ProKidney Reports Full Year 2025 Financial Results and Business Highlights

March 18, 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*
- *In a July 2025 Type B meeting, aligned with FDA on the accelerated approval pathway for rilparencel using eGFR slope as the surrogate endpoint*
- *Presented positive results from the Phase 2 REGEN-007 study of rilparencel as a late-breaking clinical trial at ASN Kidney Week 2025 followed by a peer-reviewed publication in CJASN*
- *Ended 2025 with $270.0 million in cash and cash equivalents and marketable securities, supporting operations into mid-2027*

WINSTON-SALEM, N.C., March 18, 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 full year ended December 31, 2025, and provided business highlights.

"2025 was a pivotal year for ProKidney, highlighted by positive Phase 2 REGEN-007 study results, alignment with the FDA on the accelerated approval pathway for rilparencel, and significant enrollment momentum in the Phase 3 PROACT 1 study," said Bruce Culleton, M.D., CEO of ProKidney. "Looking ahead, we are well positioned to deliver on key upcoming milestones, including completion of enrollment for the Phase 3 PROACT 1 study this year followed by pivotal eGFR slope data in the second quarter of 2027. Our mission remains highly focused on bringing a potential new treatment option to patients with advanced CKD and diabetes at high risk of kidney failure – an area of high unmet medical need."

Key Accomplishments in 2025

- Generated significant enrollment momentum in the Phase 3 PROACT 1 study, positioning the Company for a pivotal topline readout in Q2 2027 using eGFR slope.
- Confirmed with the U.S. Food and Drug Administration (FDA) in a July 2025 Type B meeting that eGFR slope in patients from the ongoing Phase 3 PROACT 1 study can serve as the surrogate endpoint and primary basis for a Biologics License Application (BLA) submission of rilparencel 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 regenerative medicine advanced therapy (RMAT) designation.
- Presented positive results from the Phase 2 REGEN-007 study of rilparencel in patients with advanced CKD and diabetes as a late-breaking clinical trial at the American Society of Nephrology (ASN) Kidney Week in November 2025, followed by a peer-reviewed publication in the Clinical Journal of the American Society of Nephrology (CJASN).
- Initiated expansion of in-house manufacturing footprint in two adjacent, company-owned facilities totaling 180,000 square feet in Winston-Salem, NC.

Anticipated Upcoming Milestones

- Mid-2026: Complete enrollment of patients to be included in the Phase 3 PROACT 1 accelerated approval efficacy analysis (n=~360)
- 2H 2026: Complete full enrollment for Phase 3 PROACT 1 confirmatory composite time-to-event analysis (n=~470)
- Throughout FY 2026: Present results from ongoing mechanism of action studies of rilparencel at medical and scientific conferences
- Q2 2027: Phase 3 PROACT 1 readout of surrogate endpoint (eGFR slope) for accelerated approval
- Q4 2027: BLA submission of rilparencel
- 2H 2028: BLA approval and commercial launch of rilparencel
- 2H 2029: Phase 3 PROACT 1 topline readout of confirmatory endpoint (composite time-to-event) for full approval

Full Year 2025 Financial Highlights

Liquidity: Cash, cash equivalents and marketable securities as of December 31, 2025, totaled $270.0 million, compared to $358.3 million as of December 31, 2024. We expect that our existing cash, cash equivalents and marketable securities held at December 31, 2025, will enable us to fund our operating expenses and capital expenditure requirements into mid-2027.

R&D Expenses: Research and development expenses were $114.1 million for the year ended December 31, 2025, compared to $127.7 million for the year ended December 31, 2024. The decrease of $13.5 million was driven primarily by decreases in clinical

study costs of $18.1 million from our clinical trials that have been completed or terminated. Additionally, operating costs have decreased $3.3 million related to the recognition of costs related to the remediation of quality management systems and processes in the 2024 period. These decreases have been offset by increases in cash and equity based compensation costs of approximately $5.5 million as we continue to hire additional personnel in the areas of clinical development, quality, manufacturing, and biostatistics to support our ongoing clinical trials. Also, clinical trial costs have increased approximately $2.4 million related to our ongoing PROACT 1 study.

G&A Expenses: General and administrative expenses were $51.8 million for the year ended December 31, 2025 compared to $56.1 million for the year ended December 31, 2024. The decrease of $4.3 million was driven primarily by decreases in impairment charges of $5.0 million related to our former facility in Greensboro, North Carolina and decreases in equity based compensation of approximately $3.4 million due to forfeitures of awards and lower fair value of recent awards. These decreases have been partially offset by increases in professional fees and other operating expenses of approximately $3.8 million driven by the domestication of our foreign subsidiaries to the U.S. in 2025 and other business initiatives.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was $151.6 million and $163.3 million for the years ended December 31, 2025, and 2024, respectively.

Shares outstanding: Class A and Class B common stock outstanding at December 31, 2025, totaled 301,070,056.

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.

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

	December 31, 2025	December 31, 2024
Assets		
Cash and cash equivalents	$ 108,537	$ 99,120
Marketable securities	161,480	259,172
Interest receivable	1,127	2,447
Prepaid assets	2,808	4,192
Prepaid clinical	3,923	11,505
Assets held for sale	–	19,368
Other current assets	2,804	80
Total current assets	280,679	395,884
Fixed assets, net	51,231	42,222

Right of use assets, net	3,664	2,967
Total assets	$ 335,574	$ 441,073
Liabilities and Stockholders' Deficit		
Accounts payable	$ 940	$ 3,633
Lease liabilities	1,071	765
Accrued expenses and other	28,731	31,137
Income taxes payable	–	682
Total current liabilities	30,742	36,217
Income tax payable, net of current portion	1,074	748
Lease liabilities, net of current portion	2,965	2,471
Total liabilities	34,781	39,436
Commitments and contingencies		
Redeemable noncontrolling interest	1,311,990	1,396,591
Stockholders' deficit		
Class A common stock, $0.0001 par value; 700,000,000 and 500,000,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively; 141,807,277 and 128,054,417 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	14	13
Class B common stock, $0.0001 par value; 500,000,000 shares authorized; 159,262,779 and 163,693,707 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	16	16
Additional paid-in capital	258,552	205,736
Accumulated other comprehensive gain	56	130
Accumulated deficit	(1,269,835)	(1,200,849)
Total stockholders' deficit	(1,011,197)	(994,954)
Total liabilities and stockholders' deficit	$ 335,574	$ 441,073

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

	2025	2024	2023
Revenue	$ 893	$ 76	$ –
Operating expenses			
Research and development	114,123	127,668	106,707
General and administrative	51,777	56,084	44,815
Total operating expenses	165,900	183,752	151,522
Operating loss	(165,007)	(183,676)	(151,522)
Other income (expense):			
Interest income	13,813	19,752	22,083
Interest expense	(4)	(9)	(12)
Net loss before income taxes	(151,198)	(163,933)	(129,451)
Income tax expense (benefit)	414	(598)	5,996
Net loss before noncontrolling interest	(151,612)	(163,335)	(135,447)
Net loss attributable to noncontrolling interest	(82,626)	(102,149)	(99,979)
Net loss available to Class A common stockholders	$ (68,986)	$ (61,186)	$ (35,468)
Weighted average shares of Class A common stock outstanding:			
Basic and diluted	133,942,736	97,916,193	61,714,225

Net loss per share attributable to Class A common stock:			
Basic and diluted	$ (0.52)	$ (0.62)	$ (0.57)

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

	Years Ended December 31,		
	2025	**2024**	**2023**
Cash flows from operating activities			
Net loss before noncontrolling interest	$ (151,612)	$ (163,335)	$ (135,447)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:			
Depreciation and amortization	6,575	5,432	3,853
Equity-based compensation	25,336	29,372	30,846
Gain on marketable securities, net	(3,417)	(6,995)	(6,018)
Loss (gain) on lease disposition	(29)	(161)	–
Impairment of long-lived assets	318	5,324	–
Loss on disposal of equipment	1,431	56	23
Changes in operating assets and liabilities			
Interest receivable	1,320	(1,072)	(1,375)
Prepaid and other assets	6,236	(5,955)	4,648
Accounts payable and accrued expenses	(5,919)	11,592	11,639
Income taxes payable	(356)	(609)	1,762
Net cash flows used in operating activities	(120,117)	(126,351)	(90,069)
Cash flows from investing activities			
Proceeds from sale of facility	18,215	–	–
Purchases of marketable securities	(217,076)	(324,023)	(471,604)
Sales and maturities of marketable securities	318,022	373,946	175,818
Purchase of equipment and facility expansion	(15,196)	(29,509)	(34,197)
Net cash flows provided by (used in) investing activities	103,965	20,414	(329,983)
Cash flows from financing activities			
Proceeds from sales of Class A common stock, net of offering costs	24,247	144,322	–
Payments on finance leases	(26)	(54)	(52)
Exercise of stock options	1,348	140	–
Repurchase of Class A common stock	–	–	(9,499)
Net cash flows provided by (used in) financing activities	25,569	144,408	(9,551)
Net change in cash and cash equivalents	9,417	38,471	(429,603)
Cash, beginning of period	99,120	60,649	490,252
Cash, end of period	$ 108,537	$ 99,120	$ 60,649
Supplemental disclosure of non-cash investing and financing activities:			
Right of use assets obtained in exchange for lease obligations	$ 2,005	$ 2,621	$ 2,594
Exchange of Class B common stock	$ 5,311	$ 15,442	$ 9,500
Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 3,426	$ 19,448	$ 2,577
Change in redemption value of noncontrolling interest	$ –	$ –	$ 79
Equipment and facility expansion included in accounts payable and accrued expenses	$ 131	$ 347	$ 218