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 21, 2024

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 21, 2024, ProKidney Corp. issued a press release to announce its financial results for the year ended December 31, 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 March 21, 2024
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 21, 2024

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

Exhibit 99.1

ProKidney Reports Full Year 2023 Financial Results and Recent Corporate Highlights

WINSTON-SALEM, N.C., March 21, 2024 -- **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 year ended December 31, 2023.

"We are very excited about the future of ProKidney. Building on the positive interim Phase 2 data that we released last Fall for rilparencel (which we sometimes refer to as REACT®) demonstrating the potential to preserve kidney function in patients with type 2 diabetes mellitus and advanced kidney disease, we look forward to the REGEN-007 Phase 2 interim data readout mid-year," said Bruce Culleton, Chief Executive Officer at ProKidney. "Our clinical data to date have shown that rilparencel may meet a current unmet medical need by preserving kidney function and delaying the onset of dialysis in high-risk patients with CKD caused by type 2 diabetes. Rilparencel has the potential to be very meaningful to this high-risk patient population where there are limited options for care outside of preparing for transplantation or dialysis."

Corporate Updates

- **Appointment of Dr. Bruce Culleton as ProKidney CEO.** In November, the Company announced Dr. Bruce Culleton assumed the role of the CEO and joined the ProKidney board of directors. Dr. Culleton joined ProKidney in July 2023 as Executive Vice President of Clinical Development and Commercialization. Dr. Culleton has dedicated his 25-year professional career to improving the health and quality of life of patients with kidney disease and held executive leadership positions at Baxter Healthcare and CVS Kidney Care, a wholly owned subsidiary of CVS Health.

- **Appointment of Nikhil Pereira-Kamath as Chief Business Officer.** As CBO, Mr. Pereira-Kamath has global responsibility for commercial strategy, defining the Company's growth and partnering activities, and overseeing the Company's project management, business development and investor relations, bringing with him over a decade of experience as a seasoned entrepreneur in addition to a strong foundation in finance. Mr. Periera-Kamath had previously joined ProKidney in July 2023 as Vice President of Business Development & Innovative Solutions. Prior to joining ProKidney, he was Chief Executive Officer and subsequently Chairman of the Board, a role he continues to hold, of Africa Healthcare Network (AHN), the largest independent provider of dialysis and kidney care in sub-Saharan Africa.

Clinical Development Updates

- Reported positive interim Phase 2 RMCL-002 study data in November, demonstrating the potential of rilparencel to preserve kidney function in moderate and high-risk patients with CKD caused by type 2 diabetes. Updated data include information from 83 patients enrolled in the

RMCL-002 study and demonstrated a safety profile in line with previous rilparencel Phase 1 & 2 trials, and similar to that of a kidney biopsy.

- As disclosed in November 2023, overall, the updated RMCL-002 data showed preservation of kidney function in several patient groups with advanced CKD caused by type 2 diabetes. Patients with Stage 4 CKD with severe albuminuria-- broadly viewed to have the highest risk of kidney failure and where there remains a significant unmet clinical need-- showed the most potential benefit. Full results from RMCL-002 are expected in 1H 2024.
- Based on these emerging results, as disclosed in November 2023, the Company is updating its ongoing PROACT 1 Phase 3 clinical study (REGEN-006) protocol to focus on patients with higher risk of kidney failure. In the PROACT 1 Phase 3 clinical study, the eGFR enrollment range will be modified from the current range of ≥20 to ≤ 50 ml/min/1.73m^2 to a new range of ≥20 to ≤ 35 ml/min/1.73m^2. The Company believes that this focus on the most severe patients will better align with RMCL-002 results and clinical feedback. No changes are planned for the Phase 3 trial, PROACT 2 (REGEN-016), which is currently ≥20 to ≤ 44 ml/min/1.73m^2**.** Maintaining the eGFR enrollment range of PROACT 2, which includes the CKD Stage 3b population, will enable the Company to seek a broader commercial label. Manufacturing has been temporarily paused while ProKidney amends the PROACT 1 protocol and concurrently, in response to Qualified Person Audit, optimizes capabilities to meet EU and Global manufacturing and quality management system standards for Phase 3 studies and prepares for transition to commercial manufacturing. No safety events were responsible for this pause and the Company expects PROACT 1 will resume, and PROACT 2 will commence, enrollment in mid-2024.
- Interim results from the ongoing REGEN-007 Phase 2 open-label trial of rilparencel in patients with stage 3 and 4 CKD caused by type 2 diabetes is expected in mid-2024, with full Cohort 1 12 month follow up data anticipated in 1H 2025.

Full Year 2023 Financial Highlights

Liquidity: Cash, cash equivalents and marketable securities as of December 31, 2023, totaled $363.0 million, compared to $490.3 million on December 31, 2022. We expect that our existing cash, cash equivalents and marketable securities held at December 31, 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 $106.7 million for the year ended December 31, 2023, compared to $82.1 million for the same period in 2022. The increase of $24.6 million was driven primarily by increases in clinical trial costs related to our Phase 3 program of approximately $16.6 million. Additionally, we have seen increases in cash and equity compensation costs of approximately $17.2 million as we continue to hire additional personnel in the areas of clinical development, quality, manufacturing, and biostatistics to support our ongoing clinical trials. Further, we have seen increases in other research and development costs of approximately $4.7 million primarily related to additional spending on manufacturing improvements, materials and professional fees. These costs have been offset by decreases in equity-based payments for services rendered by a third party in the year ended December 31, 2022.

G&A Expenses: General and administrative expenses were $44.8 million for the year ended December 31, 2023 compared $70.9 million for the same period in 2022. The decrease of $26.1 million has been primarily driven by decreases of $33.0 million associated with the recognition of equity-based

compensation costs in 2022 for shares sold at less than their fair value prior to the business combination Additionally, there have been decreases in costs related to equity-based compensation and costs related to the business combination that occurred in 2022. These decreases have been offset by increases in professional fees and cash compensation costs of approximately $7.3 million and $4.7 million, respectively.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was $135.4 million and $148.1 million for the year ended December 31, 2023 and 2022, respectively.

Shares outstanding: Class A and Class B ordinary shares outstanding as of December 31, 2023 totaled 228,178,263.

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, rilparencel (also known as REACT®), 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. Rilparencel 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 geo-political conflict 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:

Investors:
LifeSci Advisors, LLC
Daniel Ferry
Daniel@lifesciadvisors.com

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

	December 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 60,649	$ 490,252
Marketable securities	302,301	–
Interest receivable	1,375	–
Prepaid assets	3,399	2,624
Prepaid clinical	6,413	10,459
Other current assets	9	1,384
Total current assets	374,146	504,719
Fixed assets, net	42,143	10,708
Right of use assets, net	4,263	2,356
Intangible assets, net	–	213
Total assets	$ 420,552	$ 517,996
Liabilities and Shareholders' Deficit/Members' Equity		
Accounts payable	$ 5,098	$ 3,044
Lease liabilities	803	493
Accrued expenses and other	17,665	7,336
Income taxes payable	1,472	–
Total current liabilities	25,038	10,873
Income tax payable, net of current portion	568	278
Lease liabilities, net of current portion	3,610	1,906
Total liabilities	29,216	13,057
Commitments and contingencies		
Redeemable noncontrolling interest	1,494,732	1,601,555
Shareholders’ deficit / members' equity:		
Class A ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 59,880,347 and 61,540,231 issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	6	6
Class B ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 168,297,916 and 171,578,320 issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	17	18
Additional paid-in capital	36,114	7,476
Accumulated other comprehensive loss	130	–
Accumulated deficit	(1,139,663)	(1,104,116)
Total shareholders' deficit / members’ equity	(1,103,396)	(1,096,616)
Total liabilities and shareholders' deficit/members' equity	$ 420,552	$ 517,996

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

	2023	2022	2021
Operating expenses			
Research and development	$ 106,707	$ 82,070	$ 46,255
General and administrative	44,815	70,937	8,855
Total operating expenses	151,522	153,007	55,110
Operating loss	(151,522)	(153,007)	(55,110)
Other income (expense):			
Interest income	22,083	5,983	2
Interest expense	(12)	(215)	–
Net loss before income taxes	(129,451)	(147,239)	(55,108)
Income tax expense	5,996	896	38
Net loss before noncontrolling interest	(135,447)	(148,135)	(55,146)
Net loss attributable to noncontrolling interest	(99,979)	(40,103)	–
Net loss available to Class A ordinary shareholders	$ (35,468)	$ (108,032)	$ (55,146)
Weighted average Class A ordinary shares outstanding: [1]			
Basic and diluted	61,714,225	61,540,231	
Net loss per share attributable to Class A ordinary shares: [1]			
Basic and diluted	$ (0.57)	$ (0.23)	

[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 year ended December 31, 2022, represents only the period after the Business Combination to December 31, 2022.

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

	Years Ended December 31,		
	2023	**2022**	**2021**
Cash flows from operating activities			
Net loss before noncontrolling interest	$ (135,447)	$ (148,135)	$ (55,146)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:			
Depreciation and amortization	3,853	3,036	1,984
Equity-based compensation	30,846	74,469	699
Gain on marketable securities, net	(6,018)	–	–
Loss on disposal of equipment	23	–	–
Changes in operating assets and liabilities			
Interest receivable	(1,375)	–	–
Prepaid and other assets	4,648	(7,231)	(5,704)
Accounts payable and accrued expenses	11,639	494	7,868
Income taxes payable	1,762	278	–
Net cash flows used in operating activities	(90,069)	(77,089)	(50,299)
Cash flows used in investing activities			
Proceeds from sale of equipment	–	–	1
Net cash from SCS	–	108	–
Purchases of marketable securities	(471,604)	–	–
Sales of marketable securities	175,818	–	–
Purchase of equipment and facility expansion	(34,197)	(1,846)	(5,192)
Net cash flows used in investing activities	(329,983)	(1,738)	(5,191)
Cash flows from financing activities			
Payments on finance leases	(52)	(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	–
Repurchase of Class A ordinary shares	(9,499)	–	–
Repayment of related party notes payable	–	(35,000)	–
Net cash contribution	–	6,050	71,500
Net cash flows (used in) provided by financing activities	(9,551)	548,521	71,470
Net change in cash and cash equivalents	(429,603)	469,694	15,980
Cash, beginning of period	490,252	20,558	4,578
Cash, end of period	$ 60,649	$ 490,252	$ 20,558
Supplemental cash flow information:			
Cash paid during the period for income taxes, net of refunds	$ 2,857	$ 1,950	$ 68
Supplemental disclosure of non-cash investing and financing activities:			
Right of use assets obtained in exchange for lease obligations	$ 2,594	$ 1,491	$ –
Exchange of Class B ordinary shares	$ 9,500	$ –	$ –
Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 2,577	$ 5,828	$ –
Change in redemption value of noncontrolling interest	$ 79	$ –	
Equipment and facility expansion included in accounts payable and accrued expenses	$ 218	$ 51	$ 1,295