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

August 12, 2025

- *FDA confirmed at a July 2025 Type B meeting and in the subsequent meeting minutes that eGFR slope is an acceptable surrogate endpoint for accelerated approval of rilparencel in patients with type 2 diabetes and advanced CKD; FDA also confirmed that the ongoing Phase 3 PROACT 1 study may be used to support both accelerated and confirmatory approval of rilparencel*
- *More than half of the patients required for the accelerated approval analysis using eGFR slope have been enrolled in the Phase 3 PROACT 1 study; topline data anticipated in Q2 2027*
- *On July 8, 2025, ProKidney reported positive topline results from the Phase 2 REGEN-007 study; eGFR slope in Group 1 (n=24) improved by 78% after treatment with rilparencel*
- *Full results from REGEN-007 will be submitted to the American Society of Nephrology 2025 Kidney Week as a late-breaking clinical trial*
- *Ended the second quarter with $295 million in cash and cash equivalents and marketable securities, supporting operations into mid-2027*

WINSTON-SALEM, N.C., Aug. 12, 2025 (GLOBE NEWSWIRE) -- **ProKidney Corp. (Nasdaq: PROK)** ("ProKidney" or the "Company"), a leading late clinical-stage cell therapeutics company focused on chronic kidney disease (CKD), today reported financial results for the second quarter ended June 30, 2025, and provided regulatory and clinical updates.

"We've made tremendous progress in 2025, and July was a pivotal month for ProKidney with the release of positive topline data from our Phase 2 REGEN-007 study and alignment with the FDA on the accelerated approval pathway for rilparencel using eGFR slope as the surrogate endpoint," said Bruce Culleton, M.D., CEO of ProKidney. "We are now focused on maintaining enrollment momentum in the Phase 3 PROACT 1 study and preparing for a late-breaking submission of Phase 2 REGEN-007 data at ASN Kidney Week in November. Each step brings us closer to our goal of delivering a novel treatment option to patients with diabetes and advanced CKD, a population where there remains high unmet clinical need."

FDA Alignment Achieved for the Rilparencel Accelerated Approval Pathway
In a July 2025 Type B meeting, the U.S. Food and Drug Administration (FDA) confirmed that the slope of estimated glomerular filtration rate (eGFR) 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 agreed that a rilparencel effect size (versus sham controls) of at least 1.5 mL/min/1.73m^2 per year improvement would be an acceptable demonstration of efficacy in the setting of patients receiving appropriate standard of care therapies.

ProKidney anticipates topline data readout of eGFR slope as the surrogate endpoint to support an application for accelerated approval in Q2 2027. To date, more than half of the approximately 350 patients required for the accelerated approval analysis have been enrolled in the ongoing Phase 3 PROACT 1 study. The FDA also confirmed that PROACT 1 may serve as the confirmatory study to support full approval of rilparencel based on the primary time-to-event composite endpoint specified in the protocol. Formal meeting minutes from the FDA following the Type B meeting held in July 2025 confirm alignment with ProKidney. ProKidney will continue to maintain its ongoing dialogue with the FDA under rilparencel's regenerative medicine advanced therapy (RMAT) designation.

Phase 2 REGEN-007 Positive Topline Results
On July 8, 2025, ProKidney announced statistically and clinically significant topline results from the Phase 2 REGEN-007 study. Of note, in Group 1 (n=24), which replicated the rilparencel dosing schedule of the ongoing Phase 3 PROACT 1 study, kidney function stabilized. The annual decline in eGFR slope improved by 78%, from -5.8 in the pre-injection period to -1.3 mL/min /1.73m² in the period following the last rilparencel injection. This 4.6 mL/min/1.73m^2 per year difference[1] was statistically significant ($p<0.001$) and clinically meaningful. Of the 24 patients in Group 1, 15 (63%) met key Phase 3 PROACT 1 inclusion criteria, and similar efficacy results were observed in this subgroup compared to the full Group 1 results.

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

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

[1] Difference in values is due to rounding.

Second Quarter 2025 Financial Highlights
Effective July 1, 2025, ProKidney completed a domestication process through which the Company and certain subsidiaries changed their jurisdiction of incorporation from the Cayman Islands and other jurisdictions to the State of Delaware.

Liquidity: Cash, cash equivalents and marketable securities as of June 30, 2025, totaled $294.7 million, compared to $328.5 million as of March 31, 2025. We expect that our existing cash, cash equivalents and marketable securities held as of June 30, 2025, will enable us to fund our operating expenses and capital expenditures into mid-2027.

R&D Expenses: Research and development expenses were $25.9 million for the three months ended June 30, 2025, compared to $29.4 million for the same period in 2024. The decrease of approximately $3.5 million has been primarily driven by decreases in clinical study costs of approximately $7.4 million from our clinical trials that have been completed or terminated. Additionally, we saw decreases in professional fees and equity-based compensation of $1.1 million and $0.5 million, respectively. These decreases were offset by increases in costs for our ongoing Phase 3 trial of approximately $4.3 million due to continued enrollment and increased activities for the trial. Additionally, we noted increases in cash compensation of approximately $1.5 million due to the hiring of additional research and development personnel.

G&A Expenses: General and administrative expenses were $14.0 million for the three months ended June 30, 2025, compared to $13.7 million for the same period in 2024. The increase of approximately $0.4 million has been primarily driven by increases in cash compensation and other operational expenses of approximately $0.8 million and $0.4 million, respectively. These increases have been partially offset by decreases in equity-based compensation of approximately $0.7 million.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was $37.0 million and $38.5 million for the three months ended June 30, 2025 and 2024, respectively.

Shares outstanding: Class A and Class B common stock outstanding as of June 30, 2025 totaled 292,707,888.

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 in the urine albumin to creatinine ratio (UACR) from baseline of ≥ 30% and ≥ 30 mg/g. 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 chronic kidney disease through innovations in cellular therapy, was founded in 2015 after a decade of research. ProKidney's lead product candidate, rilparencel (also known as REACT ®), is a first-in-class, patented, proprietary autologous cellular therapy with RMAT designation that is being evaluated for its potential to preserve kidney function in diabetic patients at high risk of kidney failure. 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)[2]

	June 30, 2025 (Unaudited)	December 31, 2024
Assets		
Cash and cash equivalents	$ 84,940	$ 99,120
Marketable securities	209,788	259,172
Interest receivable	1,775	2,447
Prepaid assets	2,300	4,192
Prepaid clinical	5,723	11,505
Assets held for sale	19,368	19,368

Other current assets	546	80
Total current assets	324,440	395,884
Fixed assets, net	43,525	42,222
Right of use assets, net	4,168	2,967
Total assets	$ 372,133	$ 441,073
Liabilities and Stockholders' Deficit		
Accounts payable	$ 2,443	$ 3,633
Lease liabilities	903	765
Accrued expenses and other	24,916	31,137
Income taxes payable	–	682
Total current liabilities	28,262	36,217
Income tax payable, net of current portion	903	748
Lease liabilities, net of current portion	3,515	2,471
Total liabilities	32,680	39,436
Commitments and contingencies		
Redeemable noncontrolling interest	1,341,953	1,396,591
Stockholders' deficit		
Class A common stock, $0.0001 par value; 500,000,000 shares authorized; 133,418,957 and 128,054,417 issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	13	13
Class B common stock, $0.0001 par value; 500,000,000 shares authorized; 159,288,931 and 163,693,707 issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	16	16
Additional paid-in capital	231,576	205,736
Accumulated other comprehensive gain	30	130
Accumulated deficit	(1,234,135)	(1,200,849)
Total stockholders' deficit	(1,002,500)	(994,954)
Total liabilities and stockholders' deficit	$ 372,133	$ 441,073

[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 Operations - Unaudited
(in thousands, except for share and per share data)[3]

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue	$ 221	$ –	$ 451	$ –
Operating expenses				
Research and development	25,882	29,404	53,145	56,637
General and administrative	14,048	13,652	28,403	26,495
Total operating expenses	39,930	43,056	81,548	83,132
Operating loss	(39,709)	(43,056)	(81,097)	(83,132)
Other income (expense):				
Interest income	3,593	4,537	7,620	9,380
Interest expense	(1)	(3)	(1)	(5)
Net loss before income taxes	(36,117)	(38,522)	(73,478)	(73,757)
Income tax expense (benefit)	848	(56)	1,439	42

Net loss before noncontrolling interest	(36,965)	(38,466)	(74,917)	(73,799)
Net loss attributable to noncontrolling interest	(20,413)	(25,960)	(41,631)	(51,801)
Net loss available to Class A common stockholders	$ (16,552)	$ (12,506)	$ (33,286)	$ (21,998)
Weighted average shares of Class A common stock outstanding:				
Basic and diluted	130,730,840	75,908,017	129,858,450	68,429,869
Net loss per share attributable to Class A common stock:				
Basic and diluted	$ (0.13)	$ (0.16)	$ (0.26)	$ (0.32)

[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.

ProKidney Corp. and Subsidiaries
Consolidated Statements of Cash Flows - Unaudited
(in thousands)[4]

	Six Months Ended June 30,	
	2025	**2024**
Cash flows from operating activities		
Net loss before noncontrolling interest	$ (74,917)	$ (73,799)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:		
Depreciation and amortization	3,065	2,372
Equity-based compensation	12,957	15,489
Gain on marketable securities, net	(1,942)	(3,802)
Loss on lease disposition	143	–
Loss on disposal of equipment	464	131
Changes in operating assets and liabilities		
Interest receivable	672	(1,373)
Prepaid and other assets	7,202	(6,162)
Accounts payable and accrued expenses	(8,126)	(5,838)
Income taxes payable	(526)	43
Net cash flows used in operating activities	(61,008)	(72,939)
Cash flows from investing activities		
Purchases of marketable securities	(98,138)	(82,880)
Sales and maturities of marketable securities	149,239	171,445
Purchase of equipment and facility expansion	(4,247)	(1,596)
Net cash flows provided by investing activities	46,854	86,969
Cash flows from financing activities		
Proceeds from sales of Class A common stock, net of offering costs	–	139,855
Payments on finance leases	(26)	(26)
Net cash flows (used in) provided by financing activities	(26)	139,829
Net change in cash and cash equivalents	(14,180)	153,859
Cash, beginning of period	99,120	60,649
Cash, end of period	$ 84,940	$ 214,508
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	$ 5,253	$ 14,902

Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 7,756	$ 16,708
Equipment and facility expansion included in accounts payable and accrued expenses	$ 395	$ 780

[4] 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.