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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, 2023

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 2, 2023, there were 256,502,434 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, 2023

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 February 28, 2023 (the "2022 Annual Report") and (ii) our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023 and June 30, 2023 filed with the SEC on May 5, 2023 and August 21, 2023, respectively (together with this Quarterly Report on Form 10-Q, the "2023 Quarterly Reports"), include, among other things, statements about:

- our estimates regarding expenses, future revenues, 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, including the results from our ongoing Phase 1/2 trial, alignment with the FDA on the Phase 3 study design, and subsequently initiate and complete a Phase 3 trial;
- our ability to obtain 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, OCU400, OCU410, OCU410ST, NeoCart, OCU200, and OCU500, including potential delays in the initiation, enrollment, and completion of current and future clinical trials, including our ability to resolve the FDA's clinical hold on our IND application for OCU200;
- 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;
- the uncertainties in obtaining successful trial results for our product candidates and unexpected costs that may result therefrom;
- 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;
- 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, profitability, 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;
- 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 2022 Annual Report, the 2023 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 2022 Annual Report and in the 2023 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, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 53,477	$ 77,563
Marketable securities	—	13,371
Prepaid expenses and other current assets	3,081	7,558
Total current assets	56,558	98,492
Property and equipment, net	14,469	6,053
Other assets	3,660	4,087
Total assets	$ 74,687	$ 108,632
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,921	$ 8,062
Accrued expenses and other current liabilities	6,399	9,900
Operating lease obligations	540	498
Current portion of long term debt	1,276	—
Total current liabilities	11,136	18,460
Non-current liabilities		
Operating lease obligations, less current portion	3,164	3,587
Long term debt, net	1,495	2,289
Other non-current liabilities	497	244
Total non-current liabilities	5,156	6,120
Total liabilities	16,292	24,580
Commitments and contingencies (Note 13)		
Stockholders' equity		
Convertible preferred stock; $0.01 par value; 10,000,000 shares authorized at September 30, 2023 and December 31, 2022		
Series A; zero shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Series B; 54,745 shares issued and outstanding at September 30, 2023 and December 31, 2022	1	1
Common stock; $0.01 par value; 295,000,000 shares authorized, 256,621,487 and 221,721,182 shares issued, and 256,499,987 and 221,599,682 shares outstanding at September 30, 2023 and December 31, 2022, respectively	2,566	2,217
Treasury stock, at cost, 121,500 shares at September 30, 2023 and December 31, 2022	(48)	(48)
Additional paid-in capital	322,452	294,874
Accumulated other comprehensive income	27	26
Accumulated deficit	(266,603)	(213,018)
Total stockholders' equity	58,395	84,052
Total liabilities and stockholders' equity	$ 74,687	$ 108,632

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,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 6,342	$ 15,622	$ 30,069	$ 32,544
General and administrative	9,082	7,497	26,839	28,174
Total operating expenses	15,424	23,119	56,908	60,718
Loss from operations	(15,424)	(23,119)	(56,908)	(60,718)
Other income (expense), net	1,262	1,197	3,323	1,306
Net loss	$ (14,162)	$ (21,922)	$ (53,585)	$ (59,412)
Other comprehensive income (loss)				
Foreign currency translation adjustment	5	20	2	30
Unrealized gain (loss) on marketable securities	—	—	(1)	—
Comprehensive loss	$ (14,157)	$ (21,902)	$ (53,584)	$ (59,382)
Shares used in calculating net loss per common share — basic and diluted	256,492,558	216,591,011	240,222,667	212,755,746
Net loss per share of common stock — basic and diluted	$ (0.06)	$ (0.10)	$ (0.22)	$ (0.28)

See accompanying notes to condensed consolidated financial statements.

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

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount					
Balance at December 31, 2022	—	$ —	54,745	$ 1	221,721,182	$ 2,217	$ (48)	$ 294,874	$ 26	$ (213,018)	$ 84,052
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	—	—	—	—	—	—	—	—	—	(16,498)	(16,498)
Balance at March 31, 2023	—	$ —	54,745	$ 1	226,548,693	$ 2,265	$ (48)	$ 303,073	$ 25	$ (229,516)	$ 75,800
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	—	—	—	—	—	—	—	—	—	(22,925)	(22,925)
Balance at June 30, 2023	—	$ —	54,745	$ 1	256,608,552	$ 2,566	$ (48)	$ 320,181	$ 22	$ (252,441)	$ 70,281
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	—	—	—	—	—	—	—	—	—	(14,162)	(14,162)
Balance at September 30, 2023	**—**	**$ —**	**54,745**	**$ 1**	**256,621,487**	**$ 2,566**	**$ (48)**	**$ 322,452**	**$ 27**	**$ (266,603)**	**$ 58,395**

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

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount					
Balance at December 31, 2021	7	$ —	54,745	$ 1	199,502,183	$ 1,995	$ (48)	$ 225,537	$ —	$ (131,667)	$ 95,818
Stock-based compensation expense	—	—	—	—	—	—	—	3,299	—	—	3,299
Issuance of common stock for stock option exercises and restricted stock unit vesting, net	—	—	—	—	277,323	3	—	177	—	—	180
Issuance of common stock for capital raises, net	—	—	—	—	15,973,420	160	—	49,691	—	—	49,851
Net loss	—	—	—	—	—	—	—	—	—	(18,019)	(18,019)
Balance at March 31, 2022	7	$ —	54,745	$ 1	215,752,926	$ 2,158	$ (48)	$ 278,704	$ —	$ (149,686)	$ 131,129
Stock-based compensation expense	—	—	—	—	—	—	—	2,079	—	—	2,079
Issuance of common stock for stock option exercises and restricted stock unit vesting, net	—	—	—	—	515,221	5	—	356	—	—	361
Series A convertible preferred stock conversion	(7)	—	—	—	3,115	—	—	—	—	—	—
Other comprehensive income (loss)	—	—	—	—	—	—	—	—	10	—	10
Net loss	—	—	—	—	—	—	—	—	—	(19,471)	(19,471)
Balance at June 30, 2022	—	$ —	54,745	$ 1	216,271,262	$ 2,163	$ (48)	$ 281,139	$ 10	$ (169,157)	$ 114,108
Stock-based compensation expense	—	—	—	—	—	—	—	2,495	—	—	2,495
Issuance of common stock for stock option exercises and restricted stock unit vesting, net	—	—	—	—	538,675	5	—	597	—	—	602
Other comprehensive income (loss)	—	—	—	—	—	—	—	—	20	—	20
Net loss	—	—	—	—	—	—	—	—	—	(21,922)	(21,922)
Balance at September 30, 2022	**—**	**$ —**	**54,745**	**$ 1**	**216,809,937**	**$ 2,168**	**$ (48)**	**$ 284,231**	**$ 30**	**$ (191,079)**	**$ 95,303**

See accompanying notes to condensed consolidated financial statements.

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

	Nine months ended September 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (53,585)	$ (59,412)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	525	307
Amortization (accretion) on marketable securities	(182)	—
Non-cash interest expense	87	58
Non-cash lease expense	401	463
Stock-based compensation expense	7,495	7,873
Impairment of advance for COVAXIN supply	4,074	—
Loss on disposal of fixed assets related to COVAXIN	363	—
Other	379	(673)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	132	1,888
Accounts payable and accrued expenses	(10,059)	6,592
Lease obligations	(382)	(261)
Net cash used in operating activities	(50,752)	(43,165)
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	(7,754)	(2,433)
Repayment of note receivable	—	761
Net cash provided by (used in) investing activities	5,799	(1,672)
Cash flows from financing activities		
Proceeds from issuance of common stock, net	20,788	51,141
Payment of equity issuance costs	(355)	(298)
Proceeds from issuance of debt	500	500
Payment of debt issuance costs	(68)	(43)
Net cash provided by financing activities	20,865	51,300
Effect of changes in exchange rate on cash and cash equivalents	2	30
Net (decrease) increase in cash and cash equivalents	(24,086)	6,493
Cash, cash equivalents, and restricted cash at beginning of period	77,563	95,109
Cash and cash equivalents at end of period	$ 53,477	$ 101,602
Supplemental disclosure of non-cash investing and financing transactions:		
Equity issuance costs	$ —	$ 2
Purchases of property and equipment	$ 1,969	$ 1,231
Right-of-use asset related to operating leases	$ —	$ 2,916
Debt issuance costs	$ —	$ 19

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, biologics, 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.

Modifier Gene Therapy Platform

The Company is developing a modifier gene therapy platform designed to fulfill unmet medical needs related to retinal diseases, including inherited retinal diseases ("IRDs"), such as retinitis pigmentosa ("RP"), Leber congenital amaurosis ("LCA"), and Stargardt disease, as well as dry age-related macular degeneration ("AMD") with a gene-agnostic therapy. The Company's modifier gene therapy platform is based on the use of nuclear hormone receptors ("NHRs"), which have the potential to restore homeostasis—the basic biological processes in the retina. Unlike single-gene replacement therapies, which only target one genetic mutation, the Company believes that its modifier gene therapy platform, through its use of NHRs, represents a novel approach that has the potential both to address multiple retinal diseases caused by mutations in multiple genes with a gene-agnostic therapy and to address complex diseases that are potentially caused by imbalances in multiple gene networks.

The Company believes that OCU400 has the potential to be broadly effective in restoring retinal integrity and function across a range of genetically diverse IRDs, including RP and LCA. OCU400 has received Orphan Drug Designation ("ODD") from the United States Food and Drug Administration ("FDA") and Orphan Medicinal Product Designation ("OMPD") from the European Commission ("EC") for the treatment of RP and LCA.

The Company is conducting a Phase 1/2 trial to assess the safety and efficacy of unilateral subretinal administration of OCU400 in patients with nuclear receptor subfamily 2 group E member 3 ("*NR2E3")* and rhodopsin (*"RHO")*-related RP and centrosomal protein 290 ("*CEP290")*-related LCA in the United States. The Company has completed dosing adult RP patients as well as completed dosing three LCA patients including a pediatric patient in the Phase 1/2 study. In April 2023, the Company announced positive preliminary data among adult RP patients treated in the first two cohorts of the Phase 1/2 trial. In Cohorts 1 and 2 of the trial, seven participants with severe vision impairment due to RP associated with the *RHO* and *NR2E3* gene mutations received a unilateral subretinal injection of either a low dose or a medium dose of OCU400, respectively. The preliminary results showed a favorable safety profile and visual improvements after treatment with OCU400 as measured by multi-luminance mobility testing ("MLMT") and best corrected visual acuity assessment ("BCVA").

In September 2023, the Company announced a positive trial update for 12 subjects who had completed a minimum follow up of six months. The trial update was an extension of the positive preliminary data mentioned above. The positive trial update demonstrated that OCU400 continued to be generally safe and well-tolerated in subjects across different mutations and dose levels as measured by MLMT, BCVA, and Low-Luminance Visual Acuity ("LLVA"). 83%, 83%, and 75% of participants demonstrated stabilization or improvements in OCU400 treated eyes on BCVA, LLVA, and MLMT scores, respectively from baseline. 86% of participants with the *RHO* gene mutation experienced either stabilization of or increase in MLMT scores from baseline, including a subset of 29% that demonstrated a three Lux luminance level improvement. The treatment effect on *RHO*-patients supports gene-agnostic mechanism of action for OCU400. The Company also intends to initiate a Phase 3 trial for OCU400 for the treatment of RP in early 2024, subject to the outcome of the ongoing Phase 1/2 trial and discussions with the FDA on the proposed Phase 3 trial design and timeline. Subsequently, the Company is expecting to expand OCU400 Phase 3 study for LCA patients in the second half of 2024 based on Phase 1/2 study results in LCA patients and alignment with the FDA.

The Company is also developing OCU410 and OCU410ST, utilizing the nuclear receptor genes RAR-related orphan receptor A ("*RORA*"*)*, for the treatment of dry AMD and Stargardt disease, respectively. OCU410 is a potential one-time, curative therapy with a single sub-retinal injection. OCU410ST has received ODD from the FDA for the treatment of *ABCA4*-associated retinopathies, including Stargardt disease. The Company submitted Investigational New Drug ("IND") applications to the FDA for both OCU410 and OCU410ST in the second quarter of 2023. The FDA cleared the Company's IND applications, and the Company intends to dose patients in the Phase 1/2 trials by the end of 2023.

Regenerative Medicine Cell Therapy Platform

NeoCart is a Phase 3-ready, regenerative medicine 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 chondrocytes, the cells responsible for maintaining cartilage health. The chondrocytes are derived from the patient on a unique scaffold. In this therapy, healthy cartilage tissue is grown and implanted in the patient. Cartilage defects often lead to osteoarthritis if left untreated. Current surgical and nonsurgical treatment options are limited in their efficacy and durability. NeoCart has the potential to accelerate healing, reduce pain, and provide regenerative native-like cartilage strength with durable benefits post transplantation. In the Phase 2 clinical trial, NeoCart was shown to be generally well-tolerated and demonstrated greater clinical efficacy than microfracture surgery at two years after treatment. In a Phase 3 trial, NeoCart did not meet the primary endpoint of a statistically significant improvement in pain and function in a dual threshold responder analysis one year after treatment as compared to microfracture. However, in the modified Intent to Treat (mITT) population (which excludes those patients who were randomized but not treated with NeoCart), 74.2% of the NeoCart patients exhibited clinically meaningful improvements in pain and function compared to 62.0% of microfracture patients at one year (p=0.071). In this mITT population, patients treated with NeoCart achieved a statistically significant improvement in pain and function (p=0.018) six months after treatment as compared to patients treated with microfracture. Both NeoCart and microfracture were generally well tolerated and exhibited preliminary strong safety profiles. Based on this clinical benefit, the FDA granted a regenerative medicine advanced therapy ("RMAT") designation to NeoCart for the repair of full-thickness lesions of knee cartilage injuries in adults. Additionally, the Company received concurrence from the FDA on the confirmatory Phase 3 trial design. The Company is renovating an existing facility into a current Good Manufacturing Practice ("GMP") facility in accordance with the FDA's regulations in support of NeoCart manufacturing for personalized Phase 3 trial material. The Company intends to initiate the Phase 3 trial in the second half of 2024.

Inhaled Mucosal Vaccine Platform

The Company is 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. The Company's inhaled mucosal vaccine platform is driven by its conviction to serve a public health concern, which requires the endorsement and support of government funding in order to develop and ultimately commercialize its vaccine candidates. As these vaccine candidates are being developed to be administered via inhalation, the Company believes they have the potential to generate rapid local immune response in the upper airways and lungs, where viruses enter and infect the body. The Company believes this unique delivery method 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 National Institute of Allergy and Infectious Diseases' ("NIAID") Project NextGen for inclusion in clinical trials. OCU500 will be tested via two different mucosal routes, inhalation into the lungs and as a nasal spray. The clinical trials are expected to begin in early 2024. The Company is continuing the internal development of its OCU510 and OCU520 platforms to achieve IND readiness and may submit an IND application in 2024, provided it receives government funding. The Company has submitted multiple proposals to obtain government funding and is continuing discussions with relevant government agencies regarding developmental funding for its OCU510 and OCU520 platforms.

Novel Biologic Therapy for Retinal Diseases

The Company is developing OCU200, which is a novel fusion protein containing parts of human transferrin and tumstatin. OCU200 is designed to treat diabetic macular edema ("DME"), diabetic retinopathy ("DR"), and wet AMD. The Company has completed the technology transfer of manufacturing processes to its contract development and manufacturing organization ("CDMO") and has produced trial materials to initiate a Phase 1 trial. In April 2023, the FDA placed the Company's 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. The Company is working to provide the FDA with the requested information as promptly as possible. The Company expects initiation of the OCU200 clinical trial in the first half of 2024, contingent on the lift of the FDA hold and adequate availability of funding.

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 $53.6 million and $59.4 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, the Company had an accumulated deficit of $266.6 million and cash and cash equivalents totaling $53.5 million. This amount will not meet the Company's capital requirements for 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 wrong, and the Company's operating plan may change as a result of many factors currently unknown to the Company.

The Company is subject to risks, expenses, and uncertainties frequently encountered by companies in its industry. The Company intends to continue its research, development, and commercialization efforts for its product candidates, which 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 may be a negative impact on the financial viability of the Company. The Company is currently exploring 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. Failure to generate sufficient cash flows from operations, raise additional capital, or appropriately manage certain discretionary spending, could have a material adverse effect on the Company's ability to achieve its intended business objectives.

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, that are necessary to present fairly 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, 2022, included in the Company's Annual Report on Form 10-K filed with the SEC on February 28, 2023 (the "2022 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.

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, and the fair value measurement of equity instruments.

Cash and Cash Equivalents

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 $0.7 million and $2.0 million as interest income for the three and nine months ended September 30, 2023, respectively. The Company recorded $0.5 million and $0.6 million as interest income for the three and nine months ended September 30, 2022, respectively.

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 and cash equivalents, accounts payable, and accrued expenses, approximates their fair value due to the short-term nature of these instruments.

Marketable Securities

The Company accounts for marketable securities in accordance with FASB ASC Topic 320, *Investments — Debt and Equity Securities* ("ASC 320"). The Company determines the appropriate classification of its investments in debt securities at the time of purchase. Marketable securities with maturities of 90 days or less at the time of purchase are classified as cash equivalents on the condensed consolidated balance sheets. Debt securities are classified as trading securities if the security is bought and held primarily to be sold in the near term. Debt securities are classified as held-to-maturity if management has both the positive intent and ability to hold until the maturity of the security. Debt securities not classified as trading securities or held-to-maturity securities are classified as available-for-sale securities. The Company's marketable securities were previously comprised of debt securities and were classified as available-for-sale securities. The Company's marketable securities matured during the nine months ended September 30, 2023.

Available-for-sale securities are recorded at fair value based on inputs that are observable, either directly or indirectly, such as quoted prices for identical securities in active markets (Level 1) or quoted prices for similar securities in active markets or inputs that are observable (Level 2). Unrealized gains and losses are included in other comprehensive income (loss) in the condensed consolidated statements of operations and comprehensive loss. Amortization of premium or accretion of discount on debt securities are included in other income (expense), net in the condensed consolidated statements of operations and comprehensive loss.

The Company reviews investments in debt securities for other-than-temporary impairment if the fair value of the investment is less than the amortized cost basis. The assessment for other-than-temporary impairment is performed at the individual security level. To date, the Company has not recognized any impairments with respect to its debt securities.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents. The Company's cash and cash equivalents 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 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 condensed 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 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 and restricted stock units ("RSUs"), and has also accounted 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 and RSUs, 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. The Company recognizes forfeitures as they occur.

Expense related to stock-based compensation awards 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 related to stock-based compensation awards is 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 and RSU vesting are newly-issued common shares.

Estimating the fair value of stock options requires the input of subjective assumptions, including the expected life of the stock option, stock price volatility, the risk-free interest rate, and expected dividends. The assumptions used in the Company's Black-Scholes option-pricing model 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.

Recently Adopted Accounting Standards

In July 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-03, *Presentation of Financial Statements (Topic 205), Income Statement — Reporting Comprehensive Income (Topic 220), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation — Stock Compensation (Topic 718).* This standard amends various SEC paragraphs pursuant to the SEC Staff Accounting Bulletin ("SAB") No. 120, SEC Staff Announcement at the March 24, 2022 Emerging Issues Task Force Meeting, and SAB Topic 6.B, Accounting Series Release 280 — General Revision of Regulation S-X: *Income or Loss Applicable to Common Stock.* This standard did not provide any new guidance and was effective immediately. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The FASB subsequently issued amendments to ASU No. 2016-13, which had the same effective date and transition date of January 1, 2023. ASU No. 2016-13, as amended, requires that credit losses be reported using an expected losses model rather than the incurred losses model that was previously used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, these standards now require allowances to be recorded instead of reducing the amortized cost of the investment. These standards limit the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. The standard was effective for the Company on January 1, 2023. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

Recent Accounting Pronouncements

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. Early adoption is currently permitted. 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 Company does not currently expect the adoption of this standard to have a material impact on the Company's condensed consolidated financial statements.

3. Fair Value Measurements

The following table summarizes the fair value and the classification by level of input within the fair value hierarchy of financial assets as of December 31, 2022 that are recurring fair value measurements (in thousands):

	As of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$ 76,564	$ 999	$ —	$ 77,563
Marketable securities				
U.S. government agency securities and treasuries	—	7,433	—	7,433
Commercial paper	—	5,938	—	5,938
Total assets	$ 76,564	$ 14,370	$ —	$ 90,934

The valuation of the Company's cash and cash equivalents totaling $53.5 million, as of September 30, 2023, utilized Level 1 inputs. The valuation of the Company's marketable securities, which matured during the nine months ended September 30, 2023, utilized Level 2 inputs. See Note 2 for additional information. Further, the Company believes the fair value using Level 2 inputs of the borrowings under the EB-5 Loan Agreement (as defined in Note 8) approximates its carrying value. See Note 8 for additional information.

4. Marketable Securities

The Company's marketable securities matured during the nine months ended September 30, 2023. The following table provides the amortized cost basis and fair value of the Company's available-for-sale investments as of December 31, 2022 by security type as reflected on the condensed consolidated balance sheet (in thousands):

	As of December 31, 2022			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government agency securities and treasuries	$ 7,432	$ 1	$ —	$ 7,433
Commercial paper	5,938	—	—	5,938
Total marketable securities	$ 13,370	$ 1	$ —	$ 13,371

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, 2023	December 31, 2022
Furniture and fixtures	$ 337	$ 337
Machinery and equipment	1,557	1,685
Leasehold improvements	2,067	1,603
Construction in progress	11,567	3,049
Total property and equipment	15,528	6,674
Less: accumulated depreciation	(1,059)	(621)
Total property and equipment, net	$ 14,469	$ 6,053

6. Operating Leases

The Company has commitments under operating leases for office, laboratory, and future manufacturing space located in Malvern, Pennsylvania. The Company's leases have initial terms of approximately seven years and include options to extend the leases for up to 10 years. The options for extension have been excluded from the lease terms (and lease liabilities) as it is not reasonably certain that the Company will exercise such options.

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

For the years ending December 31,	Amount
Remainder of 2023	$ 194
2024	787
2025	810
2026	834
2027	834
Thereafter	978
Total	$ 4,437
Less: present value adjustment	(733)
Present value of minimum lease payments	$ 3,704

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, 2023	December 31, 2022
Research and development	$ 177	$ 1,894
Clinical	167	3,310
Professional fees	502	437
Employee-related	2,859	2,752
Fixed Assets	1,179	308
Other	1,515	1,199
Total accrued expenses and other current liabilities	$ 6,399	$ 9,900

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 4.0% 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. 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, 2023.

The carrying values of the borrowings pursuant to the Original Offering as of September 30, 2023 and December 31, 2022 are summarized below (in thousands):

	September 30, 2023	December 31, 2022
Principal outstanding	$ 2,500	$ 2,000
Plus: accrued interest	375	307
Less: unamortized debt issuance costs	(104)	(18)
Carrying value, net	2,771	2,289
Less: current portion of long term debt	(1,276)	—
Long term debt, net of current portion	$ 1,495	$ 2,289

9. Equity

Offerings of Common Stock

Public Offerings

In May 2023, the Company entered into an underwriting agreement with an underwriter, pursuant to which the Company sold 30.0 million shares of its common stock at a public offering price of $0.50 per share (the "May 2023 Public Offering"). The Company received net proceeds of $14.8 million after deducting equity issuance costs. The May 2023 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 April 21, 2023, as supplemented by a prospectus supplement, dated May 24, 2023.

In February 2022, the Company entered into an underwriting agreement with an underwriter, pursuant to which the Company sold 16.0 million shares of its common stock at a public offering price of $3.13 per share. The Company received net proceeds of $49.8 million after deducting equity issuance costs.

At-the-Market Offering

In June 2022, the Company entered into an At Market Issuance Sales Agreement (the "Sales Agreement") with certain agents, pursuant to which the Company could, from time to time, offer and sell shares of its common stock having an aggregate gross sales price of up to $160.0 million. During the nine months ended September 30, 2023, the Company sold 4.5 million shares of its common stock and received net proceeds of $5.6 million after deducting issuance costs of $0.2 million. The Sales Agreement was terminated in February 2023.

COVAXIN Preferred Stock Purchase Agreement

On March 1, 2021, the Company entered into a preferred stock purchase agreement (the "Preferred 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.

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 condensed 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 the 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 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.

10. Warrants

Canada Warrants

In July 2021, the Company entered into a consulting agreement with regard to the Company's Canadian operations (the "Canada Consulting Agreement"). Compensation under the Canada Consulting Agreement included the issuance of warrants to purchase up to 0.2 million shares of the Company's common stock (the "Canada Warrants") and cash payments of up to $3.0 million, both dependent upon the achievement of certain milestones related to COVAXIN. The Canada Warrants were issued on July 15, 2021, had an exercise price of $6.36 per share, and were accounted for in accordance with ASC 718. In connection with the Company's decision to terminate the COVAXIN program, the Canada Consulting Agreement and the Canada Warrants were terminated by mutual agreement in June 2023.

OpCo Warrants

Beginning in 2016, OpCo issued warrants to purchase the Company's common stock (the "OpCo Warrants"). As of September 30, 2023 and December 31, 2022, 0.6 million OpCo Warrants were outstanding. As of September 30, 2023, the outstanding OpCo 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 and RSUs 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,	
	2023	2022	2023	2022
General and administrative	$ 1,639	$ 2,057	$ 5,578	$ 5,769
Research and development	535	438	1,917	2,104
Total	$ 2,174	$ 2,495	$ 7,495	$ 7,873

As of September 30, 2023, the Company had $11.5 million of unrecognized stock-based compensation expense related to stock options and RSUs 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"). As of September 30, 2023, the 2014 Plan and the 2019 Plan authorize for the granting of up to 0.8 million and 28.4 million equity awards with respect to the Company's common stock, respectively. The 2014 Plan and 2019 Plan have 0.4 million and 9.5 million equity awards remaining available for future grant, respectively, as of September 30, 2023. In addition to stock options 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)
Stock options outstanding at December 31, 2022	10,851,287	$ 2.95	8.3	$ 1,385
Granted	4,850,889	$ 1.06		
Exercised	(240,000)	$ 0.41		
Forfeited	(1,886,138)	$ 2.25		
Stock options outstanding at September 30, 2023	13,576,038	$ 2.42	8.1	$ 51
Stock options exercisable at September 30, 2023	6,589,323	$ 2.72	7.4	$ 51

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 weighted average grant date fair values of stock options granted during the three and nine months ended September 30, 2022 were $2.01 and $3.19, respectively. The total fair values of stock options vested during the three and nine months ended September 30, 2023 were $0.4 million and $8.5 million, respectively. The total fair values of stock options vested during the three and nine months ended September 30, 2022 were $0.6 million and $4.6 million, respectively.

RSUs

The following table summarizes the Company's RSU activity:

	Number of Shares	Weighted Average Grant Date Fair Value
RSUs outstanding at December 31, 2022	924,810	$ 4.12
Granted	3,186,442	$ 1.20
Vested	(264,195)	$ 4.41
Forfeited	(813,729)	$ 1.56
RSUs outstanding at September 30, 2023	3,033,328	$ 1.72

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, 2023 and 2022 (in thousands, except share and per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Net loss — basic and diluted	$ (14,162)	$ (21,922)	$ (53,585)	$ (59,412)
Shares used in calculating net loss per common share — basic and diluted	256,492,558	216,591,011	240,222,667	212,755,746
Net loss per common share — basic and diluted	$ (0.06)	$ (0.10)	$ (0.22)	$ (0.28)

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 ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Stock options to purchase common stock	13,576,038	11,726,937	13,576,038	11,726,937
RSUs	3,033,328	932,879	3,033,328	932,879
Warrants	628,834	798,352	628,834	798,352
Series B Convertible Preferred Stock (as converted to common stock)	547,450	547,450	547,450	547,450
Total	17,785,650	14,005,618	17,785,650	14,005,618

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 2022 Annual Report). Commitments under the lease agreements are future minimum lease payments (see Note 6). Renovation commitments are related to retrofitting an existing facility in order to be GMP compliant (see Note 1). Commitments under debt agreements are the future payments of principal and accrued interest under the EB-5 Loan Agreement (see Note 8). In connection with the Company's decision to terminate the COVAXIN program, the Canada Consulting Agreement was terminated by mutual agreement in June 2023 (see Note 10). 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 (described within the Company's 2022 Annual Report) 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 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. The complaints seek unspecified damages, interest, attorneys' fees, and other costs. In March 2022, the Court consolidated these two related securities class action lawsuits and appointed Andre Galan Bernd Benayon to serve as lead plaintiff. The lead plaintiff's amended complaint was filed in June 2022. In March 2023, the Court granted the Company's motion to dismiss with prejudice. The lead plaintiff has appealed to the United States Court of Appeals for the Third Circuit regarding the order that was entered in March 2023, which dismissed the action with prejudice. The lead plaintiff's appellant's brief and joint appendix were filed in July 2023. The Company's appellees' brief was filed in August 2023, and the lead plaintiff's reply brief was filed in September 2023.

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 and submitted to the Court in each action a proposed order requesting a stay of the litigation pending a decision on any motion to dismiss filed in the securities class action lawsuits, which the Court entered in April 2022. In March 2023, the Court

in the securities class action lawsuits granted the Company's motion to dismiss with prejudice. The parties to the stockholder derivative lawsuits stipulated to extend the stay of litigation pending resolution of any appeal filed in the securities class action lawsuits, which the Court entered in March 2023.

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 Events

Subsequent to September 30, 2023, the Company announced via press release on October 10, 2023 that the NIAID, a part of the National Institutes of Health ("NIH"), will conduct clinical trials comparing the administration of Ocugen’s mucosal vaccine candidate, OCU500, via two different mucosal routes, inhalation into the lungs and as a nasal spray. The clinical trials are expected to begin in early 2024. The Company is currently assessing the resulting financial impacts of NIH's commitment.

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, 2022, included in our 2022 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 2022 Annual Report 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, biologics, and vaccines that improve health and offer hope for patients across the globe.

Our cutting-edge technology pipeline includes:

- **Modifier Gene Therapy Platform** — Based on the use of NHRs, we believe our modifier gene therapy platform has the potential to address many retinal diseases, including RP (OCU400), LCA (OCU400), dry AMD (OCU410), and Stargardt disease (OCU410ST), with a gene-agnostic therapy.
- **Regenerative Medicine Cell Therapy Platform** — Our Phase 3-ready regenerative medicine cell therapy, NeoCart (autologous chondrocyte-derived neocartilage), is being developed for the repair of knee cartilage injuries in adults.
- **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. The development of our inhaled mucosal vaccine platform requires the endorsement and support of government funding.
- **Novel Biologic Therapy for Retinal Diseases** — OCU200 is a novel fusion protein containing human transferrin and tumstatin. OCU200 is designed to treat DME, DR, and wet AMD.

Modifier Gene Therapy Platform

We are developing a modifier gene therapy platform designed to fulfill unmet medical needs related to retinal diseases, including IRDs, such as RP, LCA, and Stargardt disease, as well as dry AMD. Our modifier gene therapy platform is based on the use of NHRs, which have the potential to restore homeostasis—the basic biological processes in the retina. Unlike single-gene replacement therapies, which only target one genetic mutation, we believe that our modifier gene therapy platform, through its use of NHRs, represents a novel approach that has the potential both to address multiple retinal diseases caused by mutations in multiple genes with a gene-agnostic therapy and to address complex diseases that are potentially caused by imbalances in multiple gene networks.

IRDs, such as RP and LCA, can lead to visual impairment and blindness. RP and LCA are associated with over 125 mutated genes that affect over 1.6 million individuals worldwide. We believe that OCU400 has the potential to be broadly effective in restoring retinal integrity and function across a range of genetically diverse IRDs, including RP and LCA. OCU400 has received ODD from the FDA and OMPD from the EC for the treatment of RP and LCA. We believe these broad ODD and OMPD designations demonstrate that OCU400 has the potential to be a broad-spectrum therapeutic to treat multiple IRDs. These ODD and OMPD designations represent gene-agnostic broad coverage for RP and LCA and are not mutation-specific designations.

We are conducting a Phase 1/2 trial to assess the safety and efficacy of unilateral subretinal administration of OCU400 in patients with *NR2E3* and *RHO*-related *RP* and *CEP290*-related LCA in the United States. We have completed dosing adult RP patients as well as completed dosing three LCA patients including a pediatric patient in the Phase 1/2 study. In April 2023, we announced positive preliminary data among adult RP patients treated in the first two cohorts of the Phase 1/2 trial. In Cohorts 1 and 2 of the trial, seven participants with severe vision impairment due to RP associated with the *RHO* and *NR2E3* gene mutations received a unilateral subretinal injection of either a low dose (1.66×10^{10} vg/mL) or a medium dose (3.33×10^{10} vg/

mL) of OCU400, respectively. In the preliminary data analysis, the nine-month follow-up data for three patients and six-month follow-up data for four patients were evaluated. The preliminary results showed a favorable safety profile and visual improvements after treatment with OCU400 as measured by MLMT and BCVA. Over 70% of OCU400 treated eyes in low and medium dose cohorts demonstrated at least one Lux luminance level improvement in MLMT score and 67% of OCU400 treated eyes in the low dose cohort at the nine-month follow-up demonstrated at least two Lux luminance level improvement in MLMT score. Over 40% of OCU400 treated eyes demonstrated 8-11 letters of improvement as measured in BCVA score.

In September 2023, we announced a positive trial update for 12 participants who had completed a minimum follow-up of six months. The data set comprised of two participants with 12-month follow-up, five participants with nine-month follow-up, and five participants with six-month follow-up. The trial update was an extension of the positive preliminary data from April 2023. The positive trial update demonstrated that OCU400 continued to be generally safe and well-tolerated in subjects across different mutations and dose levels as measured by MLMT, BCVA, and LLVA. 83%, 83%, and 75% of participants demonstrated stabilization or improvements in OCU400 treated eyes on BCVA, LLVA, and MLMT scores, respectively from baseline. 86% of participants with the *RHO* gene mutation experienced either stabilization of or increase in MLMT scores from baseline, including a subset of 29% that demonstrated a three Lux luminance level improvement. The treatment effect on *RHO*-patients supports gene-agnostic mechanism of action for OCU400.

We also intend to initiate a Phase 3 trial for OCU400 for the treatment of RP in early 2024, subject to the outcome of the ongoing Phase 1/2 trial and discussions with the FDA on the proposed Phase 3 trial design and timeline. Subsequently, we expect to expand OCU400 Phase 3 study for LCA patients in the second half of 2024 based on Phase 1/2 study results in LCA patients and alignment with the FDA.

We are also developing OCU410 and OCU410ST, utilizing the nuclear receptor genes *RORA*, for the treatment of dry AMD and Stargardt disease, respectively. OCU410 is a potential one-time, curative therapy with a single sub-retinal injection. OCU410ST has received ODD from the FDA for the treatment of *ABCA4*-associated retinopathies, including Stargardt disease. We submitted IND applications to the FDA for both OCU410 and OCU410ST in the second quarter of 2023. The FDA cleared our IND applications, and we intend to dose patients in the Phase 1/2 trials by the end of 2023.

Regenerative Medicine Cell Therapy Platform

NeoCart is a Phase 3-ready, regenerative medicine 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 chondrocytes, the cells responsible for maintaining cartilage health. The chondrocytes are derived from the patient on a unique scaffold. In this therapy, healthy cartilage tissue is grown and implanted in the patient. Cartilage defects often lead to osteoarthritis if left untreated. Current surgical and nonsurgical treatment options are limited in their efficacy and durability. NeoCart has the potential to accelerate healing, reduce pain, and provide regenerative native-like cartilage strength with durable benefits post transplantation. In the Phase 2 clinical trial, NeoCart was shown to be generally well-tolerated and demonstrated greater clinical efficacy than microfracture surgery at two years after treatment. In a Phase 3 trial, NeoCart did not meet the primary endpoint of a statistically significant improvement in pain and function in a dual threshold responder analysis one year after treatment as compared to microfracture. However, in the modified Intent to Treat (mITT) population (which excludes those patients who were randomized but not treated with NeoCart), 74.2% of the NeoCart patients exhibited clinically meaningful improvements in pain and function compared to 62.0% of microfracture patients at one year (p=0.071). In this mITT population, patients treated with NeoCart achieved a statistically significant improvement in pain and function (p=0.018) six months after treatment as compared to patients treated with microfracture. Both NeoCart and microfracture were generally well tolerated and exhibited preliminary strong safety profiles. 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. We are renovating an existing facility into a current GMP 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 in the second half of 2024.

Inhaled Mucosal Vaccine Platform

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 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 unique delivery method 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 into the lungs and as a nasal spray. The clinical trials are expected to begin in early 2024. We are continuing the internal development of the OCU510 and OCU520 platforms to achieve IND readiness and may submit an IND application in 2024, provided we receive government funding. We have submitted multiple proposals to obtain government funding and we are continuing discussions with relevant government agencies regarding developmental funding for our OCU510 and OCU520 platforms.

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 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. We are working to provide the FDA with the requested information as promptly as possible. We expect initiation of the OCU200 clinical trial in the first half of 2024, contingent on the lift of the FDA hold and adequate availability of funding.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

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

	Three months ended September 30,		
	2023	2022	Change
Operating expenses			
Research and development	$ 6,342	$ 15,622	$ (9,280)
General and administrative	9,082	7,497	1,585
Total operating expenses	15,424	23,119	(7,695)
Loss from operations	(15,424)	(23,119)	7,695
Other income (expense), net	1,262	1,197	65
Net loss	$ (14,162)	$ (21,922)	$ 7,760

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, 2023 and 2022 (in thousands):

	Three months ended September 30,		
	2023	2022	Change
OCU400	$ 936	$ 1,101	$ (165)
OCU410 and OCU410ST	573	975	(402)
NeoCart	180	35	145
COVAXIN	440	7,030	(6,590)
Inhaled mucosal vaccine platform	36	1,005	(969)
OCU200	238	1,476	(1,238)
Unallocated costs:			
Research and development personnel costs	3,201	3,103	98
Facilities and other support costs	350	339	11
Other	388	558	(170)
Total research and development	$ 6,342	$ 15,622	$ (9,280)

Research and development expense

Research and development expense decreased by $9.3 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022. The decrease was primarily driven by $6.6 million related to the termination of the COVAXIN program; $1.2 million related to OCU200, which is driven by a decrease in preclinical activities, and $1.0 million related to the upfront payments rights to OCU500, which were incurred during the three months ended September 30, 2022.

General and administrative expense

General and administrative expense increased by $1.6 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022. The increase was primarily driven by $2.3 million in legal expenses; and $0.5 million in severance payments made to our former officer, which were incurred during the three months ended September 30, 2023. The increase was partially offset by a decrease of $0.4 million in pre-commercial expenses; $0.2 million in non-recurring office expenses incurred in connection with the opening of our corporate headquarters; and $0.6 million in employee-related expenses, including $0.4 million in stock-based compensation expense, during the three months ended September 30, 2023.

Other income (expense), net

Other income (expense), net increased by $0.1 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022. The increase was primarily driven by $0.3 million in interest earned on our cash and cash equivalents balance and $0.6 million in co-development activities related to the development of our modifier gene therapy platform. The increase was partially offset by a decrease of $0.8 million related to the repayment of the Aviceda promissory note, which was incurred during the three months ended September 30, 2022.

Comparison of the Nine Months Ended September 30, 2023 and 2022

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

	Nine months ended September 30,		
	2023	2022	Change
Operating expenses			
Research and development	$ 30,069	$ 32,544	$ (2,475)
General and administrative	26,839	28,174	(1,335)
Total operating expenses	56,908	60,718	(3,810)
Loss from operations	(56,908)	(60,718)	3,810
Other income (expense), net	3,323	1,306	2,017
Net loss	$ (53,585)	$ (59,412)	$ 5,827

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, 2023 and 2022 (in thousands):

	Nine months ended September 30,		
	2023	2022	Change
OCU400	$ 3,330	$ 2,902	$ 428
OCU410 and OCU410ST	2,043	1,392	651
NeoCart	939	143	796
COVAXIN	8,690	10,388	(1,698)
Inhaled mucosal vaccine platform	575	1,005	(430)
OCU200	570	4,035	(3,465)
Unallocated costs:			
Research and development personnel costs	11,552	10,711	841
Facilities and other support costs	1,148	874	274
Other	1,222	1,094	128
Total research and development	$ 30,069	$ 32,544	$ (2,475)

Research and development expense

Research and development expense decreased by $2.5 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. The decrease was primarily driven by $3.4 million related to OCU200, which is driven by a decrease in preclinical activities and $1.7 million related to the termination of the COVAXIN program. These decreases were partially offset by an increase of $1.1 million in technical service costs related to the development of our modifier gene therapy platform, which was offset by certain preclinical activities being completed for OCU400 as well as less work being performed due to programs nearing clinical phases for OCU410 and OCU410ST; $0.8 million related to NeoCart, driven by CMC activities; and $0.8 million in employee-related expenses during the nine months ended September 30, 2023.

General and administrative expense

General and administrative expense decreased by $1.3 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. The decrease was primarily driven by $1.6 million in pre-commercial expenses; $1.4 million in non-recurring office expenses incurred in connection with the opening of our corporate headquarters; and $0.6 million in insurance expense. The decrease was partially offset by an increase of $1.5 million in legal expenses, which was partially offset by an decrease in consulting fees; $0.9 million in employee-related expenses, which were incurred during the nine months ended September 30, 2023.

Other income (expense), net

Other income (expense), net increased by $2.0 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. The increase was primarily driven by $1.3 million in interest earned on our cash and cash equivalents balance and $0.7 million in co-development activities related to the development of our modifier gene therapy platform.

Liquidity and Capital Resources

As of September 30, 2023, we had $53.5 million in cash and cash equivalents. To date, we have not generated revenue from our product candidates, 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, 2023, we have raised an aggregate of $301.0 million to fund our operations, of which $287.2 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.

During the nine months ended September 30, 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 the May 2023 Public Offering. We received net proceeds of $14.8 million after deducting equity issuance costs.

During the nine months ended September 30, 2023, we sold 4.5 million shares of our common stock under the Sales Agreement 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 $53.6 million and $59.4 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $266.6 million. In addition, we had accounts payable and accrued expenses and other current liabilities of $9.3 million and indebtedness of $2.8 million.

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

	Nine months ended September 30,	
	2023	2022
Net cash used in operating activities	$ (50,752)	$ (43,165)
Net cash provided by (used in) investing activities	5,799	(1,672)
Net cash provided by financing activities	20,865	51,300
Effect of changes in exchange rate on cash and cash equivalents	2	30
Net (decrease) increase in cash and cash equivalents	$ (24,086)	$ 6,493

Operating activities

Cash used in operating activities was $50.8 million for the nine months ended September 30, 2023 compared to $43.2 million for the nine months ended September 30, 2022. The increase in cash used in operating activities was primarily driven by increases in our operating expenses related to the continued development of our product candidates, legal expenses, and employee-related expenses. These increases were partially offset by decreases in professional service costs and office expenses incurred in connection with the opening of our corporate headquarters, both of which were incurred during the nine months ended September 30, 2022.

Investing activities

Cash provided by investing activities was $5.8 million for the nine months ended September 30, 2023 compared to cash used in investing activities of $1.7 million for the nine months ended September 30, 2022. The increase in cash provided by investing activities was primarily driven by 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. This increase 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 and an increase of $5.3 million in purchases of property and equipment during the nine months ended September 30, 2023.

Financing activities

Cash provided by financing activities was $20.9 million for the nine months ended September 30, 2023 compared to $51.3 million for the nine months ended September 30, 2022. During the nine months ended September 30, 2023, cash provided by financing activities primarily consisted of gross proceeds of a combined $20.8 million received from the May 2023 Public Offering and pursuant to the Sales Agreement. During the nine months ended September 30, 2022, cash provided financing activities primarily consisted of gross proceeds of $50.0 million received from the underwritten offering that closed in February 2022.

Contractual Obligations

We have commitments under certain licensing and development agreements, lease obligations, commitments related to renovating an existing facility for GMP, and debt agreements. As previously disclosed in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 (the "First Quarter 10-Q"), we determined it was no longer commercially viable to further the development of COVAXIN, a monovalent COVID-19 vaccine, in our North American territories as the FDA cancelled all EUAs issued with respect to monovalent COVID-19 vaccine formulations. Accordingly, in June 2023, the Canada Consulting Agreement was terminated by mutual agreement (see Note 10). Additionally, we do not expect to fulfill any remaining commitments pursuant to the Covaxin Agreement with Bharat Biotech as a result of our decision to terminate the COVAXIN program. Except for the termination of the Canada Consulting Agreement, there have been no material changes to our contractual obligations as reported in our 2022 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 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 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 impacts of geopolitical turmoil, macroeconomic conditions, social unrest, political instability, terrorism, or other acts of war.

As of September 30, 2023, we had cash and cash equivalents of approximately $53.5 million. This amount will not meet our capital requirements for 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, 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. We will need to raise significant additional capital in order to fund our operations until we recognize significant revenue from product sales. Our management is currently evaluating 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 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 2022 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, 2023. 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 effective in ensuring that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control Over Financial Reporting

There were no 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 period covered by this report 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 2022 Annual Report. The risks described in our 2022 Annual Report and our First Quarter 10-Q are not the only risks we face. 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.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market ("Nasdaq") could result in a delisting of our common stock.

We must continue to satisfy Nasdaq continued listing requirements, including, among other things, certain corporate governance requirements and a minimum closing bid price requirement of $1.00 per share. If a company fails for 30 consecutive business days to meet the $1.00 minimum closing bid price requirement, Nasdaq will send a deficiency notice to the company, advising that it has been afforded a "compliance period" of 180 calendar days to regain compliance with the applicable requirements.

On May 1, 2023, we received a deficiency letter from Nasdaq notifying us that, for the last 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share required for continued listing on Nasdaq pursuant to the minimum closing bid price requirement. The Nasdaq deficiency letter had no immediate effect on the listing of our common stock. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been given 180 calendar days, or until October 30, 2023, to regain compliance with the minimum closing bid price requirement by causing our stock to close above $1.00 for a minimum of 10 consecutive trading days. If we do not regain compliance with the minimum closing bid price requirement by October 30, 2023, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intent to cure the deficiency during the second compliance period. On October 31, 2023, we received a letter from Nasdaq stating that, although we had not regained compliance with the minimum bid price requirement, Nasdaq determined that we are eligible for an additional 180-day period, or until April 29, 2024, to regain compliance with the minimum bid price requirement.

We can provide no assurance that we will be able to regain compliance with the minimum closing bid price requirement by April 29, 2024, or by any date, or that we will be able to remain in compliance with other Nasdaq continued listing requirements. A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock, impairing your ability to sell or purchase shares of our common stock when you wish to do so, and could result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors and employees. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow the common stock to become listed again, stabilize the market price or improve the liquidity of the common stock, prevent the common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with Nasdaq's listing requirements.

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.

None.

Item 6. Exhibits.

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

Exhibit	Description
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Interim Chief Accounting Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certifications of the Chief Executive Officer and Interim Chief Accounting Officer as required by 18 U.S.C. 1350
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	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 9, 2023

/s/ Shankar Musunuri

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

Dated: November 9, 2023

/s/ Michael Breininger

Michael Breininger, CPA, MBA, LSSBB
Corporate Controller, Interim Chief Accounting Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION

I, Shankar Musunuri, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ocugen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 9, 2023 /s/ Shankar Musunuri

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

Exhibit 31.2

CERTIFICATION

I, Michael Breininger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ocugen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 9, 2023 /s/ Michael Breininger

Michael Breininger, CPA, MBA, LSSBB
Corporate Controller, Interim Chief Accounting Officer
(Principal Financial Officer)

Exhibit 32.1

Certification

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report on Form 10-Q of Ocugen, Inc. (the “Company”) for the quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Form 10-Q"), each of the undersigned officers of the Company, does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- the Form 10-Q fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2023 /s/ Shankar Musunuri

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

Date: November 9, 2023 /s/ Michael Breininger

Michael Breininger, CPA, MBA, LSSBB
Corporate Controller, Interim Chief Accounting Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.