ProKidney Reports Business Updates and Second Quarter 2024 Financial Results

August 9, 2024

- *Reported interim REGEN-007 data that demonstrate rilparencel's potential to preserve kidney function in patients with diabetes and advanced CKD*
- *Restarted manufacturing and resumed PROACT 1 and PROACT 2 Phase 3 trials*
- *Closed $140 million upsized underwritten public offering and concurrent registered direct offering*
- *Ended the second quarter with $431.5 million in cash and cash equivalents and marketable securities, supporting operations through projected Phase 3 enrollment completion in mid-2026*

WINSTON-SALEM, N.C., Aug. 09, 2024 (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 business updates and financial results for the second quarter ended June 30, 2024.

"The interim results of REGEN-007 as presented in June support rilparencel's potential to preserve kidney function in patients with diabetes and advanced CKD," said Bruce Culleton, M.D., Chief Executive Officer. "In addition to positive clinical data, the second quarter marked several critical milestones. Manufacturing has restarted, both Phase 3 studies have resumed, and we completed a $140 million equity offering to extend our runway into mid-2026. We are resolutely focused on executing our Phase 3 program as we seek to address the unmet need in late-stage CKD patients who have limited therapeutic options before dialysis or kidney transplant."

Clinical, Corporate, and Operational Updates

- In June, we presented interim Phase 2 REGEN-007 data that showed kidney function stabilization for 18 months in patients with diabetes and advanced CKD who received rilparencel and a safety profile consistent with prior studies and comparable to kidney biopsy
- Manufacturing restarted in June and the QP Declaration of Equivalence to EU GMPs was received in July, allowing ProKidney to ship rilparencel to clinical study sites in Europe
- PROACT 1 and PROACT 2 Phase 3 trials resumed; patients have begun enrolling in PROACT 1 under the amended protocol that enriches for more advanced CKD patients
- Announced closing of an upsized $140 million underwritten public offering and concurrent registered direct offering in June, extending cash runway into mid-2026 and through the expected full enrollment of the Phase 3 studies
- Appointed Carla Poulson as Chief People Officer in May. Ms. Poulson brings approximately 25 years of experience in human resources, talent acquisition, and management development. Prior to ProKidney, Ms. Poulson served as Chief People Officer at UniQure Therapeutics, Mersana Therapeutics, Akcea Therapeutics and 10 years in senior HR leadership positions at Vertex Pharmaceuticals

Second Quarter 2024 Financial Highlights

Liquidity: Cash, cash equivalents and marketable securities as of June 30, 2024, totaled $431.5 million, compared to $363.0 million on December 31, 2023. We expect that our existing cash, cash equivalents and marketable securities held on June 30, 2024, will enable us to fund our operating expenses and capital expenditure requirements into mid-2026.

R&D Expenses: Research and development expenses were $29.4 million for the three months ended June 30, 2024, compared to $26.4 million for the same period in 2023. The increase of $3.0 million was driven primarily by increases in cash compensation costs of approximately $3.2 million as we continue to hire additional personnel in the areas of clinical development, quality, manufacturing, and biostatistics to support our ongoing clinical trials. Further, we have seen increases in professional fees of approximately $1.6 million related to the remediation of quality and manufacturing compliance deficiencies. Lastly, we have experienced increased costs for clinical operations, materials and facilities totaling approximately $2.2 million related to preparations for the restart of activities for our PROACT studies. These increases have been offset by decreased spending on manufacturing improvements and equity-based compensation costs of approximately $2.9 million and $1.3 million, respectively.

G&A Expenses: General and administrative expenses were $13.7 million for the three months ended June 30, 2024 compared to $13.5 million for the same period in 2023. The increase of $0.2 million has been primarily driven by increases in cash compensation of approximately $2.2 million. This increase has been offset by decreases in equity-based compensation of approximately $2.1 million.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was $38.5 million and $34.8 million for the three months ended June 30, 2024 and 2023, respectively.

Shares outstanding: Class A and Class B ordinary shares outstanding as of June 30, 2024, totaled 289,674,830.

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-of-its-kind, patented, proprietary autologous cellular therapy being evaluated to potentially preserve kidney function in patients with diabetes and advanced CKD. Rilparencel has received Regenerative Medicine Advanced Therapy (RMAT) designation, as well as FDA and EMA guidance, supporting its ongoing Phase 3 clinical program.

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 expectations with respect to financial results and expected cash runway, 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 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 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.

Investor Contacts:

ProKidney
Ethan Holdaway
Ethan.Holdaway@prokidney.com

LifeSci Advisors, LLC
Daniel Ferry
Daniel@lifesciadvisors.com

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

	June 30, 2024 (Unaudited)	December 31, 2023
Assets		
Cash and cash equivalents	$ 214,508	$ 60,649
Marketable securities	217,023	302,301
Interest receivable	2,748	1,375
Prepaid assets	3,532	3,399
Prepaid clinical	12,451	6,413

Other current assets	—	9
Total current assets	450,262	374,146
Fixed assets, net	42,567	42,143
Right of use assets, net	6,334	4,263
Total assets	$ 499,163	$ 420,552
Liabilities and Shareholders' Deficit		
Accounts payable	$ 2,933	$ 5,098
Lease liabilities	1,032	803
Accrued expenses and other	15,109	17,665
Income taxes payable	1,515	1,472
Total current liabilities	20,589	25,038
Income tax payable, net of current portion	568	568
Lease liabilities, net of current portion	5,640	3,610
Total liabilities	26,797	29,216
Commitments and contingencies		
Redeemable noncontrolling interest	1,444,737	1,494,732
Shareholders' deficit		
Class A ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 125,856,877 and 59,880,347 issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	13	6
Class B ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 163,817,953 and 168,297,916 issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	16	17
Additional paid-in capital	189,267	36,114
Accumulated other comprehensive (loss) gain	(6)	130
Accumulated deficit	(1,161,661)	(1,139,663)
Total shareholders' deficit	(972,371)	(1,103,396)
Total liabilities and shareholders' deficit	$ 499,163	$ 420,552

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 29,404	$ 26,364	$ 56,637	$ 51,981
General and administrative	13,652	13,455	26,495	28,714
Total operating expenses	43,056	39,819	83,132	80,695
Operating loss	(43,056)	(39,819)	(83,132)	(80,695)
Other income (expense):				
Interest income	4,537	5,965	9,380	11,262
Interest expense	(3)	(4)	(5)	(7)
Net loss before income taxes	(38,522)	(33,858)	(73,757)	(69,440)
Income tax (benefit) expense	(56)	965	42	2,292
Net loss before noncontrolling interest	(38,466)	(34,823)	(73,799)	(71,732)
Net loss attributable to noncontrolling interest	(25,960)	(25,705)	(51,801)	(52,949)
Net loss available to Class A ordinary shareholders	$ (12,506)	$ (9,118)	$ (21,998)	$ (18,783)

Weighted average Class A ordinary shares outstanding:				
Basic and diluted	75,908,017	64,562,209	68,429,869	64,551,281
Net loss per share attributable to Class A ordinary shares:				
Basic and diluted	$ (0.16)	$ (0.14)	$ (0.32)	$ (0.29)

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

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss before noncontrolling interest	$ (73,799)	$ (71,732)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:		
Depreciation and amortization	2,372	1,702
Equity-based compensation	15,489	24,222
Gain on marketable securities, net	(3,802)	(1,981)
Loss on disposal of equipment	131	3
Changes in operating assets and liabilities		
Interest receivable	(1,373)	(8,090)
Prepaid and other assets	(6,162)	2,256
Accounts payable and accrued expenses	(5,838)	12,430
Income taxes payable	43	282
Net cash flows used in operating activities	(72,939)	(40,908)
Cash flows from investing activities		
Purchases of marketable securities	(82,880)	(261,847)
Sales and maturities of marketable securities	171,445	60,768
Purchase of equipment and facility expansion	(1,596)	(4,686)
Net cash flows provided by (used in) investing activities	86,969	(205,765)
Cash flows from financing activities		
Proceeds from sales of Class A ordinary shares, net of offering costs	139,855	–
Payments on finance leases	(26)	(26)
Net cash flows provided by (used in) financing activities	139,829	(26)
Net change in cash and cash equivalents	153,859	(246,699)
Cash, beginning of period	60,649	490,252
Cash, end of period	$ 214,508	$ 243,553
Supplemental disclosure of non-cash investing and financing activities:		
Right of use assets obtained in exchange for lease obligations	$ 2,621	$ 714
Exchange of Class B ordinary shares	$ 14,902	$ –
Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 16,708	$ 380
Change in redemption value of noncontrolling interest	$ –	$ 230,209
Equipment and facility expansion included in accounts payable and accrued expenses	$ 780	$ 689