ProKidney Reports First Quarter Financial Results and Recent Corporate Highlights

May 11, 2023

WINSTON-SALEM, N.C., May 11, 2023 (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 announced financial results for the first quarter ended March 31, 2023, and provided an update on recent corporate developments.

"During the first quarter of 2023, we continued to advance the Phase 3 clinical development of REACT® to assess its potential to delay, and possibly eliminate, the need for dialysis, and in parallel we sharpened our plans for manufacturing and organizational development as we progress toward potential commercialization," said Dr. Tim Bertram, Chief Executive Officer of ProKidney. "Patient enrollment in **proact 1** continues according to plan and we target interim data by year end 2024. In addition, we recently completed enrollment in REGEN-007 with a total of 53 subjects randomized into this open-label Phase 2 study evaluating diabetic patients with Stage 3/4 CKD who either receive bilateral REACT injections three months apart, consistent with our Phase 3 studies, or receive a single REACT injection with a second injection upon satisfying certain reinjection criteria. With enrollment complete, we continue to biopsy, treat, and monitor patients following administration of REACT, evaluating them as they progress through the 18-month follow up period. Once 007 data is sufficiently mature, we plan to conduct an interim analysis and target a preliminary data report in late 2023."

James Coulston, Chief Financial Officer at ProKidney, added, "With approximately $464 million in cash, cash equivalents and marketable securities as of March 31st of this year, we remain well capitalized to continue executing on our clinical, manufacturing, and strategic objectives as we approach these and other key inflection points. The consistency of the REACT clinical results achieved to date, coupled with the steady pace at which the ProKidney team has progressed REACT through development, gives us confidence in what the future holds both for the platform and the Company."

Recent Corporate Highlights, and REACT® Clinical Development Updates

- Completed enrollment in REGEN-007, an open-label Phase 2 study evaluating two injections of the cryopreserved REACT product administered either three months apart or after one or more re-injection triggers are met, with one injection delivered into each kidney. The Company anticipates initial data from this study in late 2023.
- 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 high risk for progressing to kidney failure at sites in the U.S., UK and select other countries, with initial interim data expected by the end of 2024.
- Preparing for the initiation of patient enrollment into **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 has protocol allowances in Belgium, France, Singapore, Spain and Austria and expects to commence enrollment in the second half of 2023.
- Presented three posters supporting the potential of REACT to preserve kidney function and slow the progression of chronic kidney disease at the National Kidney Foundation (NKF) Spring Clinical Meeting 2023 (SCM23).
- Presented two abstracts on patient demographics in the ongoing REGEN-007 study and the design of the proact 2 study at the World Congress of Nephrology (WCN).
- Presented data on the safety and feasibility of the Company's image-guided injection procedure during an oral abstract session at the Society of Interventional Radiology (SIR) 2023 Annual Scientific Meeting.

First Quarter 2023 Financial Highlights

Liquidity: Cash, cash equivalents and marketable securities as of March 31, 2023, totaled $463.7 million, compared to $490.3 million on December 31, 2022.

R&D Expenses: Research and development expenses were $25.6 million for the three months ended March 31, 2023, compared to $28.5 million for the same period in 2022. The decrease of $2.9 million was driven primarily by decreases in equity-based payments offset by increases in clinical trial and cash compensation costs.

G&A Expenses: General and administrative expenses were $15.3 million for the three months ended March 31, 2023, compared to $38.0 million for the same period in 2022. The decrease of $22.7 million was primarily driven by decreases in equity-based compensation of approximately $26.0 million offset by increases in cash compensation costs as well as costs related to our operations as a public company.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was $36.9 million and $67.5 million for the three months ended March 31, 2023, and 2022, respectively.

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.

About CKD
CKD is a serious diagnosis with significant morbidity and mortality. Notably, the 5-year mortality of newly diagnosed Stage 4 CKD is higher than that of newly diagnosed non-metastatic cancer. CKD most often presents as a progressive decline in kidney function, ultimately resulting in the failure of the kidneys and the need for renal replacement therapy, such as hemodialysis or kidney transplant. One in three Americans is at risk for CKD, which currently affects approximately 75 million people in the United States and Europe and over 400 million across Asia. CKD is among the largest single expense incurred by the U.S. health care system.

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.

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

	March 31, 2023 (Unaudited)	December 31, 2022
Assets		
Cash and cash equivalents	$ 271,635	$ 490,252
Marketable securities	192,046	–
Interest receivable	5,476	–
Prepaid assets	4,950	2,624
Prepaid clinical	5,828	10,459
Other current assets	208	1,384
Total current assets	480,143	504,719
Fixed assets, net	11,810	10,708
Right of use assets, net	3,039	2,356
Intangible assets, net	159	213
Total assets	$ 495,151	$ 517,996
Liabilities and Shareholders' Deficit/Members' Equity		
Accounts payable	$ 3,801	$ 3,044
Lease liabilities	624	493
Accrued expenses and other	6,854	7,336
Total current liabilities	11,279	10,873
Income tax payable, net of current portion	426	278
Lease liabilities, net of current portion	2,468	1,906
Total liabilities	14,173	13,057
Commitments and contingencies		
Redeemable noncontrolling interest	2,082,488	1,601,555
Shareholders' deficit / members' equity:		
Class A ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 61,540,231 issued and outstanding as of March 31, 2023 and December 31, 2022	6	6
Class B ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 173,444,861and 171,578,320 issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	18	18
Additional paid-in capital	21,792	7,476
Accumulated other comprehensive income	(19)	–
Accumulated deficit	(1,623,307)	(1,104,116)
Total shareholders' deficit / members' equity	(1,601,510)	(1,096,616)
Total liabilities and shareholders' deficit/members' equity	$ 495,151	$ 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 March 31, 2023	2022
Operating expenses		
Research and development	$ 25,617	$ 28,490

General and administrative	15,259	37,972
Total operating expenses	40,876	66,462
Operating loss	(40,876)	(66,462)
Other income (expense):		
Interest income	5,297	–
Interest expense	(3)	(14)
Net loss before income taxes	(35,582)	(66,476)
Income tax expense	1,327	1,010
Net loss before noncontrolling interest	(36,909)	(67,486)
Net loss attributable to noncontrolling interest	(27,244)	–
Net loss available to Class A ordinary shareholders	$ (9,665)	$ (67,486)
Weighted average Class A ordinary shares outstanding: [1]		
Basic and diluted	61,540,231	
Net loss per share attributable to Class A ordinary shares: [1]		
Basic and diluted	$ (0.16)	

[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)

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss before noncontrolling interest	$ (36,909)	$ (67,486)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:		
Depreciation and amortization	832	710
Equity-based compensation	13,020	52,684
Gain on marketable securities, net	(492)	–
Loss on disposal of equipment	3	–
Changes in operating assets and liabilities		
Interest receivable	(5,476)	–
Prepaid and other assets	3,483	(3,843)
Accounts payable and accrued expenses	(601)	1,519
Income taxes payable	148	957
Net cash flows used in operating activities	(25,992)	(15,459)
Cash flows used in investing activities		
Purchases of marketable securities	(198,038)	–
Sales of marketable securities	6,412	–
Purchase of equipment and facility expansion	(986)	(839)
Net cash flows used in investing activities	(192,612)	(839)
Cash flows from financing activities		
Payments on finance leases	(13)	(8)
Borrowings under related party notes payable	–	20,000
Net cash contribution	–	5,550

Net cash flows (used in) provided by financing activities	(13)	25,542
Net change in cash and cash equivalents	(218,617)	9,244
Cash, beginning of period	490,252	20,558
Cash, end of period	$ 271,635	$ 29,802
Supplemental disclosure of non-cash investing activities:		
Right of use assets obtained in exchange for lease obligations	$ 714	$ 496
Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 1,352	$ –
Change in redemption value of noncontrolling interest	$ 509,526	$ –
Equipment and facility expansion included in accounts payable and accrued expenses	$ 744	$ 501