UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2024

or

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

Commission File Number: 001-36751

OCUGEN, INC.
(Exact name of registrant as specified in its charter)

Delaware	**04-3522315**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11 Great Valley Parkway
Malvern, Pennsylvania 19355
(Address of principal executive offices, including zip code)
(484) 328-4701
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	**OCGN**	**The Nasdaq Stock Market LLC (The Nasdaq Capital 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, a 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	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of November 12, 2024 there were 291,320,280 outstanding shares of the registrant's common stock, $0.01 par value per share.

OCUGEN, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2024

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Unless the context otherwise requires, references to the "Company," "we," "our," or "us" in this report refer to Ocugen, Inc. and its subsidiaries, and references to "OpCo" refer to Ocugen OpCo, Inc., the Company's wholly owned subsidiary.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts contained in this Quarterly Report on Form 10-Q regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," "would," or the negative of such terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are based on assumptions and expectations that may not be realized and are inherently subject to risks, uncertainties, and other factors, many of which cannot be predicted with accuracy and some of which might not even be anticipated.

The forward-looking statements in this Quarterly Report on Form 10-Q and those contained in (i) our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission ("SEC") on April 16, 2024 (the "2023 Annual Report") and (ii) our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 and June 30, 2024 filed with the SEC on May 14, 2024 and August 8, 2024, respectively (together with this Quarterly Report on Form 10-Q, the "2024 Quarterly Reports") include, among other things, statements about:

- our estimates regarding expenses, future revenues, and capital requirements, as well as the timing, availability of, and the need for, additional financing to continue to advance our product candidates;
- our activities with respect to OCU400, OCU410 and OCU410ST, including the results from our ongoing Phase 1/2 trials for OCU400 and OCU410ST, our ability to continue dosing patients for our Phase 3 trial for OCU400 for the treatment of retinitis pigmentosa ("RP"), our ability to reach alignment with the United States Food and Drug Administration ("FDA") on the Phase 3 trial design for OCU400 for the treatment of Leber congenital amaurosis ("LCA"), and our ability to subsequently initiate and complete a Phase 3 trial for the treatment of LCA;
- our ability to obtain additional funding from government agencies in the United States and/or other countries to continue the development of our inhaled mucosal vaccine platform;
- the uncertainties associated with the clinical development and regulatory approval of our product candidates including potential delays in the initiation, enrollment, and completion of current and future clinical trials;
- our ability to realize any value from our product candidates and preclinical programs being developed and anticipated to be developed, in light of inherent risks and difficulties involved in successfully commercializing products and the risk that our products, if approved, may not achieve broad market acceptance;
- our ability to comply with regulatory schemes and other regulatory developments applicable to our business in the United States and other countries;
- the performance of third-parties upon which we depend, including contract development and manufacturing organizations, suppliers, manufacturers, group purchasing organizations, distributors, and logistics providers;
- the pricing and reimbursement of our product candidates, if commercialized;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- developments relating to our competitors and our industry;
- our ability to obtain and maintain patent protection, or obtain licenses to intellectual property and defend our intellectual property rights against third-parties;
- our ability to maintain our relationships and contracts with our key collaborators and commercial partners and our ability to establish additional collaborations and partnerships;
- our ability to recruit and retain key scientific, technical, commercial, and management personnel and to retain our executive officers;
- matters relating to or arising from the restatement of our previously issued financial statements included in our 2022 Annual Report on Form 10-K as well as unaudited interim financial statements included in our Quarterly Reports on Forms 10-Q for each of the quarterly and year to date periods ended September 30, 2022, June 30, 2022, March 31, 2022, September 30, 2023, June 30, 2023, and March 31, 2023;

- our ability to comply with stringent United States and applicable foreign government regulations with respect to the manufacturing of pharmaceutical products, including compliance with current Good Manufacturing Practice regulations, and other relevant regulatory authorities;
- the extent to which health epidemics and other outbreaks of communicable diseases, geopolitical turmoil, macroeconomic conditions, social unrest, political instability, terrorism, or acts of war could disrupt our business and operations, including impacts on our development programs, global supply chain, and collaborators and manufacturers; and
- other matters discussed under the heading "Risk Factors" contained in the 2023 Annual Report, the 2024 Quarterly Reports, and in any other documents we have filed with the SEC.

We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in our 2023 Annual Report and in the 2024 Quarterly Reports, particularly under the section titled "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations, investments, or other significant transactions we may make.

You should read this Quarterly Report on Form 10-Q and the documents we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we do not assume any obligation to update any forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Solely for convenience, tradenames and trademarks referred to in this Quarterly Report on Form 10-Q appear without the ® or ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owners will not assert their rights, to these tradenames or trademarks, as applicable. All tradenames, trademarks, and service marks included or incorporated by reference in this Quarterly Report on Form 10-Q are the property of their respective owners. The name NeoCart has not been evaluated or cleared by the FDA.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

OCUGEN, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash	$ 38,696	$ 39,462
Prepaid expenses and other current assets	1,977	3,509
Total current assets	40,673	42,971
Property and equipment, net	17,130	17,290
Restricted cash	305	—
Other assets	3,828	4,286
Total assets	$ 61,936	64,547
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,494	$ 3,172
Accrued expenses and other current liabilities	12,475	13,343
Operating lease obligations	477	574
Current portion of long term debt	1,316	—
Total current liabilities	15,762	17,089
Non-current liabilities		
Operating lease obligations, less current portion	3,419	3,567
Long term debt, net	1,571	2,800
Other non-current liabilities	554	527
Total non-current liabilities	5,544	6,894
Total liabilities	21,306	23,983
Commitments and contingencies (Note 13)		
Stockholders' equity		
Convertible preferred stock; $0.01 par value; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023		
Series B Convertible Preferred Stock; zero shares issued and outstanding at September 30, 2024 and 54,745 shares issued and outstanding at December 31, 2023	—	1
Common stock; $0.01 par value; 390,000,000 shares authorized, 290,384,252 and 256,688,304 shares issued, and 290,262,752 and 256,566,804 shares outstanding at September 30, 2024 and December 31, 2023, respectively	2,904	2,567
Treasury stock, at cost, 121,500 shares at September 30, 2024 and December 31, 2023	(48)	(48)
Additional paid-in capital	364,092	324,191
Accumulated other comprehensive income	23	20
Accumulated deficit	(326,341)	(286,167)
Total stockholders' equity	40,630	40,564
Total liabilities and stockholders' equity	$ 61,936	$ 64,547

See accompanying notes to condensed consolidated financial statements.

OCUGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Collaborative arrangement revenue	$ 1,136	$ 3,699	$ 3,291	$ 4,627
Total revenue	1,136	3,699	3,291	4,627
Operating expenses				
Research and development	8,108	7,048	23,836	31,794
General and administrative	6,280	9,082	20,372	26,839
Total operating expenses	14,388	16,130	44,208	58,633
Loss from operations	(13,252)	(12,431)	(40,917)	(54,006)
Other income (expense), net	282	714	743	1,898
Net loss	$ (12,970)	$ (11,717)	$ (40,174)	$ (52,108)
Other comprehensive income (loss)				
Foreign currency translation adjustment	(5)	5	3	2
Unrealized gain (loss) on marketable securities	$ —	$ —	$ —	$ (1)
Comprehensive loss	$ (12,975)	$ (11,712)	$ (40,171)	$ (52,107)
Net loss attributable to common shareholders— basic and diluted	(12,970)	(11,717)	(40,128)	(52,108)
Weighted shares used in calculating net loss per common share — basic and diluted	278,171,593	256,492,558	264,303,494	240,222,667
Net loss per share attributable to common shareholders — basic and diluted	$ (0.05)	$ (0.05)	$ (0.15)	$ (0.22)
Net loss attributable to Series B Convertible Preferred shareholders — basic and diluted	—	—	(46)	—
Weighted shares used in calculating net loss per Series B Convertible Preferred Stock — basic and diluted	—	—	54,745	—
Net loss per share attributable to Series B Convertible Preferred shareholders — basic and diluted	$ —	$ —	$ (0.84)	$ —

See accompanying notes to condensed consolidated financial statements.

OCUGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)
(Unaudited)

	Series B Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount					
Balance at December 31, 2023	54,745	$ 1	256,688,304	$ 2,567	$ (48)	$ 324,191	$ 20	$ (286,167)	$ 40,564
Stock-based compensation expense	—	—	—	—	—	1,761	—	—	1,761
Issuance of common stock for stock option exercises and restricted stock unit vesting, net	—	—	758,460	8	—	(153)	—	—	(145)
Other comprehensive income (loss)	—	—	—	—	—	—	5	—	5
Net loss	—	—	—	—	—	—	—	(11,924)	(11,924)
Balance at March 31, 2024	54,745	$ 1	257,446,764	$ 2,575	$ (48)	$ 325,799	$ 25	$ (298,091)	$ 30,261
Stock-based compensation expense	—	—	—	—	—	1,898	—	—	1,898
Issuance of common stock for stock option exercises and restricted stock unit vesting, net	—	—	95,860	1	—	44	—	—	45
Series B Convertible Preferred Stock reacquisition	(54,745)	(1)	—	—	—	1	—	—	—
Other comprehensive income (loss)	—	—	—	—	—	—	3	—	3
Net loss	—	—	—	—	—	—	—	(15,280)	(15,280)
Balance at June 30, 2024	**—**	**$ —**	**257,542,624**	**$ 2,576**	**$ (48)**	**$ 327,742**	**$ 28**	**$ (313,371)**	**$ 16,927**
Stock-based compensation expense	—	—	—	—	—	1,892	—	—	1,892
Issuance of common stock for stock option exercises and restricted stock unit vesting, net	—	—	124,237	1	—	48	—	—	49
Issuance of Common Stock for capital raises, net	—	—	32,717,391	327	—	34,410	—	—	34,737
Other comprehensive income (loss)	—	—	—	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	—	(12,970)	(12,970)
Balance at September 30, 2024	**—**	**$ —**	**290,384,252**	**$ 2,904**	**$ (48)**	**$ 364,092**	**$ 23**	**$ (326,341)**	**$ 40,630**

OCUGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (CONTINUED)
(in thousands, except share amounts)
(Unaudited)

	Series B Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount					
Balance at December 31, 2022	54,745	$ 1	221,721,182	$ 2,217	$ (48)	$ 294,874	$ 26	$ (223,089)	$ 73,981
Stock-based compensation expense	—	—	—	—	—	2,689	—	—	2,689
Issuance of common stock for stock option exercises and restricted stock unit vesting, net	—	—	348,555	3	—	(4)	—	—	(1)
Issuance of common stock for capital raises, net	—	—	4,478,956	45	—	5,514	—	—	5,559
Other comprehensive income (loss)	—	—	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	—	—	(17,326)	(17,326)
Balance at March 31, 2023	54,745	$ 1	226,548,693	$ 2,265	$ (48)	$ 303,073	$ 25	$ (240,415)	$ 64,901
Stock-based compensation expense	—	—	—	—	—	2,632	—	—	2,632
Issuance of common stock for stock option exercises and restricted stock unit vesting, net	—	—	59,859	1	—	9	—	—	10
Issuance of common stock for capital raises, net	—	—	30,000,000	300	—	14,467	—	—	14,767
Other comprehensive income (loss)	—	—	—	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	—	—	—	(23,065)	(23,065)
Balance at June 30, 2023	**54,745**	**$ 1**	**256,608,552**	**$ 2,566**	**$ (48)**	**$ 320,181**	**$ 22**	**$ (263,480)**	**$ 59,242**
Stock-based compensation expense	—	—	—	—	—	2,174	—	—	2,174
Issuance of common stock for stock option exercises and restricted stock unit vesting, net	—	—	12,935	—	—	97	—	—	97
Other comprehensive income (loss)	—	—	—	—	—	—	5	—	5
Net loss	—	—	—	—	—	—	—	(11,717)	(11,717)
Balance at September 30, 2023	**54,745**	**$ 1**	**256,621,487**	**$ 2,566**	**$ (48)**	**$ 322,452**	**$ 27**	**$ (275,197)**	**$ 49,801**

See accompanying notes to condensed consolidated financial statements.

OCUGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Nine months ended September 30,	
	2024	2023
Cash flows from operating activities		
Net loss	$ (40,174)	$ (52,108)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,370	525
Amortization (accretion) on marketable securities	—	(182)
Non-cash interest expense	87	87
Non-cash lease expense	634	401
Non-cash (income) expense from collaborative arrangements, net	(2,406)	(1,134)
Stock-based compensation expense	5,551	7,495
Impairment of advance for COVAXIN supply	—	4,074
Loss on disposal of fixed assets related to COVAXIN	—	363
Other	28	379
Changes in assets and liabilities:		
Prepaid expenses and other current assets	1,701	132
Accounts payable and accrued expenses	2,048	(10,402)
Lease obligations	(617)	(382)
Net cash used in operating activities	(31,778)	(50,752)
Cash flows from investing activities		
Purchases of marketable securities	—	(3,947)
Proceeds from the maturities of marketable securities	—	17,500
Purchases of property and equipment	(3,372)	(7,754)
Net cash (used in) provided by investing activities	(3,372)	5,799
Cash flows from financing activities		
Proceeds (payments) from issuance of common stock, net	37,575	20,788
Payment of equity issuance costs	(2,889)	(355)
Proceeds from issuance of debt	—	500
Payment of debt issuance costs	—	(68)
Net cash provided by financing activities	34,686	20,865
Effect of changes in exchange rate on cash and restricted cash	3	2
Net (decrease) in cash and restricted cash	(461)	(24,086)
Cash and restricted cash at beginning of period	39,462	77,563
Cash and restricted cash at end of period	$ 39,001	$ 53,477
Supplemental disclosure of non-cash investing and financing transactions:		
Purchases of property and equipment	$ —	$ 1,969
Series B Convertible Preferred Stock reacquisition	$ 1	$ —
Right-of-use asset related to operating leases	$ 103	$ —

See accompanying notes to condensed consolidated financial statements.

OCUGEN, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Nature of Business

Ocugen, Inc., together with its wholly owned subsidiaries ("Ocugen" or the "Company"), is a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies and vaccines that improve health and offer hope for patients across the globe. The Company is headquartered in Malvern, Pennsylvania, and manages its business as one operating segment.

Going Concern

The Company has incurred recurring net losses since inception and has funded its operations to date through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes and debt, and grant proceeds. The Company incurred net losses of approximately $40.2 million and $52.1 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, the Company had an accumulated deficit of $326.3 million and cash totaling $38.7 million. This amount will not be sufficient to fund the Company's operations over the next 12 months after the date that the condensed consolidated financial statements are issued. Due to the inherent uncertainty involved in making estimates and the risks associated with the research, development, and commercialization of biotechnology products, the Company may have based this estimate on assumptions that may prove to be different than actuals, and the Company's operating plan may change as a result of many factors currently unknown to the Company.

Subsequent to September 30, 2024, the Company entered into a debt financing transaction with Avenue Capital for net proceeds of $29.2 million, refer to Note 14 for additional information. Despite this additional funding, the Company is subject to risks and uncertainties frequently encountered by companies in its industry, and while the Company intends to continue its research, development, and commercialization efforts for its product candidates, the Company will require significant additional funding. If the Company is unable to obtain additional funding in the future and/or its research, development, and commercialization efforts require higher than anticipated capital, there will be a negative impact on the financial viability of the Company. The Company will continue to explore options to fund its operations through public and private placements of equity and/or debt, payments from potential strategic research and development arrangements, sales of assets, licensing and/or collaboration arrangements with pharmaceutical companies or other institutions, funding from the government, particularly for the development of the Company's novel inhaled mucosal vaccine platform, or funding from other third parties. Such financing and funding may not be available at all, or on terms that are favorable to the Company. While Company management believes that it has a plan to fund operations, its plan may not be successfully implemented. If we cannot obtain the necessary funding, we will need to delay, scale back, or eliminate some or all of our research and development programs and commercialization efforts; consider other various strategic alternatives, including a merger or sale; or cease operations. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition, and results of operations could be materially adversely affected.

As a result of these factors, together with the anticipated continued spending that will be necessary to continue to research, develop, and commercialize the Company's product candidates, there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that these condensed consolidated financial statements are issued. The condensed consolidated financial statements do not contain any adjustments that might result from the resolution of any of the above uncertainties.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying unaudited condensed consolidated financial statements included herein have been prepared in conformity with generally accepted accounting principles in the United States ("GAAP") and under the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim reporting. The accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair statement of the Company's financial position, results of operations, and cash flows. The condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosures of the Company normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted under the SEC's rules and regulations. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto for the year ended December 31, 2023,

included in the Company's Annual Report on Form 10-K filed with the SEC on April 16, 2024 (the "2023 Annual Report"). The condensed consolidated financial statements include the accounts of Ocugen and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Restatement of Previously Reported Condensed Consolidated Financial Statements

As previously disclosed, the condensed consolidated financial statements include material corrections to the three and nine months ended September 30, 2023, which were presented in Note 16 to the audited consolidated financial statements and notes thereto for the year ended December 31, 2023 in the Company's 2023 Form 10-K filed on April 16, 2024. As noted in the 2023 Form 10-K, the Company discovered that in prior years it had not appropriately accounted for its collaboration arrangements, including the determination of the transaction price, calculating the progress towards the satisfaction of the performance obligations under the collaborative arrangements, and determining the value of the non-cash consideration received and recognized as research and development expense. The Company also corrected the presentation of the revenue previously recognized within Other income (expense), net to Collaborative arrangement revenue in its Consolidated Statements of Operations and Comprehensive Loss.

The misstatements were material to the Company's previously issued financial statements and as a result, the Company has restated its Consolidated Balance Sheets, Consolidated Statements of Operations and Comprehensive Loss, Consolidated Statements of Stockholders' Equity, and Consolidated Statements of Cash Flows as of and for the fiscal year ended December 31, 2022. The restatement includes adjustments to Collaborative arrangement revenue, Research and development expenses, Other income (expense), net and Accrued expenses and other current liabilities during the impacted periods. The Company has also corrected certain other identified immaterial errors that were identified during the impacted periods impacting Research and development expenses, General and administrative expenses, and Accrued expenses and other current liabilities.

Revision to Previously Reported Financial Statements

During the preparation of the Company's unaudited condensed consolidated financial statements as of and for the quarterly period ended September 30, 2024, the Company concluded to revise its financial statements to treat the Series B Convertible Preferred Stock as a second class of common stock for purposes of presenting earnings per share. In accordance with the guidance in ASC 260, equity classified shares of stock need to be assessed to determine if they are preferred stock or are in substance common shares and therefore represent a second class of common shares. The rights of the Series B Convertible Preferred Stock were substantially equivalent to common shares and they did not have any material preferential rights compared to common shares. As such, the Company concluded that it should have considered the Series B Convertible Preferred Stock to be a second class of common stock for purposes of presenting earnings per share under the two-class method. Additionally, for the three and six months ended June 30, 2024, the Company previously reduced the net loss attributable to common shareholders by a deemed dividend of $4,988 thousand related to the reacquisition by the Company of the Series B Convertible Preferred Stock. This adjustment should not have been made as the guidance for adjusting the numerator to reflect the implicit gain or loss upon the re-acquisition of shares is only applicable to shares which are substantively considered preferred stock for earnings per share purposes. The impact of these errors is immaterial to the previously filed financial statements. Accordingly, in this filing, the Company revised earnings per share to separately present loss per share for common stock and for the Series B Convertible Preferred Stock and also removed the deemed dividend which previously reduced the net loss attributable to common shareholders for the three and six months ended June 30, 2024. The Company has not revised and will not revise any periods prior to January 1, 2024 because the impact of the error to those periods is also immaterial. The 2024 revisions will be reflected in the comparative 2024 periods in future filings where those periods are included with appropriate disclosures.

The impacts of the revision to the previously reported, unaudited condensed consolidated financial statements are summarized within the tables below.

Impact of the revision for the period ended March 31, 2024 **(in thousands, except share and per share amounts)**

	Three months ended March 31, 2024 (as previously reported)	Adjustment	Three months ended March 31, 2024 (as adjusted)
Net loss	$ (11,924)	—	(11,924)
Net loss attributable to common shareholders— basic and diluted	(11,924)	25	(11,899)
Weighted shares used in calculating net loss per common share — basic and diluted	257,232,636	—	257,232,636
Net loss per share attributable to common shareholders — basic and diluted	(0.05)		(0.05)
Net loss attributable to Series B Convertible Preferred shareholders — basic and diluted	—	(25)	(25)
Weighted shares used in calculating net loss per Series B Convertible Preferred Stock — basic and diluted	—	54,745	54,745
Net loss per share attributable to Series B Convertible Preferred shareholders — basic and diluted	—		(0.46)

Impact of the revision for the periods ended June 30, 2024 **(in thousands, except share and per share amounts)**

	Three months ended June 30, 2024 (as previously reported)	Adjustment	Three months ended June 30, 2024 (as adjusted)
Net loss	$ (15,280)	—	(15,280)
Reacquired Series B Convertible Preferred Stock	4,988	(4,988)	—
Net loss attributable to common shareholders— basic and diluted	(10,292)	(4,967)	(15,259)
Weighted shares used in calculating net loss per common share — basic and diluted	257,353,857	—	257,353,857
Net loss per share attributable to common shareholders — basic and diluted	(0.04)		(0.06)
Net loss attributable to Series B Convertible Preferred shareholders — basic and diluted	—	(21)	(21)
Weighted shares used in calculating net loss per Series B Convertible Preferred Stock — basic and diluted	—	54,745	54,745
Net loss per share attributable to Series B Convertible Preferred shareholders — basic and diluted	—		(0.38)

	Six months ended June 30, 2024 (as previously reported)	Adjustment	Six months ended June 30, 2024 (as adjusted)
Net loss	$ (27,204)	—	(27,204)
Reacquired Series B Convertible Preferred Stock	4,988	(4,988)	—
Net loss attributable to common shareholders— basic and diluted	(22,216)	(4,941)	(27,157)
Weighted shares used in calculating net loss per common share — basic and diluted	257,293,247	—	257,293,247
Net loss per share attributable to common shareholders — basic and diluted	(0.09)		(0.11)
Net loss attributable to Series B Convertible Preferred shareholders — basic and diluted	—	(47)	(47)
Weighted shares used in calculating net loss per Series B Convertible Preferred Stock — basic and diluted	—	54,745	54,745
Net loss per share attributable to Series B Convertible Preferred shareholders — basic and diluted	—		(0.86)

The accounting policies of the Company, as applied in the condensed consolidated financial statements presented herein, are substantially the same as presented in the Company's 2023 Form 10-K filed on April 16, 2024, except as may be indicated below.

Use of Estimates

In preparing the condensed consolidated financial statements in conformity with GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting period. Due to the inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions. These estimates and assumptions include those used in the accounting for research and development contracts, including clinical trial accruals, determination of the collaborative arrangements' transaction price, calculating the progress towards the satisfaction of the performance obligations under the collaborative arrangements, and determining the value of the non-cash consideration received under collaborative arrangements.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash equivalents may include bank demand deposits and money market funds that invest primarily in certificates of deposit, commercial paper, and U.S. government agency securities and treasuries. The Company records interest income received on its cash and cash equivalents to other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. The Company recorded $0.3 million and $0.8 million as interest income for the three and nine months ended September 30, 2024, respectively. The Company recorded $0.7 million and $2.0 million as interest income for the three and nine months ended September 30, 2023, respectively. The Company's restricted cash balance as of September 30, 2024 consisted of cash held to collateralize a corporate credit card account and a line of credit related to an operating lease in the event of a payment default.

The following table provides a reconciliation of cash and restricted cash from the condensed consolidated balance sheets to the total amount shown in the condensed consolidated statements of cash flows (in thousands):

	As of September 30,	
	2024	2023
Cash	$ 38,696	$ 53,477
Restricted cash	305	—
Total cash and restricted cash	$ 39,001	$ 53,477

Fair Value Measurements

The Company follows the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 820, *Fair Value Measurements* ("ASC 820"), which defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1 — quoted prices in active markets for identical assets or liabilities

Level 2 — quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 — inputs that are unobservable (for example, cash flow modeling inputs based on assumptions)

The carrying value of certain financial instruments, including cash, accounts payable, and accrued expenses, approximates their fair value due to the short-term nature of these instruments.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and restricted cash. The Company's cash and restricted cash are held in accounts at financial institutions that may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to significant credit risk beyond the standard credit risk associated with commercial banking relationships.

Leases

The Company determines if an arrangement is or contains a lease at inception. This determination generally depends on whether the arrangement conveys to the Company the right to control the use of an explicitly or implicitly identified fixed asset for a period of time in exchange for consideration. Control of an underlying asset is conveyed to the Company, if the Company obtains the rights to direct the use of and to obtain substantially all of the economic benefits from using the underlying asset. The Company's lease agreements include lease and non-lease components, which the Company has elected not to account for separately for all classes of underlying assets. Lease expense for variable lease components is recognized when the obligation is probable.

The Company currently leases real estate classified as operating leases. Operating leases are included in other assets and operating lease obligations in the Company's consolidated balance sheets. At lease commencement, the Company records a lease liability based on the present value of the lease payments over the expected lease term including any options to extend the lease that the Company is reasonably certain to exercise and records a corresponding right-of-use lease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date. Lease expense is recognized on a straight-line basis over the lease term and recognized as research and development expense or general and administrative expense based on the underlying nature of the expense. FASB ASC Topic 842, *Leases* ("ASC 842") requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. The implicit interest rates were not readily determinable in the Company's current operating leases. As such, the incremental borrowing rates were used based on the information available at the commencement dates in determining the present value of lease payments.

The lease term for the Company's leases includes the non-cancellable period of the lease plus any additional periods covered by either an option to extend (or not to terminate) the lease that the Company is reasonably certain to exercise, or an option to extend (or not to terminate) the lease controlled by the lessor.

Lease payments included in the measurement of the lease liability are comprised of fixed payments, variable payments that depend on an index or rate, and amounts probable to be payable under the exercise of an option to purchase the underlying asset if reasonably certain.

Variable payments not dependent on an index or rate associated with the Company's leases are recognized when the event, activity, or circumstance is probable. Variable payments include the Company's proportionate share of certain utilities and other operating expenses and are presented as operating expenses in the Company's condensed consolidated statements of operations and comprehensive loss in the same line item as expense arising from fixed lease payments.

Impairment of long-lived Assets

The Company reviews its assets, including property and equipment, for impairment whenever changes in circumstances or events may indicate that the carrying amounts are not recoverable. These indicators include, but are not limited to, a significant change in the extent or manner in which an asset is used or its physical condition, a significant decrease in the market price of an asset, or a significant adverse change in the business or the industry that could affect the value of an asset. An asset is tested for impairment by comparing the net carrying value of the asset to the undiscounted net cash flows to be generated from the use and eventual disposition of the asset.

Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). The Company has issued stock-based compensation awards including stock options, restricted stock units ("RSUs"), and market-condition based restricted stock units ("PSUs"), and also accounts for certain issuances of preferred stock and warrants in accordance with ASC 718. ASC 718 requires all stock-based payments, including grants of stock options, RSUs, and PSUs, to be recognized in the condensed consolidated statements of operations and comprehensive loss based on their grant date fair values. The Company uses the Black-Scholes option-pricing model to determine the fair value of stock options granted. For RSUs, the fair value of the RSU is determined by the market price of a share of the Company's common stock on the grant date. For PSUs, the Company determines fair value by using a Monte Carlo simulation technique. The Company recognizes forfeitures as they occur.

Expense related to stock-based compensation awards granted with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Stock-based compensation awards generally vest over a one to three year requisite service period. Stock options have a contractual term of 10 years. Expense for stock-based compensation awards with performance-based vesting conditions is only recognized when the performance-based vesting condition is deemed probable to occur. Expense for stock-based compensation awards with market-based and service-based vesting conditions is recognized ratably over the grantee's requisite service period. Compensation cost is not adjusted based on the actual achievement of the market-based performance goals. Expense related to stock-based compensation awards are recorded to research and development expense or general and administrative expense based on the underlying function of the individual that was granted the stock-based compensation award. Shares issued upon stock option exercise, PSU and RSU vesting are newly-issued common shares.

Estimating the fair value of stock options requires the input of subjective assumptions, including the expected term of the stock option, stock price volatility, the risk-free interest rate, and expected dividends. Estimating the fair value of PSUs requires the input of subjective assumptions, including stock price volatility, total shareholder return ("TSR") ranking, the risk-free rate, and expected dividends. The assumptions used in the Company's Black-Scholes option-pricing model and Monte Carlo simulation technique represent management's best estimates and involve a number of variables, uncertainties, assumptions, and the application of management's judgment, as they are inherently subjective. If any assumptions change, the Company's stock-based compensation expense could be materially different in the future.

The assumptions used in Ocugen's Black-Scholes option-pricing model for stock options and in Ocugen's Monte Carlo simulation technique for PSUs are as follows, unless noted otherwise:

Expected Term. As Ocugen does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term, the expected term of employee stock options subject to service-based vesting conditions is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin No. 107, whereby the expected term equals the

arithmetic average of the vesting term and the original contractual term of the stock option. This expected term assumption is not an assumption used in the Company's Monte Carlo simulation technique for PSUs. The expected term of the PSUs is equal to the performance period of the PSUs.

Expected Volatility. The expected volatility is based on historical volatilities of Ocugen and similar entities within Ocugen's industry for periods commensurate with the assumed expected term.

Risk-Free Interest Rate. The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.

Expected Dividends. The expected dividend yield is 0% because Ocugen has not historically paid, and does not expect for the foreseeable future to pay, a dividend on its common stock.

TSR ranking. The Company's TSR, over a three-year period, is relative to the TSR, for that same period, as related to other companies within the Nasdaq Biotechnology index. This assumption is only used for the market-based PSUs.

Collaborative Arrangements and Revenue Recognition

The Company analyzes its collaborative arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards. This assessment is performed throughout the life of the arrangements based on changes to the arrangements. For collaborative arrangements within the scope of ASC 808 the Company may analogize to ASC 606 for certain elements.

The Company identifies the goods or services promised within each collaborative arrangement and assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

The allocation of the transaction price to the performance obligations in proportion to their standalone selling prices is determined at contract inception. If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the counterparty and the transfer of the promised goods or services to the counterparty will be one year or less. The Company assessed its collaboration arrangements in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in any of its arrangements.

The Company recognizes as collaboration revenue the amount of the transaction price that is allocated to the respective performance obligation as each performance obligation is satisfied over time, with progress toward completion measured based on actual costs incurred relative to total estimated costs to be incurred over the life of the arrangement. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete their performance obligations under the arrangements. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Adjustments to original estimates will be required as work progresses and additional information becomes known, even though the scope of the work required under the contract may not change. Any adjustment as a result of a change in estimates is made when facts develop, events become known, or an adjustment is otherwise warranted.

Under the Company's collaborative arrangements, the timing of revenue recognition and receipt of consideration may differ, and result in assets and liabilities. Assets represent revenues recognized in excess of the consideration received under

collaborative arrangement. Liabilities represent the consideration received in excess of revenues recognized under collaborative arrangement.

Recently Adopted Accounting Standards

In August 2020, the FASB issued ASU No. 2020-06, *Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40)*. This standard will have an effective and transition date of January 1, 2024. This standard simplifies an issuer's accounting for convertible instruments by eliminating two of the three models that require separate accounting for embedded conversion features as well as simplifies the settlement assessment that entities are required to perform to determine whether a contract qualifies for equity classification. This standard also requires entities to use the if-converted method for all convertible instruments in the diluted earnings per share calculation and includes the effect of potential share settlement (if the effect is more dilutive) for instruments that may be settled in cash or shares, except for certain liability-classified share-based payment awards. The standard requires new disclosures about events that occur during the reporting period that cause conversion contingencies to be met and about the fair value of a public business entity's convertible debt at the instrument level, among other things. The adoption of ASU 2020-06 on January 1, 2024 did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures". This guidance is intended to enhance the transparency and decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the U.S. and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively. Early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its condensed consolidated financial statements disclosures.

In November 2023, the FASB issued ASU 2023-07 “Segment Reporting: Improvements to Reportable Segment Disclosures”. This guidance expands public entities’ segment disclosures primarily by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment’s profit or loss and assets. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments are required to be applied retrospectively to all prior periods presented in an entity’s financial statements. The Company is currently evaluating this guidance to determine the impact it may have on its condensed consolidated financial statements related disclosures.

3. License and Development Agreements

Co-Development and Commercialization Agreement with CanSino Biologics, Inc.

The Company entered into a co-development and commercialization agreement with CanSino Biologics, Inc. ("CanSinoBIO") with respect to the development and commercialization of the Company's modifier gene therapy product candidates, OCU400, OCU410, and OCU410ST. The co-development and commercialization agreement was originally entered into in September 2019 ("the Original CanSinoBIO Agreement") with regards to OCU400 and was subsequently amended in September 2021 and November 2022 ("the Amendments"), to include OCU410 and OCU410ST, respectively. The Company concluded that the Original CanSinoBIO Agreement and the Amendments are separate agreements (collectively referred to as the "CanSinoBio Agreements"). Pursuant to the CanSinoBIO Agreements, the Company and CanSinoBIO are collaborating on the development of the Company's modifier gene therapy platform. CanSinoBIO is responsible for the chemistry, manufacturing, and controls development and manufacture of clinical supplies of such products and is responsible for the costs associated with such activities. CanSinoBIO has an exclusive license to develop, manufacture, and commercialize the Company's modifier gene therapy platform in and for China, Hong Kong, Macau, and Taiwan (the "CanSinoBIO Territory"), and the Company maintains exclusive development, manufacturing, and commercialization rights with respect to the Company's modifier gene therapy platform outside the CanSinoBIO Territory (the "Company Territory").

Should any of the product candidates be commercialized in the CanSinoBIO Territory, CanSinoBIO will pay to the Company an annual royalty between mid- and high-single digits based on Net Sales (as defined in the CanSinoBIO Agreements) of the products included in the Company's modifier gene therapy platform in the CanSinoBIO Territory. The Company will pay to CanSinoBIO an annual royalty between low- and mid-single digits based on Net Sales of the products included in the Company's modifier gene therapy platform in the Company Territory.

Accounting analysis and revenue recognition

The Company determined the collaboration arrangements with CanSinoBIO, are within the scope of ASC 808 and has analogized to ASC 606 to account for CanSinoBIO's access to its IP as well as data generated in connection with the co-development activities to be undertaken by Ocugen. These elements of the arrangements are not distinct and are accounted for as a single performance obligation.

The non-cash consideration to be received related to the Company's satisfaction of the performance obligation includes but is not limited to services related to chemistry, manufacturing, and controls development and manufacture of clinical supplies of such products through completion of pre-clinical, clinical, regulatory, and other commercialization readiness services. The estimated market value of the co-development services to be performed by CanSinoBIO, represents variable consideration that is included in the transaction price. The Company recognizes collaborative arrangement revenue over time using an input method using ratio of costs incurred to date compared to total estimated costs required to satisfy the performance obligation under the CanSinoBIO Agreements.

The Company constrained the transaction price related to certain future co-development services and future royalties, as it assessed that it is probable that the inclusion of such variable consideration could result in a significant reversal of cumulative revenue in future periods. The variable consideration, which is based on continued successful development of our programs, is reevaluated at each reporting period and as changes in circumstances occur.

The services provided by CanSinoBIO are recorded as research and development expense as incurred and the difference between the revenue and expense recognized is recorded on the Company's balance sheet as a contract liability within Accrued expenses and other current liabilities. The related revenue recognized was recorded in the condensed consolidated statements of operations and comprehensive loss as collaborative arrangement revenue and was approximately $3.3 million and $4.6 million for the nine months ended September 30, 2024 and 2023, respectively. The related expense incurred for services provided by CanSinoBIO was recorded in the condensed consolidated statements of operations and comprehensive loss as research and development expense and was approximately $0.9 million and $3.5 million for the nine months ended September 30, 2024 and 2023, respectively.

The contract liability was $8.1 million and $10.1 million as of September 30, 2024 and 2023, respectively. Revenue recognized for the nine months ended September 30, 2024, that was included in the contract liabilities balances as of January 1, 2024 was approximately $3.3 million. Revenue recognized for the nine months ended September 30, 2023, that was included in the contract liabilities balances as of January 1, 2023, was approximately $4.6 million.

4. Fair Value Measurements

The Company believes the fair value using Level 2 inputs of the borrowings under the EB-5 Loan Agreement (as defined in Note 8) approximate their carrying value.

5. Property and Equipment

The following table provides a summary of the major components of property and equipment as reflected on the condensed consolidated balance sheets (in thousands):

	September 30, 2024	December 31, 2023
Furniture and fixtures	$ 433	$ 337
Machinery and equipment	3,179	1,557
Leasehold improvements	16,089	2,086
Construction in progress	—	14,540
Total property and equipment	19,701	18,520
Less: accumulated depreciation	(2,571)	(1,230)
Total property and equipment, net	$ 17,130	$ 17,290

6. Operating Leases

The Company has commitments under operating leases for office, laboratory, and manufacturing space in Malvern, Pennsylvania and other locations. The Company's corporate headquarters, located in Malvern, Pennsylvania, lease has an initial term of approximately seven years and includes options to extend the lease for up to 10 years, which the Company has not

elected to account for since it is not reasonably certain that the Company will exercise such option. The Company's current GMP facility, located in Malvern, Pennsylvania, lease has an initial term of seven years and includes an option to extend the lease for up to five years, which the Company has elected to account for since it is reasonably certain that the Company will exercise such option. The Company leases three other general use facilities, within the United States, which have initial terms of two to three years and contain no option to extend.

The Company's future minimum base rent payments are approximately as follows (in thousands):

For the years ending December 31,	Amount
Remainder of 2024	$ 208
2025	845
2026	869
2027	867
2028	884
2029	705
Thereafter	$ 978
Total	$ 5,356
Less: present value adjustment	(1,460)
Present value of minimum lease payments	$ 3,896

7. Accrued Expenses and Other Current Liabilities

The following table provides a summary of the major components of accrued expenses and other current liabilities as reflected on the condensed consolidated balance sheets (in thousands):

	September 30, 2024	December 31, 2023
Research and development	$ 155	$ 212
Clinical	892	84
Professional fees	724	580
Employee-related	2,040	1,791
Deferred revenue relating to collaborative arrangements	8,119	10,525
Other	545	151
Total accrued expenses and other current liabilities	$ 12,475	$ 13,343

8. Debt

In September 2016, in connection with the U.S. government's foreign national investor program, commonly known as the EB-5 Program, the Company entered into a financing arrangement (the "EB-5 Loan Agreement") which provided for cumulative borrowings of up to $10.0 million from EB5 Life Sciences, L.P. ("EB-5 Life Sciences") as the lender. Pursuant to the EB-5 Loan Agreement, borrowings were made in $0.5 million increments with a fixed interest rate of 4% per annum (the "Original Offering"). The borrowings pursuant to the Original Offering are secured by substantially all of the Company's assets, with the exception of any patents, patent applications, pending patents, patent licenses, patent sublicenses, trademarks, and other intellectual property rights held by the Company.

Under the terms and conditions of the Original Offering, the Company borrowed $1.0 million during 2016, $0.5 million during 2020, $0.5 million in September 2022, and an additional $0.5 million in May 2023. Issuance costs were recognized as a reduction to the loan balance and are amortized to interest expense over the term of each borrowing. Pursuant to the Original Offering, each outstanding borrowing, including accrued interest, becomes due upon the seventh anniversary of its disbursement date, subject to certain extension provisions. In January 2024, the Company entered into an agreement to extend the current portion of borrowings owed under the EB-5 Loan Agreement to March 2025. Once repaid, amounts cannot be re-drawn.

The March 2022 EB-5 Reform and Integrity Act of 2022 (the "RIA") enacted changes to the EB-5 Program, including but not limited to: raising the minimum investment amount for a targeted employment area (the "TEA") from its previous level of $0.5 million to its new level of $0.8 million, as well as modifying the process for the creation of TEAs. Under the previous regime, the state in which the TEA would be located could send a letter in support of efforts to designate a TEA. Under the current regime, only U.S. Citizenship and Immigration Services can designate TEAs.

In connection with the aforementioned changes to the EB-5 Program, the Original Offering was amended in May 2023 (the "Amended Offering"). Pursuant to the terms and conditions of the Amended Offering, EB-5 Life Sciences now provides for cumulative borrowings of up to $20.0 million. Future borrowings can be made in increments of $0.8 million with a fixed interest rate of 4.0% per annum. Each future borrowing pursuant to the Amended Offering, including accrued interest, will become due upon the seventh anniversary of its disbursement date. The Company has not made any borrowings pursuant to the Amended Offering as of September 30, 2024.

The carrying values of the borrowings pursuant to the Original Offering as of September 30, 2024 and December 31, 2023 are summarized below (in thousands):

	September 30, 2024	December 31, 2023
Principal outstanding	$ 2,500	$ 2,500
Plus: accrued interest	475	400
Less: unamortized debt issuance costs	(88)	(100)
Carrying value, net	2,887	2,800
Less: current portion of long term debt	(1,316)	—
Long term debt, net of current portion	$ 1,571	$ 2,800

9. Equity

Offerings of Common Stock

Public Offering

In July 2024, the Company entered into an underwriting agreement with an underwriter, pursuant to which the Company agreed to issue and sell to the underwriter in a public offering (the "July 2024 Public Offering") 30.4 million shares of its common stock, par value $0.01 per share, at a public offering price of $1.15 per share (the "Offering Price"). Pursuant to the terms of the underwriting agreement, the Company granted to the underwriter a 30-day option to purchase up to an additional 4,565,217 shares of common stock at the offering price (the "Option Shares") at the public offering price, less underwriting discounts and commissions. The offering closed in August 2024. The net proceeds to the Company from the offering, excluding any exercise by the underwriter of its 30-day option to purchase any of the option shares, were $32.3 million after deducting the underwriting discounts and commissions and offering expenses paid to the Company. The July 2024 Public Offering was made pursuant to the Company's Registration Statement on Form S-3, which was previously filed with the SEC and became effective on May 1, 2024. In August 2024, the underwriter exercised their option to purchase 2,282,608 Option Shares at the Offering Price. The net proceeds to the Company from the exercise of the underwriter's option were $2.4 million after deducting the underwriting discounts and commissions and offering expenses paid to the Company.

Increase in Capital Stock

In July 2024, the Company's certificate of incorporation was amended to increase the total number of shares of all classes of stock the Company has authority to issue to four hundred million shares. This consists of three hundred ninety million shares of Common Stock, par value $0.01 per share (the "Common Stock"), and ten million shares of Preferred Stock, par value $0.01 per share ("the Preferred Stock").

COVAXIN Stock Purchase Agreement

On March 1, 2021, the Company entered into a stock purchase agreement (the "Stock Purchase Agreement") with Bharat Biotech International Limited ("Bharat Biotech"), pursuant to which the Company agreed to issue and sell 0.1 million shares of the Company's Series B Convertible Preferred Stock, par value $0.01 per share (the "Series B Convertible Preferred Stock"), at a price per share equal to $109.60, to Bharat Biotech. On March 18, 2021, the Company issued the Series B Convertible

Preferred Stock as an advance payment of $6.0 million for the supply of COVAXIN, a monovalent vaccine, to be provided by Bharat Biotech pursuant to a Development and Commercial Supply Agreement (the "Supply Agreement").

Each share of Series B Convertible Preferred Stock was convertible, at the option of Bharat Biotech, into 10 shares of the Company's common stock (the "Conversion Ratio") only after (i) the Company received stockholder approval to increase the number of authorized shares of common stock under its Sixth Amended and Restated Certificate of Incorporation, which the Company received in April 2021, and (ii) the Company's receipt of shipments by Bharat Biotech of the first 10.0 million doses of COVAXIN manufactured by Bharat Biotech pursuant to the Supply Agreement, and further on the terms and subject to the conditions set forth in the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock. The conversion rate of the Series B Convertible Preferred Stock was subject to adjustment in the event of a stock dividend, stock split, reclassification, or similar event with respect to the Company's common stock. In May 2024, Bharat Biotech and the Company entered into a Stock Forfeiture Agreement whereby the outstanding shares of Series B Convertible Preferred Stock were redeemed.

The Company accounted for the issuance of the Series B Convertible Preferred Stock in accordance with ASC 718 and recorded its grant date fair value of $5.0 million within stockholders' equity during the year ended December 31, 2021, with a corresponding short-term asset for the advanced payment for the supply of COVAXIN included in prepaid expenses and other current assets in the consolidated balance sheet as of December 31, 2021. The Company utilized the traded common stock price, adjusted by the Conversion Ratio, to value the Series B Convertible Preferred Stock and the Finnerty model to estimate a 15% discount rate for the lack of marketability of the instrument. The valuation incorporated Level 3 inputs in the fair value hierarchy, including the estimated time until the instrument's liquidity and estimated volatility of the Company's common stock as of the grant date. As of December 31, 2022, the remaining balance of the short-term asset for the advanced payment for the supply of COVAXIN was $4.1 million.

In April 2023, the FDA announced the cancellation of all emergency use authorizations ("EUA") issued with respect to monovalent COVID-19 vaccine formulations. Consequently, the Company determined it was no longer commercially viable to further the development of COVAXIN in its North American territories. During the three and nine months ended September 30, 2023, the Company wrote off the remaining balance of the short-term asset for the advanced payment for the supply of COVAXIN of $4.1 million to research and development expense in the condensed consolidated statements of operations and comprehensive loss. As referenced above, in May 2024, the outstanding shares of Series B Convertible Preferred Stock were reacquired.

10. Warrants

Beginning in 2016, the Company issued warrants to purchase common stock. As of September 30, 2024 and December 31, 2023, 0.6 million warrants were outstanding. As of September 30, 2024, the outstanding warrants had a weighted average exercise price of $6.23 per share and expire between 2026 and 2027.

11. Stock-Based Compensation

Stock-based compensation expense for stock options, RSUs and PSUs is reflected in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
General and administrative	$ 1,315	$ 1,639	$ 3,965	$ 5,578
Research and development	577	535	1,586	1,917
Total	$ 1,892	$ 2,174	$ 5,551	$ 7,495

As of September 30, 2024, the Company had $7.2 million of unrecognized stock-based compensation expense related to stock options, RSUs and PSUs outstanding, which is expected to be recognized over a weighted-average period of 1.6 years.

Equity Plans

The Company maintains two equity compensation plans, the 2014 Ocugen OpCo, Inc. Stock Option Plan (the "2014 Plan") and the Ocugen, Inc. 2019 Equity Incentive Plan (the "2019 Plan", collectively with the 2014 Plan, the "Plans"). On the first business day of each fiscal year, pursuant to the "Evergreen" provision of the 2019 Plan, the aggregate number of shares that

may be issued under the 2019 Plan will automatically increase by a number equal to the lesser of 4% of the total number of shares of the Company's common stock outstanding on December 31st of the prior year, or a number of shares determined by the Board of Directors. As of September 30, 2024, the 2014 Plan and the 2019 Plan authorize for the granting of up to 0.8 million and 38.6 million equity awards in respect to the Company's common stock, respectively. The 2014 Plan and 2019 Plan have 0.5 million and 16.1 million equity awards remaining available for future grant, respectively, as of September 30, 2024. In addition to stock options, PSUs and RSUs granted under the Plans, the Company has granted certain stock options and RSUs as material inducements to employment in accordance with Nasdaq Listing Rule 5635 (c)(4), which were granted outside of the Plans.

Stock Options to Purchase Common Stock

The following table summarizes the Company's stock option activity:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (In Thousands)
Options outstanding at December 31, 2023	13,161,228	$ 2.38	7.86	$ 337
Granted	3,965,725	0.96		
Exercised	(284,788)	0.57		183
Forfeited	(677,354)	3.71		
Options outstanding at September 30, 2024	16,164,811	$ 2.01	7.7	$ 1,949
Vested and expected to vest at September 30, 2024	16,164,811	$ 2.01	7.7	$ 1,949
Options exercisable at September 30, 2024	9,602,087	$ 2.40	6.8	$ 1,072

The weighted average grant date fair values of stock options granted during the three and nine months ended September 30, 2024 were $1.19 and $0.81, respectively. The weighted average grant date fair values of stock options granted during the three and nine months ended September 30, 2023 were $0.41 and $0.87, respectively. The total fair value of stock options vested during the three and nine months ended September 30, 2024 were $0.2 million and $6.0 million, respectively. The total fair values of stock options vested during the three and nine months ended September 30, 2023 were $0.4 and $8.5 million, respectively.

RSUs

The following table summarizes the Company's unvested RSU activity:

	Number of Shares	Weighted Average Grant Date Fair Value
RSUs unvested at December 31, 2023	2,982,661	$ 1.63
Granted	39,738	$ 0.51
Vested	(994,042)	$ 1.94
Forfeited	(56,405)	$ 1.64
RSUs unvested at September 30, 2024	1,971,952	$ 1.46

PSUs

In December 2023, pursuant to the 2019 Plan, the Compensation Committee of the Company's Board of Directors adopted a performance restricted stock unit agreement (the "PSU Agreement"). Pursuant to the PSU Agreement, the Company granted 615,467 and 256,885 of market-based performance stock units at target on January 2, 2024 and April 16, 2024, respectively. All of these PSUs cliff vest after the requisite service period ending on December 31, 2026. The PSUs have the potential to be earned at between 0% and 200% of the number of awards granted depending on the level of growth of the Company's total

shareholder return ("TSR") as compared to the TSR of the companies within the Nasdaq Biotechnology Index over the performance period. The fair value of the market-based PSUs was determined using a Monte Carlo simulation technique.

The following table summarizes the unvested PSU activity:

	Number of Shares	Weighted Average Grant-Date Fair Value
PSUs unvested at December 31, 2023	—	$ —
Granted	872,352	$ 1.71
Vested	—	$ —
Forfeited	—	$ —
PSUs unvested at September 30, 2024	872,352	$ 1.71

12. Net Loss Per Share of Common Stock

The following table sets forth the computation of basic and diluted net loss per share for the three and nine months ended September 30, 2024 and 2023 (in thousands, except share and per share amounts). For purposes of earnings per share, the Series B Convertible Preferred shares have the same characteristics as common stock and have no liquidation or other material preferential rights over common stock and accordingly, have been considered as a second class of common stock in the computation of net loss per share regardless of their legal form. Losses are allocated between the common shares and the Series B Convertible Preferred Stock on a pro rata basis as they share equally in losses and residual net assets on an as-converted basis.

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Net loss attributable to common shareholders— basic and diluted	(12,970)	(11,717)	(40,128)	(52,108)
Weighted shares used in calculating net loss per common share — basic and diluted	278,171,593	256,492,558	264,303,494	240,222,667
Net loss per share attributable to common shareholders — basic and diluted	$ (0.05)	$ (0.05)	$ (0.15)	$ (0.22)
Net loss attributable to Series B Convertible Preferred shareholders — basic and diluted	—	—	(46)	—
Weighted shares used in calculating net loss per Series B Convertible Preferred Stock — basic and diluted	—	—	54,745	—
Net loss per share attributable to Series B Convertible Preferred shareholders — basic and diluted	$ —	$ —	$ (0.84)	$ —

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding, as their inclusion would have been antidilutive:

	Three months and nine months ended September 30,	
	2024	2023
Stock options to purchase common stock	16,164,811	13,576,038
RSUs	1,971,952	3,033,328
PSUs	872,352	—
Warrants	628,725	628,834
Series B Convertible Preferred Stock (as converted to common stock)	—	547,450
Total	19,637,840	17,785,650

13. Commitments and Contingencies

Commitments

The Company has commitments under certain license and development agreements, lease agreements, commitments related to renovating an existing facility for GMP, and debt agreements. Commitments under certain license and development agreements include annual payments, payments upon the achievement of certain milestones, and royalty payments based on net sales of licensed products (commitments under the Company's license and development agreements are more fully described within the Company's 2023 Annual Report). Commitments under lease agreements are future minimum lease payments (see Note 6). Commitments under debt agreements are the future payment of principal and accrued interest under the EB-5 Loan Agreement (see Note 8). Additionally, the Company does not expect to fulfill any commitments under the amended Co-Development, Supply and Commercialization Agreement (the "Covaxin Agreement") with Bharat Biotech as a result of the termination of the COVAXIN program.

Contingencies

In June 2021, a securities class action lawsuit was filed against the Company and certain of its agents in the U.S. District Court for the Eastern District of Pennsylvania ("Court") (Case No. 2:21-cv-02725) that purported to state a claim for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, based on statements made by the Company concerning the announcement of the Company's decision to pursue the submission of a Biologics License Application ("BLA") for COVAXIN for adults ages 18 years and older rather than pursuing an EUA. In July 2021, a second securities class action lawsuit was filed against the Company and certain of its agents in the Court (Case No. 2:21-cv-03182) that also purported to state a claim for alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, based on the same statements as the first complaint. In March 2022, the Court consolidated these two related securities class action lawsuits and appointed a lead plaintiff. In March 2024, the Third Circuit affirmed the Court's decision to dismiss with prejudice the consolidated securities class action lawsuits.

In August 2021, a stockholder derivative lawsuit was filed derivatively on behalf of the Company against certain of its agents and the nominal defendant Ocugen in the Court (Case No. 2:21-cv-03876) that purported to state a claim for breach of fiduciary duty and contribution for violations of Sections 10(b) and 21(d) of the Exchange Act, based on facts and circumstances relating to the securities class action lawsuits and seeking contribution and indemnification in connection with claims asserted in the securities class action lawsuits. In September 2021, a second stockholder derivative lawsuit was filed derivatively on behalf of the Company against certain of its agents and the nominal defendant Ocugen in the Court (Case No. 2:21-cv-04169) that purported to state a claim for breach of fiduciary duties, unjust enrichment, abuse of control, waste of corporate assets, and contribution for violations of Sections 10(b) and 21(d) of the Exchange Act, based on the same allegations as the first complaint. The parties to both stockholder derivative lawsuits stipulated to the consolidation of the two stockholder derivative lawsuits. In April 2024, the Court dismissed without prejudice the consolidated stockholder derivative lawsuits.

In April 2024, a securities class action lawsuit was filed against the Company and certain of its agents in the Court (Case No. 2:24-cv-01500) that purported to state a claim for alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, based on statements made by the Company concerning the Company's previously-issued audited consolidated financial statements for each fiscal year beginning January 1, 2020 and its previously-issued unaudited condensed consolidated financial statements for each of the first three quarters in such years and the effectiveness of the Company's disclosure controls and procedures during each such period. The complaint seeks unspecified damages, interest, attorneys' fees, and other costs. In October 2024, the lead plaintiff filed an amended complaint, and the Company intends to file a motion to dismiss by December 6, 2024.

In May 2024, a stockholder derivative lawsuit was filed on behalf of the Company against certain of its agents and the nominal defendant Ocugen in the Court (Case No. 2:24-cv-02234) that purported to state a claim for breach of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations of Section 14(a) of the Exchange Act, and contribution for violations of Sections 10(b) and 21(d) of the Exchange Act, based on the facts and circumstances relating to the securities class action and seeking damages and certain governance reforms in connection with claims asserted in the securities class action. In June 2024, the Court approved the parties' joint stipulation for an order staying the derivative lawsuit pending resolution of a motion to dismiss in the related securities class action. In the third quarter of 2024, four additional stockholder derivative lawsuits were filed on behalf of the Company against certain of its agents and the nominal defendant Ocugen in the Court (Case Nos. 2:24-cv-03119, 2:24-cv-03209, 2:24-cv-04813, 2:24-cv-04864) asserting similar facts and claims as the first complaint.

The Company believes that the lawsuits are without merit and intends to vigorously defend against them. At this time, no assessment can be made as to their likely outcome or whether the outcome will be material to the Company. No information is available to indicate that it is probable that a loss has been incurred and can be reasonably estimated as of the date of the condensed consolidated financial statements and, as such, no accrual for the loss has been recorded within the condensed consolidated financial statements.

14. Subsequent Event

Subsequent to September 30, 2024, the Company entered into a debt financing transaction with Avenue Capital for net proceeds of $29.2 million. The loan has a maturity date of November 1, 2028, of which the first 24 months are interest only, and bears interest at a variable rate per annum equal to the greater of the Prime Rate plus 4.25% or 12.25%. Additionally, the Lender has the right to convert an aggregate amount of up to $6.0 million of the outstanding principal amount into shares of Common Stock at a conversion price per share equal to a 80% of the trading price on the date of conversion, which shall be at Lenders' option. In the event the Company elects to prepay the Term Loans in full, Lenders shall have 10 days to elect to exercise its conversion right prior to such prepayment. All conversion rights shall terminate on Term Loans payoff. Notwithstanding the foregoing, the aggregate amount of Common Stock issued pursuant to the "Conversion Right" and the "Equity Grant" shall not exceed a number of shares equal to 19.9% of the Company's outstanding Common Stock. The agreement is collateralized by all of the Company's assets in which the agent is granted senior secured lien. The Company also grants the Lenders a negative pledge on the Company's intellectual property. In connection with the debt financing transaction, the Company entered into a Subscription Agreement with Avenue Capital, pursuant to which the Company issued 1,056,338 shares of Common Stock to Avenue Capital with an issue date of November 6, 2024.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements for the year ended December 31, 2023, included in our 2023 Annual Report. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and related financing, include forward-looking statements that involve risks, uncertainties, and assumptions. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. Except as required by law, we undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events, or otherwise. You should read the "Risk Factors" section included in our 2023 Annual Report, 2024 Quarterly Reports, and the "Risk Factors" and "Disclosure Regarding Forward-Looking Statements" sections of this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies and vaccines that improve health and offer hope for patients across the globe.

Our technology pipeline includes:

- **Modifier Gene Therapy Platform** — Based on the use of nuclear hormone receptors ("NHRs"), we believe our modifier gene therapy platform has the potential to address many retinal diseases, including rare genetic diseases such as retinitis pigmentosa ("RP") (OCU400) and Leber congenital amaurosis ("LCA") (OCU400), with a gene-agnostic approach. We also believe our modifier gene therapy platform has the potential to address multifactorial retinal diseases including dry age-related macular degeneration ("dAMD") using OCU410, which affects millions of patients in the United States alone, and Stargardt disease (OCU410ST), which is a rare genetic disease. We are actively dosing patients in the U.S. in a Phase 3 liMeliGhT clinical trial for OCU400 for the treatment of RP. We also received approval from Health Canada to initiate a Phase 3 trial for OCU400 for the treatment of RP. In August 2024, we received approval from the FDA to begin our expanded access program (EAP) for the treatment of adult patients, aged 18 or older, with RP. After completion of a Phase 1/2 trial for OCU400 for the treatment of LCA, we will discuss alignment for Phase 3 strategy with the FDA. OCU410 is currently dosing in Phase 2 of the ArMaDa Phase 1/2 clinical trial for the treatment of geographic atrophy ("GA"), an advanced form of dAMD. Additionally, OCU410ST, has completed Phase 1 of the GARDian Phase 1/2 clinical trial for the treatment of Stargardt disease. Both OCU410 and OCU410ST studies have completed the low, medium, and high dose cohorts in the Phase 1 part of the Phase 1/2 trials to date.
- **Novel Biologic Therapy for Retinal Diseases** — OCU200 is a novel fusion protein consisting of two human proteins, tumstatin and transferrin. OCU200 possesses unique features which potentially enable it to treat vascular complications of diabetic macular edema ("DME"), diabetic retinopathy ("DR"), and wet age related macular degeneration ("AMD"). Tumstatin is the active component of OCU200 and binds to integrin receptors, which play a crucial role in disease pathogenesis. Transferrin is expected to facilitate the targeted delivery of tumstatin into the retina and choroid and potentially help increase the interaction between tumstatin and integrin receptors. In October 2024, we announced that the FDA cleared the investigational new drug application for the Phase 1 clinical trial for OCU200. We expect initiation of the OCU200 clinical trial in the fourth quarter of 2024.
- **Regenerative Cell Therapy Platform** — Our Phase 3-ready regenerative cell therapy platform technology, which includes NeoCart (autologous chondrocyte-derived neocartilage), is being developed for the repair of knee cartilage injuries in adults. We received concurrence from the FDA on the confirmatory Phase 3 trial design and have completed renovating an existing facility into a current Good Manufacturing Practice ("cGMP") facility to support clinical study and initial commercial launch. This facility is needed to generate patient-specific NeoCart implant from chondrocytes derived from knee biopsy. We intend to initiate the Phase 3 trial contingent on adequate availability of funding.
- **Inhaled Mucosal Vaccine Platform** — Our next-generation, inhaled mucosal vaccine platform includes OCU500, a COVID-19 vaccine; OCU510, a seasonal quadrivalent flu vaccine; and OCU520, a combination quadrivalent seasonal flu and COVID-19 vaccine. We have completed IND-enabling studies and GMP manufacturing of clinical trial material for OCU500. We are currently collaborating with the National Institute of Allergy and Infectious Diseases ("NIAID") for early clinical studies for OCU500. NIAID intends to initiate a Phase 1 clinical trial after IND clearance. We are continuing discussions with relevant government agencies as well as strategic partners regarding developmental funding for our OCU510 and OCU520 platforms.

Modifier Gene Therapy Platform

We are developing a modifier gene therapy platform designed to fulfill unmet medical needs related to retinal diseases, including inherited retinal diseases ("IRDs"), such as RP, LCA, Stargardt disease; and multifactorial diseases such as dAMD. Our modifier gene therapy platform is based on the use of NHRs, which have the potential to achieve homeostasis — the basic biological processes in the retina to restore a healthy state from a diseased state. Unlike single gene replacement therapies, which only target one genetic mutation, our modifier gene therapy platform, through its use of NHRs, represents a unique, gene-agnostic approach to address not just the mutated gene but provide a molecular "reset" of health and survival of gene networks. OCU400, our lead product candidate in our modifier gene therapy platform, has received Orphan Drug Designation ("ODD") from the FDA for RP and LCA, a regenerative medicine advanced therapy ("RMAT") designation for the treatment of RP associated with *NR2E3* and rhodopsin ("*RHO")* mutations from the FDA, and Orphan Medicinal Product Designation ("OMPD") from the European Commission ("EC"), based on the recommendation of the European Medicines Agency ("EMA"), for RP and LCA. These broad ODD, RMAT, and OMPD designations further support the broad (gene-agnostic) therapeutic potential of OCU400 to treat multiple IRDs such as RP and LCA associated with mutations in multiple genes.

We completed enrolling, dosing, and recruiting RP and LCA patients in the Phase 1/2 trial for OCU400. The objective of this study was to assess the safety and efficacy of unilateral subretinal administration of OCU400 in *NR2E3* and rhodopsin ("*RHO")*-related RP patients and centrosomal protein 290 ("*CEP290")*-related LCA patients in the United States.

In February 2024, in continuation of the preliminary analyses update, we announced an update for 18 participants. The trial update was an extension of the positive preliminary data from September 2023. The positive trial update demonstrated that OCU400 continued to be generally safe and well-tolerated in subjects across different mutations and dose levels. 89% of participants demonstrated preservation or improvement in OCU400 treated eyes either on best corrected visual acuity ("BCVA") or low-luminance visual acuity ("LLVA") or multi-luminance mobility test ("MLMT") scores from baseline. 78% of participants demonstrated stabilization or improvement in OCU400 treated eyes in MLMT scores from baseline. 80% of *RHO* mutation subjects experienced either stabilization or increase in MLMT scores from baseline.

In April 2024, the FDA cleared our IND amendment to initiate a Phase 3 liMeliGhT clinical trial of OCU400 for RP. OCU400 is the first gene therapy program to enter Phase 3 with a broad RP indication. This Phase 3 trial will enroll 150 subjects, distributed 1:1 into two separate arms (RHO: N=75, and Gene Agnostic: N=75). In each arm subjects will be further randomized into 2:1 ratio to treated and untreated control groups. Subjects will be followed for a year after dosing for primary end point analyses. In the Phase 1/2 OCU400 clinical trial a MLMT scale was the primary functional endpoint. For the Phase 3 OCU400 clinical trial, an updated mobility course will be used, Luminance Dependent Navigation Assessment ("LDNA") that includes a wider range of light intensity (0.04-500 Lux) and Lux Levels (0-9) with a uniform correlation between Lux level and Lux intensity. More than 60% of intent-to-treat (ITT) patients from the Phase 1/2 clinical trial (*RHO* and *NR2E3*) meet the responder criteria (Responder ≥ 2 Lux level improvement) for Phase 3.

In April 2024, the Committee for Medicinal Products for Human Use (CHMP) of the EMA reviewed the study design, endpoints and planned statistical analysis of the pivotal OCU400 Phase 3 liMeliGhT clinical trial for RP and provided acceptability of the U.S.-based trial for submission of a Marketing Authorization Application (MAA). The EMA provided this opinion based on safety, tolerability, and efficacy of OCU400 demonstrated in the Phase 1/2 study.

In June 2024, the first patient was dosed in the Phase 3 clinical trial for OCU400 for the treatment of RP. The Phase 3 clinical trial is on track to complete enrollment in the first half of 2025, file the Biologics License Application ("BLA") and MAA in the first half of 2026, and pursue commercialization in 2027. After completion of Phase 1/2 for OCU400 for the treatment of LCA, we will discuss alignment for Phase 3 strategy with the FDA.

In August 2024, we received notification from the FDA to begin our EAP for the treatment of adult patients with RP with OCU400. This program is available for patients with early, intermediate to advanced RP with at least minimal retinal preservation who may benefit from the mechanism of action of OCU400 prior to approval of the BLA.

We also received approval from Health Canada to initiate a Phase 3 trial for OCU400 for the treatment of RP. The Health Canada trial will run in parallel with the U.S. FDA trial, expediting the ability to potentially provide a gene-agnostic treatment option to approximately 110,000 patients in the United States and Canada.

OCU410 and OCU410ST are being developed utilizing the nuclear receptor gene RAR-related orphan receptor A ("*RORA")*, for the treatment of GA secondary to dAMD and Stargardt disease, respectively. OCU410 is a potential one-time, curative therapy with a single sub-retinal injection. OCU410 targets multiple pathways associated with AMD pathogenesis, in contrast to products currently approved or under development that treat only one cause of GA, require multiple injections per year, and

have safety considerations. OCU410ST has received ODD from the FDA for the treatment of *ABCA4*-associated retinopathies, including Stargardt disease.

OCU410 is currently dosing in Phase 2 of the Phase 1/2 ArMaDa clinical trial. OCU410ST has completed Phase 1, and the DSMB approved enrollment for the second phase of the Phase 1/2 GARDian clinical trial.

Phase 2 of the OCU410 ArMaDa clinical trial is a randomized expansion phase in which subjects will be randomized in a 1:1:1 ratio to either one of two OCU410 dose groups or to an untreated control group. We plan to complete dosing in the Phase 1/2 ArMaDa clinical trial by early 2025.

In November 2023, the first patient was dosed in the Phase 1/2 trial to assess the safety and efficacy of OCU410ST for Stargardt disease. Phase 1 is a multicenter, open-label, dose ranging study. Phase 2 will be a randomized, outcome accessor-blinded, dose-expansion study in which adult and pediatric subjects will be randomized in a 1:1:1 ratio to either one of two OCU410ST dose groups or to an untreated control group. In August 2024, we announced the high dose was complete in the third cohort of Phase 1/2 study. In October 2024, we announced that the DSMB approved proceeding to Phase 2 using high and medium doses.

Novel Biologic Therapy for Retinal Diseases

We are developing OCU200, which is a novel fusion protein containing parts of human transferrin and tumstatin. OCU200 is designed to treat DME, DR, and wet AMD. We have completed the technology transfer of manufacturing processes to our contract development and manufacturing organization ("CDMO") and have produced trial materials to initiate a Phase 1 trial. In April 2023, the FDA placed our IND application to initiate a Phase 1 trial targeting DME on clinical hold, as part of the FDA's request for additional information related to CMC. In October 2024, we announced that the FDA lifted the clinical hold on our IND application for the Phase 1 clinical trial for OCU200. We expect initiation of the OCU200 clinical trial in the fourth quarter of 2024.

Regenerative Cell Therapy Platform

NeoCart is a Phase 3-ready, regenerative cell therapy technology that combines breakthroughs in bioengineering and cell processing to enhance the autologous cartilage repair process. NeoCart is a three-dimensional tissue-engineered disc of new cartilage that is manufactured by growing the patient's own chondrocytes, the cells responsible for maintaining cartilage health. Current surgical and nonsurgical treatment options for knee cartilage injuries in adults are limited in their efficacy and durability. In prior clinical studies, Phase 2 and Phase 3, NeoCart has shown potential to accelerate healing, reduce pain, and provide regenerative native-like cartilage strength with durable benefits post transplantation. NeoCart was shown to be generally well-tolerated and demonstrated greater clinical efficacy than microfracture surgery at two years after treatment. Based on this clinical benefit, the FDA granted a RMAT designation to NeoCart for the repair of full-thickness lesions of knee cartilage injuries in adults. Additionally, we received concurrence from the FDA on the confirmatory Phase 3 trial design where chondroplasty will be used as a control group. We have completed renovating an existing facility into a cGMP facility in accordance with the FDA's regulations in support of NeoCart manufacturing for personalized Phase 3 trial material. We intend to initiate the Phase 3 trial contingent on adequate availability of funding.

Inhaled Mucosal Vaccine Platform

We are party to an exclusive license agreement (as amended, "WU License Agreement") with The Washington University in St. Louis ("Washington University"), pursuant to which we licensed the rights to develop, manufacture, and commercialize an inhaled mucosal COVID-19 vaccine for the prevention of COVID-19 in the United States, Europe, Japan, South Korea, Australia, China, and Hong Kong (the "Mucosal Vaccine Territory"). In addition, we internally developed technology related to the flu and COVID-19's vaccine design and filed intellectual property. We are developing a next-generation, inhalation-based mucosal vaccine platform based on a novel ChAd vector, which includes OCU500, a COVID-19 vaccine; OCU510, a seasonal quadrivalent flu vaccine; and OCU520, a combination quadrivalent seasonal flu and COVID-19 vaccine. Our inhaled mucosal vaccine platform is driven by our conviction to serve a major public health concern, which requires the endorsement and support of government funding in order to develop and ultimately commercialize our vaccine candidates. As these vaccine candidates are being developed to be administered via inhalation, we believe they have the potential to generate rapid local immune response in the upper airways and lungs, where viruses enter and infect the body. We believe this novel delivery route may help reduce or prevent infection and transmission as well as provide protection against new virus variants. In October 2023, OCU500 was selected by the NIAID Project NextGen for inclusion in clinical trials. OCU500 will be tested via two different mucosal routes, inhalation and intranasal delivery. NIAID intends to initiate a Phase 1 clinical trial after IND

clearance. We are continuing discussions with relevant government agencies as well as strategic partners regarding developmental funding for our OCU510 and OCU520 platforms.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table summarizes the results of our operations for the three months ended September 30, 2024 and 2023 (in thousands):

	Three months ended September 30,		
	2024	2023	Change
Collaborative arrangement revenue	$ 1,136	$ 3,699	$ (2,563)
Total Revenue	1,136	3,699	(2,563)
Operating expenses			
Research and development	8,108	7,048	1,060
General and administrative	6,280	9,082	(2,802)
Total operating expenses	14,388	16,130	(1,742)
Loss from operations	(13,252)	(12,431)	(821)
Other income (expense), net	282	714	(432)
Net loss	$ (12,970)	$ (11,717)	$ (1,253)

We believe the following table provides more transparency as to the type of research and development expenses incurred. The following table summarizes our research and development expenses by product candidate for the three months ended September 30, 2024 and 2023 (in thousands):

	Three months ended September 30,		
	2024	2023	Change
OCU400	$ 1,492	$ 1,334	$ 158
OCU410 and OCU410ST	759	884	(125)
NeoCart	104	194	(90)
COVAXIN	(65)	452	(517)
Inhaled mucosal vaccine platform	664	36	628
OCU200	48	238	(190)
Unallocated costs:			
Research and development personnel costs	3,745	3,209	536
Facilities and other support costs	791	338	453
Other	570	363	207
Total research and development	$ 8,108	$ 7,048	$ 1,060

Collaborative arrangement revenue

Collaborative arrangement revenue decreased by $2.6 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. The decrease was due to our quarterly reassessment of the amount of co-development services provided by us to the business partner in the collaboration agreement.

Research and development expense

Research and development expense increased by $1.1 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. The increase was primarily due to $0.6 million related to OCU500, which is driven by an increase in preclinical activities and GMP manufacturing of Phase 1 clinical trial material; $0.5 million in employee-related expenses; $0.5 million primarily driven by an increase in depreciation expense. These increases were partially offset by a decrease of $0.5 million related to the termination of the COVAXIN program; $0.2 million related to OCU200, which is driven by a decrease in preclinical activities.

General and administrative expense

General and administrative expense decreased by $2.8 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. The decrease was primarily due to $2.2 million in professional services fees and $0.6 million related to reduced headcount.

Other income (expense), net

Other income (expense), net decreased by $0.4 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. The decrease was primarily due to $0.4 million in interest earned on our cash and restricted cash, which had a lower average balance compared to prior year.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table summarizes the results of our operations for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine months ended September 30,		
	2024	2023	Change
Collaboration revenue	$ 3,291	$ 4,627	$ (1,336)
Total revenues	3,291	4,627	(1,336)
Operating expenses			
Research and development	23,836	31,794	(7,958)
General and administrative	20,372	26,839	(6,467)
Total operating expenses	44,208	58,633	(14,425)
Loss from operations	(40,917)	(54,006)	13,089
Other income (expense), net	743	1,898	(1,155)
Net loss	$ (40,174)	$ (52,108)	$ 11,934

We believe the following table provides more transparency as to the type of research and development expenses incurred. The following table summarizes our research and development expenses by product candidate for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine months ended September 30,		
	2024	2023	Change
OCU400	$ 5,190	$ 3,942	$ 1,248
OCU410 and OCU410ST	2,598	3,168	(570)
NeoCart	459	966	(507)
COVAXIN	8	8,719	(8,711)
Inhaled mucosal vaccine platform	2,160	591	1,569
OCU200	324	571	(247)
Unallocated costs:			
Research and development personnel costs	9,590	11,552	(1,962)
Facilities and other support costs	2,168	1,147	1,021
Other	1,339	1,138	201
Total research and development	$ 23,836	$ 31,794	$ (7,958)

Collaborative arrangement revenue

Collaborative arrangement revenue decreased by $1.3 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. The decrease was due to our quarterly reassessment of the amount of co-development services provided by us to the business partner in the collaboration agreement.

Research and development expense

Research and development expense decreased by $8.0 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. The decrease was primarily due to $8.7 million related to the termination of the COVAXIN program and $2.0 million related to reduced headcount. These decreases were partially offset by an increase of $1.6 million related to OCU500, which is driven by an increase in preclinical activities and GMP manufacturing of Phase 1 clinical trial material and $1.2 million related to OCU400, which is driven by an increase in non-cash co-development services provided by our collaboration arrangements business partner.

General and administrative expense

General and administrative expense decreased by $6.5 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. The decrease was primarily due to $3.1 million in professional service fees and $3.1 million related to reduced headcount.

Other income (expense), net

Other income (expense), net decreased by $1.2 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. The decrease was primarily due to $1.1 million in interest earned on our cash and restricted cash, which had a lower average balance compared to prior year.

Liquidity and Capital Resources

As of September 30, 2024, we had $38.7 million in cash. We have not generated revenue from our product candidates to date, and have primarily funded our operations through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes and debt, and grant proceeds. Since our inception and through September 30, 2024, we have raised a gross aggregate of $338.9 million to fund our operations, of which $325.1 million was from gross proceeds from the sale of our common stock and warrants, $10.3 million was from the issuance of convertible notes, $3.3 million was from the issuance of debt, and $0.2 million was from grant proceeds.

Subsequent to September 30, 2024, the Company entered into a debt financing transaction with Avenue Capital for net proceeds of $29.2 million. The loan has a maturity date of November 1, 2028, of which the first 24 months are interest only, and bears interest at a variable rate per annum equal to the greater of the Prime Rate plus 4.25% or 12.25%. Additionally, the Lender has the right to convert an aggregate amount of up to $6.0 million of the outstanding principal amount into shares of Common Stock at a conversion price per share equal to a 80% of the trading price on the date of conversion, which shall be at Lenders' option. In the event the Company elects to prepay the Term Loans in full, Lenders shall have 10 days to elect to exercise its conversion right prior to such prepayment. All conversion rights shall terminate on Term Loans payoff. Notwithstanding the foregoing, the aggregate amount of Common Stock issued pursuant to the “Conversion Right” and the “Equity Grant” shall not exceed a number of shares equal to 19.9% of the Company’s outstanding Common Stock. The agreement is collateralized by all of the Company’s assets in which the agent is granted senior secured lien. The Company also grants the Lenders a negative pledge on the Company’s intellectual property. In connection with the debt financing transaction, the Company entered into a Subscription Agreement with Avenue Capital, pursuant to which the Company issued 1,056,338 shares of Common Stock to Avenue Capital with an issue date of November 6, 2024.

During the three months ended September 30, 2024, we issued and sold 32.7 million shares of our common stock at a public offering price of $1.15 per share pursuant to the July 2024 Public Offering. We received net proceeds of $34.7 million after deducting equity issuance costs.

During the year ended December 31, 2023, we issued and sold 30.0 million shares of our common stock at a public offering price of $0.50 per share pursuant to an underwriting agreement (the "May 2023 Public Offering"). We received net proceeds of $14.8 million after deducting equity issuance costs.

During the year ended December 31, 2023, we sold 4.5 million shares of our common stock under the At Market Issuance Sales Agreement ("Sales Agreement") with certain agents and received net proceeds of $5.6 million after deducting equity issuance costs of $0.2 million. The Sales Agreement was terminated in February 2023.

Since our inception, we have devoted substantial resources to research and development and have incurred significant net losses and may continue to incur net losses in the future. We incurred net losses of approximately $40.2 million and $52.1 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $326.3 million. In addition, we had accounts payable and accrued expenses and other current liabilities of $14.0 million and indebtedness of $2.9 million.

The following table provides a summary of our cash flows for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine months ended September 30,	
	2024	2023
Net cash used in operating activities	$ (31,778)	$ (50,752)
Net cash (used in) provided by investing activities	(3,372)	5,799
Net cash provided by financing activities	34,686	20,865
Effect of changes in exchange rate on cash and restricted cash	3	2
Net (decrease) in cash and restricted cash	$ (461)	$ (24,086)

Operating activities

Cash used in operating activities was $31.8 million for the nine months ended September 30, 2024, and primarily consisted of a net loss of $40.2 million adjusted for non-cash items including stock-based compensation of $5.6 million, depreciation and amortization of $1.4 million, non-cash lease expense of $0.6 million, non-cash expense from collaborative arrangements, net of $2.4 million, other non-cash items of $0.1 million, and a change in net working capital of $3.1 million.

Cash used in operating activities was $50.8 million for the nine months ended September 30, 2023, and primarily consisted of a net loss of $52.1 million adjusted for non-cash items including $4.4 million in expenses related to COVAXIN, due to the impairment of the advanced payment for the supply of COVAXIN as well as the associated loss on the disposal of related fixed assets, stock-based compensation of $7.5 million, non-cash expense from collaborative arrangements, net of $1.1 million, non-cash lease expense of $0.4 million, depreciation and amortization of $0.5 million, other non-cash items of $0.3 million, and a change in net working capital of $10.7 million.

Investing activities

Cash used in investing activities was $3.4 million for the nine months ended September 30, 2024, and primarily consisted of payments related to the purchases of property and equipment. Cash provided by investing activities was $5.8 million for the nine months ended September 30, 2023, and primarily consisted of gross proceeds of $17.5 million from the maturities of marketable securities, classified as available-for-sale, during the nine months ended September 30, 2023, which was partially offset by purchases of $3.9 million of marketable securities, classified as available-for-sale, during the nine months ended September 30, 2023 as well as purchases of $7.8 million of property and equipment during the nine months ended September 30, 2023.

Financing activities

Cash provided by financing activities was $34.7 million for the nine months ended September 30, 2024 compared to cash provided by financing activities of $20.9 million for the nine months ended September 30, 2023. During the nine months ended September 30, 2024, cash provided by financing activities primarily consisted of gross proceeds of $37.6 million received from the July 2024 Public Offering before deducting equity issuance costs of $2.9 million. During the nine months ended September 30, 2023, cash provided financing activities primarily consisted of gross proceeds of $20.8 million received from the May 2023 Public Offering and pursuant to the Sales Agreement.

Contractual Obligations

We have commitments under certain licensing and development agreements, lease obligations, debt agreements, and consulting agreements. There have been no material changes to our contractual obligations as reported in our 2023 Annual Report.

Funding requirements

We expect to continue to incur significant expenses in connection with our ongoing activities, particularly as we continue research and development, including preclinical and clinical development of our product candidates, prepare to manufacture our product candidates, prepare for the potential commercialization of our product candidates, add operational, financial, and information systems to execute our business plan, maintain, expand, and protect our patent portfolio, explore strategic licensing, acquisition, and collaboration opportunities to expand our product candidate pipeline to support our future growth; expand headcount to support our development, commercialization, and business efforts, and operate as a public company.

Factors impacting our future funding requirements include, without limitation, the following:

- the initiation, progress, timing, costs, and results of trials for our product candidates;
- the preparation and submission of Investigational New Drug applications, or INDs, with the FDA for current and future product candidates;
- the outcome, timing, and cost of the regulatory approval process for our product candidates;
- the costs of manufacturing and commercialization;
- the costs related to doing business internationally with respect to the development and commercialization of our product candidates;
- the cost of filing, prosecuting, defending, and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the acquisition of or in-licensing of additional product candidates and technologies;
- the costs of expanding infrastructure to support our development, commercialization, and business efforts, including the costs related to the development of a laboratory and manufacturing facility;
- the costs involved in recruiting and retaining skilled personnel;
- the extent to which we in-license or acquire other products, product candidates, or technologies and out-license our product candidates; and
- the impact of geopolitical turmoil, macroeconomic conditions, social unrest, political instability, terrorism, or other acts of war.

As of September 30, 2024, we had cash of approximately $38.7 million. This amount will not be sufficient to fund our operations over the next 12 months. Due to the inherent uncertainty involved in making estimates and the risks associated with the research, development, and commercialization of biotechnology products, we may have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. Given this uncertainty, and despite the additional funding from the debt transaction with Avenue Capital, we will need to raise significant additional capital in order to fund our operations until we recognize significant revenue from product sales. Our management continues to evaluate different strategies to obtain the funding required for our future operations. These strategies may include, but are not limited to: public and private placements of equity and/or debt, payments from potential strategic research and development arrangements, sales of assets, licensing and/or collaboration arrangements with pharmaceutical companies or other institutions, funding from the government, particularly for the development of our novel inhaled mucosal vaccine platform, or funding from other third parties. Our ability to secure funding is subject to numerous risks and uncertainties, including, but not limited to the impact of the geopolitical turmoil, macroeconomic conditions, and the impact of inflation and as a result, there can be no assurance that these funding efforts will be successful. If we cannot obtain the necessary funding, we will need to delay, scale back, or eliminate some or all of our research and development programs and commercialization efforts; consider other various strategic alternatives, including a merger or sale; or cease operations. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition, and results of operations could be materially adversely affected.

As a result of these factors, together with the anticipated continued spending that will be necessary to continue to research, develop, and commercialize our product candidates, there is substantial doubt about our ability to continue as a going concern within one year after the date that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q are issued.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements 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.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of financial statements in conformity with GAAP requires us to make judgments, estimates, and assumptions in the preparation of our condensed consolidated financial statements. Actual results could differ from those estimates. There have been no material changes to our critical accounting policies and estimates as reported in our 2023 Annual Report.

Recently Adopted Accounting Pronouncements

For a discussion of recently adopted accounting pronouncements, see Note 2 in the notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of September 30, 2024. Based upon this evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are not effective because of a material weakness related to the design and operating effectiveness of controls over the accounting for collaborative arrangements that was disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023. Notwithstanding the identified material weakness, the Company's management, including our principal executive officer and principal financial officer, has concluded the Company's Condensed consolidated financial statements included in this Form 10-Q present fairly, in all material respects, the Company's financial condition, results of operations and cash flows at and for the periods presented in accordance with U.S. generally accepted accounting principles.

Remediation

The Company’s plan to remediate the identified material weakness was previously described in Part II, Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2023. The remediation plan includes improving the design and operation of management's controls over the technical accounting analysis, the determination of the transaction price, calculating the progress towards the satisfaction of the performance obligations under the collaborative arrangements, and determining the value of the non-cash consideration received under collaborative arrangements. Specifically, during the three months ended September 30, 2024, the Company implemented controls to obtain relevant information from third parties on a timely basis, including actual costs incurred, actual noncash consideration received, and estimates to complete and review the accounting for collaborative arrangements during the financial statement close process. The material weakness cannot be considered remediated until the newly designed and implemented controls operate effectively for a sufficient period of time and management has concluded, through testing, that the control is operating effectively.

Changes in Internal Control Over Financial Reporting

The third quarter 2024 remediation activities described above are changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

For a discussion of legal proceedings, see Note 13 in the notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors.

Except as set forth below, there have been no material changes in our risk factors as previously disclosed in our 2023 Annual Report. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, or future results.

The terms of our Loan and Security Agreement with Avenue Capital Management II, L.P. and the lenders listed therein require us to meet certain operating covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

On November 6, 2024, we entered into a Loan and Security Agreement with Avenue Capital Management II, L.P. and related entities (together, "Avenue") (the "Loan and Security Agreement") that is secured by a lien on all of our assets. The Loan and Security Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to protect and maintain our intellectual property and comply with all applicable laws, deliver certain financial reports and maintain insurance coverage. Negative covenants include, among others, covenants restricting us from transferring any part of our business or intellectual property, incurring additional indebtedness, engaging in mergers or acquisitions, repurchasing shares, paying dividends or making other distributions, making investments, and creating other liens on our assets, including our intellectual property, in each case subject to customary exceptions. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. These restrictions may include, among other things, limitations on the incurrence of additional debt and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. If we default under the terms of the Loan and Security Agreement or any future debt facility, Avenue may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we were to be liquidated, Avenue's right to repayment would be senior to the rights of the holders of our common stock. Avenue could declare an event of default upon the occurrence of any event that could reasonably be expected to result in what they interpret as a material adverse effect as defined under the Loan and Security Agreement. Any declaration by Avenue of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

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

During the period covered by this Quarterly Report on Form 10-Q, there were no sales by us of unregistered securities or purchases of equity securities by us that were not previously reported by us in a Current Report on Form 8-K.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the three months ended September 30, 2024, no directors or "officers," as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K.

Item 6. Exhibits.

The exhibits listed below are filed or furnished in this Quarterly Report on Form 10-Q:

	Description
	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
	Certification of the Chief Accounting Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
	Certifications of the Chief Executive Officer and Chief Accounting Officer as required by 18 U.S.C. 1350
	Inline XBRL Instance Document
	Inline XBRL Taxonomy Extension Schema Document
	Inline XBRL Taxonomy Extension Calculation Linkbase Document
	Inline XBRL Taxonomy Extension Definition Linkbase Document
	Inline XBRL Taxonomy Extension Label Linkbase Document
	Inline XBRL Taxonomy Extension Presentation Linkbase Document
	The cover page from this Quarterly Report on Form 10-Q, formatted in Inline XBRL

* Filed herewith.

** Furnished 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.

Ocugen, Inc.

Dated: November 14, 2024

/s/ Shankar Musunuri

Shankar Musunuri, Ph.D., MBA
Chairman, Chief Executive Officer, & Co-Founder
(Principal Executive Officer)

Dated: November 14, 2024

/s/ Ramesh Ramachandran

Ramesh Ramachandran, CPA, MBA, CMA
Chief Accounting Officer
(Principal Financial Officer)