ProKidney Reports Third Quarter 2022 Financial Results and Recent Corporate Highlights

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WINSTON-SALEM, N.C., Nov. 14, 2022 (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 third quarter ended September 30, 2022, and provided an update on recent corporate developments.

"During the third quarter of 2022, we made significant advancement in our mission to improve the lives and outcomes for people with CKD. In July, ProKidney listed on the Nasdaq exchange and raised capital that optimally positions us to meet our anticipated clinical milestones. This capitalization moves us closer to bringing REACT® to patients in need as we report data from ongoing studies of REACT, advance additional studies, and launch our second global Phase 3 study, **proact 2** (formerly REGEN-016). We believe that the steps we are taking today will help set the stage for a successful year ahead," said Dr. Tim Bertram, Chief Executive Officer of ProKidney.

Dr. Libbie McKenzie, Chief Medical Officer at ProKidney, commented, "Throughout 2022, we have continued to execute on our clinical development and regulatory strategy, furthering enrollment in our ongoing REACT studies including our first global Phase 3 study, **proact 1** (formerly REGEN-006), highlighting the proactive nature of REACT to potentially stabilize or improve kidney function and reduce the risk of kidney failure. Our Phase 2 clinical trial, REGEN-007, remains on track to report interim data by the third quarter of 2023. We are grateful to our investigators, the patients and their caregivers for their continued support and look forward to sharing data as it becomes available."

Corporate Highlights and REACT® Clinical Development Program

- Received allowance of the **proact 1** Phase 3 study protocol for its investigational candidate REACT by the United Kingdom's (UK) MHRA. This follows submission of a clinical trial application for the **proact 1** Phase 3 study protocol previously allowed by the Food & Drug Administration (FDA) in the United States (U.S.), where recruitment is actively underway, and now allows ProKidney to begin patient recruitment at clinical trial sites in the UK beginning in early 2023.

- Received favorable scientific advice from the European Medicines Agency (EMA) on the adequacy of its Phase 3 development program, consisting of **proact 1** and **proact 2,** to support an eventual marketing authorization application (MAA).

- Remain on-track and continue to enroll subjects in the **proact 1** global Phase 3 randomized, blinded, sham-controlled study to assess the efficacy of up to two REACT injections, given three months apart, and delivered once into each kidney. The study aims to enroll up to 600 subjects, with first interim data expected in the fourth quarter of 2024.

- Anticipate beginning enrollment in the first quarter of 2023 for the **proact 2** global Phase 3 study. **Proact 2** is a randomized, blinded, sham-controlled study to assess the efficacy of up to two REACT injections, given three months apart, and delivered once into each kidney, which will enroll patients in the EU, Latin America and Asia Pacific regions. **Proact 1 and 2** combined are anticipated to provide a registrational package in the U.S. and EU.

- Remain on-track and continue to enroll subjects in a Phase 2 study (REGEN-007), a prospective, randomized, open-label, repeat dose, double-arm, controlled safety and efficacy study of REACT in subjects with type 1 or 2 diabetes and CKD, in which one injection of REACT will occur in each kidney. REGEN-007 has been expanded to enroll up to 50 subjects, with initial interim data expected in mid-2023.

- Delivered podium presentations during the Advances in Research: Regenerative Medicine and Bioartificial Kidney Pre-session Program at the American Society of Nephrology (ASN)

Annual Meeting, Kidney Week 2022; Mayo Clinic (Jacksonville) Inaugural Renal Regenerative Medicine Symposium; Innovation in Dialysis: Expediting Advances Symposium (IDEAS Symposium, University of Washington, Seattle); International Pediatric Nephrology Association (Calgary Alberta). Additionally, five posters were presented at ASN, which are available on the ProKidney website, covering a range of topics, including new insights on the mechanism of action of REACT and translational applications. Further, real-world data analyses of CKD prevalence, gender differences in disease progression and prescriber trends of newly introduced CKD medications by the professional community.

- Successfully completed a listing on Nasdaq raising net proceeds of $512 million to fund ongoing Phase 2 and 3 development programs for REACT, accelerate manufacturing scale-out, and ultimately prepare for its global commercial launch to treat patients with late-stage CKD and at high risk of kidney failure, subject to regulatory approvals.

Third Quarter Financial Highlights

Cash Position: Cash and cash equivalents as of September 30, 2022, was $506.3 million, compared to $20.6 million on December 31, 2021. In connection with the closing of the business combination with Social Capital Suvretta Holding Corp. III (SCS), on July 11, 2022, ProKidney received gross proceeds of $596.5 million. A portion of these proceeds was used to repay $35.2 million of related party notes and $49.4 million of expenses previously incurred by SCS and fees incurred in connection with the PIPE placement.

R&D Expenses: Research and development expenses were $21.1 million for the three months ended September 30, 2022, compared to $14.7 million for the same period in 2021. The increase of $6.4 million was driven by a $2.0 million increase in cash-based compensation costs, driven primarily by the hiring of additional members of the management team and other senior positions to strengthen our internal resources as we enter Phase 3 development and prepare for commercialization. Other research and development costs related to professional fees, quality control and manufacturing improvements increased by approximately $2.1 million. Further, non-cash costs of $1.7 million were recorded for equity-based compensation related to awards granted during 2022.

G&A Expenses: General and administrative expenses were $14.4 million and $2.3 million for the three months ended September 30, 2022, and 2021, respectively. The increase of $12.1 million was primarily driven by increases in non-cash equity-based compensation expenses of approximately $2.6 million due to additional awards granted during 2022, increases of approximately $2.0 million in professional service fees associated with the SCS business combination, increases of approximately $4.5 million related to director and officer insurance coverage associated with our operations as a public company including the costs related to a director and officers tail insurance policy with respect to SCS, increases in cash-based compensation expenses of $0.7 million, due to the hiring of additional personnel and increases in legal and professional service fees of approximately $1.9 million primarily driven by costs associated with operating as a public company.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was $33.9 million and $17.1 million for the three months ended September 30, 2022, and 2021.

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, autologous cellular therapy with the potential to not only slow and stabilize the progression of CKD, but in some cases potentially drive meaningful improvement in kidney function. 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
There are no therapies that effectively reverse late-stage 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 expenses 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, 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 combined 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 impact of COVID-19 or geo-political conflict such as the war in Ukraine on the Company's business; and other risks and uncertainties indicated from time to time in the Company's 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
Lroth@burnsmc.com

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

ProKidney Corp. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Cash and cash equivalents	$ 506,327	$ 20,558
Prepaid assets	3,549	588
Prepaid clinical	9,337	6,100
Other current assets	158	25
Total current assets	519,371	27,271
Fixed assets, net	10,695	11,358
Right of use assets, net	2,105	1,241
Intangible assets, net	267	428
Total assets	$ 532,438	$ 40,298
Liabilities and Equity		
Accounts payable	$ 3,453	$ 2,834
Lease liabilities	426	267
Accrued expenses and other	5,962	9,213
Total current liabilities	9,841	12,314
Income tax payable, net of current portion	309	–
Lease liabilities, net of current portion	1,717	1,067
Total liabilities	11,867	13,381
Commitments and contingencies		
Redeemable noncontrolling interest	1,616,896	–
Shareholders' deficit / members' equity:		
Class A units (186,500,000 issued and outstanding at December 31, 2021)	–	186,500
Class B units (7,767,122 issued and outstanding at December 31, 2021)	–	1,927
Class A ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 61,540,231 issued and outstanding as of September 30, 2022	6	–
Class B ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 171,210,060 issued and outstanding as of September 30, 2022	18	–
Additional paid-in capital	1,456	–
Accumulated deficit	(1,097,805)	(161,510)
Total shareholders' deficit / members' equity	(1,096,325)	26,917
Total liabilities and equity	$ 532,438	$ 40,298

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 21,132	$ 14,742	$ 61,180	$ 35,570
General and administrative	14,440	2,339	61,592	5,831
Total operating expenses	35,572	17,081	122,772	41,401
Operating loss	(35,572)	(17,081)	(122,772)	(41,401)
Other income (expense):				
Interest income	1,581	—	1,581	1
Interest expense	(29)	(1)	(213)	–
Net loss before income taxes	(34,020)	(17,082)	(121,404)	(41,400)
Income tax (benefit) expense	(75)	60	2,158	76
Net and comprehensive loss before noncontrolling interest	(33,945)	(17,142)	(123,562)	(41,476)
Net loss and comprehensive loss attributable to noncontrolling interest	(22,017)	–	(22,017)	–
Net loss and comprehensive loss available to Class A ordinary shareholders	$ (11,928)	$ (17,142)	$ (101,545)	$ (41,476)
Weighted average Class A ordinary shares outstanding: [1]				
Basic and diluted	61,540,231		61,540,231	
Net loss per share attributable to Class A ordinary shares: [1]				
Basic and diluted	$ (0.13)		$ (0.13)	

[1] For the three and nine months ended September 30, 2022, net loss per Class A ordinary share and weighted average Class A ordinary shares outstanding is representative of the period from July 11, 2022 through September 30, 2022, the period following the Business Combination,

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities		
Net loss before noncontrolling interest	$ (123,562)	$ (41,476)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:		
Depreciation and amortization	2,245	1,397
Equity-based compensation	65,529	524
Gain on disposal of equipment	–	1
Changes in operating assets and liabilities		
Prepaid and other assets	(5,810)	(1,819)
Accounts payable and accrued expenses	(39)	4,064
Income taxes payable	309	–
Net cash flows used in operating activities	(61,328)	(37,309)
Cash flows used in investing activities		
Net cash from SCS	108	–
Purchase of equipment and facility expansion	(1,540)	(4,652)
Net cash flows used in investing activities	(1,432)	(4,652)
Cash flows from financing activities		
Payments on finance leases	(24)	(22)
Proceeds from Business Combination, including PIPE financing, net of associated costs of $37,856	542,503	–
Borrowings under related party notes payable	35,000	–
Repayment of related party notes payable	(35,000)	–
Net cash contribution	6,050	41,500
Net cash flows provided by financing activities	548,529	41,478

Net change in cash and cash equivalents	485,769	(483)
Cash, beginning of period	20,558	4,578
Cash, end of period	$ 506,327	$ 4,095
Supplemental disclosure of non-cash investing activities:		
Right of use assets obtained in exchange for lease obligations	$ 1,124	$ –
Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 3,084	$ –
Equipment and facility expansion included in accounts payable and accrued expenses	$ 380	$ 1,339