

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2023

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 001-40560

ProKidney Corp.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands

(State or other jurisdiction of
incorporation or organization)

2000 Frontis Plaza Blvd., Suite 250

Winston-Salem, NC

(Address of principal executive offices)

98-1586514

(I.R.S. Employer
Identification No.)

27103

(Zip Code)

Registrant's telephone number, including area code: (336) 999-7028

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes No

Class of Stock

Shares Outstanding as of November 14, 2023

Class A ordinary shares, par value \$0.0001 per share

67,136,714

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

ProKidney Corp.
Condensed Consolidated Balance Sheets
(in thousands, except 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

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ProKidney Corp.
Condensed Consolidated Statements of Operations - Unaudited
(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, as defined in Note 1, 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. For more information refer to Note 8.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ProKidney Corp.
Condensed Consolidated Statements of Comprehensive Loss - Unaudited
(in thousands, except for share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss including noncontrolling interest	\$ (41,991)	\$ (33,945)	\$ (113,723)	\$ (123,562)
Other comprehensive (loss) income:				
Unrealized gain (loss) on marketable securities	241	–	(244)	–
Other comprehensive loss	241	–	(244)	–
Total comprehensive loss including noncontrolling interest	(41,750)	(33,945)	(113,967)	(123,562)
Less: Total comprehensive loss attributable to noncontrolling interest	(30,829)	(22,017)	(84,136)	(22,017)
Total comprehensive loss attributable to Class A ordinary shareholders	<u>\$ (10,921)</u>	<u>\$ (11,928)</u>	<u>\$ (29,831)</u>	<u>\$ (101,545)</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ProKidney Corp.
Condensed Consolidated Statements of Changes in Redeemable Noncontrolling Interest and Shareholders' Deficit / Members' Equity - Unaudited
(in thousands, except for share and per share data)

For the Three Months Ended September 30, 2023

	Redeemable Noncontrolling Interest	Class A Ordinary Shares		Class B Ordinary Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Deficit / Members' Equity
		Shares	Amount	Shares	Amount				
Balance as of July 1, 2023	1,779,198	61,590,231	\$ 6	173,663,427	\$ 18	30,957	\$(127)	\$ 3,108	\$(1,322,254)
Equity-based compensation	2,629	-	-	-	-	10,365	-	-	10,365
Issuance of Class A ordinary shares	-	-	-	-	-	-	-	-	-
Vesting of Class B restricted stock rights	-	-	-	180,972	-	-	-	-	-
Exchange of Class B ordinary shares for Class A ordinary shares	(64)	5,069	-	(5,069)	-	64	-	-	64
Impact of equity transactions on redeemable noncontrolling interest	21	-	-	-	-	(21)	-	-	(21)
Unrealized loss on marketable securities	178	-	-	-	-	-	63	-	63
Net loss	(31,007)	-	-	-	-	-	-	(10,984)	(10,984)
Change in redemption value of noncontrolling interest	(230,130)	-	-	-	-	-	-	230,130	230,130
Balance as of September 30, 2023	1,520,825	61,595,300	\$ 6	173,839,330	\$ 18	41,365	\$(64)	\$ 3,962	\$(1,092,637)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ProKidney Corp.
Condensed Consolidated Statements of Changes in Redeemable Noncontrolling Interest and Shareholders' Deficit / Members' Equity - Unaudited
(in thousands, except for share and per share data)

	For the Three Months Ended September 30, 2022										
		Class A Units		Class B Units	Class A Ordinary Shares		Class B Ordinary Shares		Addition Paid-in Capital	Accumulated Deficit	Total Shareholders' Deficit / Members' Equity
		Units	Amount	Profits Interests	Shares	Amount	Shares	Amount			
Balance as of July 1, 2022	\$ -	186,500	\$ 500	\$ 64	-	\$ -	-	\$ -	\$ -	(25,112)	\$ 6,537
Equity-based compensation / payments prior to Business Combination	-	-	-	480	-	-	-	-	-	-	480
Net loss prior to the Business Combination	-	-	-	-	-	-	-	-	-	(4,015)	(4,015)
Effect of the Business Combination, including net proceeds of shares sold through the PIPE transaction	1,635,829	(186,500)	(186,500)	(71,644)	61,540,231	6	170,723,961	18	-	(83,457)	(1,092,694)
Equity-based compensation after the Business Combination	2,908	-	-	-	-	-	-	-	1,456	-	1,456
Vesting of Class B restricted stock rights	-	-	-	-	-	-	486,099	-	-	-	-
Impact of equity transactions on redeemable noncontrolling interest	176	-	-	-	-	-	-	-	-	(176)	(176)
Net loss after the Business Combination	(22,017)	-	-	-	-	-	-	-	-	(7,913)	(7,913)
Balance as of September 30, 2022	\$ 1,616,896	-	\$ -	\$ -	\$ 31	\$ 6	\$ 060	\$ 18	\$ 6	(1,097,805)	\$ 6,325

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ProKidney Corp.

Condensed Consolidated Statements of Changes in Redeemable Noncontrolling Interest and Shareholders' Deficit / Members' Equity - Unaudited
(in thousands, except for share and per share data)

For the Nine Months Ended September 30, 2023

	Redeemable Noncontrolling Interest	Class A Ordinary Shares		Class B Ordinary Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Deficit / Members' Equity
		Shares	Amount	Shares	Amount				
Balance as of January 1, 2023	1,601,555	61,540,231	6	171,578,320	18	7,476	–	(1,104,116)	(1,096,616)
Equity-based compensation	7,848	–	–	–	–	29,368	–	–	29,368
Issuance of Class A ordinary shares	–	50,000	–	–	–	–	–	–	–
Vesting of Class B restricted stock rights	–	–	–	2,266,079	–	–	–	–	–
Exchange of Class B ordinary shares for Class A ordinary shares	(64)	5,069	–	(5,069)	–	64	–	–	64
Impact of equity transactions on redeemable noncontrolling interest	(4,457)	–	–	–	–	4,457	–	–	4,457
Unrealized loss on marketable securities	(180)	–	–	–	–	–	(64)	–	(64)
Net loss	(83,956)	–	–	–	–	–	–	(29,767)	(29,767)
Change in redemption value of noncontrolling interest	79	–	–	–	–	–	–	(79)	(79)
Balance as of September 30, 2023	<u>\$ 1,520,825</u>	<u>61,595,300</u>	<u>\$ 6</u>	<u>173,839,330</u>	<u>\$ 18</u>	<u>\$ 5</u>	<u>\$ (64)</u>	<u>\$ (1,133,962)</u>	<u>\$ (1,092,637)</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ProKidney Corp.

Condensed Consolidated Statements of Changes in Redeemable Noncontrolling Interest and Shareholders' Deficit / Members' Equity - Unaudited
(in thousands, except for share and per share data)

For the Nine Months Ended September 30, 2022											
	Redeemable Noncontrolling Interest	Class A Units		Class B Units	Class A Ordinary Shares		Class B Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Deficit / Members' Equity
		Units	Amount	Profits Interests	Shares	Amount	Shares	Amount			
Balance as of January 1, 2022	\$ —	186,500,000	\$ 500	1,927	—	\$ —	—	\$ —	\$ —	(161,510)	\$ 26,917
Capital contribution	—	—	—	6,050	—	—	—	—	—	—	6,050
Equity-based compensation / payments prior to Business Combination	—	—	—	63,667	—	—	—	—	—	—	63,667
Net loss prior to the Business Combination	—	—	—	—	—	—	—	—	—	(93,632)	(93,632)
Effect of the Business Combination, including net proceeds of shares sold through the PIPE transaction	1,635,829	(186,500,000)	(186,500)	(71,644)	61,540,231	6	170,723,961	18	—	(834,574)	(1,092,694)
Equity-based compensation after the Business Combination	2,908	—	—	—	—	—	—	—	1,456	—	1,456
Vesting of Class B restricted stock rights	—	—	—	—	—	—	486,099	—	—	—	—
Impact of equity transactions on redeemable noncontrolling interest	176	—	—	—	—	—	—	—	—	(176)	(176)
Net loss after the Business Combination	(22,017)	—	—	—	—	—	—	—	—	(7,913)	(7,913)
Balance as of September 30, 2022	\$ 1,616,896	—	\$ —	\$ —	61,540,231	\$ 6	171,210,060	\$ 18	\$ 6	\$ 1,459,805	(1,096,325)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ProKidney Corp.
Condensed Consolidated Statements of Cash Flows – Unaudited
(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

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ProKidney Corp.
Notes to Unaudited Condensed Consolidated Financial Statements

Note 1: Description of Business and Basis of Presentation

Description of Business

ProKidney Corp. (the “Company” or “ProKidney”) was originally incorporated as Social Capital Suvretta Holdings Corp. III (“SCS”). SCS was a blank check company incorporated as a Cayman Islands exempted company on February 25, 2021. SCS was incorporated for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses.

On January 18, 2022, SCS executed a definitive business combination agreement (the “Business Combination Agreement”), with ProKidney LP (“PKLP”), a limited partnership under the laws and regulations of Ireland. Pursuant to the terms of the Business Combination Agreement, PKLP became a subsidiary of SCS and was organized in an umbrella partnership corporation (“Up-C”) structure, which would provide potential future tax benefits for SCS when the equity holders ultimately exchanged their pass-through interests for Class A ordinary shares. The transaction closed (the “Closing”) on July 11, 2022 (the “Closing Date”). Upon consummation of the transaction, SCS changed its name to ProKidney Corp.

The business combination between SCS and PKLP (the “Business Combination”) resulted in gross proceeds of approximately \$596,537,000. This amount reflected a contribution of \$21,737,000 of cash held in SCS’ trust account, net of redemptions, and a \$574,800,000 concurrent private placement of Class A ordinary shares of the combined company, priced at \$10.00 per share (the “PIPE Placement”). Upon close, these proceeds were used to repay the outstanding balance of \$35,000,000 under PKLP’s two promissory note agreements with certain holders of its Class A Units (the “Promissory Notes”) and related accrued interest. Additionally, the proceeds were used to pay those expenses previously incurred by SCS related to the Business Combination of approximately \$21,029,000 as well as advisory and placement fees of approximately \$29,389,000 incurred in connection with the PIPE Placement.

The Business Combination was accounted for as a reverse recapitalization transaction between entities under common control, through which PKLP was considered the accounting acquiror and predecessor entity. The Business Combination was reflected as the equivalent of PKLP issuing stock for the net assets of SCS accompanied by a recapitalization with no goodwill or intangible assets recognized.

ProKidney Corp., through its operating subsidiaries, ProKidney, which is incorporated under the Cayman Islands Companies Act (as amended) as an exempted company (“ProKidney-KY”) and ProKidney LLC, a limited liability company under the laws of Delaware (“ProKidney-US”) is focused on the development of its Renal Autologous Cell Therapy, which has the potential to preserve kidney function in patients with chronic kidney disease or delay or eliminate the need for dialysis and organ transplantation.

Principles of Consolidation

ProKidney is a holding company, and its principal asset is a controlling equity interest in PKLP and its wholly-owned operating subsidiaries ProKidney-KY and ProKidney-US. The Company has determined that PKLP is a variable-interest entity for accounting purposes and that ProKidney is the primary beneficiary of PKLP because (through its managing member interest in PKLP and the fact that the senior management of ProKidney is also the senior management of PKLP) it has the power and benefits to direct all of the activities of PKLP, which include those that most significantly impact PKLP’s economic performance. The Company has therefore consolidated PKLP’s results pursuant to Accounting Standards Codification Topic 810, “Consolidation” in its Condensed Consolidated Financial Statements. As of September 30, 2023, various holders own non-voting interests in PKLP, representing a 73.8% economic interest in PKLP, effectively restricting ProKidney’s interest to 26.2% of PKLP’s economic results, subject to increase in the future, should ProKidney purchase additional non-voting common units (“PKLP Units”) of PKLP, or should the holders of PKLP Units decide to exchange such units (together with shares of Class B ordinary shares) for Class A ordinary shares (or cash) pursuant to the Exchange Agreement (as defined in Note 6). The Company will not be required to provide financial or other support for PKLP. However, ProKidney will control its business and other activities through its managing member interest in PKLP, and its management is the management of PKLP. Nevertheless, because ProKidney will have no material assets other than its interests in PKLP and its subsidiaries, any financial difficulties at PKLP could result in ProKidney recognizing a loss.

All intercompany transactions and balances have been eliminated.

Note 2: Significant Accounting Policies

Unaudited Interim Financial Statements

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The accompanying Condensed Consolidated Balance Sheet as of September 30, 2023, Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2023 and 2022, Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2023 and 2022, Condensed Consolidated Statement of Changes in Redeemable Noncontrolling Interest and Shareholders’ Deficit / Members’ Equity for the three and nine months ended September 30, 2023 and 2022 and Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2023 and 2022 are unaudited. These unaudited financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission (the “SEC”) for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements.

The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company’s financial position as of September 30, 2023, the results of operations for the three and nine months ended September 30, 2023 and 2022 and cash flows for the nine months ended September 30, 2023 and 2022. Certain prior year amounts have been reclassified to conform to the current year presentation. The December 31, 2022 Condensed Consolidated Balance Sheet included herein was derived from the audited financial statements but does not include all disclosures or notes required by GAAP for complete financial statements. These financial statements should be read in conjunction with the audited financial statements and the accompanying notes for the year ended December 31, 2022, contained in the Company’s Annual Report on Form 10-K filed with the SEC on March 28, 2023, as amended on April 27, 2023.

Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”). These unaudited consolidated financial statements are presented in U.S. Dollars.

Interim results are not necessarily indicative of results for an entire year.

Use of Estimates

The preparation of unaudited condensed consolidated financial statements, in accordance with GAAP, requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the condensed consolidated financial statements, and the amounts of expenses during the reported periods. Certain estimates in these condensed consolidated financial statements have been made in connection with the calculation of research and development expenses, equity-based compensation expense and the provision for or benefit from income taxes. The Company bases its estimates on historical experience and various other assumptions, including in certain circumstances future projections, which management believes to be reasonable under the circumstances. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

Cash Equivalents and Marketable Securities

The Company considers all highly liquid investments with an original maturity of 90 days or less on the date of purchase to be cash equivalents. The carrying value of cash and cash equivalents approximates fair value due to the short-term nature of these items.

The Company’s investments in marketable debt securities have been classified and accounted for as available-for-sale. The Company classifies its marketable debt securities as short-term due to its availability for use in its current operations. The cost of securities sold is determined using the specific identification method.

The Company considers all available evidence to evaluate if a credit loss exists, and if so, recognizes an allowance for credit loss.

Concentrations of Credit Risk

Cash and equivalents are the primary financial instruments held by the Company that are potentially subject to concentrations of credit risk. The Company’s cash and equivalents are deposited in accounts at large financial institutions, and such amounts may exceed federally insured limits.

Accrued Expenses

Accrued expenses as presented in the Condensed Consolidated Balance Sheets as of September 30, 2023 and December 31, 2022 consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Compensation	\$ 3,952	\$ 3,355
Clinical study related costs	2,353	1,636
Facility expansion costs	1,860	–
Accrued legal costs	1,089	436
Manufacturing improvement costs	4,280	678
Accrued consulting and professional fees	1,006	1,210
Other accrued expenses	924	21
Total accrued expenses and other	<u>\$ 15,464</u>	<u>\$ 7,336</u>

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, benefits, third party license fees, and external costs of outside vendors engaged to conduct manufacturing and preclinical development activities and clinical trials.

The Company records accruals based on estimates of services received, efforts expended, and amounts owed pursuant to contracts with numerous contract research organizations. In the normal course of business, the Company contracts with third parties to perform various clinical study activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events and the completion of portions of the clinical study or similar conditions. The objective of the Company's accrual policy is to match the recording of expenses in its financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical studies are recognized based on the company's estimate of the degree of completion of the event or events specified in the specific clinical study.

The Company records nonrefundable advance payments it makes for future research and development activities as prepaid expenses. Prepaid expenses are recognized as expense in the Condensed Consolidated Statement of Operations and Comprehensive Loss as the Company receives the related goods or services

Costs incurred in obtaining technology licenses are charged to research and development expense as purchased in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use.

Fixed Assets

Fixed assets are stated at cost, less accumulated depreciation. Generally, expenditures for maintenance and repairs are charged to expense and major improvements or replacements are capitalized. The Company computes depreciation and amortization using the straight-line method over the estimated useful life of the asset. Leasehold improvements are amortized over the lesser of, the life of the lease or the estimated useful life of the leasehold improvement. The estimated useful lives are as follows:

Buildings	25-30 years
Computer equipment and software	3-5 years
Furniture and equipment	5-7 years
Leasehold improvements	remainder of lease term

Fixed assets consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Land	\$ 3,067	\$ –
Buildings	22,490	–
Leasehold improvements	10,867	10,537
Furniture and equipment	3,624	2,376
Computer equipment and software	848	889
Construction in progress	8,487	1,614
Less: accumulated depreciation	(6,769)	(4,708)
Total fixed assets, net	<u>\$ 42,614</u>	<u>\$ 10,708</u>

Depreciation expense for the three and nine months ended September 30, 2023 was \$807,000 and \$2,084,000, respectively. Depreciation expense for the three and nine months ended September 30, 2022 was \$627,000 and \$1,825,000, respectively.

Intangible Assets

Intangible assets are comprised of acquired assembled workforce, which are accounted for in accordance with ASC 350 - Intangibles - Goodwill and Other. The acquired assembled workforce is amortized on a straight-line basis over the useful life of five years. The following table summarizes information related to the Company's assembled workforce intangible asset (in thousands):

	<u>September 30, 2023</u>	<u>December 31, 2022</u>
Gross carrying amount	\$ 1,073	\$ 1,073
Accumulated amortization	1,021	860
Net carrying amount	<u>\$ 52</u>	<u>\$ 213</u>

Estimated amortization expense as of September 30, 2023 for the remaining three months of 2023 was \$47,000 and \$5,000 for the year ended December 31, 2024. Amortization expense relating to the assembled workforce intangible asset was \$54,000 and \$161,000 for each of the three and nine months ended September 30, 2023 and 2022, respectively.

Impairment of Long-Lived Assets

Long-lived assets such as fixed assets and intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. No impairment charges have been recorded for the three and nine months ended September 30, 2023 and 2022.

Income Taxes

The Company uses the liability method in accounting for income taxes as required by ASC Topic 740 — Income Taxes, under which deferred tax assets and liabilities are recorded for the future tax consequences attributable to the differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is recorded to reduce the carrying amounts of deferred tax assets unless it is more likely than not that such assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, available taxes in the carryback periods, projected future taxable income and tax planning strategies in making this assessment. Accordingly, the Company has provided a full valuation allowance to offset the net deferred tax assets at September 30, 2023 and December 31, 2022.

Interest and penalties related to income taxes are included in the benefit (expense) for income taxes in the Company's Condensed Consolidated Statements of Operations and Comprehensive Loss. The Company has not incurred any significant interest or penalties related to income taxes in any of the periods presented.

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. A three-level fair value hierarchy that prioritizes the inputs used to measure fair value is described below. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities
- Level 2 – Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable through correlation with market data
- Level 3 – Unobservable inputs that are supported by little or no market data, which require the reporting entity to develop its own assumptions

The carrying values of cash equivalents, accounts payable, and accrued liabilities approximate fair value due to the short-term nature of these instruments.

Leases

The Company determines if an arrangement is a lease at inception. Balances recognized related to the Company's operating and finance leases are included in right-of-use assets, net and lease liabilities in the Condensed Consolidated Balance Sheets. Right of use assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Lease terms may include options to extend or terminate the lease if it is reasonably certain that the Company will exercise the option. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of future payments. The right of use asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The Company has elected a practical expedient to not separate its lease and non-lease components and instead account for them as a single lease component. Leases with a term of 12 months or less are not recorded on the balance sheet.

Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Lease payments for short-term leases are recorded to operating expense on a straight-line basis and variable lease payments are recorded in the period in which the obligation for those payments is incurred.

Contingent Liabilities

The Company records reserves for contingent liabilities when it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements, and the amount of the loss can be reasonably estimated.

Equity-Based Compensation

Compensation expense for share-based compensation awards issued is based on the fair value of the award at the date of grant, and compensation expense is recognized for those awards earned over the service period on a straight-line basis. The Company records forfeitures of share-based compensation awards as they occur.

The grant date fair value of stock option awards is estimated using the Black-Scholes option pricing formula. Due to the lack of sufficient historical trading information with respect to its own shares, the Company estimates expected volatility based on a portfolio of selected stocks of companies believed to have market and economic characteristics similar to its own. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. Due to a lack of historical exercise data, the Company estimates the expected life of its outstanding stock options using the simplified method specified under Staff Accounting Bulletin Topic 14.D.2.

Segments

The Company operates in only one segment.

Note 3: Investments

Cash equivalents and marketable securities are measured at fair value and within Level 2 in the fair value hierarchy, because we use quoted market prices to the extent available or alternative pricing sources and models utilizing market observable inputs to determine fair value.

The following tables summarize our cash equivalents and marketable securities measured at fair value on a recurring basis as of September 30, 2023 (in thousands):

	Fair Value Hierarchy	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash Equivalents	Marketable Securities
Money market funds	Level 2	\$ 1,037	\$ –	\$ –	\$ 1,037	\$ 1,037	\$ –
Time deposits	Level 2	30,506	9	(17)	30,498	–	30,498
Commercial paper	Level 2	132,166	35	(224)	131,977	–	131,977
Government bonds	Level 2	12,500	–	(24)	12,476	–	12,476
Corporate debt securities	Level 2	30,017	4	(27)	29,994	–	29,994
Total		<u>\$ 206,226</u>	<u>\$ 48</u>	<u>\$ (292)</u>	<u>\$ 205,982</u>	<u>\$ 1,037</u>	<u>\$ 204,945</u>

The following table shows the fair value of the Company's cash equivalents and marketable securities, by contractual maturity, as of September 30, 2023 (in thousands):

	September 30, 2023	
Due in 1 year or less	\$	205,982
Due in 1 year through 5 years		–
Total	\$	205,982

The following table shows fair values and gross unrealized losses recorded to accumulated other comprehensive income, aggregated by category and the length of time that individual securities have been in a continuous loss position as of September 30, 2023 (in thousands):

	Less than 12 months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Time deposits	\$ 12,990	\$ (17)	\$ –	\$ –	\$ 12,990	\$ (17)
Commercial paper	91,160	(224)	–	–	91,160	(224)
Government bonds	12,476	(24)	–	–	12,476	(24)
Corporate debt securities	14,989	(27)	–	–	14,989	(27)
Total	\$ 131,615	\$ (292)	\$ –	\$ –	\$ 131,615	\$ (292)

The Company holds debt securities of companies with high credit quality and has determined that there was no material change in the credit risk of its debt securities during the nine months ended September 30, 2023. As such, the Company has not recognized an allowance for credit losses related to our marketable debt securities during the nine months ended September 30, 2023 and 2022.

Note 4: Income Taxes

ProKidney is considered to be an exempted Cayman Islands company and is presently not subject to income taxes or income tax filing requirements in the Cayman Islands or the United States.

The Company's subsidiary, PKLP, is organized as a limited partnership and is classified as a partnership for U.S. income tax purposes, and as such, only records a provision for federal and state income taxes on its subsidiaries organized as C corporations or which have elected to be treated as corporations for U.S. federal income tax purposes.

The Company's subsidiary, ProKidney-US, is treated as a C corporation, and therefore a provision for federal and state taxes has been recorded. The difference between the Company's effective tax rates and the U.S. statutory rate of 21% is primarily attributable to PKLP and ProKidney-KY being treated as partnerships for income tax purposes.

The Company's subsidiary, ProKidney-KY, has been granted, by the Government in Council of the Cayman Islands, tax concessions under an undertaking certificate exempting it from any tax levied on profits, income, gains or appreciations in relation to its operations or in the nature of estate duty or inheritance tax for a period of twenty years from January 20, 2016. ProKidney-KY elected to be treated as an entity disregarded from its owner for U.S. tax purposes, and as a result, it has not recorded an income tax provision.

As discussed in Note 6, the Company is party to a tax receivable agreement with a related party which provides for the payment by the Company to holders of PKLP prior to the Closing ("Closing ProKidney Unitholders") of 85% of the amount of cash savings, if any, in U.S. federal, state and local income tax or franchise tax that the Company actually realizes (or, in some circumstances, the Company is deemed to realize) as a result of certain transactions. As no transactions have occurred which would trigger a liability under this agreement, the Company has not recognized any liability related to this agreement as of September 30, 2023.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, available taxes in the carryback periods, projected future taxable income and tax planning strategies in making this assessment.

There were no net unrecognized tax benefits as of September 30, 2023 which, if recognized, would affect our effective tax rate. We expect none of the gross unrecognized tax benefits will decrease within the next year.

There were no significant changes in the Company's uncertain tax positions during the nine months ended September 30, 2023.

Note 5: Leases

The Company has operating leases for real estate (primarily its operating facilities) and certain equipment with various expiration dates. The Company also has one finance lease for certain equipment. Rent expense was \$276,000 and \$150,000, for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022, the Company's rent expense was \$736,000 and \$379,000, respectively. Cash paid for operating leases during the nine months ended September 30, 2023, was \$578,000.

The following table summarizes the classification of operating and finance lease assets and obligations in the Company's Condensed Consolidated Balance Sheets as of September 30, 2023 and December 31, 2022 (in thousands):

	September 30, 2023	December 31, 2022
Operating leases:		
Right of use assets	\$ 2,558	\$ 2,285
Operating lease liabilities, current	\$ 625	\$ 458
Operating lease liabilities, noncurrent	1,991	1,858
Total operating lease liabilities	<u>\$ 2,616</u>	<u>\$ 2,316</u>
Finance leases:		
Right of use assets	\$ 159	\$ 71
Finance lease liabilities, current	\$ 51	\$ 35
Finance lease liabilities, noncurrent	118	48
Total finance lease liabilities	<u>\$ 169</u>	<u>\$ 83</u>

Maturities of lease liabilities for the Company's operating and finance leases are as follows as of September 30, 2023 (in thousands):

	Operating Leases	Finance Leases	Total
2023	\$ 207	\$ 16	\$ 223
2024	839	62	901
2025	849	32	881
2026	772	22	794
2027	438	22	460
Thereafter	29	40	69
Total lease payments	<u>3,134</u>	<u>194</u>	<u>3,328</u>
Less: imputed interest	(518)	(25)	(543)
Present value of lease liabilities	<u>\$ 2,616</u>	<u>\$ 169</u>	<u>\$ 2,785</u>

The weighted average remaining lease term for operating leases is 3.7 years, and 4.7 years for finance leases. The weighted average discount rate for operating leases is 9.5% and 6.6% for finance leases.

Note 6: Related Party Transactions*Exchange Agreement*

On the Closing Date, the Company entered into an exchange agreement with PKLP and certain Closing ProKidney Unitholders (the "Exchange Agreement") pursuant to which, subject to the procedures and restrictions therein, from and after the waiver or expiration of any contractual lock-up period (including pursuant to the Lock-Up Agreement (as defined below)) the holders of Post-Combination ProKidney Common Units as defined in the Exchange Agreement (or certain permitted transferees thereof) will have the right from time to time at and after 180 days following the Closing to exchange their Post-Combination ProKidney Common Units and an equal number of Class B ordinary shares of the Company on a one-for-one basis for Class A ordinary shares of the Company (the "Exchange"); provided, that, subject to certain exceptions, the Company, at its sole election, subject to certain restrictions, may, other than in the case of certain secondary offerings, instead settle all or a portion of the Exchange in cash based on a volume weighted average price ("VWAP") of a Class A ordinary share. The Exchange Agreement provides that, as a general matter, a holder of Post-Combination ProKidney Common Units will not have the right to exchange Post-Combination ProKidney Common Units if the Company determines that such exchange would be prohibited by law or regulation or would violate other agreements with the

Company and its subsidiaries to which the holder of Post-Combination ProKidney Common Units may be subject, including the Second Amended and Restated ProKidney Limited Partnership Agreement and the Exchange Agreement.

Lock-Up Agreement

On the Closing Date, the Company, SCS Sponsor III LLC and certain Closing ProKidney Unitholders entered into a lock-up agreement (the “Lock-Up Agreement”). The Lock-Up Agreement contains certain restrictions on transfer with respect to the SCS Sponsor III LLC and the Closing ProKidney Unitholders party thereto. Such restrictions begin at the Closing and end on the earlier of (i) the date that is 180 days after the Closing and (ii)(a) for 33% of the Lock-Up Shares (other than the Earnout Shares and the PIPE Shares), the date on which the last reported sale price of a Class A ordinary share of the Company equals or exceeds \$12.50 per share for any 20 trading days within any 30-trading day period commencing at least 30 days after the Closing and (b) for an additional 50% of the Lock-Up Shares (other than the Earnout Shares and the Private Placement Shares (as each such term is defined in the Lock-Up Agreement)), the date on which the last reported sale price of a Class A ordinary share of the Company equals or exceeds \$15.00 per share for any 20 trading days within any 30-trading day period commencing at least 30 days after the Closing. Notwithstanding the above, (i) the lock-up period for any Earnout Shares will expire not earlier than 180 days after such Earnout Shares are issued; (ii) 50% of the Lock-Up Shares held by certain Closing ProKidney Unitholders and their affiliates will remain locked up until the earlier of four years following the Closing and the date that PKLP receives notice of any regulatory market authorization, including full or conditional authorization, to market its lead product candidate, Renal Autologous Cell Therapy (but, in any event, not earlier than 180 days following the Closing or (in the case of Earnout Shares) the date of issuance); and (iii) the lock-up period for the Private Placement Shares expired 30 days after the Closing. The restrictions on transfer set forth in the Lockup Agreement are subject to customary exceptions.

During January 2023, the lock-up period for 50% of the shares held by the Closing ProKidney Unitholders (other than the Earnout Shares) expired.

Tax Receivable Agreement

On the Closing Date, the Company entered into a tax receivable agreement (the “Tax Receivable Agreement”) with the Closing ProKidney Unitholders. Pursuant to the Tax Receivable Agreement, among other things, the Company will be required to pay the Closing ProKidney Unitholders party thereto 85% of certain tax savings recognized by the Company, if any, as a result of the increases in tax basis attributable to exchanges by the Closing ProKidney Unitholders of Post-Combination ProKidney Common Units for Class A ordinary shares of the Company or, subject to certain restrictions, cash, pursuant to the Exchange Agreement and certain other tax attributes of PKLP and tax benefits related to entering into the Tax Receivable Agreement.

Earnout Rights

At the Closing, certain shareholders were issued an aggregate of 17,500,000 Earnout Restricted Common Units and 17,500,000 Earnout Restricted Stock Rights (collectively, the “Earnout Rights”). The Earnout Rights vest in three equal tranches if, during the five-year period after Closing, the VWAP of a Class A ordinary share reaches \$15.00 per share, \$20.00 per share and \$25.00 per share. Likewise, the Earnout Rights will vest upon a change of control with a per share price exceeding those same VWAP thresholds within a five-year period immediately following the Closing. Upon vesting, the Earnout Rights will automatically convert into Post Combination ProKidney Common Units and Class B ordinary shares.

Related Party Debt

On January 18, 2022, in connection with the execution of the Business Combination Agreement, the Company entered into the Promissory Notes. Through the Promissory Notes, the holders could fund up to \$100,000,000 to support the operational financing needs of the Company prior to the Closing. These notes bore interest at a rate of 3% per annum and were due upon the earliest of either (i) the date on which the Business Combination closed or (ii) January 17, 2023.

During the nine months ended September 30, 2022, the Company borrowed \$35,000,000 under the Promissory Notes. During the three and nine months ended September 30, 2022, the Company recognized interest expense of \$27,000 and \$207,000, respectively related to the Promissory Notes. The amounts due under the Promissory Notes were paid, and the Promissory Notes were effectively terminated, upon Closing as described in Note 1.

Consulting Services Agreement between ProKidney-KY and Nefro Health

On January 1, 2020, ProKidney-KY (formerly known as inRegen) entered into a consulting services agreement with Nefro Health (“Nefro”), an Irish partnership controlled and majority-owned by Mr. Pablo Legorreta, a director of the Company, ProKidney GP Limited, a private limited company incorporated under the laws of Ireland (“Legacy GP”) and a holder of over 5% of Class A

Units in PKLP, pursuant to which Nefro provides consulting services for the research and development of the Company's product candidates, including the conduct of clinical trials in North America and the European Union, the design and manufacturing of ProKidney's product candidates as well as pre-commercialization activities, which are primarily performed by Mr. Legorreta. Under the agreement, Nefro receives \$25,000 per quarter and is reimbursed for any out-of-pocket expenses incurred in connection with activities Nefro conducted under the agreement. ProKidney-KY has paid Nefro an aggregate of \$25,000 and \$75,000 for the each of the three and nine month periods ended September 30, 2023 and 2022, respectively. The initial term of the consulting services agreement continued through December 31, 2020 and was renewed pursuant to the provision allowing for automatic renewals for additional periods of one year each unless terminated by either party by providing written notice to the other party at least ninety (90) days prior to the scheduled termination date. Either party may terminate this agreement upon the occurrence of a material breach by the other party in the performance of its obligations under the agreement or in respect of any provision, representation, warranty or covenant if such breach has not been cured within thirty (30) days after receiving written notice from the non-breaching party. Additionally, either of the parties may terminate the consulting services agreement for any reason upon giving thirty (30) days' advance notice of such termination to the other party. In the event of such termination, ProKidney-KY will be obligated to pay Nefro any earned but unpaid consulting fee as of the termination date.

Consulting Services Agreement between ProKidney-US and Nefro Health

On January 1, 2020, ProKidney-US (formerly known as Twin City Bio, LLC) entered into a consulting services agreement with Nefro, pursuant to which Nefro provides consulting services for the research and development of the Company's product candidates, including the conduct of clinical trials in North America and the European Union, the design and manufacturing of the Company's product candidates as well as pre-commercialization activities, which are primarily performed by Mr. Legorreta. Under the agreement, Nefro receives \$25,000 per quarter and is reimbursed for any out-of-pocket expenses incurred in connection with activities Nefro conducted under the agreement. ProKidney-US has paid Nefro an aggregate of \$25,000 and \$75,000 for each of the three and nine month periods ended September 30, 2023 and 2022, respectively. The initial term of the consulting services agreement continued through December 31, 2020 and was renewed pursuant to the provision allowing for automatic renewals for additional periods of one year each unless terminated by either party by providing written notice to the other party at least ninety (90) days prior to the scheduled termination date. Either party may terminate this agreement upon the occurrence of a material breach by the other party in the performance of its obligations under the agreement or in respect of any provision, representation, warranty or covenant if such breach has not been cured within thirty (30) days after receiving written notice from the non-breaching party. Additionally, either of the parties may terminate the consulting services agreement for any reason upon giving thirty (30) days' advance notice of such termination to the other party. In the event of such termination, ProKidney-US will be obligated to pay Nefro any earned but unpaid consulting fee as of the termination date.

Note 7: Redeemable Noncontrolling Interest

The Company is subject to the Exchange Agreement with respect to the Post-Combination ProKidney Common Units representing the outstanding 73.8% noncontrolling interest in PKLP (see Note 1). The Exchange Agreement requires the surrender of an equal number of Post-Combination ProKidney Common Units and Class B ordinary shares for (i) Class A ordinary shares on a one-for-one basis or (ii) cash (based on the fair market value of the Class A ordinary shares as determined pursuant to the Exchange Agreement), at the Company's option (as the managing member of PKLP), subject to customary conversion rate adjustments for share splits, share dividends and reclassifications. The exchange value is determined based on a five-day VWAP of the Class A ordinary shares as defined in the Exchange Agreement, subject to customary conversion rate adjustments for share splits, share dividends and reclassifications.

The redeemable noncontrolling interest is recognized at the higher of (1) its initial fair value plus accumulated earnings/losses associated with the noncontrolling interest or (2) the redemption value as of the balance sheet date. At September 30, 2023, the redeemable noncontrolling interest was recorded based on its initial fair value plus accumulated losses associated with the noncontrolling interest which was higher than the redemption value as of the balance sheet date.

Changes in the Company's ownership interest in PKLP while the Company retains its controlling interest in PKLP are accounted for as equity transactions, and the Company is required to adjust noncontrolling interest and equity for such changes. The following is a summary of net income attributable to the Company and transfers to noncontrolling interest (in thousands):

	For the Three Months Ended September 30, 2023	For the Nine Months Ended September 30, 2023	For the Period from July 11, 2022 through September 30, 2022
Net loss available to Class A ordinary shareholders	\$ (10,984)	\$ (29,767)	\$ (7,913)
(Increase)/Decrease in ProKidney Corp. accumulated deficit for impact of subsidiary equity-based compensation	2,629	7,848	2,908
(Increase)/Decrease in ProKidney Corp. additional paid-in capital for exchange of Common Units in ProKidney LP for Class A ordinary shares	(64)	(64)	–
(Increase)/Decrease in ProKidney Corp. additional paid-in capital for vesting of Restricted Common Units in ProKidney LP	21	(4,457)	176
Change from net loss available to Class A ordinary shareholders and change in ownership interest in ProKidney LP	<u>\$ (8,398)</u>	<u>\$ (26,440)</u>	<u>\$ (4,829)</u>

Note 8: Net Loss per Share

Basic net loss per share is calculated by dividing net loss attributable to Class A ordinary shareholders by the weighted-average shares of Class A ordinary shares outstanding without the consideration for potential dilutive securities. Diluted net loss per share represents basic net loss per share adjusted to include the effects of all potentially dilutive shares. Diluted net loss per share is the same as basic loss per share for all periods as the inclusion of potentially issuable shares would be antidilutive.

The Company analyzed the calculation of net loss per share for periods prior to 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, as presented on the unaudited consolidated statements of operations, represents only the period after the Business Combination to September 30, 2022.

The following table sets forth the computation of basic and diluted net loss per share for the three and nine months ended September 30, 2023 and the period from July 11, 2022 through September 30, 2022 (in thousands, except share and per share amounts):

	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023	Period from July 11, 2022 through September 30, 2022
Numerator			
Net loss	\$ (41,991)	\$ (113,723)	\$ (29,930)
Less: Net loss attributable to noncontrolling interests	(31,007)	(83,956)	(22,017)
Net loss available to Class A ordinary shareholders of ProKidney Corp., basic and diluted	<u>\$ (10,984)</u>	<u>\$ (29,767)</u>	<u>\$ (7,913)</u>
Denominator			
Weighted average Class A ordinary shares or ProKidney Corp. outstanding, basic and diluted	61,592,876	61,565,298	61,540,231
Net loss per Class A Unit			
Net loss per Class A ordinary share of ProKidney Corp., basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.48)</u>	<u>\$ (0.13)</u>

Outstanding anti-dilutive securities not included in the diluted net loss per share calculation include the following:

	As of September 30, 2023	Period from July 11, 2022 through September 30, 2022
Antidilutive securities		
ProKidney Corp. Class B ordinary shares	173,839,330	171,210,060
Unvested Restricted Stock Rights	5,644,596	8,766,071
Earnout Rights	17,500,000	17,500,000
Legacy SCS Restricted Share Units	–	50,000
Stock options granted under the 2022 Equity Incentive Plan	17,356,148	129,370

Note 9: Equity Based Compensation

2022 Incentive Equity Plan

On July 11, 2022, the shareholders of the Company approved the ProKidney Corp. 2022 Incentive Equity Plan (the “2022 Plan”) which provides for the issuance of equity based awards to the Company’s employees, non-employee directors, individual consultants, advisors and other service providers. As of September 30, 2023, there were 35,809,951 Class A ordinary shares reserved for issuance. The 2022 Plan provides for the issuance of equity awards in the form of incentive stock options, which are intended to satisfy the requirements of Section 422 of the Internal Revenue Code of 1986, as amended, or nonqualified stock options, which are not intended to meet those requirements, stock appreciation rights, restricted stock, restricted stock units, performance awards or other cash or stock-based awards as determined appropriate by the plan administrator. In settlement of its obligations under this plan, the Company will issue new Class A ordinary shares.

The Company has issued incentive and non-qualified stock option awards under the 2022 Plan to certain employees and non-employee directors of the Company. Given that the Company has established a full valuation allowance against its deferred tax assets, the Company has recognized no tax benefit related to these awards.

Time-Vested Awards

The Company uses the Black-Scholes option pricing model to calculate the fair value of time-vested stock options granted. These awards generally vest ratably over a three or four-year period and the option awards expire after a term of ten years from the date of grant. The fair value of stock options granted was estimated using the following assumptions during the nine months ended September 30, 2023:

	For the Nine Months Ended September 30, 2023
Expected volatility	81.3% - 84.0%
Expected life of options, in years	5.2 - 6.1
Risk-free interest rate	3.5% - 4.3%
Expected dividend yield	0.0%

The following table summarizes the activity related to the Company's time-vested stock option awards granted under the 2022 Plan for the nine months ended September 30, 2023:

	Number of Shares	Weighted Average Exercise Price
Time-vested options outstanding at January 1, 2023	5,865,108	\$ 10.30
Granted	8,234,543	9.82
Forfeited	(383,110)	9.32
Time-vested options outstanding at September 30, 2023	13,716,541	\$ 10.04
Time-vested options exercisable at September 30, 2023	1,919,253	\$ 9.79
Weighted average remaining contractual life	8.9 years	
Time-vested options vested and expected to vest at September 30, 2023	13,716,541	\$ 10.04
Weighted average remaining contractual life	8.9 years	

For the three and nine months ended September 30, 2023, the Company recognized \$6,608,000 and \$15,276,000 of compensation expense related to time-vested awards under the 2022 Plan, respectively. These amounts are exclusive of the expense related to the modification of awards as discussed below. As of September 30, 2023, the Company had total unrecognized stock-based compensation expense of approximately \$77,305,000 related to the time-vested grants under the 2022 Plan, which is expected to be recognized on a straight-line basis over a weighted average period of 3.2 years. The weighted average grant date fair value for the option grants during the three and nine months ended September 30, 2023 was \$8.61 and \$7.11, respectively.

The aggregate intrinsic value of the in-the-money time-vested awards outstanding as well as those exercisable as of September 30, 2023 was \$0.

Market-Vested Awards

The Company also has outstanding 3,639,607 market-vested options with an exercise price of \$10.33 as of September 30, 2023. These awards contain both time and market based vesting conditions. The market conditions become satisfied in equal one-third tranches upon the Company's Class A ordinary shares exceeding a volume weighted average price hurdle of \$15.00, \$20.00 and \$25.00, respectively, for 20 trading days within any 30 consecutive trading day period occurring prior to July 11, 2027. Once the market condition for a tranche is satisfied, such tranche will continue to be subject to time-vesting conditions and will vest ratably on each of the first, second and third anniversaries of the date that such tranche satisfied the performance vesting condition described above. Due to the market condition included in this grant, the Company used the Geometric Brownian Motion/Monte Carlo model to value these awards.

For the three and nine months ended September 30, 2023, the Company recognized \$2,825,000 and \$8,383,000 of compensation expense related to market-vested awards under the 2022 Plan, respectively. As of September 30, 2023, the Company had total unrecognized stock-based compensation expense of approximately \$17,604,000 related to the market-vested awards outstanding under the 2022 Plan. There were no market-vested awards granted during the three and nine months ended September 30, 2023 and 2022.

The aggregate intrinsic value of the in-the-money market based awards outstanding as of September 30, 2023 was \$0. There were no market based awards vested at September 30, 2023.

Legacy Profits Interests

The Deed for the Establishment of a Limited Partnership of PKLP, dated as of August 5, 2021 (the "Limited Partnership Agreement") which replaced the Amended and Restated Limited Liability Company Agreement of ProKidney LLC as the governing

document of the parent entity in the Company, allowed for the issuance of Profits Interests (as defined in the Limited Partnership Agreement) to employees, directors, other service providers of the Company and others denominated in the form of one or more Class B Units of PKLP (as defined in the Limited Partnership Agreement).

Under the Limited Partnership Agreement, Legacy GP determined the terms and conditions of the Profits Interests issued. The threshold value assigned to each grant was not to be less than the fair market value of PKLP on the date of grant. Profits Interests awarded would vest at a rate of 25% on the latter of the first anniversary of employment and the first anniversary of the Acquisition Date with the remaining 75% to vest in increments of 25% on each anniversary following the first anniversary date, ratably over a three or four-year period from the date of grant, in annual installments of 33.3% over the three-year period from the date of grant, in increments of 6.25% each calendar quarter following the first anniversary date, or were fully vested upon issuance.

On January 17, 2022, PKLP amended and restated its Limited Partnership Agreement (the “Amended and Restated Limited Partnership Agreement”) which provided that certain qualified distribution events would result in holders of Profits Interests receiving disproportionate distributions from PKLP until each such holder’s valuation threshold had been reduced to zero in order to “catch up” such holder’s distributions to its pro rata share of aggregate cumulative distributions, and once sufficient distributions to a holder of Profits Interests had been made in accordance with the foregoing, the associated Class B Units of PKLP would automatically be converted into Class A Units of PKLP (as defined in the Limited Partnership Agreement).

Upon consummation of the Business Combination discussed in Note 1, PKLP’s existing Class B and B-1 Units were “caught up” and were converted into Class A Units of PKLP. The resulting vested and unvested Class A Units of PKLP were then recapitalized into Post-Combination ProKidney Common Units or Restricted Common Units of the Company, respectively. This recapitalization resulted in a decrease in the number of awards held by each participant. As such, the number of Profits Interests and related per unit values within these financial statements have been adjusted to reflect this recapitalization. Upon recapitalization, the Restricted Common Units maintained the vesting schedules associated with the original Profits Interest awards.

The following table summarizes the activity related to the Profits Interest awards for the nine months ended September 30, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested awards outstanding at January 1, 2023	8,369,795	\$ 7.08
Vested	(2,266,101)	6.47
Forfeited	(459,098)	7.71
Awards outstanding at September 30, 2023	<u>5,644,596</u>	<u>\$ 7.27</u>

As of September 30, 2023, the unrecognized compensation expense related to these awards was \$31,603,000. The current weighted average remaining period over which the unrecognized compensation expense is expected to be recognized is 2.2 years. The weighted average grant date fair value of the Profits Interests awarded during the nine months ended September 30, 2022, was \$7.43 per Class B-1 unit of PKLP (as defined in the Limited Partnership Agreement), as adjusted for the effects of the recapitalization. There were no Profits Interests awarded during the three and nine months ended September 30, 2023 or the three months ended September 30, 2022.

Modification to Equity Based Compensation Awards

On January 17, 2022, the Limited Partnership Agreement was amended and restated to provide that certain qualified distribution events would result in the holders of Profits Interests receiving disproportionate distributions from PKLP until each such holder’s threshold value was reduced to zero in order to “catch up” such holder’s distributions to its pro rata share of aggregate cumulative distributions, and once sufficient distributions to a holder of Profits Interests had been made in accordance with the foregoing, the associated Class B Units would automatically be converted into Class A Units.

This amendment constituted a modification to the Class B-1 Units in PKLP outstanding as of the date of the modification under the provisions of ASC Topic 718. In connection with the modification of its outstanding share-based compensation awards, the Company will recognize total additional compensation expense of \$5,437,000 related to awards granted to its employees. The portion of this additional compensation expense attributable to vested awards of \$3,715,000 was recognized immediately upon modification during the six months ended June 30, 2022.

During the nine months ended September 30, 2023, the Company also modified the vesting terms of outstanding time-based stock options issued to certain personnel upon their separation. This amendment constituted a modification of the awards under the provisions of ASC Topic 718 and resulted in the recognition of an additional \$3,011,000 of compensation expense during the nine months ended September 30, 2023.

Issuance of Profits Interests to Service Provider

During the nine months ended September 30, 2022, the Company issued 2,253,033 fully vested Class B-1 Units in PKLP to a third-party service provider as payment for research and development services provided in prior periods. The Company had previously recognized expense of \$2,502,000 for these services based on the liability related to the services incurred. As the fair value of shares issued to satisfy that obligation was higher than the amount previously expensed, the Company recognized additional research and development expense of \$14,080,000 during the nine months ended September 30, 2022.

Purchase of Class B-1 Units in PKLP

Certain of the Company's employees, board members and service providers purchased 6,648,353 of Class B-1 Units in PKLP, as adjusted for the recapitalization, for total cash proceeds of \$6,050,000 during the nine months ended September 30, 2022, respectively. Since these Class B-1 Units in PKLP were fully vested upon purchase and contained no service requirements, the Company immediately recognized the difference between the purchase price and the estimated fair value for these Class B-1 Units in PKLP of \$34,254,000 as equity-based compensation expense during the nine months ended September 30, 2022, respectively. No such sales occurred during the three and nine months ended September 30, 2023 or the three months ended September 30, 2022.

Fair Value Estimate for Profits Interest

Prior to the Business Combination, PKLP was privately held with no active public market for its equity instruments. Therefore, for financial reporting purposes, management determined the estimated per share fair value of PKLP's equity shares (including Profits Interests) using contemporaneous valuations. These contemporaneous valuations were done using methodologies consistent with the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, also known as the Practice Aid.

For the Profits Interest Awards awarded during the six months ended June 30, 2022, the valuation approach utilized a hybrid method which consists of a combination of an Option Pricing Method ("OPM") and a Probability Weighted Expected Return Method ("PWERM") approach. Weighting allocations were assigned to the OPM and PWERM methods based upon the expected likelihood of possible future liquidity events, including the Business Combination.

Under the OPM approach, the fair value of the total equity of PKLP within each scenario was first estimated using a back-solve method wherein the equity value is derived from a recent transaction in PKLP's own securities, and then the total equity value is allocated to the various components of the capital structure, including the Profits Interests, using an OPM or a waterfall approach based on the specific rights of each of the equity classes. The OPM used the fair value of the total equity of PKLP within a scenario as a starting point and incorporates assumptions made regarding the expected returns and volatilities that are consistent with the expectations of market participants, and distribution of equity values is produced which cover the range of events that an informed market participant might expect. This process creates a range of equity values both between and within scenarios. The fair value measurement is sensitive to changes in the unobservable inputs. Changes in those inputs might result in a higher or lower fair value measurement.

The PWERM approach is a scenario-based analysis that estimates the value per share of ordinary shares based on the probability-weighted present value of expected future equity values for the ordinary shares, under various possible future liquidity event scenarios, including the proposed Business Combination, in light of the rights and preferences of each class and series of stock, including the Profits Interests, discounted for a lack of marketability.

In performing these valuations, management considered all objective and subjective factors that they believed to be relevant, including management's best estimate of PKLP's business condition, prospects, and operating performance at each valuation date. Within the valuations performed, a range of factors, assumptions, and methodologies were used. The significant factors included trends within the industry, the prices at which PKLP sold its Class A Units, the rights and preferences of the Class A Units relative to the Class B Units at the time of each measurement date, the results of operations, financial position, status of research and development efforts, stage of development and business strategy, the lack of an active public market for the units, and the likelihood of achieving an exit event in light of prevailing market conditions.

The following reflects the key assumptions used in each of the valuation scenarios for the awards granted during the nine months ended September 30, 2022:

	OPM	PWERM
Total equity value (in thousands)	\$234,551 - \$280,400	\$ 1,750,000
Expected volatility of total equity	95%	60% - 90%
Discount for lack of market	30%	7% - 15%
Expected time to exit event	3.4 years - 3.7 years	0.1 years - 0.5 years

Compensation Expense

Compensation expense related to share-based awards is included in research and development and general and administrative expense as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	\$ 4,881	\$ 1,682	\$ 13,324	\$ 20,385
General and administrative	8,112	3,162	23,891	45,144
Total equity-based compensation expense	<u>\$ 12,993</u>	<u>\$ 4,844</u>	<u>\$ 37,215</u>	<u>\$ 65,529</u>

Note 10: Subsequent Events

On October 30, 2023, the Company issued 5,541,414 Class A ordinary shares in exchange for 5,541,414 Class B ordinary shares and an equal number of Post-Combination ProKidney Common Units.

On November 10, 2023, the Company's board of directors terminated, without cause, Tim Bertram, Ph.D., Chief Executive Officer of the Company, effective November 15, 2023 (the "Effective Date"), following which Dr. Bertram is expected to continue to serve as a consultant of the Company. On the Effective Date, and pursuant to the terms of Dr. Bertram's employment agreement, Dr. Bertram will also resign from the Board of Directors of the Company. The Company expects to enter into a separation and consulting agreement with Dr. Bertram.

In addition, on November 10, 2023, the Company's board of directors appointed Bruce Culleton, MD, as Chief Executive Officer and director of the Company, as of the Effective Date. The Company expects to enter into a new Employment Agreement with Dr. Culleton, to serve as the Chief Executive Officer of the Company that will become effective and replace Dr. Culleton's previous employment agreement as of the Effective Date.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

As used in this Quarterly Report on Form 10-Q, the “Company”, the “Registrant”, “we” or “us” refer to ProKidney Corp. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes that appear elsewhere in this report. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, assumptions and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed in the Risk Factors section of the Annual Report on Form 10-K filed with the Securities and Exchange Commission, and elsewhere in this report under “Part II, Other Information—Item 1A, Risk Factors.” Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies and operations, financing plans, potential growth opportunities, potential market opportunities, potential results of our drug development efforts or trials, and the effects of competition. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as “anticipates,” “believes,” “could,” “seeks,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would” or similar expressions and the negatives of those terms. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management’s plans, estimates, assumptions and beliefs only as of the date of this report. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Overview

We are a clinical-stage biotechnology business with a transformative proprietary cell therapy platform capable of treating multiple chronic kidney diseases using a patient’s own cells isolated from the patient intended for treatment. Our approach seeks to redefine the treatment of chronic kidney disease (“CKD”), shifting the emphasis away from management of kidney failure to the restoration, preservation or improvement of kidney function to stop or delay progression of CKD. Our lead product candidate, which we refer to as REACT, is designed to preserve kidney function in a CKD patient’s diseased kidneys. REACT is a product that includes selected renal cells (“SRC”) prepared from a patient’s own, autologous, renal cells. SRC are formulated into a product for reinjection into the patient’s kidneys using a minimally invasive outpatient procedure that can be repeated if necessary. Because REACT is a personalized treatment composed of cells prepared from a patient’s own kidney, there is no need for treatment with immunosuppressive therapies, which are required during a patient’s lifetime when a patient receives a kidney transplant from another, allogeneic donor.

We are currently conducting a Phase 3 development program and multiple Phase 2 clinical trials for REACT in subjects with moderate to severe diabetic kidney disease. We also recently completed a Phase 1 clinical trial for REACT in subjects with congenital anomalies of the kidney and urinary tract (“CAKUT”). REACT has been generally well tolerated by subjects with moderate to severe diabetic kidney disease in Phase 1 and 2 clinical testing to date. It has also been shown to preserve kidney function and limit kidney injury in subjects based on measurements of iohexol renal clearance and urinary albumin-to-creatinine ratio (“UACR”). REACT has received regenerative medicine advanced therapy (“RMAT”) designation from the United States Food and Drug Administration (the “FDA”).

Since our inception, we have devoted substantially all of our resources to raising capital, organizing and staffing our Company, business and scientific planning, conducting discovery and research activities, acquiring or discovering product candidates, establishing and protecting our intellectual property portfolio, developing and progressing REACT and preparing for clinical trials, establishing arrangements with third parties for the manufacture of component materials, and providing general and administrative support for these operations. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

Recent Developments

On November 10, 2023, the Company’s board of directors terminated, without cause, Tim Bertram, Ph.D., Chief Executive Officer of the Company, effective November 15, 2023 (the “Effective Date”), following which Dr. Bertram is expected to continue to serve as a consultant of the Company. On the Effective Date, and pursuant to the terms of Dr. Bertram’s employment agreement, Dr. Bertram will also resign from the Board of Directors of the Company. In addition, on November 10, 2023, our board of directors appointed Bruce Culleton, MD, as Chief Executive Officer and director of the Company, as of the Effective Date.

RMCL-002

RMCL-002 is an ongoing Phase 2, prospective, randomized, double-arm, deferred treatment, open-label, repeat dose, safety and efficacy study of REACT in subjects with CKD caused by type 2 diabetes.

The first subject was enrolled in this study in February 2017, and subjects are now undergoing follow-up. The primary objective of this study is to assess the safety and efficacy of up to two REACT injections given approximately six months apart in Type 2 diabetic patients with eGFRs between 20 and 50 ml/min/1.73m², with both doses delivered into the biopsied kidney using an outpatient, minimally invasive, percutaneous approach under conscious sedation. Patients were eligible to receive up to two doses of REACT of 3x10⁶ cells/g-KWest.

Patients were randomized (1:1) to the active treatment group or the deferred treatment group (i.e., the control group) following kidney biopsy. Subjects in the active treatment group received their first REACT injection as soon as the REACT product was manufactured and shipped to the clinical site. After approximately six months, a second injection was given, as appropriate, into the biopsied kidney. In contrast, subjects in the deferred treatment group underwent a 12-month period of observation after kidney biopsy. The deferred treatment group allowed assessment of the rate of change in kidney function and co-morbidities in a non-injected group compared to the active treated arm. During this time, patients received contemporaneous, standard-of-care therapy for CKD while undergoing follow-up evaluations every three months, similar to subjects in the active treatment group. Consequently, the study design included a randomized control group receiving standard-of-care treatment for the first 12 months and a randomized, active treatment group which received up to two REACT injections and follow-up evaluations during the same period of time. After 12 months, subjects from the deferred treatment group were eligible to receive a series of up to two REACT injections given approximately six months apart, as appropriate, administered into the biopsied kidney. In both treatment groups, as per study protocol, if the eGFR of any subject fell below 20 ml/min/1.73m², that subject would not receive their REACT injection, whether it was their first or second REACT injection.

The aggregate number of subjects enrolled for the Phase 2 clinical trial was 83 of which 41 subjects were enrolled into the active treatment group and 42 subjects were enrolled into the deferred treatment group. We are on track to complete all follow-up visits for all remaining subjects in the fourth quarter of 2023.

Updated interim data from the ongoing study were released in November 2023 and included data from the 83 patients enrolled. The interim dataset revealed a safety profile in line with previously reported data from earlier Phase 1 and Phase 2 trials, with tolerability similar to that of a routine kidney biopsy. Overall, the updated trial data demonstrated REACT's potential for kidney function preservation in patients with advanced CKD caused by diabetes, with the most notable potential benefit shown in patients who had the highest risk of kidney failure (CKD Stage 4 with moderate to severe albuminuria). Albuminuria refers to the presence of an excess of the protein albumin in urine, which is a sign of kidney injury.

We expect to provide full data of our RMCL-002 Phase 2 study in the first half of 2024. Results from interim data may not be indicative of results from future data.

REGEN-007

REGEN-007 is an ongoing Phase 2, prospective, randomized, open-label, repeat dose, double-arm, controlled safety and efficacy study of REACT in subjects with type 1 or 2 diabetes and CKD.

The primary objective of this study is to assess the safety and efficacy of up to two REACT injections given approximately three months apart to patients with Type 1 and 2 diabetic kidney disease with eGFRs between 20 and 50 ml/min/1.73m² and delivered into biopsied and non-biopsied contralateral kidneys using a minimally invasive percutaneous approach. This is compared to a single REACT injection followed by monitoring and a potential second injection delivered into the non-biopsied contralateral kidney using a minimally invasive percutaneous approach triggered by a 20% decrease in eGFR and/or a 30% increase in urinary albumin-creatinine ratio (UACR) delivered within approximately 60 days of the trigger being met. In previous Phase 2 studies, we injected REACT into the same kidney twice. Based on a generally favorable safety profile observed in previous studies, we are now proceeding with the injection of REACT into both kidneys in REGEN-007. We expect the data generated by REGEN-007 will enable us to better understand the impact of REACT on kidney function from injections in both kidneys.

We have completed enrollment in REGEN-007 with a total of 53 subjects. We anticipate reporting interim data from this study in mid-2024.

REGEN-016/proact 2 trial

REGEN-016 (proact 2) is a planned Phase 3, randomized, single-blinded, sham control arm, bi-lateral kidney dose, controlled efficacy study of REACT in subjects with Stages 3b and 4 CKD caused by type 2 diabetes (specifically eGFR between 20 ml and 44 ml min/1.73m² with moderate to severe albuminuria (UACR between 300 and 5,000 mg/g)). This study will be implemented in clinical centers in Europe, Latin America, Asia-Pacific and some United States centers.

The primary objective of this study is to assess the efficacy of up to two REACT injections given three months apart and delivered into biopsied and non-biopsied contralateral kidneys using a minimally invasive percutaneous approach. Enrolled subjects will be stratified based upon stage of disease and standard of care (e.g., SGLT2 and/or MRA use) then randomized (1:1) to the treatment group or the "masked" sham control group prior to kidney biopsy. The total planned enrollment is 600 subjects.

The primary composite endpoint is the time from first injection to the earliest of:

- At least 40% reduction in eGFR, using the 2009 CKD-EPI serum creatinine equation, sustained for 30 days;
- eGFR <15 mL/min/1.73m² using the 2009 CKD-EPI serum creatinine equation, sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
- renal or cardiovascular death.

A recent audit by the Company's contracted Qualified Person (QP) to evaluate our readiness for release and distribution of REACT in the EU identified certain deficiencies in the documentation of the quality management systems to be addressed prior to release and distribution of product for EU clinical sites. Manufacturing is therefore paused while we optimize our capabilities to meet EU and global standards for our Phase 3 program and prepare for a transition to commercial manufacturing. We expect proact 2 will commence enrollment in the first half of 2024. No safety events have necessitated this pause.

REGEN-006/proact 1 trial

REGEN-006 (proact 1) is a Phase 3, randomized, single-blinded, bi-lateral kidney dose, sham control arm, controlled efficacy study of REACT in subjects with CKD caused by type 2 diabetes and is being amended to focus on a subset of patients with Stage 4 CKD (eGFR between 20 ml and 30 ml min/1.73m²) and late Stage 3b CKD (eGFR between 30 ml and 35 ml min/1.73m²) with moderate to severe albuminuria.

The primary objective of this study is to assess the efficacy of up to two REACT injections given three months apart and delivered into biopsied and non-biopsied contralateral kidneys using a minimally invasive percutaneous approach. The originally planned enrollment of 600 total subjects in this study will be increased to include the approximately 50 subjects already enrolled and who meet the planned amended trial eligibility criteria, for a total target enrollment of approximately 650 patients.

The primary composite endpoint is the time from first injection to the earliest of:

- At least 40% reduction in eGFR, using the 2009 CKD-EPI serum creatinine equation, sustained for 30 days;
- eGFR <15 mL/min/1.73m² using the 2009 CKD-EPI serum creatinine equation, sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
- renal or cardiovascular death.

Subjects will be randomized (1:1) to the treatment group or the "masked" sham control group prior to kidney biopsy. REGEN-006 will be conducted in clinical centers in the United States, Canada, Australia, Mexico, Taiwan and the United Kingdom.

In concert with our pause of manufacturing to optimize our capabilities to meet EU and global standards for our Phase 3 program and prepare for a transition to commercial manufacturing, and based on the interim data from RMCL-002 and feedback from payer and health technology assessment (HTA) experts, we are proactively modifying REGEN-006 to increase probability of success. This includes a focus on patients at highest risk of kidney disease progression and who are of interest to payers due to the significant cost burden associated with their medical care. Based on feedback from our clinical sites, we also intend to incorporate additional administrative changes to improve operational efficiencies and clinical site engagement. No safety issues have required any of these protocol changes. We anticipate submitting protocol amendments for this study to regulatory agencies in early 2024 and anticipate reinitiating enrollment of subjects during the first half of 2024.

Commercial Manufacturing Strategy

In preparation for our commercial manufacturing needs in the event that REACT receives regulatory approval, through our wholly-owned subsidiary, ProKidney Acquisition Company, LLC, we completed the closing of the purchase of a 210,000 square foot facility and approximately 22 acres of land in Greensboro, North Carolina, in July 2023. Under the terms of the purchase agreement, we paid approximately \$25.5 million in cash for the facility and property. In connection with the purchase, the city of Greensboro, North Carolina, Guilford County, North Carolina and the North Carolina State Economic Investment Committee have approved incentive packages under which ProKidney is eligible to receive, in aggregate, up to approximately \$33.7 million in tax credits, as well as up to \$1.9 million in energy credits from Duke Energy. Receipt of these incentives is based upon the achievement of certain milestones, including the creation of at least 330 new jobs on or before December 31, 2028, and project investment of approximately \$458 million made, or caused to be made, by the Company in real and personal property by December 31, 2027.

Other Global Developments

In 2022, various central banks around the world (including the Federal Reserve in the United States) raised interest rates. While these rate increases have not had a significant adverse impact on the Company to date, the impact of such rate increases on the overall financial markets and the economy may adversely impact the Company in the future, including by making capital more difficult and

costly to obtain on reasonable terms and when needed. In addition, the global economy has experienced and is continuing to experience high levels of inflation and global supply chain disruptions. We continue to monitor these supply chain, inflation and interest rate factors, as well as the uncertainty resulting from the overall economic environment.

In addition, although we have no operations in or direct exposure to Russia, Belarus, Ukraine, Israel and Palestine, we have experienced limited constraints in availability and increasing costs required to obtain some materials and supplies due, in part, to the negative impact of the Russia-Ukraine military conflict on the global economy, which contributed to global supply chain disruptions. To date, our business has not been materially impacted by the conflict; however, as the conflict continues or worsens, it may adversely impact our business, financial condition or results of operations.

Financial Operations Overview

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts for REACT or any other product candidates are successful and result in marketing approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such agreements.

Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with our research and development activities, including the development of REACT.

Research and development costs include:

- external research and development expenses incurred under agreements with CROs and other scientific development services;
- costs of other outside consultants, including their fees and related travel expenses;
- costs related to compliance with quality and regulatory requirements;
- costs of laboratory supplies and acquiring and developing clinical trial materials;
- payments made under third-party licensing agreements;
- personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation expenses, for individuals involved in research and development activities; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, insurance and other internal operating costs.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated balance sheets as prepaid clinical or as a component of total accrued expenses and other. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized, even when there is no alternative future use for the research and development. The capitalized amounts are recorded as prepaid clinical and are expensed as the related goods are delivered or the services are performed.

Research and development activities are central to our business model. We expect that our research and development expenses will increase significantly for the foreseeable future as REACT moves into later stages of clinical development.

The successful development of REACT and any product candidates we may develop in the future is highly uncertain. Therefore, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development and commercialization of any of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of REACT or potential future product candidates, if approved. This is due to the numerous risks and uncertainties associated with developing product candidates, many of which are outside of our control, including the uncertainty of:

- the timing and progress of non-clinical and clinical development activities;
- the number and scope of non-clinical and clinical programs we decide to pursue;

- our ability to maintain our current research and development programs and to establish new ones;
- establishing an appropriate safety-profile;
- the number of sites and patients involved in our clinical trials;
- the countries in which the clinical trials are conducted;
- per patient trial costs;
- successful patient enrollment in, and the initiation of, clinical trials, as well as drop out or discontinuation rates;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA and comparable foreign regulatory authorities;
- the number of trials required for regulatory approval;
- the timing, receipt and terms of any regulatory approvals from applicable regulatory authorities;
- our ability to establish new licensing or collaboration arrangements;
- the performance of our future collaborators, if any;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- significant and changing government regulation and regulatory guidance;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work;
- obtaining, maintaining, defending and enforcing patent claims or other intellectual property rights;
- the potential benefits of REACT over other therapies;
- launching commercial sales of REACT, if approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of REACT following approval.

Any changes in the outcome of any of these variables could mean a significant change in the costs and timing associated with the development of our product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never obtain regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits and equity-based compensation expenses for individuals involved in our executive, finance, corporate and administrative functions, as well as expenses for outside professional services, including legal, audit, accounting and tax-related services and other consulting fees, facility-related expenses, which include depreciation costs and other allocated expenses for rent and maintenance of facilities, insurance costs, recruiting costs, travel expenses and other general administrative expenses.

We expect that our general and administrative expenses will increase significantly for the foreseeable future as our business expands and we hire additional personnel to support our operations. We also anticipate increased expenses associated with being a public company, including costs for legal, audit, accounting, investor and public relations, tax-related services, director and officer insurance, and regulatory costs related to compliance with the rules and regulations of the United States Securities and Exchange Commission (the "SEC") as well as listing standards applicable to companies listed on a national securities exchange.

Other Income (Expense)

Other income consists primarily of interest income earned on cash, cash equivalents and marketable securities.

Income Tax Expense

Income tax expense reflects federal and state taxes on income earned by our subsidiary that is organized as a C corporation for U.S. income tax purposes.

Results of Operations

Comparison of Three Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		
	2023	2022	Change
Operating expenses:			
Research and development	\$ 32,198	\$ 21,132	\$ 11,066
General and administrative	14,419	14,440	(21)
Total operating expense	46,617	35,572	11,045
Loss from operations	(46,617)	(35,572)	(11,045)
Interest income	5,541	1,581	3,960
Interest expense	(2)	(29)	27
Net loss before taxes	(41,078)	(34,020)	(7,058)
Income tax expense (benefit)	913	(75)	988
Net and comprehensive loss before noncontrolling interest	(41,991)	(33,945)	(8,046)
Net loss and comprehensive loss attributable to noncontrolling interest	(31,007)	(22,017)	(8,990)
Net loss and comprehensive loss available to Class A ordinary shareholders	<u>\$ (10,984)</u>	<u>\$ (11,928)</u>	<u>\$ 944</u>

Research and development expenses

The increase in research and development expenses of approximately \$11.1 million was primarily driven by the following:

- increases in costs of \$3.2 million related to equity-based compensation driven by additional grants of equity awards to employees;
- increases in cash-based compensation costs of approximately \$2.3 million due to the hiring of additional personnel particularly in the areas of clinical development, quality and biostatistics as we move forward with our clinical programs;
- increases in costs of approximately \$4.2 million related to proact-1 and proact-2 as proact-1 continues to enroll additional subjects and proact-2 continues to incur costs related to start-up activities; and
- increases in other research and development costs of approximately \$1.2 million related to additional spending on manufacturing improvements and professional fees.

General and administrative expenses

General and administrative expenses were consistent between the three months ended September 30, 2023 and 2022 driven by the following:

- decreases in costs associated with the business combination (the "Business Combination") between Social Capital Suvretta Holdings Corp. III and ProKidney LP ("PKLP"), including certain insurance costs of approximately \$5.0 million, offset by
- increases in equity-based compensation of approximately \$5.0 million related driven by grants of equity awards to employees during 2023.

Income tax expense

Income tax expense for the three months ended September 30, 2023 increased from the three months ended September 30, 2022 due to an increase in the effective tax rate driven by the change in the valuation allowance which was impacted by the timing of deductions for qualified research and development costs.

Comparison of Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,		
	2023	2022	Change
Operating expenses:			
Research and development	\$ 84,179	\$ 61,180	\$ 22,999
General and administrative	43,133	61,592	(18,459)
Total operating expense	127,312	122,772	4,540
Loss from operations	(127,312)	(122,772)	(4,540)
Interest income	16,803	1,581	15,222
Interest expense	(9)	(213)	204
Net loss before taxes	(110,518)	(121,404)	10,886
Income tax expense	3,205	2,158	1,047
Net and comprehensive loss before noncontrolling interest	(113,723)	(123,562)	9,839
Net loss and comprehensive loss attributable to noncontrolling interest	(83,956)	(22,017)	(61,939)
Net loss and comprehensive loss available to Class A ordinary shareholders	<u>\$ (29,767)</u>	<u>\$ (101,545)</u>	<u>\$ 71,778</u>

Research and development expenses

The increase in research and development expenses of approximately \$23.0 million was primarily driven by the following:

- increases in cash-based compensation costs of approximately \$7.9 million due to the hiring of additional personnel in the areas of manufacturing and quality associated with the need to support our Phase 3 clinical trials and in the areas of clinical development and biostatistics as our development programs continue to progress;
- increases in equity-based compensation costs of approximately \$7.0 million related to the issuance of additional equity awards made to employees;
- increases in costs of approximately \$13.1 million related to proact-1 and proact-2, as proact-1 continues to enroll additional subjects and proact-2 continues to incur costs related to start-up activities;
- increases in costs related to our other clinical trials of approximately \$2.2 million particularly driven by costs for REGEN-007 now that we have completed enrollment of that trial as well as start-up activities for REGEN-015;
- increases in costs of approximately \$2.5 million related to additional spending on professional fees;
- increases in costs related to facilities and manufacturing improvements of \$2.3 million; and
- increases in manufacturing material costs of \$0.9 million, offset by;
- decreases in costs of \$14.1 million related to equity-based payments for services rendered by a third-party which were adjusted to the fair value of the awards issued upon their grant date in the nine months ended September 30, 2022.

General and administrative expenses

The decrease in general and administrative expenses of approximately \$18.5 million was primarily driven by the following:

- decreases in equity-based compensation of approximately \$21.3 million, as such expense was higher for the nine months ended September 30, 2023 due to the sale of Class B-1 Units of PKLP at amounts less than their fair value offset by;
- increases in professional fees and insurance costs of approximately \$1.6 million related to our operations as a public company; and
- increases in cash-based compensation expenses of approximately \$1.2 million due to the hiring of additional personnel.

Income tax expense

Income tax expense for the nine months ended September 30, 2023 increased from the nine months ended September 30, 2022 due to an increase in the effective tax rate driven by the change in the valuation allowance which was impacted by the timing of deductions for qualified research and development costs.

Liquidity and Capital Resources

Sources of liquidity

Since our inception, we have not recognized any revenue and have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. From our inception through September 30, 2023, we funded our operations primarily through capital contributions from the holders of PKLP and the proceeds obtained through the Business Combination and related private placement financing.

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 through 2024. We have based this estimate on assumptions that may prove to be wrong and we could exhaust our capital resources sooner than we expect.

We expect our expenses to increase substantially if, and as, we:

- initiate and continue research and clinical development of our product candidates, including in particular our clinical trials for REACT;
- incur third-party manufacturing costs to support our non-clinical studies and clinical trials of our product candidate and, if approved, its commercialization;
- seek to identify and develop additional product candidates;
- make investment in developing internal manufacturing capabilities; and
- seek regulatory and marketing approvals for our product candidates.

In addition, since the closing of the Business Combination we have begun incurring additional costs associated with operating as a public company, including significant legal, audit, accounting, investor and public relations, regulatory, tax-related, director and officer insurance premiums and other expenses. Developing pharmaceutical products, including conducting clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any product candidates or generate revenue from the sale of any product candidate for which we may obtain marketing approval. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product that we do not expect to be commercially available for at least several years, if ever.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the public or private sale of equity, government or private party grants, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain additional funding, we could be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or any commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. If we raise funds through strategic collaborations or other similar arrangements with third parties, we may have to relinquish valuable rights to our technology, future- revenue streams, research programs or product candidates or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our shares. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses, and there is no assurance that we will ever be profitable or generate positive cash flow from operating activities.

Cash Flows

Cash Flows for the Nine Months Ended September 30, 2023 and 2022

The following table provides information regarding our cash flows for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Net cash flows used in operating activities	\$ (64,685)	\$ (61,328)
Net cash flows used in investing activities	(234,139)	(1,432)
Net cash flows (used in) provided by financing activities	(39)	548,529
Net change in cash and cash equivalents	<u>\$ (298,863)</u>	<u>\$ 485,769</u>

Operating Activities

Net cash used in operating activities was approximately \$64.7 million for the nine months ended September 30, 2023, reflecting a net loss of approximately \$113.7 million and uses driven by changes in working capital of approximately \$12.8 million. Such uses were partially offset by non-cash charges and gains on investments of \$36.2 million. The non-cash charges primarily consisted of equity-based compensation expense of \$37.2 million and depreciation and amortization expense of \$2.7 million. The changes in working capital primarily relate to the timing of payments made to our vendors for services performed and the recognition of receivable amounts related to interest on our marketable security investments.

Net cash used in operating activities was approximately \$61.3 million for the nine months ended September 30, 2022, reflecting a net loss of \$123.6 million and uses driven by changes in working capital of approximately \$5.5 million, partially offset by non-cash charges of \$67.8 million. The non-cash charges primarily consisted of equity-based compensation expense of \$65.5 million and depreciation and amortization expense of \$2.2 million.

The approximately \$3.4 million increase in cash used in operating activities for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily driven by an increase in net loss after adjusting for the non-cash charges and gains on investments of approximately \$21.7 million offset by a decrease in the use of cash related to the timing of payments to our vendors and receipt of interest amounts due.

Investing Activities

Net cash used in investing activities was approximately \$234.1 million and \$1.4 million for the nine months ended September 30, 2023 and 2022, respectively. The cash used in investing activities during the nine months ended September 30, 2023 was primarily related to the investment of a portion of the proceeds raised through the Business Combination in marketable securities coupled with the purchase of land and a building in Greensboro, North Carolina.

Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2023 was an insignificant amount. Net cash provided by financing activities was \$548.5 million for the nine months ended September 30, 2022 and relates to the sale of Class A and B-1 Units of PKLP during that period.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements. Our consolidated financial statements are prepared in accordance with GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 2 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies, allowing them to delay the adoption of those standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our consolidated financial statements may not be comparable to the financial statements of companies that are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make our ordinary shares less attractive to investors.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The Company's exposure to changes in interest rates relates primarily to the Company's investment portfolio. The goals of our investment strategy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities that management believes to be of high credit quality. All securities in our investment portfolio are not leveraged and are, due to their short-term nature, subject to minimal interest rate risk. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the value of our investment portfolio.

Foreign Currency Risk

We do not have any material foreign currency exposure.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, management has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of September 30, 2023. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2023, our disclosure controls and procedures were effective in causing material information relating to us (including our consolidated subsidiaries) to be recorded, processed, summarized and reported by management on a timely basis and to ensure the quality and timeliness of our public disclosures pursuant to SEC disclosure obligations.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, with the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error and mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of controls.

The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or because the degree of compliance with the policies or procedures

may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Changes to Internal Control over Financial Reporting

We previously reported a material weakness in our internal control over financial reporting related to the Company's accounting for complex financial instruments, which condition existed prior to the Closing of the Business Combination. That material weakness has been remediated. There have been no other changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Website Availability of Reports and other Corporate Governance Information

The Company maintains a comprehensive corporate governance program, including Corporate Governance Guidelines for its Board of Directors, Board Guidelines for Assessing Director Independence and charters for its Audit Committee, Nominating and Corporate Governance Committee and Compensation Committee. The Company maintains a corporate investor relations website, <https://investors.prokidney.com/>, where stockholders and other interested persons may review, without charge, among other things, corporate governance materials and certain SEC filings, which are generally available on the same business day as the filing date with the SEC on the SEC's website <http://www.sec.gov>. The contents of our website are not made a part of this Quarterly Report on Form 10-Q.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors.

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows, and prospects. These risks are discussed more fully in the section entitled "Risk Factors" in our Registration Statement on Form 10-K filed with the SEC on March 28, 2023, as amended on April 27, 2023.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

There were no sales of unregistered equity securities during the three months ended September 30, 2023.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
31.1*	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>

- 31.2* [Certification of Principal Financial Officer Pursuant to Rules 13a-14\(a\) and 15d-14\(a\) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 32.1* [Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 32.2* [Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 101* The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, formatted in iXBRL (Inline Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets (unaudited), (ii) Condensed Consolidated Statements of Operations (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited), (iv) Condensed Consolidated Statements of Changes in Redeemable Noncontrolling Interest and Stockholders' Deficit (unaudited), (v) Consolidated Statements of Cash Flows (unaudited) and (vi) Notes to Condensed Consolidated Financial Statements (unaudited), tagged as blocks of text and including detailed tags.
- 104* The cover page from this Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, formatted in Inline XBRL.

* Filed herewith.

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 thereunto duly authorized.

Company Name

Date: November 14, 2023

By: /s/ Timothy A. Bertram

Name: Timothy A. Bertram

Title: Chief Executive Officer

(Principal Executive Officer)

Date: November 14, 2023

By: /s/ James Coulston

Name: James Coulston

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Timothy A. Bertram, certify that:

1. I have reviewed this Form 10-Q of ProKidney Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2023

By: /s/ Timothy A. Bertram
Timothy A. Bertram
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, James Coulston, certify that:

1. I have reviewed this Form 10-Q of ProKidney Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2023

By: /s/ James Coulston

James Coulston

Chief Financial Officer

(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of ProKidney Corp. (the "Company") on Form 10-Q for the period ending September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2023

By: /s/ Timothy A. Bertram

Timothy A. Bertram

Chief Executive Officer

(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of ProKidney Corp. (the "Company") on Form 10-Q for the period ending September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2023

By: /s/ James Coulston

James Coulston

Chief Financial Officer

(Principal Financial and Accounting Officer)
