ProKidney Reports Second Quarter Financial Results and Recent Corporate Highlights

August 10, 2023

WINSTON-SALEM, N.C., Aug. 10, 2023 (GLOBE NEWSWIRE) -- ProKidney Corp. (Nasdaq: PROK) ("ProKidney" or the "Company"), a leading late clinical-stage cellular therapeutics company focused on dialysis-free living for those with chronic kidney disease (CKD), today announced financial results for the second quarter ended June 30, 2023, and provided an update on recent corporate developments.

"In the second quarter, and throughout the first half of 2023, we steadily advanced our REACT development programs, including our initial Phase 3 study, **proact 1**, that is assessing the potential for REACT to delay or halt the progression of moderate to severe diabetic CKD," said Dr. Tim Bertram, Chief Executive Officer of ProKidney. "Looking ahead, we expect to reach several important inflection points in the coming months, including updated interim data from our Phase 2 RMCL-002 study in the second half of 2023, potentially furthering an understanding of the durability of kidney function preservation found with REACT in patients with advanced stage CKD. Around the end of 2023, we are also planning to report on the progress of participants in our open-label Phase 2 REGEN-007 study of REACT. That study is designed to elicit visibility into the potential kidney outcomes of our commercial stage REACT formulation when injected into both kidneys. We expect that these readouts could provide significant insight into the potential of REACT to preserve kidney health and delay the need for dialysis in patients with advanced CKD. With regard to our maturation toward becoming a commercial stage organization, we recently took an important step with the purchase of the Greensboro facility that we expect will expand our future manufacturing capacity for a potential commercial launch of REACT pending regulatory approval."

Recent Corporate Highlights, and REACT® Clinical Development Updates

- Closed on purchase of a 210,000 square foot facility and approximately 22 acres of land in Greensboro, N.C., that will support future potential commercial manufacturing needs for REACT. Received an incentive package totaling up to approximately $33.7 million in tax credits, as well as up to $1.9 million in energy credits from Duke Energy. Receipt of these incentives is based upon the achievement of certain milestones, including the creation of at least 330 new jobs on or before December 31, 2028, and project investment of approximately $458 million made, or caused to be made, by the company in real and personal property by December 31, 2027.
- Continued enrolling subjects in **proact 1**, a Phase 3 randomized, blinded, sham-controlled study evaluating up to two doses of REACT given three months apart, with one dose delivered into each kidney. The study's target enrollment is 600 patients at sites in the U.S., UK and select other countries at high risk for progressing to kidney failure, with initial interim data expected by the end of 2024.
- Continued preparation to initiate patient enrollment in **proact 2,** a Phase 3 randomized, blinded, sham-controlled study to assess the safety and efficacy of up to two REACT injections, given three months apart, and delivered once into each kidney, for patients primarily in the EU, Latin America and Asia Pacific regions. The Company recently implemented protocol modifications to reflect the evolving standard-of-care, ongoing regulatory interactions, and facilitation of potential commercial access. These modifications include a long-term (60 month) follow-up period and stratification at randomization based on CKD stage and SGLT2 or sMRA use. Protocol allowances have been received in Australia, Belgium, Brazil, Columbia, France, Italy, Malaysia, Portugal, Singapore, and Spain. ProKidney expects to commence enrollment in the second half of 2023 with initial interim data expected by the end of 2025.
- Presented a poster on REGEN-007 patient demographics at the 60th European Renal Association (ERA) Congress.

Second Quarter 2023 Financial Highlights

Liquidity: Cash, cash equivalents and marketable securities as of June 30, 2023, totaled $446.1 million, compared to $490.3 million on December 31, 2022.

R&D Expenses: Research and development expenses were $26.4 million for the three months ended June 30, 2023, compared to $11.6 million for the same period in 2022. The increase of $14.8 million was driven primarily by increases in cash and equity compensation costs of approximately $5.9 million as we continue to hire additional personnel in the areas of clinical development, quality, manufacturing, and biostatistics to support our ongoing clinical trials and look to build our commercial manufacturing capabilities. Additionally, we have seen increases in clinical trial costs of approximately $6.2 million related primarily to our Phase 3 program and our REGEN-007 clinical trial.

G&A Expenses: General and administrative expenses were $13.5 million for the three months ended June 30, 2023, compared to $9.2 million for the same period in 2022. The increase of $4.3 million was primarily driven by increases in legal fees and insurance costs related to our operation as a public company coupled with professional fees incurred in connection with our planned commercial scale manufacturing expansion.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was $34.8 million and $22.1 million for the three months ended June 30, 2023, and 2022, respectively.

Shares outstanding: Class A and Class B ordinary shares outstanding at June 30, 2023 totaled 235,253,658.

About ProKidney
ProKidney, a pioneer in the treatment of CKD through innovations in cellular therapy, was founded in 2015 after a decade of research. ProKidney's lead product candidate, REACT® (Renal Autologous Cell Therapy), is a first-of-its-kind, patented, proprietary autologous cellular therapy with the potential to preserve kidney function in patients at high risk of kidney failure. Late-stage CKD patients, Stage 3b - 4, are a key target population for REACT therapy. REACT has received Regenerative Medicine Advanced Therapy (RMAT) designation, as well as FDA and EMA guidance, supporting its ongoing Phase 3 clinical program that launched in January 2022. For more information, 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 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 COVID-19 or geo-political conflict such as the war in Ukraine 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.

Contacts:

Corporate:
Glenn Schulman, PharmD, MPH
SVP, Investor Relations
glenn.schulman@prokidney.com

Investors:
Burns McClellan
Lee Roth / Julia Weilman
lroth@burnsmc.com / jweilman@burnsmc.com

Media:
Burns McClellan
Selina Husain / Robert Flamm, Ph.D.
shusain@burnsmc.com / rflamm@burnsmc.com

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

	June 30, 2023 (Unaudited)	December 31, 2022
Assets		
Cash and cash equivalents	$ 243,553	$ 490,252
Marketable securities	202,575	–
Interest receivable	8,090	–
Prepaid assets	4,226	2,624
Prepaid clinical	7,385	10,459
Other current assets	603	1,384
Total current assets	466,432	504,719
Fixed assets, net	14,803	10,708
Right of use assets, net	2,880	2,356
Intangible assets, net	106	213
Total assets	$ 484,221	$ 517,996
Liabilities and Shareholders' Deficit/Members' Equity		
Accounts payable	$ 2,832	$ 3,044
Lease liabilities	654	493
Accrued expenses and other	20,945	7,336
Income taxes payable	66	–
Total current liabilities	24,497	10,873
Income tax payable, net of current portion	494	278
Lease liabilities, net of current portion	2,286	1,906
Total liabilities	27,277	13,057
Commitments and contingencies		
Redeemable noncontrolling interest	1,779,198	1,601,555
Shareholders’ deficit / members' equity:		
Class A ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 61,590,231 and 61,540,231 issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	6	6
Class B ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 173,663,427 and 171,578,320 issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	18	18
Additional paid-in capital	30,957	7,476
Accumulated other comprehensive loss	(127)	–
Accumulated deficit	(1,353,108)	(1,104,116)
Total shareholders' deficit / members’ equity	(1,322,254)	(1,096,616)
Total liabilities and shareholders' deficit/members' equity	$ 484,221	$ 517,996

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,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 26,364	$ 11,558	$ 51,981	$ 40,048
General and administrative	13,455	9,180	28,714	47,152
Total operating expenses	39,819	20,738	80,695	87,200
Operating loss	(39,819)	(20,738)	(80,695)	(87,200)

Other income (expense):				
Interest income	5,965	–	11,262	–
Interest expense	(4)	(170)	(7)	(184)
Net loss before income taxes	(33,858)	(20,908)	(69,440)	(87,384)
Income tax expense	965	1,223	2,292	2,233
Net loss before noncontrolling interest	(34,823)	(22,131)	(71,732)	(89,617)
Net loss attributable to noncontrolling interest	(25,705)	–	(52,949)	–
Net loss available to Class A ordinary shareholders	$ (9,118)	$ (22,131)	$ (18,783)	$ (89,617)
Weighted average Class A ordinary shares outstanding: [1]				
Basic and diluted	64,562,209		64,551,281	
Net loss per share attributable to Class A ordinary shares: [1]				
Basic and diluted	$ (0.14)		$ (0.29)	

[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.

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

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss before noncontrolling interest	$ (71,732)	$ (89,617)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:		
Depreciation and amortization	1,702	1,462
Equity-based compensation	24,222	60,685
Gain on marketable securities, net	(1,981)	–
Loss on disposal of equipment	3	–
Changes in operating assets and liabilities		
Interest receivable	(8,090)	–
Deferred offering costs	–	(6,905)
Prepaid and other assets	2,256	(5,320)
Accounts payable and accrued expenses	12,430	(520)
Income taxes payable	282	1,730
Net cash flows used in operating activities	(40,908)	(38,485)
Cash flows used in investing activities		
Purchases of marketable securities	(261,847)	–
Sales of marketable securities	60,768	–
Purchase of equipment and facility expansion	(4,686)	(1,225)
Net cash flows used in investing activities	(205,765)	(1,225)
Cash flows from financing activities		
Payments on finance leases	(26)	(16)
Borrowings under related party notes payable	–	35,000
Net cash contribution	–	6,050
Net cash flows (used in) provided by financing activities	(26)	41,034

Net change in cash and cash equivalents	(246,699)	1,324
Cash, beginning of period	490,252	20,558
Cash, end of period	$ 243,553	$ 21,882
Supplemental disclosure of non-cash investing activities:		
Right of use assets obtained in exchange for lease obligations	$ 714	$ 878
Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 380	$ –
Change in redemption value of noncontrolling interest	$ 230,209	$ –
Equipment and facility expansion included in accounts payable and accrued expenses	$ 689	$ 529