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 12, 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 November 12, 2024, ProKidney Corp. (the "Company") issued a press release to announce its financial results for the quarter ended September 30, 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 November 12, 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: November 12, 2024

By: /s/ James Coulston

James Coulston
Chief Financial Officer

Exhibit 99.1

ProKidney Reports Third Quarter 2024 Financial Results along with Regulatory and Clinical Development Updates Following Successful FDA Type B Meeting

- *FDA confirmed in a recent FDA Type B meeting under RMAT designation that the PROACT 1 Phase 3 study could be sufficient to support a full U.S. regulatory approval of rilparencel*
- *FDA also confirmed in that Type B meeting that the accelerated approval pathway is available for rilparencel if an acceptable surrogate endpoint, which may include eGFR slope, is used*
- *Presented five posters at the ASN Kidney Week, including one late-breaking clinical trial and four posters on rilparencel's product characterization and MOA*
- *Ended the third quarter with $406.8 million in cash and cash equivalents and marketable securities, supporting operations into 2027*

WINSTON-SALEM, N.C., November 12, 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 financial results for the third quarter ended September 30, 2024, and gave several regulatory and clinical development updates.

"Following a successful FDA Type B meeting, we are pleased to announce that the FDA agrees that the Phase 3 PROACT 1 study could be sufficient to support a potential BLA submission and full regulatory approval, validating our recent decision to focus on expediting PROACT 1," stated Bruce Culleton, M.D., Chief Executive Officer. "Notably, the FDA also confirmed that ProKidney could consider using eGFR slope as a surrogate endpoint on an accelerated approval pathway for rilparencel. We look forward to continuing our dialogue with the FDA, under RMAT designation, to accelerate rilparencel's path to market and address the high unmet need in patients with advanced CKD and diabetes."

Regulatory and Clinical Development Updates

- In October, ProKidney had a Type B meeting with the U.S. Food and Drug Administration (FDA) to discuss updates to rilparencel's registrational trial strategy. The FDA confirmed that REGEN-006 (PROACT 1), a single, large, multi-center, well-controlled Phase 3 trial designed to demonstrate substantial evidence of effectiveness and safety, could be sufficient to support a potential Biologics License Application (BLA) submission. Additionally, the FDA confirmed that the accelerated approval pathway is available to rilparencel and that the Company could consider estimated glomerular filtration rate (eGFR) slope as a surrogate endpoint for accelerated approval. ProKidney will continue to engage with the FDA, under its regenerative medicine advanced therapy (RMAT) designation, to further define the details supporting this accelerated pathway.
- In late October, the Company presented five poster presentations at the American Society of Nephrology's (ASN) Kidney Week. This included a poster presentation in the late-breaking clinical trial session on the Phase 2 REGEN-007 study, and four poster presentations focused on rilparencel's mechanism of action (MOA) and product characteristics.

Third Quarter 2024 Financial Highlights

Liquidity: Cash, cash equivalents and marketable securities as of September 30, 2024, totaled $406.8 million, compared to $363.0 million on December 31, 2023. We expect that our existing cash, cash equivalents and marketable securities held on September 30, 2024, will enable us to fund our operating expenses and capital expenditure requirements into 2027.

R&D Expenses: Research and development expenses were $31.3 million for the three months ended September 30, 2024, compared to $32.2 million for the same period in 2023. The decrease of $0.9 million was driven primarily by decreases in costs for clinical operations of approximately $2.5 million driven by the wind down of activities related to PROACT 2 as well as decreases in the cost for other trials. Additionally, we have seen decreases in spending on manufacturing process development and equity-based compensation costs of approximately $1.8 million and $1.9 million, respectively. These decreases have been partially offset by increases in cash compensation costs of approximately $3.5 million as we continue to hire additional personnel in the areas of clinical development, quality and manufacturing and increases in operational costs of $1.4 million as we continue to expand operations and purchase materials to support our Phase 3 clinical program.

G&A Expenses: General and administrative expenses were $17.7 million for the three months ended September 30, 2024, compared to $14.4 million for the same period in 2023. The increase of $3.3 million has been primarily driven by the recognition of a non-cash impairment charge of $5.3 million related to our Greensboro facility and increases in cash compensation of approximately $2.0 million. These increases have been partially offset by decreases in equity-based compensation of approximately $4.1 million.

Net Loss Before Noncontrolling Interest: Net loss before noncontrolling interest was $41.1 million and $42.0 million for the three months ended September 30, 2024 and 2023, respectively.

Shares outstanding: Class A and Class B ordinary shares outstanding as of September 30, 2024, totaled 291,661,950.

About the Phase 3 REGEN-006 (PROACT 1) Clinical Trial

REGEN-006 is an ongoing Phase 3, randomized, blinded, sham controlled safety and efficacy study of rilparencel in subjects with type 2 diabetes and advanced CKD. The study protocol was amended in 1H 2024 to focus on a subset of patients with stage 4 CKD (eGFR 20-30ml min/1.73m^2) and late stage 3b CKD (eGFR 30-35ml min/1.73m^2) with accompanying albuminuria (urine albumin-to-creatinine ratio, or UACR less than 5,000 mg/g for patients with eGFR 20-30ml min/1.73m^2 and 300-5,000 mg/g for patients with eGFR 30-35ml min/1.73m^2). The total planned enrollment is approximately 685 subjects. Subjects are randomized (1:1) to the treatment group and the sham control group prior to kidney biopsy or a sham biopsy procedure, respectively. Subjects in the treatment group are to receive the first rilparencel injection within 18 weeks of kidney biopsy. After three months it is intended that a second rilparencel injection be given into the contralateral kidney. Subjects in the control group, who previously underwent the sham biopsy procedure, are to receive two sham injections at similar time points as the treatment group. The primary objective is to assess the efficacy of up to two rilparencel injections using a minimally invasive percutaneous approach. The primary composite endpoint is the time from first injection to the

earliest of: at least 40% reduction in eGFR; eGFR <15 mL/min/1.73m², and/or chronic dialysis, and/or renal transplant; or renal or cardiovascular death.

About ProKidney Corp.

ProKidney, a pioneer in the treatment of chronic kidney disease 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 in Phase 2 and Phase 3 studies for its potential to preserve kidney function in diabetic patients at high risk of kidney failure. Rilparencel has received Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA. 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 beliefs that the FDA agrees that the Company's Phase 3 REGEN-006 (PROACT 1) trial could be sufficient to support a potential BLA submission and full regulatory approval and that the Company could consider using eGFR slope as a surrogate endpoint on an accelerated approval pathway for rilparencel, expectations with respect to financial results and expected cash runway, including the Company's expectation that current cash will support operating plans into 2027, 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 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 risk that results of the Company's clinical trials may not support approval; the risk that the FDA could require additional studies before approving the Company's drug candidates; 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
Consolidated Balance Sheets
(in thousands, except for share data)

	September 30, 2024 (Unaudited)	December 31, 2023
Assets		
Cash and cash equivalents	$ 108,088	$ 60,649
Marketable securities	298,724	302,301
Interest receivable	5,102	1,375
Prepaid assets	6,227	3,399
Prepaid clinical	11,053	6,413
Other current assets	1,031	9
Total current assets	430,225	374,146
Fixed assets, net	38,519	42,143
Right of use assets, net	6,049	4,263
Total assets	$ 474,793	$ 420,552
Liabilities and Shareholders' Deficit		
Accounts payable	$ 2,850	$ 5,098
Lease liabilities	1,067	803
Accrued expenses and other	21,264	17,665
Income taxes payable	–	1,472
Total current liabilities	25,181	25,038
Income tax payable, net of current portion	772	568
Lease liabilities, net of current portion	5,372	3,610
Total liabilities	31,325	29,216
Commitments and contingencies		
Redeemable noncontrolling interest	1,423,180	1,494,732
Shareholders' deficit		
Class A ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 127,920,274 and 59,880,347 issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	13	6
Class B ordinary shares, $0.0001 par value; 500,000,000 shares authorized; 163,741,676 and 168,297,916 issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	16	17
Additional paid-in capital	199,509	36,114
Accumulated other comprehensive (loss) gain	321	130
Accumulated deficit	(1,179,571)	(1,139,663)
Total shareholders' deficit	(979,712)	(1,103,396)
Total liabilities and shareholders' deficit	$ 474,793	$ 420,552

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 31,250	$ 32,198	$ 87,887	$ 84,179
General and administrative	17,723	14,419	44,218	43,133
Total operating expenses	48,973	46,617	132,105	127,312
Operating loss	(48,973)	(46,617)	(132,105)	(127,312)
Other income (expense):				
Interest income	5,580	5,541	14,960	16,803
Interest expense	(2)	(2)	(7)	(9)
Net loss before income taxes	(43,395)	(41,078)	(117,152)	(110,518)
Income tax (benefit) expense	(2,342)	913	(2,300)	3,205
Net loss before noncontrolling interest	(41,053)	(41,991)	(114,852)	(113,723)
Net loss attributable to noncontrolling interest	(23,143)	(31,007)	(74,944)	(83,956)
Net loss available to Class A ordinary shareholders	$ (17,910)	$ (10,984)	$ (39,908)	$ (29,767)
Weighted average Class A ordinary shares outstanding:				
Basic and diluted	126,173,463	61,592,876	87,818,229	61,565,298
Net loss per share attributable to Class A ordinary shares:				
Basic and diluted	$ (0.14)	$ (0.18)	$ (0.45)	$ (0.48)

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

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss before noncontrolling interest	$ (114,852)	$ (113,723)
Adjustments to reconcile net loss before noncontrolling interest to net cash flows used in operating activities:		
Depreciation and amortization	3,858	2,707
Equity-based compensation	22,424	37,216
Gain on marketable securities, net	(5,521)	(3,675)
Impairment charges	5,324	–
Loss on disposal of equipment	186	21
Changes in operating assets and liabilities		
Interest receivable	(3,728)	(714)
Prepaid and other assets	(8,489)	5,094
Accounts payable and accrued expenses	(114)	7,774
Income taxes payable	(1,268)	615
Net cash flows used in operating activities	(102,180)	(64,685)
Cash flows from investing activities		
Purchases of marketable securities	(277,291)	(301,701)
Sales and maturities of marketable securities	286,625	100,187
Purchase of equipment and facility expansion	(4,000)	(32,625)
Net cash flows provided by (used in) investing activities	5,334	(234,139)
Cash flows from financing activities		
Proceeds from sales of Class A ordinary shares, net of offering costs	144,325	–
Payments on finance leases	(40)	(39)
Net cash flows provided by (used in) financing activities	144,285	(39)
Net change in cash and cash equivalents	47,439	(298,863)
Cash, beginning of period	60,649	490,252
Cash, end of period	$ 108,088	$ 191,389
Supplemental disclosure of non-cash investing and financing activities:		
Right of use assets obtained in exchange for lease obligations	$ 2,621	$ 714
Exchange of Class B ordinary shares	$ 15,357	$ 64
Impact of equity transactions and compensation on redeemable noncontrolling interest	$ 18,748	$ 3,207
Change in redemption value of noncontrolling interest	$ –	$ 79
Equipment and facility expansion included in accounts payable and accrued expenses	$ 910	$ 1,386