ProKidney Reports First Quarter 2026 Financial Results and Business Highlights

May 15, 2026

- *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 (GLOBE NEWSWIRE) -- **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

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 ≥ 20%, and/or an increase of ≥ 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/1.73m^2) and late Stage 3b CKD (eGFR 30-35 mL/min/1.73m^2) with accompanying albuminuria (UACR less than 5,000 mg/g for patients with eGFR 20-30 mL/min/1.73m^2 and 300-5,000 mg/g for patients with eGFR 30-35 mL/min /1.73m^2). 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

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 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.

ProKidney Contact
Ethan Holdaway
Ethan.Holdaway@prokidney.com

Media Contact
Audra Friis
audrafriis@sambrown.com

Investor Relations Contact
Daniel Ferry
Daniel@lifesciadvisors.com

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	234,902	280,679

Fixed assets, net	54,441	51,231
Right of use assets, net	3,441	3,664
Total assets	$ 292,784	$ 335,574
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	25,931	30,742
Income tax payable, net of current portion	1,074	1,074
Lease liabilities, net of current portion	2,675	2,965
Total liabilities	29,680	34,781
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	(1,023,783)	(1,011,197)
Total liabilities and stockholders' deficit	$ 292,784	$ 335,574

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	45,159	41,618
Operating loss	(44,933)	(41,388)
Other income (expense):		
Interest income	2,327	4,027
Interest expense	(15)	–
Net loss before income taxes	(42,621)	(37,361)
Income tax expense	—	591
Net loss before noncontrolling interest	(42,621)	(37,952)
Net loss attributable to noncontrolling interest	(22,584)	(21,218)
Net loss available to Class A common stockholders	$ (20,037)	$ (16,734)

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	$ (0.14)	$ (0.13)

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	$ 101,895	$ 97,805
Supplemental disclosure of non-cash investing and financing activities:		
Right of use assets obtained in exchange for lease obligations	$ –	$ 322
Exchange of Class B common stock	$ 26	$ 2,418
Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 2,366	$ 4,426
Equipment and facility expansion included in accounts payable and accrued expenses	$ 859	$ 1,653