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): May 10, 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: 336 999-7019

(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 May 10, 2024, ProKidney Corp. issued a press release to announce its financial results for the quarter ended March 31, 2024. 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 May 10, 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: May 10, 2024

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

Exhibit 99.1

ProKidney Reports Business Updates and First Quarter 2024 Financial Results

- *Final results from RMCL-002 Phase 2 trial to be presented in the Late Breaking Clinical Trials session at the European Renal Association (ERA) Congress on May 25, 2024. An investor call to provide a perspective on CKD with Dr. Arnold Silva and Dr. Steven Coca and a recap of the RMCL-002 data is planned for May 28, 2024*
- *On schedule to resume manufacturing and PROACT 1 Phase 3 trial, commence PROACT 2 Phase 3 trial, and readout interim results from the ongoing REGEN-007 Phase 2 trial in mid-2024*
- *Strengthened leadership team with appointment of two key hires across Clinical and Technical Operations*
- *Ended the first quarter with $329 million in cash and cash equivalents and marketable securities, supporting operating plans into Q4 2025*

WINSTON-SALEM, N.C., May 10, 2024 – **ProKidney Corp. (Nasdaq: PROK)** ("ProKidney" or the "Company"), a leading late clinical-stage cellular therapeutics company focused on chronic kidney disease (CKD), today reported business updates and financial results for the first quarter ended March 31, 2024.

"With the full results of RMCL-002 to be presented at the European Renal Association Congress later this month and the upcoming interim readout of REGEN-007 in mid-2024, we look forward to further elucidating the effect of rilparencel in preserving kidney function in patients with type 2 diabetes and CKD," said Bruce Culleton, Chief Executive Officer. "I believe our recent hires of Dr. Ulrich Ernst and Lucio Tozzi will prove invaluable in the execution of our planned manufacturing and Phase 3 study milestones. With our PROACT 1 protocol amendment completed and submitted to the FDA, we look forward to the resumption of the study as we focus on patients with severe CKD. Rilparencel has the potential to be meaningful in this high-risk patient population where there are limited therapeutic options for care."

Clinical Updates

- **ERA Congress in Stockholm, Sweden from May 23-26, 2024.** ProKidney will present the Phase 2 RMCL-002 final results abstract titled "Rilparencel Renal Autologous Cell Therapy for Patients with Stage 3-4 CKD and Type 2 Diabetes: Results from a Phase 2 Clinical Trial" in the Late Breaking Clinical Trials session at 15:30-15:45 CEST on May 25, 2024. An investor call to provide a perspective on CKD with Dr. Arnold Silva and Dr. Steven Coca and a recap of the RMCL-002 data is planned for May 28, 2024. Further details will be provided.

- **The PROACT 1 Phase 3 study (REGEN-006) protocol amendment** has been completed and was submitted to the FDA in late March. This amendment updated the 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 focusing on patients with more severe CKD will better align with RMCL-002 results and feedback from payers and providers. The Company continues to expect PROACT 1 will resume enrollment, and PROACT 2 will commence enrollment, in mid-2024.

Corporate Updates

- **Bank of America Securities Health Care Conference in Las Vegas, NV from May 14-16, 2024.** Senior members of the management team will be participating in a fireside chat and one-on-one meetings at the upcoming conference. Interested investors should contact their Bank of America representative to schedule meetings.

- **Appointment of Ulrich Ernst, Ph.D as Executive Vice President of Technical Operations.** In March, the Company announced Dr. Ernst joined as EVP of Technical Operations and as part of the ProKidney Executive Leadership Team. Dr. Ernst brings over 30 years of experience in the biopharmaceutical industry with a focus on process development, manufacturing and facility oversight, and supply chain operations in the cell space. Prior to ProKidney, Dr. Ernst was Senior Vice President of Technical Operations at Iovance Biotherapeutics, Chief Operating Officer at Amunix Operating Inc., and Senior Vice President of Manufacturing Operations at Cytovance Biologics.

- **Appointment of Lucio Tozzi as Senior Vice President of Global Clinical Operations.** In January, Mr. Tozzi joined as SVP of Global Clinical Operations. Mr. Tozzi also brings over 30 years of experience in international drug development and execution of clinical trials across multiple therapeutic categories. Prior to ProKidney, Mr. Tozzi was Senior Vice President and Head of Clinical Operations at Summit Therapeutics and Rain Oncology, and, prior to that, Vice President of Clinical Operations at Protagonist Therapeutics.

First Quarter 2024 Financial Highlights

Liquidity: Cash, cash equivalents and marketable securities as of March 31, 2024, totaled $329.0 million, compared to $363.0 million on March 31, 2023. We expect that our existing cash, cash equivalents and marketable securities held on March 31, 2024, 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 $27.2 million for the three months ended March 31, 2024, compared to $25.6 million for the same period in 2023. The increase of $1.6 million was driven primarily by increases in cash compensation costs of approximately $3.2 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 professional fees of approximately $2.6 million primarily related to the remediation of documentation deficiencies within our quality management systems. These increases have been partially offset by decreases in spending of

approximately $2.1 million on our Phase 3 program due to the pause in enrollment as well as decreased spending on manufacturing improvements of approximately $2.5 million.

G&A Expenses: General and administrative expenses were $12.8 million for the three months ended March 31, 2024 compared to $15.3 million for the same period in 2023. The decrease of $2.4 million has been primarily driven by decreases in equity-based compensation of approximately $4.8 million, and was partially offset by increases in cash compensation and professional fees of approximately $1.7 million and $0.9 million, respectively.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was $35.3 million and $36.9 million for the three months ended March 31, 2024 and 2023, respectively.

Shares outstanding: Class A and Class B ordinary shares outstanding as of March 31, 2024 totaled 229,344,883.

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.

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

	March 31, 2024 (Unaudited)	December 31, 2023
Assets		
Cash and cash equivalents	$ 84,389	$ 60,649
Marketable securities	244,609	302,301
Interest receivable	1,903	1,375
Prepaid assets	3,106	3,399
Prepaid clinical	6,151	6,413
Other current assets	—	9
Total current assets	340,158	374,146
Fixed assets, net	41,937	42,143
Right of use assets, net	5,668	4,263
Total assets	$ 387,763	$ 420,552
Liabilities and Shareholders' Deficit		
Accounts payable	$ 3,376	$ 5,098
Lease liabilities	1,092	803
Accrued expenses and other	13,263	17,665
Income taxes payable	1,570	1,472
Total current liabilities	19,301	25,038
Income tax payable, net of current portion	568	568
Lease liabilities, net of current portion	4,859	3,610
Total liabilities	24,728	29,216
Commitments and contingencies		
Redeemable noncontrolling interest	1,459,097	1,494,732
Shareholders' deficit		
Class A ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 61,621,330 and 59,880,347 issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	6	6
Class B ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 167,723,553 and 168,297,916 issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	17	17
Additional paid-in capital	53,114	36,114
Accumulated other comprehensive (loss) gain	(44)	130
Accumulated deficit	(1,149,155)	(1,139,663)
Total shareholders' deficit	(1,096,062)	(1,103,396)
Total liabilities and shareholders' deficit	$ 387,763	$ 420,552

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

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses		
Research and development	$ 27,233	$ 25,617
General and administrative	12,843	15,259
Total operating expenses	40,076	40,876
Operating loss	(40,076)	(40,876)
Other income (expense):		
Interest income	4,843	5,297
Interest expense	(2)	(3)
Net loss before income taxes	(35,235)	(35,582)
Income tax expense	98	1,327
Net loss before noncontrolling interest	(35,333)	(36,909)
Net loss attributable to noncontrolling interest	(25,841)	(27,244)
Net loss available to Class A ordinary shareholders	$ (9,492)	$ (9,665)
Weighted average Class A ordinary shares outstanding:		
Basic and diluted	60,951,721	61,540,231
Net loss per share attributable to Class A ordinary shares:		
Basic and diluted	$ (0.16)	$ (0.16)

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

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss before noncontrolling interest	$ (35,333)	$ (36,909)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:		
Depreciation and amortization	1,102	832
Equity-based compensation	7,679	13,020
Gain on marketable securities, net	(2,313)	(492)
Loss on disposal of equipment	28	3
Changes in operating assets and liabilities		
Interest receivable	(529)	(5,476)
Prepaid and other assets	564	3,483
Accounts payable and accrued expenses	(5,942)	(601)
Income taxes payable	98	148
Net cash flows used in operating activities	(34,646)	(25,992)
Cash flows from investing activities		
Purchases of marketable securities	(55,415)	(198,038)
Sales and maturities of marketable securities	114,774	6,412
Purchase of equipment and facility expansion	(960)	(986)
Net cash flows provided by (used in) investing activities	58,399	(192,612)
Cash flows from financing activities		
Payments on finance leases	(13)	(13)
Net cash flows used in financing activities	(13)	(13)
Net change in cash and cash equivalents	23,740	(218,617)
Cash, beginning of period	60,649	490,252
Cash, end of period	$ 84,389	$ 271,635
Supplemental disclosure of non-cash investing and financing activities:		
Right of use assets obtained in exchange for lease obligations	$ 1,674	$ 714
Exchange of Class B ordinary shares	$ 2,289	$ –
Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 7,507	$ 1,352
Change in redemption value of noncontrolling interest	$ –	$ 509,526
Equipment and facility expansion included in accounts payable and accrued expenses	$ 305	$ 744