ProKidney Reports Third Quarter 2025 Financial Results and Provides Regulatory and Clinical Updates

November 10, 2025

- *Full results from the Phase 2 REGEN-007 study of rilparencel were recently presented as a late-breaking clinical trial at the American Society of Nephrology (ASN) Kidney Week 2025*
- *More than half of the patients required for the Phase 3 REGEN-006 (PROACT 1) accelerated approval analysis using estimated glomerular filtration rate (eGFR) slope have been enrolled; topline results anticipated in Q2 2027*
- *Ended the third quarter with $272 million in cash and cash equivalents and marketable securities, supporting operations into mid-2027*

WINSTON-SALEM, N.C., Nov. 10, 2025 (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 third quarter ended September 30, 2025, and provided regulatory and clinical updates.

"The Phase 2 REGEN-007 full results recently presented at ASN Kidney Week further strengthen the body of evidence supporting our ongoing Phase 3 PROACT 1 study and underscore the potential of rilparencel to become a novel treatment option for patients with advanced CKD and diabetes," said Bruce Culleton, M.D., Chief Executive Officer of ProKidney. "In Group 1, which mirrored the dosing regimen being evaluated in the ongoing Phase 3 PROACT 1 study, treatment with rilparencel led to statistically significant and clinically meaningful stabilization of kidney function. Notably, 63% of Group 1 patients met the key PROACT 1 inclusion criteria, and similar efficacy was observed in this subgroup compared to the overall Group 1 results. We remain focused on the continued execution of PROACT 1 to bring a potential new treatment option to patients with advanced CKD and diabetes at high risk of kidney failure, an area of significant unmet need."

Phase 2 REGEN-007 Full Results Recently Presented at ASN Kidney Week 2025
On November 6, 2025, ProKidney presented full results from the Phase 2 REGEN-007 study evaluating rilparencel in patients with advanced CKD and diabetes. The data, featured in a late-breaking clinical trials presentation, further demonstrate the potential of rilparencel to preserve kidney function in patients with advanced CKD and diabetes who are at high risk of kidney failure. Highlights include:

- In Group 1 (n=24), bilateral kidney injection with rilparencel resulted in a 4.6 mL/min/1.73m^2 improvement in the annual decline in eGFR slope; this 78% improvement was statistically significant and clinically meaningful ($p<0.001$)
- Among Group 1 patients, 15 of 24 (63%) met key Phase 3 PROACT 1 inclusion criteria; in this subgroup, bilateral kidney injection resulted in a 5.5 mL/min/1.73m^2 improvement in the annual decline in eGFR slope; this 85% improvement was statistically significant and clinically meaningful ($p=0.005$)
- Post-hoc analysis of patient subgroups on standard-of-care (SOC) medications, including sodium-glucose cotransporter-2 inhibitors (SGLT2i) and glucagon-like peptide-1 receptor agonists (GLP-1 RA), suggest rilparencel had a treatment effect incremental to that observed with SOC
- Rilparencel was well tolerated and had an acceptable safety profile

Phase 3 PROACT 1 Registrational Program Update: Alignment Achieved with FDA on Accelerated Path
In a July 2025 Type B meeting, the U.S. Food and Drug Administration (FDA) confirmed 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. The 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. More than half of the approximately 360 patients required for the accelerated approval analysis using eGFR slope had been enrolled as of August 2025. Topline data readout to support an application for accelerated approval is anticipated in Q2 2027. Rilparencel is the only cell therapy in a Phase 3 clinical study for the treatment of CKD and type 2 diabetes.

Third Quarter 2025 Financial Highlights

Liquidity: Cash, cash equivalents and marketable securities as of September 30, 2025, totaled $271.7 million, compared to $358.3 million on December 31, 2024. ProKidney expects that its existing cash, cash equivalents and marketable securities held on September 30, 2025, will enable the Company to fund its operating expenses and capital expenditure requirements into mid-2027.

R&D Expenses: Research and development expenses were $26.8 million for the three months ended September 30, 2025,

compared to $31.3 million for the same period in 2024. The decrease of $4.4 million was driven primarily by decreases in costs for clinical operations of approximately $4.2 million driven by the wind down of activities related to REGEN-016 and our other clinical trials that have been completed or terminated. Additionally, the Company has seen decreases in spending on manufacturing process development and professional fees of approximately $1.5 million and $0.9 million, respectively. These decreases have been partially offset by increases in equity and cash compensation costs of approximately $1.4 million as the Company continues to hire additional personnel to support our operations and increases in materials costs of $1.2 million to support the Phase 3 clinical program.

G&A Expenses: General and administrative expenses were $11.9 million for the three months ended September 30, 2025, compared to $17.7 million for the same period in 2024. The decrease of $5.8 million has been primarily driven by the decrease in the amount of non-cash impairment charges of $5.0 million related to the Greensboro facility and decreases in cash and equity compensation of approximately $1.9 million. These increases have been partially offset by increases in professional fees of approximately $0.8 million.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was $35.8 million and $41.1 million for the three months ended September 30, 2025 and 2024, respectively.

Shares outstanding: Class A and Class B common stock outstanding as of September 30, 2025 totaled 295,266,876.

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 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 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 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 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)[1]

	September 30, 2025 (Unaudited)	December 31, 2024
Assets		
Cash and cash equivalents	$ 95,323	$ 99,120
Marketable securities	176,402	259,172
Interest receivable	1,237	2,447
Prepaid assets	3,516	4,192
Prepaid clinical	4,351	11,505
Assets held for sale	19,050	19,368
Other current assets	110	80
Total current assets	299,989	395,884
Fixed assets, net	47,754	42,222

Right of use assets, net	3,865	2,967
Total assets	$ 351,608	$ 441,073
Liabilities and Stockholders' Deficit		
Accounts payable	$ 1,942	$ 3,633
Lease liabilities	991	765
Accrued expenses and other	26,068	31,137
Income taxes payable	62	682
Total current liabilities	29,063	36,217
Income tax payable, net of current portion	962	748
Lease liabilities, net of current portion	3,245	2,471
Total liabilities	33,270	39,436
Commitments and contingencies		
Redeemable noncontrolling interest	1,326,358	1,396,591
Stockholders' deficit		
Class A common stock, $0.0001 par value; 700,000,000 and 500,000,000 shares authorized as of September 30, 2025 and December 31, 2024, respectively; 135,977,945 and 128,054,417 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	14	13
Class B common stock, $0.0001 par value; 500,000,000 shares authorized; 159,288,931 and 163,693,707 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	16	16
Additional paid-in capital	242,480	205,736
Accumulated other comprehensive gain	74	130
Accumulated deficit	(1,250,604)	(1,200,849)
Total stockholders' deficit	(1,008,020)	(994,954)
Total liabilities and stockholders' deficit	$ 351,608	$ 441,073

[1] For presentation purposes, unless otherwise noted, "ordinary shares" before the domestication and "common stock" subsequent to the domestication are referred to herein as common stock

ProKidney Corp. and Subsidiaries
Consolidated Statements of Operations - Unaudited
(in thousands, except for share and per share data)[2]

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue	$ 217	$ –	$ 668	$ –
Operating expenses				
Research and development	26,821	31,250	79,966	87,887
General and administrative	11,935	17,723	40,338	44,218
Total operating expenses	38,756	48,973	120,304	132,105
Operating loss	(38,539)	(48,973)	(119,636)	(132,105)
Other income (expense):				
Interest income	3,258	5,580	10,878	14,960
Interest expense	(2)	(2)	(3)	(7)
Net loss before income taxes	(35,283)	(43,395)	(108,761)	(117,152)
Income tax expense (benefit)	560	(2,342)	1,999	(2,300)

Net loss before noncontrolling interest	(35,843)	(41,053)	(110,760)	(114,852)
Net loss attributable to noncontrolling interest	(19,374)	(23,143)	(61,005)	(74,944)
Net loss available to Class A common stockholders	$ (16,469)	$ (17,910)	$ (49,755)	$ (39,908)
Weighted average shares of Class A common stock outstanding:				
Basic and diluted	134,992,796	126,173,463	131,588,705	87,818,229
Net loss per share attributable to Class A common stock:				
Basic and diluted	$ (0.12)	$ (0.14)	$ (0.38)	$ (0.45)

[2] For presentation purposes, unless otherwise noted, "ordinary shares" before the domestication and "common stock" subsequent to the domestication are referred to herein as common stock.

ProKidney Corp. and Subsidiaries
Consolidated Statements of Cash Flows - Unaudited
(in thousands)[3]

	Nine Months Ended September 30,	
	2025	**2024**
Cash flows from operating activities		
Net loss before noncontrolling interest	$ (110,760)	$ (114,852)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:		
Depreciation and amortization	4,738	3,858
Equity-based compensation	19,633	22,424
Gain on marketable securities, net	(2,674)	(5,521)
Loss on lease disposition	143	–
Impairment of long-lived assets	318	5,324
Loss on disposal of equipment	474	186
Changes in operating assets and liabilities		
Interest receivable	1,210	(3,728)
Prepaid and other assets	7,795	(8,489)
Accounts payable and accrued expenses	(8,075)	(114)
Income taxes payable	(406)	(1,268)
Net cash flows used in operating activities	(87,604)	(102,180)
Cash flows from investing activities		
Purchases of marketable securities	(176,676)	(277,291)
Sales and maturities of marketable securities	261,992	286,625
Purchase of equipment and facility expansion	(9,444)	(4,000)
Net cash flows provided by investing activities	75,872	5,334
Cash flows from financing activities		
Proceeds from sales of Class A common stock, net of offering costs	7,102	144,325
Payments on finance leases	(21)	(40)
Exercise of stock options	854	–
Net cash flows provided by financing activities	7,935	144,285
Net change in cash and cash equivalents	(3,797)	47,439
Cash, beginning of period	99,120	60,649
Cash, end of period	$ 95,323	$ 108,088
Supplemental disclosure of non-cash investing and financing activities:		
Right of use assets obtained in exchange for lease obligations	$ 2,005	$ 2,621

Exchange of Class B common stock	$ 5,252	$ 15,357
Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 3,903	$ 18,748
Equipment and facility expansion included in accounts payable and accrued expenses	$ 835	$ 910

[3] For presentation purposes, unless otherwise noted, “ordinary shares” before the domestication and “common stock” subsequent to the domestication are referred to herein as common stock.