

**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): November 14, 2023

PROKIDNEY CORP.

(Exact name of Registrant as Specified in Its Charter)

Cayman Islands
(State or Other Jurisdiction
of Incorporation)

001-40560
(Commission File Number)

98-1586514
(IRS Employer
Identification No.)

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

27103
(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 November 14, 2023, ProKidney Corp. issued a press release to announce its financial results for the quarter ended September 30, 2023. 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 November 14, 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: November 14, 2023

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



ProKidney Reports Third Quarter Financial Results

WINSTON-SALEM, N.C., November 14, 2023 -- **ProKidney Corp. (Nasdaq: PROK)** ("ProKidney"), 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, 2023.

"Building off of our positive corporate update, and with nearly \$400 million in cash, cash equivalents and marketable securities as of September 30th of this year, ProKidney continues to be well capitalized to continue executing on both of our Phase 2 and Phase 3 trials in high-risk CKD patients in need," said James Coulston, Chief Financial Officer at ProKidney. "With cash expected to fund operations into the fourth quarter of 2025 and interim data readouts for REGEN-007 during that period, we remain well capitalized to continue executing on our development strategy, toward our ultimate goal of bringing REACT to patients in need."

ProKidney management will be hosting a webcast and investor conference call today, November 14, 2023, at 8:00 a.m. ET. The live webcast presentation may be accessed [here](#). Further, you may listen to the presentation by dialing 1-877-407-0784 (US) or 1-201-689-8560 (International) and entering the Conference ID: 13742672. Following the completion of the presentation, a replay of the webcast will also be accessible on the investor relations section of ProKidney website [here](#).

Third Quarter 2023 Financial Highlights

Liquidity: Cash, cash equivalents and marketable securities as of September 30, 2023, totaled \$396.3 million, compared to \$490.3 million on December 31, 2022. We expect that our existing cash, cash equivalents and marketable securities held at September 30, 2023, will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2025.

R&D Expenses: Research and development expenses were \$32.2 million for the three months ended September 30, 2023, compared to \$21.1 million for the same period in 2022. The increase of \$11.1 million was driven primarily by increases in cash and equity compensation costs of approximately \$5.5 million as we continue to hire additional personnel in the areas of clinical development, quality, manufacturing, and biostatistics to support our ongoing clinical trials. Clinical trial costs related to our Phase 3 program have increased approximately \$4.2 million. Additionally, we have seen increases in other research and development costs of approximately \$1.2 million primarily related to additional spending on manufacturing improvements and professional fees.

G&A Expenses: General and administrative expenses were \$14.4 million for each of the three months ended September 30, 2023 and 2022. While the overall costs were relatively consistent between periods, the decreases in costs incurred related to the business combination in the 2022 period were offset by higher equity-based compensation costs incurred in the 2023 period.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was \$42.0 million and \$33.9 million for the three months ended September 30, 2023, and 2022, respectively.

Shares outstanding: Class A and Class B ordinary shares outstanding at September 30, 2023 totaled 235,434,630.

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 being evaluated to potentially preserve kidney function in diabetic patients at high risk of kidney failure. 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, please 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:

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

	September 30, 2023 (Unaudited)	December 31, 2022
Assets		
Cash and cash equivalents	\$ 191,389	\$ 490,252
Marketable securities	204,945	–
Interest receivable	714	–
Prepaid assets	4,169	2,624
Prepaid clinical	5,203	10,459
Other current assets	3	1,384
Total current assets	406,423	504,719
Fixed assets, net	42,614	10,708
Right of use assets, net	2,717	2,356
Intangible assets, net	52	213
Total assets	\$ 451,806	\$ 517,996
Liabilities and Shareholders' Deficit/Members' Equity		
Accounts payable	\$ 4,476	\$ 3,044
Lease liabilities	676	493
Accrued expenses and other	15,464	7,336
Income taxes payable	371	–
Total current liabilities	20,987	10,873
Income tax payable, net of current portion	522	278
Lease liabilities, net of current portion	2,109	1,906
Total liabilities	23,618	13,057
Commitments and contingencies		
Redeemable noncontrolling interest	1,520,825	1,601,555
Shareholders' deficit / members' equity:		
Class A ordinary shares, \$0.0001 par value; 500,000,000 shares authorized; 61,595,300 and 61,540,231 issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	6	6
Class B ordinary shares, \$0.0001 par value; 500,000,000 shares authorized; 173,839,330 and 171,578,320 issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	18	18
Additional paid-in capital	41,365	7,476
Accumulated other comprehensive loss	(64)	–
Accumulated deficit	(1,133,962)	(1,104,116)
Total shareholders' deficit / members' equity	(1,092,637)	(1,096,616)
Total liabilities and shareholders' deficit/members' equity	\$ 451,806	\$ 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	\$ 32,198	\$ 21,132	\$ 84,179	\$ 61,180
General and administrative	14,419	14,440	43,133	61,592
Total operating expenses	46,617	35,572	127,312	122,772
Operating loss	(46,617)	(35,572)	(127,312)	(122,772)
Other income (expense):				
Interest income	5,541	1,581	16,803	1,581
Interest expense	(2)	(29)	(9)	(213)
Net loss before income taxes	(41,078)	(34,020)	(110,518)	(121,404)
Income tax expense (benefit)	913	(75)	3,205	2,158
Net loss before noncontrolling interest	(41,991)	(33,945)	(113,723)	(123,562)
Net loss attributable to noncontrolling interest	(31,007)	(22,017)	(83,956)	(22,017)
Net loss available to Class A ordinary shareholders	<u>\$ (10,984)</u>	<u>\$ (11,928)</u>	<u>\$ (29,767)</u>	<u>\$ (101,545)</u>
Weighted average Class A ordinary shares outstanding: ⁽¹⁾				
Basic and diluted	61,592,876	61,540,231	61,565,298	61,540,231
Net loss per share attributable to Class A ordinary shares: ⁽¹⁾				
Basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.13)</u>	<u>\$ (0.48)</u>	<u>\$ (0.13)</u>

⁽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. The basic and diluted net loss per share attributable to Class A ordinary shareholders for the three and nine months ended September 30, 2022, represents only the period after the Business Combination to September 30, 2022.

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

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities		
Net loss before noncontrolling interest	\$ (113,723)	\$ (123,562)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:		
Depreciation and amortization	2,707	2,245
Equity-based compensation	37,216	65,529
Gain on marketable securities, net	(3,675)	–
Loss on disposal of equipment	21	–
Changes in operating assets and liabilities		
Interest receivable	(714)	–
Prepaid and other assets	5,094	(5,810)
Accounts payable and accrued expenses	7,774	(39)
Income taxes payable	615	309
Net cash flows used in operating activities	(64,685)	(61,328)
Cash flows used in investing activities		
Net cash from SCS	–	108
Purchases of marketable securities	(301,701)	–
Sales of marketable securities	100,187	–
Purchase of equipment and facility expansion	(32,625)	(1,540)
Net cash flows used in investing activities	(234,139)	(1,432)
Cash flows from financing activities		
Payments on finance leases	(39)	(24)
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
Net cash flows (used in) provided by financing activities	(39)	548,529
Net change in cash and cash equivalents	(298,863)	485,769
Cash, beginning of period	490,252	20,558
Cash, end of period	\$ 191,389	\$ 506,327
Supplemental disclosure of non-cash investing and financing activities:		
Right of use assets obtained in exchange for lease obligations	\$ 714	\$ 1,124
Exchange of Class B ordinary shares	\$ 64	\$ –
Impact of equity transactions and compensation on redeemable noncontrolling interest	\$ 3,207	\$ 3,084
Change in redemption value of noncontrolling interest	\$ 79	\$ –
Equipment and facility expansion included in accounts payable and accrued expenses	\$ 1,386	\$ 380

