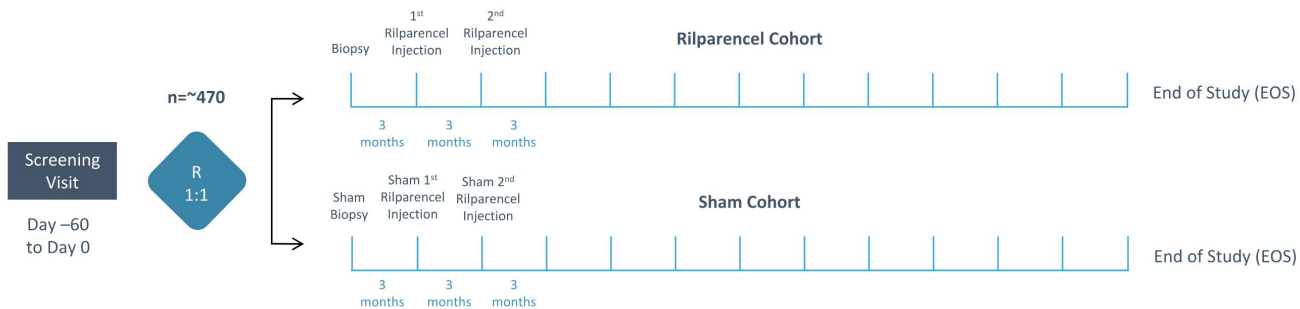


Bilateral injections

ESKD = End-Stage Kidney Disease

REGEN-006 (PROACT 1) Rilparencel Registrational Program

Topline results for the eGFR slope surrogate endpoint anticipated in Q2 2027



Key Entry Criteria

- Type 2 diabetes and CKD
- 30-80 years of age
- eGFR ≥ 20 and ≤ 35 mL/min/1.73m²
- UACR 300-5,000 mg/g for eGFR 30-35
- Not on renal dialysis, HbA1c <9.5%

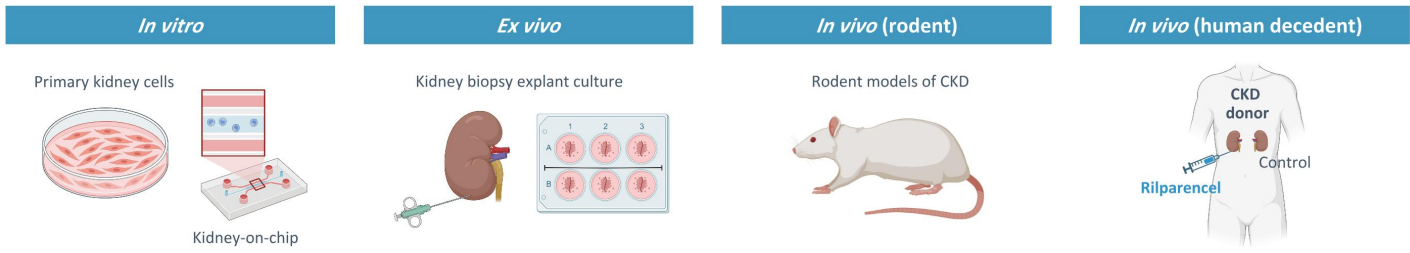
Surrogate Endpoint (Accelerated Approval Pathway)

- Annualized eGFR slope is the surrogate endpoint
- Efficacy analysis set is expected to contain approximately 320 patients and will include all patients with *at least* 6 months of follow-up after first injection
- Expected to have 80% power to detect an effect size in annualized eGFR slope of 1.5 mL/min/1.73m², which the FDA agreed would be an acceptable demonstration of efficacy in the setting of patients receiving appropriate standard of care therapies

Confirmatory Composite Time-to-Event 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
- (The confirmatory analysis will be triggered when 122 participants have at least one event)

Increased Investment in R&D to Improve Understanding of Rilparencel MOA



Advantages

- | | | | |
|--|---|---|--|
| <ul style="list-style-type: none"> • Quick: Fast design-test-learn cycles • High throughput: Simultaneously test multiple variables to deconvolute MoA • Cost-effective | <ul style="list-style-type: none"> • Native tissue structure & cell-cell interactions maintained • Fast design-test-learn cycles • Medium throughput | <ul style="list-style-type: none"> • Intact whole body physiology • Long-term post-treatment studies feasible | <ul style="list-style-type: none"> • Most representative of clinical setting • Serial biopsies & sampling possible to uncover temporal MoA |
|--|---|---|--|

Anticipated Results

- | | |
|--|--|
| <ul style="list-style-type: none"> • Whole genome expression profile in diseased & normal kidney cells +/- rilparencel treatment • Identification of key factors expressed by rilparencel, & the disease pathways they act upon, which are necessary & sufficient for its therapeutic effect | <ul style="list-style-type: none"> • Multi-omic gene expression, protein, & metabolite profiles in diseased kidney, urine, & blood +/- rilparencel treatment • Single-cell & spatial datasets integrated with histopathological changes • Association of molecular biomarker findings with clinically relevant measurements |
|--|--|

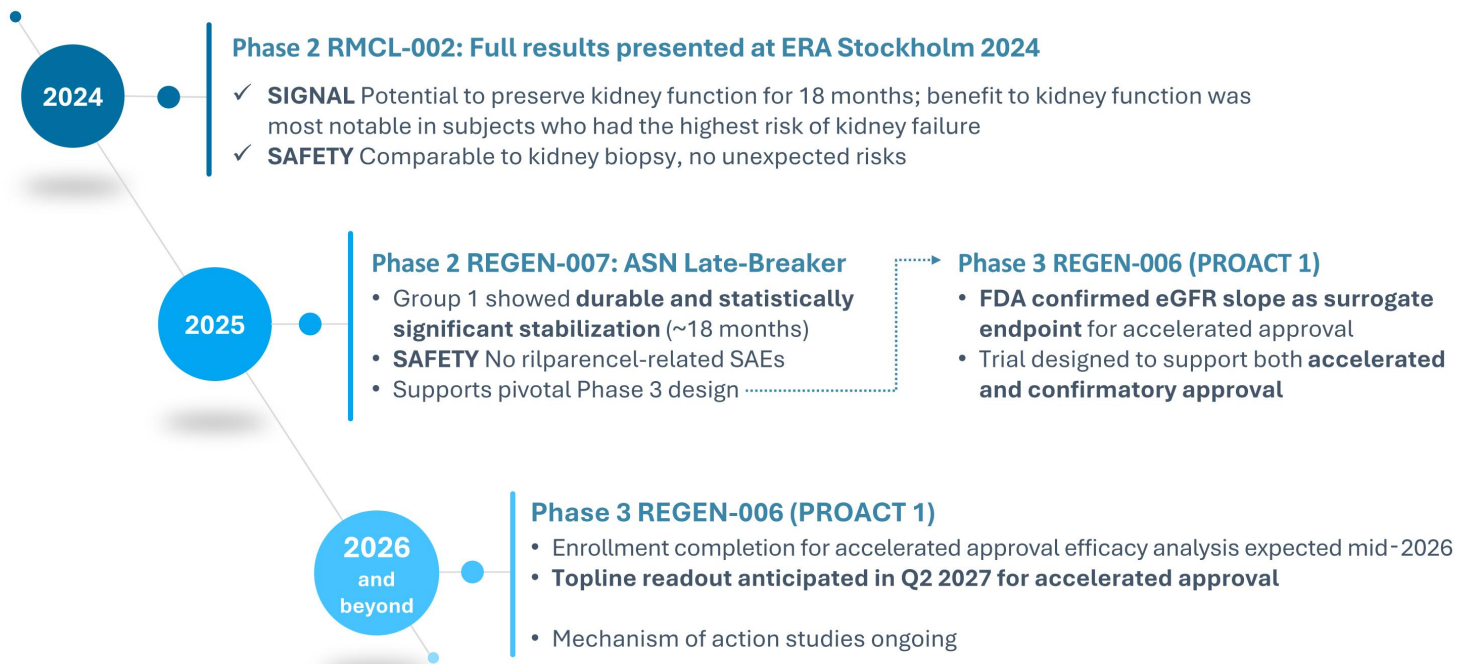


RILPARENCEL CLINICAL RESULTS

Advancing Cell Therapy For Chronic Kidney Disease

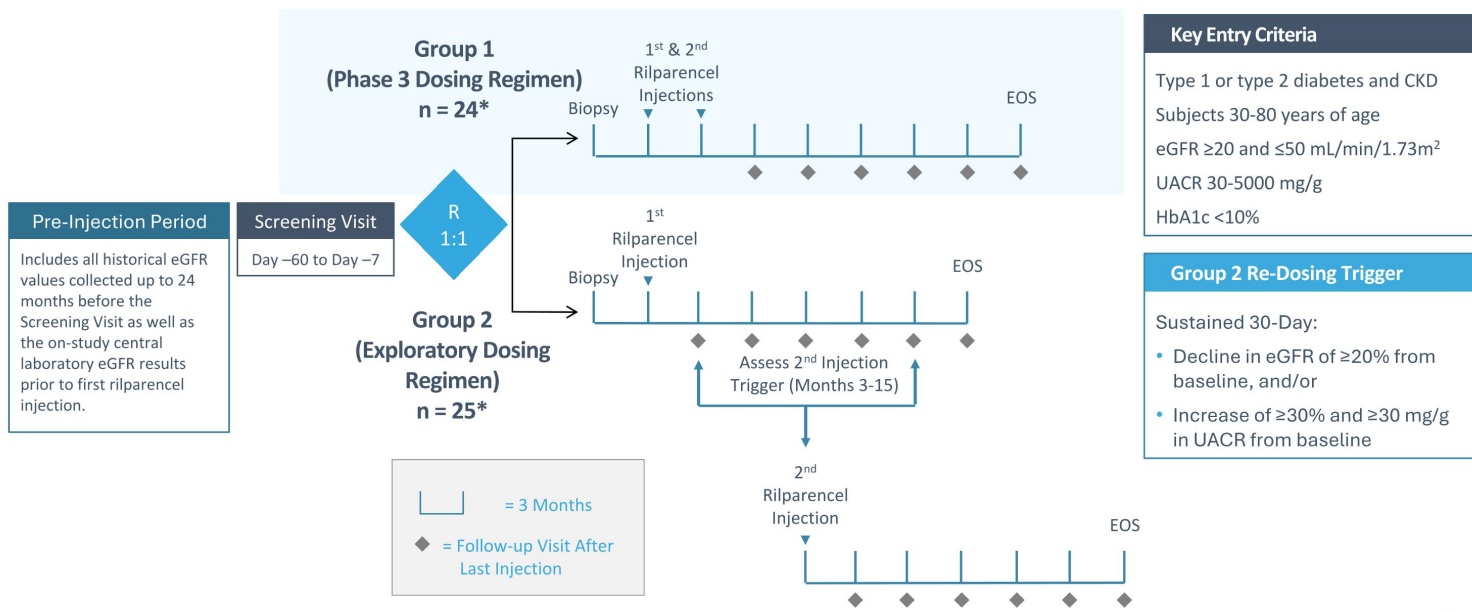
PROKIDNEY 

Clinical Progression: From Proof to Pivotal



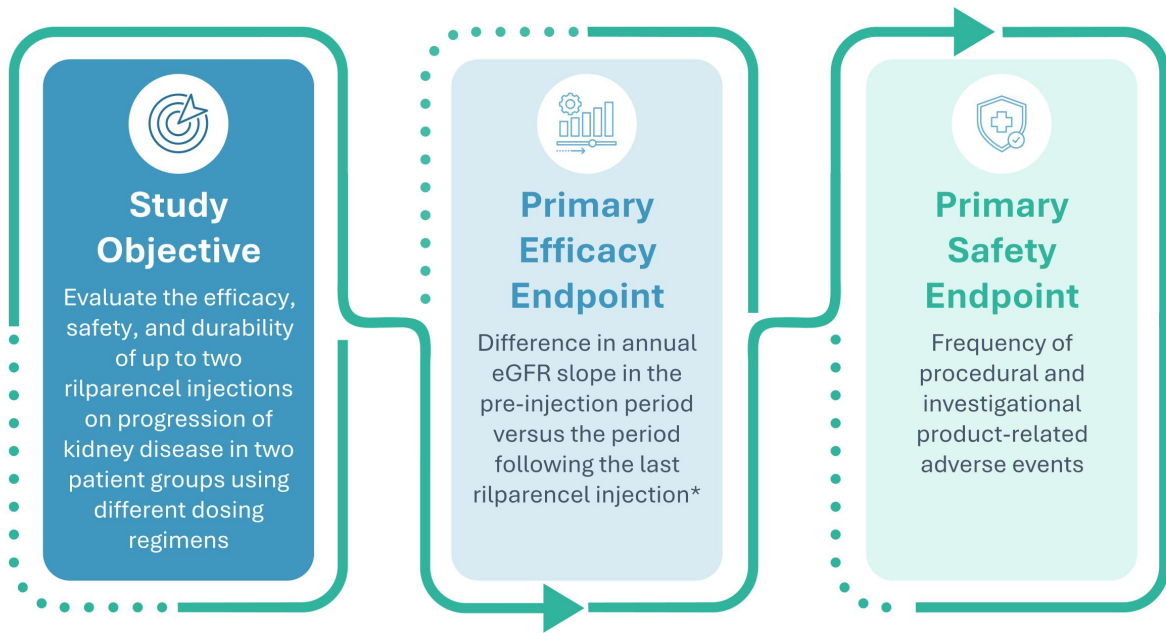
REGEN-007 Trial Design

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



*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

Objectives and Endpoints



*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.


Baseline Characteristics

REGEN-007 (n=49)	Group 1 (n=24)	Group 2 (n=25)
Age, years (<i>mean +/- SD</i>)	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%
Type 1 Diabetes : Type 2 Diabetes, %	13% : 88%	32% : 68%
Blood pressure, mm HG (<i>mean</i>)	137 / 76	132 / 77
eGFR, ml/min/1.73m ² (<i>mean +/- SD</i>)	31 +/- 8	34 +/- 12
UACR mg/g, (<i>median (IQR)</i>)	792 (71, 1955)	229 (77, 780)
HbA1c, % (<i>mean (SD)</i>)	7.2% (1.3)	7.8% (1.4)
ACE/ARB Use, %	75%	84%
SGLT2i Use, %	42%	32%
GLP-1 RA Use, %	33%	44%
MRA/NsMRA Use, %	17%	4%

HbA1c = hemoglobin A1c; ACE = angiotensin converting enzyme; ARB = angiotensin II receptor blockers; SGLT2i = sodium-glucose cotransporter-2 protein inhibitor; GLP-1 RA = glucagon-like peptide-1 receptor agonist
 NsMRA = non-steroidal mineralocorticoid receptor antagonist

Kidney Function Stabilized in Both Groups After Treatment with Rilparencel

Group 1 <i>(Phase 3 Dosing Regimen; n=24)</i>	Group 2 <i>(Exploratory Dosing Regimen; n=25)</i>
<p>Annual decline in eGFR slope¹ improved by 78% from -5.84 in the pre-injection period to -1.27 in the period following the last rilparencel injection.</p> <p>This 4.57 (1.95, 7.18)* mL/min/1.73m² per year difference was statistically significant (p<0.001) and clinically meaningful.</p> <p>Median follow-up after the last injection was approximately 18 months.</p>	<p>Annual decline in eGFR slope¹ improved by 50% from -3.40 in the pre-injection period to -1.71 in the period following the last rilparencel injection.</p> <p>This 1.70 (-0.24, 3.63)* mL/min/1.73m² per year difference was not statistically significant (p=0.085) but suggests evidence of a dose response.</p> <p>Median follow-up after the last injection was approximately 18 months.</p>

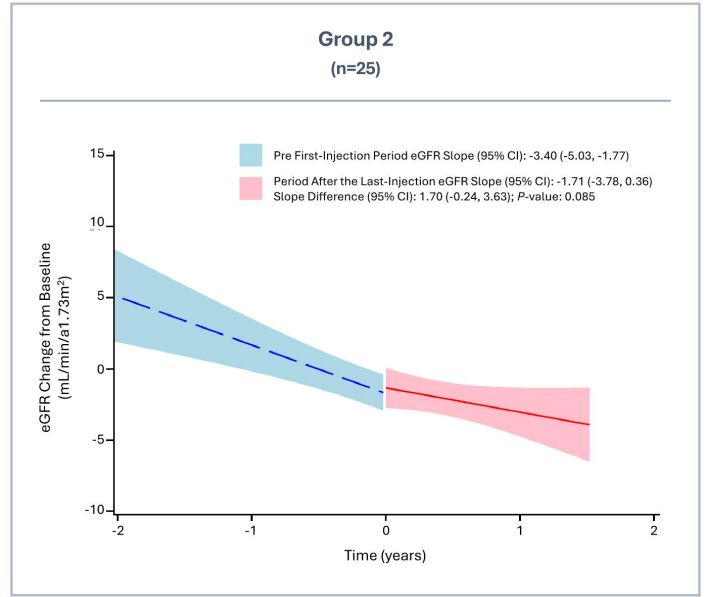
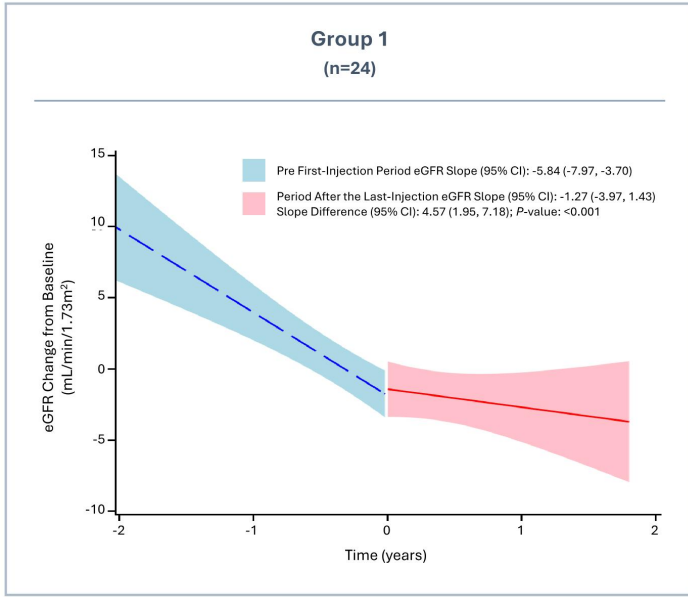


SAFETY (n=49)

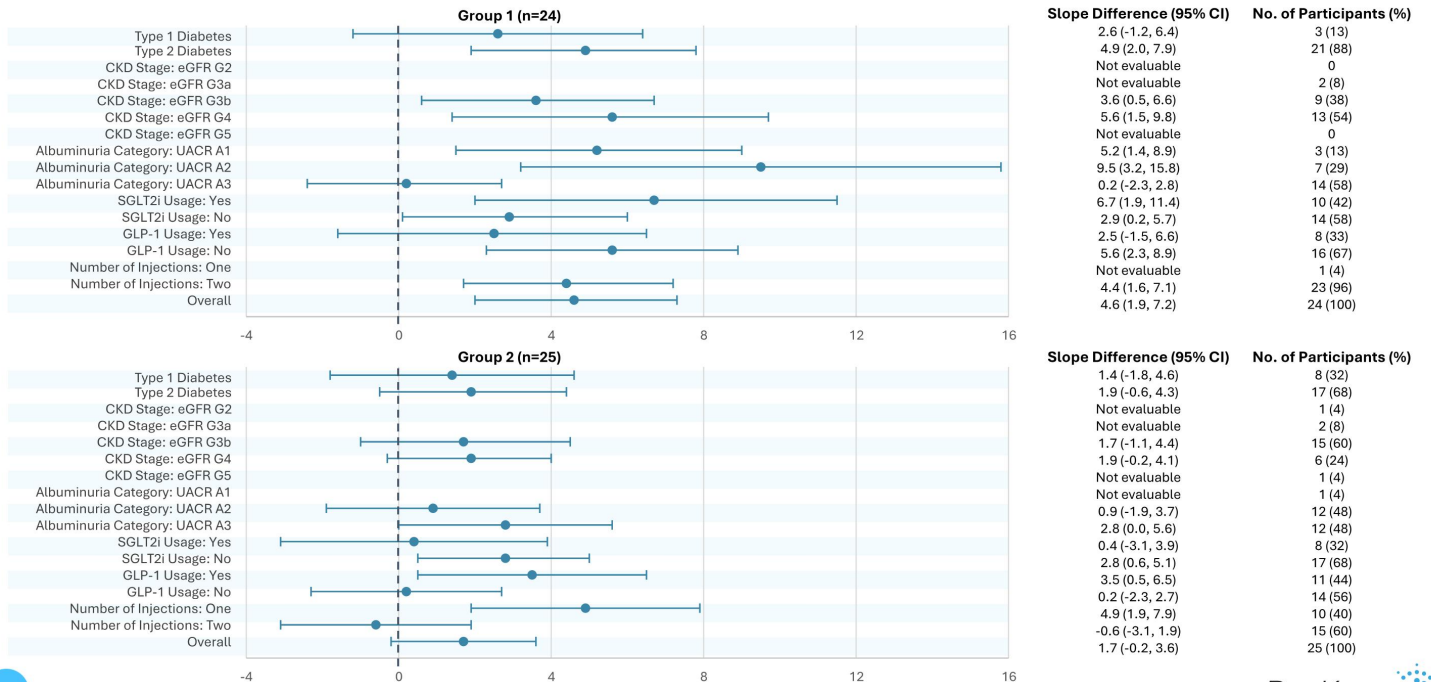
No rilparencel-related serious adverse events were observed across all patients in the study who received at least one rilparencel injection. The safety profile was consistent with previously reported study results and comparable to a kidney biopsy.

1. Annual eGFR slope calculated in mL/min/1.73m² using a linear mixed effects model
*(95% CI)

Kidney Function Stabilizes for 18 Months After Treatment with Rilparencel



In Group 1, Meaningful Differences in eGFR Slope Were Observed Across Most Subgroups



Group 1 | SGLT2i Use Summary

- Ten patients (42%) were on SGLT2i at baseline; 3 of these 10 patients discontinued SGLT2i after receiving rilparencel
- An additional 8 patients (33%) initiated SGLT2i after receiving rilparencel
- In total, 18 patients (75%) received SGLT2i at some point during the study

Patient	Number of months prior to first rilparencel injection
1	5
2	6
3	7
4	8
5	8
6	11
7	14
8	16
9	21
10	21
Median	10 months
Mean	12 months

Patient	Number of months <i>after</i> first rilparencel injection
1	2
2	6
3	7
4	8
5	11
6	12
7	13
8	13
Median	10 months
Mean	9 months

Baseline Characteristics: Patients Meeting Key Phase 3 PROACT 1 Inclusion Criteria

PROACT 1 Subgroup (n=22)	Group 1 (n=15)	Group 2 (n=7)
Age, years (<i>mean +/- SD</i>)	65 +/- 9	60 +/- 7
Female : Male, %	40% : 60%	29% : 71%
Hispanic or Latino, %	0%	0%
Race, %		
Black or African American	13%	29%
White	87%	71%
Other	0%	0%
Type 1 Diabetes : Type 2 Diabetes, %	0% : 100%	0% : 100%
Blood pressure, mm HG (<i>mean</i>)	136 / 75	130 / 77
eGFR, mL/min/1.73m ² (<i>mean +/- SD</i>)	26 +/- 4	27 +/- 8
UACR mg/g, (<i>median (IQR)</i>)	935 (54, 2033)	544 (47, 1982)
HbA1c, % (<i>mean (SD)</i>)	7.2% (1.4)	7.9% (2.2)
ACE/ARB Use, %	73%	100%
SGLT2i Use, %	40%	29%
GLP-1 RA Use, %	40%	71%
MRA/NsMRA Use, %	13%	0%

HbA1c = hemoglobin A1c; ACE = angiotensin converting enzyme; ARB = angiotensin II receptor blockers; SGLT2i = sodium-glucose cotransporter-2 protein inhibitor; GLP-1 RA = glucagon-like peptide-1 receptor agonist
 NsMRA = non-steroidal mineralocorticoid receptor antagonist

Similar Efficacy Results Were Observed in Patients Meeting Key Phase 3 PROACT 1 Inclusion Criteria

GROUP 1 <i>(Phase 3 Dosing Regimen; n=15)</i>	GROUP 2 <i>(Exploratory Dosing Regimen; n=7)</i>
<p>Annual decline in eGFR slope¹ improved by 85% from -6.46 in the pre-injection period to -0.95 in the period following the last rilparencel injection.</p> <p>This 5.51 (1.69, 9.33)* mL/min/1.73m² per year difference was statistically significant (p=0.005) and clinically meaningful.</p> <p>Median follow-up after the last injection was approximately 18 months.</p>	<p>Annual decline in eGFR slope¹ improved by 57% from -7.70 in the pre-injection period to -3.29 in the period following the last rilparencel injection.</p> <p>This 4.41 (0.57, 8.25)* mL/min/1.73m² per year difference was statistically significant (p=0.025) and clinically meaningful.</p> <p>Median follow-up after the last injection was approximately 18 months.</p>

Analysis Inclusion Criteria	<ul style="list-style-type: none"> • Type 2 diabetes • Stage 4 CKD and UACR mg/g ≤ 5000, <u>or</u> • eGFR 30-35 mL/min/1.73m² and UACR 300-5000
------------------------------------	---

1. Annual eGFR slope calculated in mL/min/1.73m² using a linear mixed effects model
*(95% CI)

No Rilparencel-Related Serious Adverse Events Were Observed

Adverse Event	Biopsy # of SAEs (n=51)	Rilparencel Injection # of SAEs (n=49)	Rilparencel # of SAEs (n=49)
Acute Kidney Injury	2	-	-
Death	-	-	-
Hematoma	2	1	-
Hematuria	1	-	-
Hydronephrosis	1	-	-

Key Findings

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

Next Steps

- **FOCUS** on the continued enrollment of patients in our registrational **Phase 3 PROACT 1** study
- **COMPLETE** mechanism of action studies
- **PREPARE** for BLA submission and commercial launch



EXECUTING WITH STRENGTH
Financial Snapshot

PROKIDNEY 

Strong Balance Sheet, Clear Path to Value Creation

KEY FINANCIALS

Shares Outstanding

302,059,626*

Cash Position

\$225M**

Runway

Expected to fund operations into mid-2027

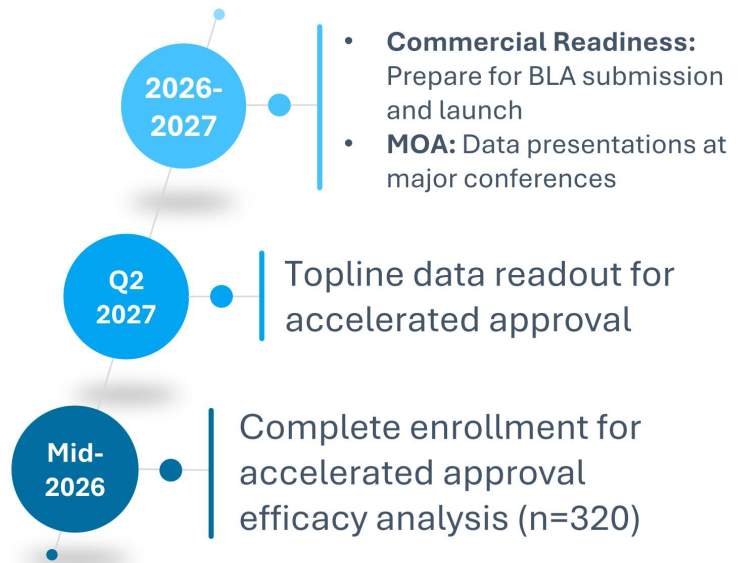
Analyst Coverage

8 Firms

*As of May 15, 2026

**Cash, cash equivalents and marketable securities as of March 31, 2026

MILESTONES



Patients Want More Time

We are building a future where advanced CKD treatment means more options and more hope

PROKIDNEY 