ProKidney Reports First Quarter 2025 Financial Results and Business Highlights

May 12, 2025

- *Full data from Group 1 in the Phase 2 REGEN-007 study expected in Q2 2025*
- *FDA previously confirmed in a Q4 2024 Type B meeting that the accelerated approval pathway is available for rilparencel; additional details on the accelerated pathway are expected in mid-2025 after our planned Type B meeting with the FDA*
- *Ended the first quarter with $328.5 million in cash and cash equivalents and marketable securities, supporting operations into mid-2027*

WINSTON-SALEM, N.C., May 12, 2025 (GLOBE NEWSWIRE) -- **ProKidney Corp. (Nasdaq: PROK)** ("ProKidney" or the "Company"), a leading late clinical-stage cellular therapeutics company focused on chronic kidney disease (CKD), today reported financial results and business highlights for the first quarter ended March 31, 2025.

"The next two quarters are important for ProKidney as we approach two key milestones: the release of full Group 1 data from the Phase 2 REGEN-007 study and a regulatory update on the accelerated approval pathway for rilparencel following a planned Type B meeting with the FDA," said Bruce Culleton, M.D., CEO of ProKidney. "With cash runway into mid-2027, we are in a strong financial position to continue executing our Phase 3 PROACT 1 study. I appreciate the continued engagement from our investigators, patients, and the ProKidney team as we work to address a significant unmet therapeutic need in patients with advanced CKD and type 2 diabetes."

Business Highlights

- Full data from Group 1 of the Phase 2 REGEN-007 study are expected in Q2 2025 and will comprise approximately 20 patients who have received two rilparencel injections, with an average follow-up of approximately 18 months.
- In a Type B meeting held in Q4 2024, the U.S. Food and Drug Administration (FDA) confirmed that the accelerated approval pathway is available for rilparencel if an acceptable surrogate endpoint, which may include eGFR slope, is used. Additional details on the potential accelerated approval pathway are expected in mid-2025 after our planned Type B meeting with the FDA.

First Quarter 2025 Financial Highlights

Liquidity: Cash, cash equivalents and marketable securities as of March 31, 2025, totaled $328.5 million, compared to $358.3 million as of December 31, 2024. We expect that our existing cash, cash equivalents and marketable securities held at March 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 relatively consistent between periods at $27.3 million for the three months ended March 31, 2025, compared to $27.2 million for the same period in 2024. We saw increases in cash compensation and facility costs of approximately $1.1 million and $1.0 million, respectively, which were due to the hiring of additional personnel and expansion of our facilities. These increases were offset by a decrease of $1.4 million in clinical trial cost as increases for our Phase 3 trial were outpaced by decreases from our other trials due to timing of activities or termination. Additionally, we experienced decreases in professional fees of $0.8 million related to the remediation of quality and manufacturing compliance deficiencies.

G&A Expenses: General and administrative expenses were $14.4 million for the three months ended March 31, 2025, compared to $12.8 million for the same period in 2024. The increase of approximately $1.5 million has been primarily driven by increases in cash compensation and professional fees of approximately $1.2 million and $0.8 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 $38.0 million and $35.3 million for the three months ended March 31, 2025 and 2024, respectively.

Shares outstanding: Class A and Class B ordinary shares outstanding as of March 31, 2025 totaled 292,697,802.

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 type 2 diabetes and advanced CKD. The study protocol was amended in 1H 2024 to focus on a subset of patients with stage 4 CKD (eGFR 20-30ml min/1.73m^2) and late stage 3b CKD (eGFR 30-35ml min/1.73m^2) with accompanying albuminuria (urine albumin-to-creatinine ratio, or UACR, less than 5,000 mg/g for patients with eGFR 20-30ml min/1.73m^2 and 300-5,000 mg/g for patients with eGFR 30-35ml 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. Subjects in the treatment group are to receive the first rilparencel injection within 18 weeks of kidney biopsy. After three months it is

intended that a second rilparencel injection be given into the contralateral kidney. Subjects in the control group, who previously underwent the sham biopsy procedure, are to receive two sham injections at similar time points as the treatment group. The primary objective is to assess the efficacy of up to two rilparencel injections using a minimally invasive percutaneous approach. 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 the Phase 2 REGEN-007 Clinical Trial

REGEN-007 is an ongoing 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 are allocated to two treatment groups using different dosing regimens. Group 1 replicates the dosing schedule for the Phase 3 REGEN-006 clinical study in which patients receive two rilparencel injections – one in each kidney, three months apart. Group 2 tests an exploratory dosing regimen to investigate whether physiological triggers, rather than a time-based trigger, could optimize multiple administrations of rilparencel. In Group 2, patients receive a single rilparencel dose in one kidney and a second dose in the contralateral kidney only if triggered by a sustained eGFR decline 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 is to assess the safety, efficacy, and durability of up to two rilparencel injections on renal function progression.

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 being evaluated in Phase 2 and Phase 3 studies for its potential to preserve kidney function in diabetic patients at high risk of kidney failure. Rilparencel has received Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA. 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 the FDA agrees that the Company's Phase 3 REGEN-006 (PROACT 1) trial could be sufficient to support a potential BLA submission and full regulatory approval and that the Company could consider using eGFR slope 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 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 planned domestication to the United States; the inability to maintain the listing of the Company's Class A ordinary shares on the Nasdaq; the inability of the Company's Class A ordinary shares to remain included in the Russell 3000® Index or similar indices and the potential negative impact on the trading price of the Class A shares 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)

	March 31, 2025 (Unaudited)	December 31, 2024
Assets		
Cash and cash equivalents	$ 97,805	$ 99,120
Marketable securities	230,693	259,172
Interest receivable	1,752	2,447
Prepaid assets	3,014	4,192
Prepaid clinical	6,968	11,505
Assets held for sale	19,368	19,368
Other current assets	62	80
Total current assets	359,662	395,884
Fixed assets, net	43,326	42,222
Right of use assets, net	3,073	2,967
Total assets	$ 406,061	$ 441,073
Liabilities and Shareholders' Deficit		
Accounts payable	$ 3,122	$ 3,633
Lease liabilities	857	765
Accrued expenses and other	27,572	31,137
Income taxes payable	1,257	682
Total current liabilities	32,808	36,217
Income tax payable, net of current portion	764	748
Lease liabilities, net of current portion	2,512	2,471
Total liabilities	36,084	39,436
Commitments and contingencies		
Redeemable noncontrolling interest	1,368,530	1,396,591
Shareholders' deficit		
Class A ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 129,536,121 and 128,054,417 issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	13	13
Class B ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 163,161,681 and 163,693,707 issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	16	16
Additional paid-in capital	218,926	205,736
Accumulated other comprehensive gain	75	130
Accumulated deficit	(1,217,583)	(1,200,849)
Total shareholders' deficit	(998,553)	(994,954)
Total liabilities and shareholders' deficit	$ 406,061	$ 441,073

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

	Three Months Ended March 31,	
	2025	2024
Revenue	$ 230	$ –
Operating expenses		
Research and development	27,263	27,233
General and administrative	14,355	12,843
Total operating expenses	41,618	40,076
Operating loss	(41,388)	(40,076)
Other income (expense):		
Interest income	4,027	4,843
Interest expense	–	(2)
Net loss before income taxes	(37,361)	(35,235)
Income tax expense	591	98
Net loss before noncontrolling interest	(37,952)	(35,333)
Net loss attributable to noncontrolling interest	(21,218)	(25,841)
Net loss available to Class A ordinary shareholders	$ (16,734)	$ (9,492)
Weighted average Class A ordinary shares outstanding:		
Basic and diluted	128,976,366	60,951,721
Net loss per share attributable to Class A ordinary shares:		
Basic and diluted	$ (0.13)	$ (0.16)

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

	Three Months Ended March 31,	
	2025	2024
Cash flows from operating activities		
Net loss before noncontrolling interest	$ (37,952)	$ (35,333)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:		
Depreciation and amortization	1,600	1,102
Equity-based compensation	6,416	7,679
Gain on marketable securities, net	(1,069)	(2,313)
Loss on disposal of equipment	300	28
Changes in operating assets and liabilities		
Interest receivable	695	(529)
Prepaid and other assets	5,729	564
Accounts payable and accrued expenses	(5,902)	(5,942)
Income taxes payable	591	98
Net cash flows used in operating activities	(29,592)	(34,646)
Cash flows from investing activities		
Purchases of marketable securities	(55,449)	(55,415)
Sales and maturities of marketable securities	84,873	114,774
Purchase of equipment and facility expansion	(1,135)	(960)
Net cash flows provided by investing activities	28,289	58,399
Cash flows from financing activities		

Payments on finance leases	(12)	(13)
Net cash flows used in financing activities	(12)	(13)
Net change in cash and cash equivalents	(1,315)	23,740
Cash, beginning of period	99,120	60,649
Cash, end of period	$ 97,805	$ 84,389
Supplemental disclosure of non-cash investing and financing activities:		
Right of use assets obtained in exchange for lease obligations	$ 322	$ 1,674
Exchange of Class B ordinary shares	$ 2,418	$ 2,289
Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 4,426	$ 7,507
Equipment and facility expansion included in accounts payable and accrued expenses	$ 1,653	$ 305