UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 28, 2023

PROKIDNEY CORP.

(Exact name of Registrant as Specified in Its Charter)

Cayman Islands	**001-40560**	**98-1586514**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2000 Frontis Plaza Blvd. Suite 250 Winston-Salem, North Carolina	**27103**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 336 999-7029

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A ordinary shares, $0.0001 par value per share	PROK	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 28, 2023, ProKidney Corp. issued a press release to announce its financial results for the fourth quarter and fiscal year ended December 31, 2022. A copy of the press release is furnished as Exhibit 99.1.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that section, and shall not be deemed to be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated March 28, 2023
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROKIDNEY CORP.

Date: March 28, 2023

By: /s/ James Coulston
James Coulston
Chief Financial Officer

ProKidney Reports Fourth Quarter Financial Results and Recent Corporate Highlights

WINSTON-SALEM, N.C. – March 28, 2023 – 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 fourth quarter ended December 31, 2022, and provided an update on recent corporate developments.

“Throughout 2022, we made great progress in our mission to develop and provide a treatment with the potential to preserve kidney function in patients with late-stage CKD who are at high risk for kidney failure,” said Dr. Tim Bertram, Chief Executive Officer of ProKidney. “The first of two pivotal Phase 3 trials of REACT® is progressing with enrollment, as are several ongoing Phase 2 clinical studies, while the second Phase 3 trial continues to advance toward enrollment. Moreover, our accomplishments over the past year leave us well positioned to deliver on multiple potential value-creating milestones in 2023, including interim data from REGEN-007, our open-label Phase 2 study designed with contralateral kidney injections to provide visibility into potential outcomes of our global Phase 3 program. We remain actively engaged with the FDA, facilitated by REACT’s RMAT designation, to ensure that the steps we are taking today are positioning REACT for future success.

We continue to believe that our balance sheet, strengthened by the more than $500 million in net proceeds from our PIPE financing in July 2022, will be sufficient to fund operations through 2024 when we expect to report topline data from **proact1** which, if positive, could help support a future BLA submission for potential U.S. regulatory approval.”

Dr. Joseph Stavas, SVP and Head of Global Clinical Development, Safety and Interventional Procedures, added, “We have meaningfully advanced the execution of our clinical development strategy, including regular interactions with the physician community at key medical congresses, aimed at broadening awareness of REACT among physicians. We look forward to advancing our REACT clinical trials, and to reporting additional data as it becomes available.”

Recent Corporate Highlights, and REACT® Clinical Development Updates

- Continued enrolling subjects in **proact1**, 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 in the U.S. and select additional countries, with initial interim data expected at the end of 2024.
- Received allowance of the **proact1** study protocol from the UK Medicines and Healthcare Products Regulatory Agency, Health Canada and the Taiwan Food and Drug Administration,

allowing the Company to recruit patients at clinical trial sites in these countries, in addition to the U.S.

- Continued to progress toward the initiation of **proact2,** a 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, which will enroll patients primarily in the EU, Latin America and Asia Pacific regions. The Company currently has protocol allowances in Belgium, France, Singapore, Spain and Austria, with additional country-specific allowances pending. **Proact1** and **2**, combined, are intended to provide the basis for registrational packages in the U.S. and EU.
- Demonstrated REACT's potential to preserve kidney function in patients with severe (Stage 4) near-kidney-failure diabetic CKD in a Phase 2 clinical study (REGEN-003), the results of which were published in the *Journal of Blood Purification.*
- Presented data on the safety and feasibility of the Company's image-guided injection procedure at the Society of Interventional Radiology (SIR) 2023 Annual Scientific Meeting.
- Received favorable scientific advice from the European Medicines Agency on the adequacy of our Phase 3 development program to support a potential Marketing Authorization Application.

Fourth Quarter 2022 Financial Highlights

Cash Position: Cash and cash equivalents as of December 31, 2022, were $490.3 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, including approximately $20 million held in SCS's trust account with the remaining amount from PIPE investors. A portion of these proceeds was used to repay $35.2 million of related party notes, $49.4 million of expenses previously incurred by SCS and fees incurred in connection with the PIPE and business combination.

R&D Expenses: Research and development expenses were $20.9 million for the three months ended December 31, 2022, compared to $10.7 million for the same period in 2021. The increase of $10.2 million was driven by a $2.5 million increase in cash-based compensation costs, driven primarily by the hiring of additional members of the management team to strengthen our development and commercial expertise as we conduct a mid- and late-stage registrational development program. Costs related to our clinical trials for the three months ended December 31, 2022, increased by approximately $2.9 million as compared to the three months ended December 31, 2021, driven primarily by increased activities for our **proact1** and **proact2** trials. Further, non-cash costs of $3.3 million were recorded for equity-based compensation related to awards granted during 2022.

G&A Expenses: General and administrative expenses were $9.3 million for the three months ended December 31, 2022, compared to $3.0 million for the same period in 2021. The increase of $6.3 million was primarily driven by increases in non-cash equity-based compensation expenses of approximately $5.4 million due to additional awards granted during 2022, increases of approximately $1.1 million related to costs associated with operating as a public company, which consist primarily of director and officer insurance coverage, and professional service fees.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was $24.6 million and $13.7 million for the three months ended December 31, 2022, and 2021, 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, 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 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 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 our Annual Report on Form 10-K and the Company's 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
Lroth@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)

	December 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 490,252	$ 20,558
Prepaid assets	2,624	588
Prepaid clinical	10,459	6,100
Other current assets	1,384	25
Total current assets	504,719	27,271
Fixed assets, net	10,708	11,358
Right of use assets, net	2,356	1,241
Intangible assets, net	213	428
Total assets	$ 517,996	$ 40,298
Liabilities and Shareholders' Deficit/Members' Equity		
Accounts payable	$ 3,044	$ 2,834
Lease liabilities	493	267
Accrued expenses and other	7,336	9,213
Total current liabilities	10,873	12,314
Income tax payable, net of current portion	278	–
Lease liabilities, net of current portion	1,906	1,067
Total liabilities	13,057	13,381
Commitments and contingencies		
Redeemable noncontrolling interest	1,601,555	–
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 December 31, 2022	6	–
Class B ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 171,578,320 issued and outstanding as of December 31, 2022	18	–
Additional paid-in capital	7,476	–
Accumulated deficit	(1,104,116)	(161,510)
Total shareholders' deficit / members’ equity	(1,096,616)	26,917
Total liabilities and shareholders' deficit/members' equity	$ 517,996	$ 40,298

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

	Three Months Ended December 31, (Unaudited)		Years Ended December 31,	
	2022	**2021**	**2022**	**2021**
Operating expenses				
Research and development	$ 20,890	$ 10,685	$ 82,070	$ 46,255
General and administrative	9,345	3,024	70,937	8,855
Total operating expenses	30,235	13,709	153,007	55,110
Operating loss	(30,235)	(13,709)	(153,007)	(55,110)
Other income (expense):				
Interest income	4,402	1	5,983	2
Interest expense	(2)	–	(215)	–
Net loss before income taxes	(25,835)	(13,708)	(147,239)	(55,108)
Income tax (benefit) expense	(1,262)	(38)	896	38
Net and comprehensive loss before noncontrolling interest	(24,573)	(13,670)	(148,135)	(55,146)
Net loss and comprehensive loss attributable to noncontrolling interest	(18,086)	–	(40,103)	–
Net loss and comprehensive loss available to Class A ordinary shareholders	$ (6,487)	$ (13,670)	$ (108,032)	$ (55,146)
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	$ (0.11)		$ (0.23)	

[1] For the three months and year ended December 31, 2022, net loss per Class A ordinary share and weighted average Class A ordinary shares outstanding reflects the period from July 11, 2022 through December 31, 2022, the period following the Business Combination.

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

	Years Ended December 31, 2022	2021
Cash flows from operating activities		
Net loss before noncontrolling interest	$ (148,135)	$ (55,146)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:		
Depreciation and amortization	3,036	1,984
Equity-based compensation	74,469	699
Changes in operating assets and liabilities		
Prepaid and other assets	(7,231)	(5,704)
Accounts payable and accrued expenses	494	7,868
Income taxes payable	278	–
Net cash flows used in operating activities	(77,089)	(50,299)
Cash flows used in investing activities		
Proceeds from sale of equipment	–	1
Net cash from SCS	108	–
Purchase of equipment and facility expansion	(1,846)	(5,192)
Net cash flows used in investing activities	(1,738)	(5,191)
Cash flows from financing activities		
Payments on finance leases	(32)	(30)
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	71,500
Net cash flows provided by financing activities	548,521	71,470
Net change in cash and cash equivalents	469,694	15,980
Cash, beginning of period	20,558	4,578
Cash, end of period	$ 490,252	$ 20,558
Supplemental cash flow information:		
Cash paid during the period for income taxes, net of refunds	$ 1,950	$ 68
Supplemental disclosure of non-cash investing activities:		
Right of use assets obtained in exchange for lease obligations	$ 1,491	$ –
Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 5,828	$ –
Equipment and facility expansion included in accounts payable and accrued expenses	$ 51	$ 1,295