



ProKidney Reports Full Year 2024 Financial Results and Business Highlights

March 17, 2025

- Significant progress was made in 2024, including refining the Phase 3 program to accelerate rilparencel's path to market in the U.S., the release of positive Phase 2 data, restarting manufacturing, and securing \$140 million of equity to extend cash runway into mid-2027
- In Q4 2024, the FDA confirmed in a Type B meeting that the accelerated approval pathway is available for rilparencel if an acceptable surrogate endpoint, which may include eGFR slope, is used; additional details expected in mid-2025
- Full data from Group 1 in the Phase 2 REGEN-007 study expected in Q2 2025; interim data from June 2024 showed kidney function stabilization for 18 months in patients with advanced CKD and diabetes
- Ended the fourth quarter with \$358 million in cash and cash equivalents and marketable securities, supporting operations into mid-2027

WINSTON-SALEM, N.C., March 17, 2025 (GLOBE NEWSWIRE) -- **ProKidney Corp. (Nasdaq: PROK)** ("ProKidney"), a leading late clinical-stage cellular therapeutics company focused on chronic kidney disease (CKD), today announced financial results and business highlights for the year ended December 31, 2024.

"2024 was a pivotal year for ProKidney, marked by significant progress across our clinical, regulatory, manufacturing, and financial initiatives," said Bruce Culleton, M.D., CEO of ProKidney. "We refined our Phase 3 program to focus on advanced CKD patients with the highest unmet need, engaged in discussions with the FDA to accelerate rilparencel's path to market, improved and restarted our manufacturing process, and secured \$140 million in equity funding. Looking ahead, 2025 will be a critical inflection point, with the expected release of full Group 1 data from the Phase 2 REGEN-007 study and an update on the accelerated approval pathway for the Phase 3 PROACT 1 study after our planned Type B meeting with the FDA. Our objective is clear: expedite rilparencel's path to market in the U.S. to bring a new therapeutic option to patients with advanced CKD and diabetes at high risk of requiring dialysis."

Business Highlights

- In a Q4 2024 Type B meeting, 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. The FDA also confirmed that REGEN-006 (PROACT 1), a single, large, multi-center, well-controlled Phase 3 study, could be sufficient to support a potential Biologics License Application (BLA) submission. Thus, the Company discontinued the Phase 3 REGEN-016 (PROACT 2) study, which was focused on enrollment outside the U.S.
- 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 June 2024, ProKidney announced interim results from REGEN-007, which showed stabilization of kidney function for 18 months in 13 patients with advanced CKD and diabetes.

Full Year 2024 Financial Highlights

Liquidity: Cash, cash equivalents and marketable securities as of December 31, 2024, totaled \$358.3 million, compared to \$363.0 million on December 31, 2023. We expect that our existing cash, cash equivalents and marketable securities held at December 31, 2024, will enable us to fund our operating expenses and capital expenditure requirements into mid-2027.

R&D Expenses: Research and development expenses were \$127.7 million for the year ended December 31, 2024, compared to \$106.7 million for the year ended December 31, 2023. The increase of \$21.0 million was driven primarily by increases in cash-based compensation costs of approximately \$12.2 million as we continue to hire additional personnel in the areas of clinical development, quality, manufacturing, and biostatistics to support our ongoing clinical trials. Clinical trial costs have increased approximately \$7.7 million as we have progressed our Phase 3 study. Additionally, operating costs have increased \$4.5 million reflecting costs related to remediation of quality management systems and processes in the first half of 2024. These increases were partially offset by a decrease in equity-based compensation costs of approximately \$3.4 million.

G&A Expenses: General and administrative expenses were \$56.1 million for the year ended December 31, 2024 compared to \$44.8 million for the year ended December 31, 2023. The increase of \$11.3 million was driven primarily by increases in cash-based compensation of \$5.4 million due to the hiring of personnel and severance cost for terminated employees; the recognition of an impairment charge of \$5.3 million related to our Greensboro, North Carolina facility and increases in equity-based compensation. These increases were partially offset by decreases in operating costs of \$2.1 million related to decreased legal and professional fees and other operating costs.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was \$163.3 million and \$135.4 million for the

years ended December 31, 2024, and 2023, respectively.

Shares outstanding: Class A and Class B ordinary shares outstanding at December 31, 2024 totaled 291,748,124.

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/1.73m²) and late stage 3b CKD (eGFR 30-35ml min/1.73m²) with accompanying albuminuria (urine albumin-to-creatinine ratio, or UACR less than 5,000 mg/g for patients with eGFR 20-30ml min/1.73m² and 300-5,000 mg/g for patients with eGFR 30-35ml min/1.73m²). 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 $\geq 20\%$, and/or an increase in the urine albumin to creatinine ratio (UACR) from baseline of $\geq 30\%$ 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: the inability to maintain the listing of the Company's Class A ordinary shares on the Nasdaq; 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, 2024	December 31, 2023
Assets		
Cash and cash equivalents	\$ 99,120	\$ 60,649
Marketable securities	259,172	302,301
Interest receivable	2,447	1,375
Prepaid assets	4,192	3,399
Prepaid clinical	11,505	6,413
Assets held for sale	19,368	—
Other current assets	80	9
Total current assets	395,884	374,146
Fixed assets, net	42,222	42,143
Right of use assets, net	2,967	4,263
Total assets	\$ 441,073	\$ 420,552
Liabilities and Shareholders' Deficit		
Accounts payable	\$ 3,633	\$ 5,098
Lease liabilities	765	803
Accrued expenses and other	31,137	17,665
Income taxes payable	682	1,472
Total current liabilities	36,217	25,038
Income tax payable, net of current portion	748	568
Lease liabilities, net of current portion	2,471	3,610
Total liabilities	39,436	29,216
Commitments and contingencies		
Redeemable noncontrolling interest	1,396,591	1,494,732
Shareholders' deficit		
Class A ordinary shares, \$0.0001 par value; 500,000,000 shares authorized; 128,054,417 and 59,880,347 issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	13	6
Class B ordinary shares, \$0.0001 par value; 500,000,000 shares authorized; 163,693,707 and 168,297,916 issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	16	17
Additional paid-in capital	205,736	36,114
Accumulated other comprehensive gain	130	130

Accumulated deficit	(1,200,849)	(1,139,663)
Total shareholders' deficit	(994,954)	(1,103,396)
Total liabilities and shareholders' deficit	<u>\$ 441,073</u>	<u>\$ 420,552</u>

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

	<u>2024</u>	<u>2023</u>	<u>2022</u>
Revenue	\$ 76	\$ -	\$ -
Operating expenses			
Research and development	127,668	106,707	82,070
General and administrative	56,084	44,815	70,937
Total operating expenses	183,752	151,522	153,007
Operating loss	(183,676)	(151,522)	(153,007)
Other income (expense):			
Interest income	19,752	22,083	5,983
Interest expense	(9)	(12)	(215)
Net loss before income taxes	(163,933)	(129,451)	(147,239)
Income tax (benefit) expense	(598)	5,996	896
Net loss before noncontrolling interest	(163,335)	(135,447)	(148,135)
Net loss attributable to noncontrolling interest	(102,149)	(99,979)	(40,103)
Net loss available to Class A ordinary shareholders	<u>\$ (61,186)</u>	<u>\$ (35,468)</u>	<u>\$ (108,032)</u>
Weighted average Class A ordinary shares outstanding:			
Basic and diluted ⁽¹⁾	97,916,193	61,714,225	61,540,231
Net loss per share attributable to Class A ordinary shares:			
Basic and diluted ⁽¹⁾	<u>\$ (0.62)</u>	<u>\$ (0.57)</u>	<u>\$ (0.23)</u>

⁽¹⁾ The Company analyzed the calculation of net loss per share for periods prior to the business combination with Social Capital Suvretta Holdings Corp. III (the "Business Combination"), on July 11, 2022 and determined that it resulted in values that would not be meaningful to the users of the consolidated financial statements, as the capital structure completely changed as a result of the Business Combination. Therefore, net loss per share information has not been presented for periods prior to the Business Combination. The basic and diluted net loss per share attributable to Class A ordinary shareholders for the year ended December 31, 2022, represents the period from July 11, 2022 through December 31, 2022.

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

	Years Ended December 31,		
	<u>2024</u>	<u>2023</u>	<u>2022</u>
Cash flows from operating activities			
Net loss before noncontrolling interest	\$ (163,335)	\$ (135,447)	\$ (148,135)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:			
Depreciation and amortization	5,432	3,853	3,036
Equity-based compensation	29,372	30,846	74,469
Gain on marketable securities, net	(6,995)	(6,018)	-
Gain on lease disposition	(161)	-	-

Impairment charges	5,324	–	–
Loss on disposal of equipment	56	23	–
Changes in operating assets and liabilities			
Interest receivable	(1,072)	(1,375)	–
Prepaid and other assets	(5,955)	4,648	(7,231)
Accounts payable and accrued expenses	11,592	11,639	494
Income taxes payable	(609)	1,762	278
Net cash flows used in operating activities	<u>(126,351)</u>	<u>(90,069)</u>	<u>(77,089)</u>
Cash flows from investing activities			
Net cash from SCS	–	–	108
Purchases of marketable securities	(324,023)	(471,604)	–
Sales and maturities of marketable securities	373,946	175,818	–
Purchase of equipment and facility expansion	(29,509)	(34,197)	(1,846)
Net cash flows provided by (used in) investing activities	<u>20,414</u>	<u>(329,983)</u>	<u>(1,738)</u>
Cash flows from financing activities			
Proceeds from sales of Class A ordinary shares, net of offering costs	144,322	–	–
Proceeds from Business Combination, including PIPE financing, net of associated costs of \$37,856	–	–	542,503
Payments on finance leases	(54)	(52)	(32)
Borrowings under related party notes payable	–	–	35,000
Exercise of stock options	140	–	–
Repurchase of Class A ordinary shares	–	(9,499)	–
Repayment of related party notes payable	–	–	(35,000)
Net cash contribution	–	–	6,050
Net cash flows provided by (used in) financing activities	<u>144,408</u>	<u>(9,551)</u>	<u>548,521</u>
Net change in cash and cash equivalents	38,471	(429,603)	469,694
Cash, beginning of period	60,649	490,252	20,558
Cash, end of period	<u>\$ 99,120</u>	<u>\$ 60,649</u>	<u>\$ 490,252</u>
Supplemental cash flow information:			
Cash paid during the period for income taxes, net of refunds	<u>\$ 73</u>	<u>\$ 2,857</u>	<u>\$ 1,950</u>
Supplemental disclosure of non-cash investing and financing activities:			
Right of use assets obtained in exchange for lease obligations	<u>\$ 2,621</u>	<u>\$ 2,594</u>	<u>\$ 1,491</u>
Exchange of Class B ordinary shares	<u>\$ 15,442</u>	<u>\$ 9,500</u>	<u>\$ –</u>
Impact of equity transactions and compensation on redeemable noncontrolling interest	<u>\$ 19,448</u>	<u>\$ 2,577</u>	<u>\$ 5,828</u>
Change in redemption value of noncontrolling interest	<u>\$ –</u>	<u>\$ 79</u>	<u>\$ –</u>
Equipment and facility expansion included in accounts payable and accrued expenses	<u>\$ 347</u>	<u>\$ 218</u>	<u>\$ 51</u>