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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 June 30, 2022

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)

263 Great Valley Parkway
Malvern, Pennsylvania 19355
(Former name, former address, and former fiscal year, if changed since last report)

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 July 29, 2022, there were 216,565,916 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 JUNE 30, 2022

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, 2022 (the "2021 Annual Report") and (ii) our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 filed with the SEC on May 6, 2022 (the "First Quarter 10-Q") include, among other things, statements about:

- our estimates regarding expenses, future revenues, capital requirements, as well as the timing and availability of and the need for additional financing to continue to advance our product candidates;
- our activities with respect to BBV152, known as COVAXIN, our vaccine candidate for the prevention of COVID-19 caused by SARS-CoV-2 in humans, in collaboration with Bharat Biotech International Limited ("Bharat Biotech"), including our plans and expectations regarding clinical development, manufacturing, pricing, regulatory review and compliance, reliance on third parties, and commercialization;
- our plans regarding the submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for adults ages 18 years and older, including the need for a Phase 2/3 immuno-bridging and broadening clinical trial and safety clinical trial to support a BLA submission for COVAXIN;
- the ability of our collaboration partner, Bharat Biotech, to successfully respond to the deficiencies identified in an inspection conducted by the World Health Organization ("WHO") and any potential impact of these deficiencies on the regulatory and commercialization pathway available for COVAXIN;
- our ability to successfully continue dosing participants and subsequently complete the Phase 2/3 immuno-bridging and broadening clinical trial, as well as our ability to initiate the safety clinical trial;
- our activities with respect to assessing a regulatory pathway for the pediatric use of COVAXIN in the United States;
- our activities with respect to resolving the deficiencies communicated by Health Canada in its Notice of Deficiency on our New Drug Submission for COVAXIN, including our responses provided to Health Canada;
- our activities with respect to commercializing COVAXIN in Mexico for use in adults over the age of 18 years and the submission to Comisión Federal para la Protección contra Riesgos Sanitarios for emergency use authorization for COVAXIN in Mexico for pediatric use in ages two to 18 years;
- our ability to successfully obtain adequate supply of COVAXIN from Bharat Biotech, including any impact on clinical or commercial supply in light of the deficiencies identified in the inspection by the WHO, as well as to complete a technology transfer to our third-party manufacturer, Jubilant HollisterStier, and engage such manufacturer on commercially acceptable terms;
- anticipated market demand for COVAXIN for the adult and pediatric populations in North America;
- our ability to successfully continue and subsequently complete the Phase 1/2 clinical trial for OCU400;
- the uncertainties associated with the clinical development and regulatory approval of our product candidates, including potential delays in the initiation, commencement, enrollment, and completion of current and future clinical trials;
- our ability to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of the inherent risks and difficulties involved in successfully bringing product candidates to market and the risk that products will not achieve broad market acceptance;
- uncertainties in obtaining successful clinical trial results for product candidates and unexpected costs that may result therefrom;

- our ability to comply with regulatory schemes applicable to our business and other regulatory developments in the United States, Canada, Mexico, and other foreign countries; including the extent to which developments with respect to the COVID-19 pandemic will affect the regulatory pathway available for COVID-19 vaccines in such 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 or retain key scientific, technical, commercial, and management personnel and to retain our executive officers;
- our ability to comply with stringent United States, Canadian, Mexican, and other foreign government regulations with respect to the manufacturing of pharmaceutical products, including current Good Manufacturing Practice compliance, and other relevant regulatory authorities;
- the extent to which health epidemics and other outbreaks of communicable diseases, including the COVID-19 pandemic, geopolitical turmoil, including the ongoing invasion of Ukraine by Russia or increased trade restrictions between the United States, Russia, China, and other countries, social unrest, political instability, terrorism, or other 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 2021 Annual Report, the First Quarter 10-Q, and in any other documents we file 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 the 2021 Annual Report and in the First Quarter 10-Q, particularly under the sections 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, or investments 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 owner 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. Further, for ease of reference, the name "COVAXIN" is used throughout this Quarterly Report on Form 10-Q to refer to the vaccine candidate, BBV152. The name COVAXIN has not been evaluated or cleared by the FDA or Health Canada.

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

	June 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 115,005	$ 94,958
Prepaid expenses and other current assets	7,564	7,688
Total current assets	122,569	102,646
Property and equipment, net	3,153	1,164
Restricted cash	—	151
Other assets	4,366	1,800
Total assets	$ 130,088	$ 105,761
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 5,921	$ 2,312
Accrued expenses	4,103	4,325
Operating lease obligations	314	363
Total current liabilities	10,338	7,000
Non-current liabilities		
Operating lease obligations, less current portion	3,892	1,231
Long term debt, net	1,750	1,712
Total non-current liabilities	5,642	2,943
Total liabilities	15,980	9,943
Commitments and contingencies (Note 12)		
Stockholders' equity		
Convertible preferred stock; $0.01 par value; 10,000,000 shares authorized at June 30, 2022 and December 31, 2021		
Series A; zero and seven shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	—	—
Series B; 54,745 shares issued and outstanding at June 30, 2022 and December 31, 2021	1	1
Common stock; $0.01 par value; 295,000,000 shares authorized, 216,271,262 and 199,502,183 shares issued, and 216,149,762 and 199,380,683 shares outstanding at June 30, 2022 and December 31, 2021, respectively	2,163	1,995
Treasury stock, at cost, 121,500 shares at June 30, 2022 and December 31, 2021	(48)	(48)
Additional paid-in capital	281,139	225,537
Accumulated other comprehensive income	10	—
Accumulated deficit	(169,157)	(131,667)
Total stockholders' equity	114,108	95,818
Total liabilities and stockholders' equity	$ 130,088	$ 105,761

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 June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 9,007	$ 18,853	$ 16,922	$ 21,725
General and administrative	10,558	6,757	20,677	10,942
Total operating expenses	19,565	25,610	37,599	32,667
Loss from operations	(19,565)	(25,610)	(37,599)	(32,667)
Other income (expense), net	94	(342)	109	(362)
Net loss	$ (19,471)	$ (25,952)	$ (37,490)	$ (33,029)
Other comprehensive income (loss)				
Foreign currency translation adjustment	10	—	10	—
Comprehensive loss	$ (19,461)	$ (25,952)	$ (37,480)	$ (33,029)
Shares used in calculating net loss per common share — basic and diluted	215,862,977	195,572,189	210,806,330	190,960,775
Net loss per share of common stock — basic and diluted	$ (0.09)	$ (0.13)	$ (0.18)	$ (0.17)

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, 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	—	—	—	—	277,323	3	—	177	—	—	180
Issuance of common stock for underwritten offering, 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	—	—	—	—	488,843	5	—	404	—	—	409
Issuance of common stock upon restricted stock unit vesting, net	—	—	—	—	26,378	—	—	(48)	—	—	(48)
Series A convertible preferred stock conversion	(7)	—	—	—	3,115	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	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**

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, 2020	7	$ —	—	$ —	184,133,384	$ 1,841	$ (48)	$ 93,059	$ —	$ (73,302)	$ 21,550
Stock-based compensation expense	—	—	—	—	—	—	—	833	—	—	833
Issuance of common stock for stock option exercises	—	—	—	—	157,468	2	—	174	—	—	176
At-the-market common stock issuance, net	—	—	—	—	987,000	10	—	4,839	—	—	4,849
Registered direct offering common stock issuance, net	—	—	—	—	3,000,000	30	—	21,174	—	—	21,204
Series B Convertible Preferred Stock issuance, net	—	—	54,745	1	—	—	—	4,953	—	—	4,954
Net loss	—	—	—	—	—	—	—	—	—	(7,077)	(7,077)
Balance at March 31, 2021	7	$ —	54,745	$ 1	188,277,852	$ 1,883	$ (48)	$ 125,032	$ —	$ (80,379)	$ 46,489
Stock-based compensation expense	—	—	—	—	—	—	—	2,095	—	—	2,095
Issuance of common stock for stock option and warrant exercises	—	—	—	—	538,893	5	—	366	—	—	371
Registered direct offering common stock issuance, net	—	—	—	—	10,000,000	100	—	93,306	—	—	93,406
Net loss	—	—	—	—	—	—	—	—	—	(25,952)	(25,952)
Balance at June 30, 2021	**7**	**$ —**	**54,745**	**$ 1**	**198,816,745**	**$ 1,988**	**$ (48)**	**$ 220,799**	**$ —**	**$ (106,331)**	**$ 116,409**

See accompanying notes to condensed consolidated financial statements.

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

	Six months ended June 30,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (37,490)	$ (33,029)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	166	93
Non-cash interest expense	38	40
Non-cash lease expense	334	134
Stock-based compensation expense	5,378	2,928
Gain on forgiveness of Paycheck Protection Program note	—	(426)
Impairment on note receivable	—	758
Changes in assets and liabilities:		
Prepaid expenses and other assets	132	965
Accounts payable and accrued expenses	2,844	1,483
Lease obligations	(265)	(130)
Other assets	—	100
Net cash used in operating activities	(28,863)	(27,084)
Cash flows from investing activities		
Purchase of property and equipment	(1,589)	(524)
Issuance of note receivable	—	(750)
Net cash used in investing activities	(1,589)	(1,274)
Cash flows from financing activities		
Proceeds from issuance of common stock	50,586	128,496
Tax payments for net share settlement of restricted stock units	(48)	—
Payment of equity issuance costs	(200)	(8,525)
Financing lease principal payments	—	(10)
Net cash provided by financing activities	50,338	119,961
Effect of changes in exchange rate on cash, cash equivalents, and restricted cash	10	—
Net increase in cash, cash equivalents, and restricted cash	19,896	91,603
Cash, cash equivalents, and restricted cash at beginning of period	95,109	24,190
Cash, cash equivalents, and restricted cash at end of period	$ 115,005	$ 115,793
Supplemental disclosure of non-cash investing and financing transactions:		
Series B Convertible Preferred Stock issuance	$ —	$ 4,988
Exercise of warrants	$ —	$ 603
Forgiveness of Paycheck Protection Program note	$ —	$ 426
Equity issuance costs	$ 69	$ —
Purchase of property and equipment	$ 491	$ 78
Right-of-use asset related to operating leases	$ 2,918	$ 926

See accompanying notes to condensed consolidated financial statements.

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

1. Nature of Business

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

COVID-19 Vaccine Candidate

In February 2021, the Company entered into a Co-Development, Supply and Commercialization Agreement with Bharat Biotech International Limited ("Bharat Biotech"), pursuant to which the Company obtained an exclusive right and license under certain of Bharat Biotech's intellectual property rights, with the right to grant sublicenses to develop, manufacture, and commercialize BBV152, known as COVAXIN, for the prevention of COVID-19 caused by SARS-CoV-2 in the United States, its territories, and possessions. In June 2021 and April 2022, the Company entered into amendments to the Co-Development, Supply and Commercialization Agreement (as so amended, the "Covaxin Agreement"), pursuant to which the parties agreed to expand the Company's rights to develop, manufacture, and commercialize COVAXIN to include Canada and Mexico, respectively, in addition to the United States, its territories, and possessions (the "Ocugen Covaxin Territory"). COVAXIN is a whole-virion inactivated COVID-19 vaccine candidate and is formulated with the inactivated SARS-CoV-2 virus, an antigen, and an adjuvant. COVAXIN utilizes a toll-like receptor 7/8 agonist molecule (IMDG) adsorbed to alum (Algel) as an adjuvant designed to boost COVAXIN's immunogenicity. The adjuvant used in the formulation of COVAXIN is the first adjuvant in an authorized or approved vaccine against an infectious disease to activate toll-like receptor 7/8. COVAXIN requires a two-dose vaccination regimen given 28 days apart and is stored in standard vaccine storage conditions (2-8°C). COVAXIN is formulated such that the same dosage can be administered to adults and children alike. COVAXIN was granted an Emergency Use Listing ("EUL") by the World Health Organization ("WHO") in November 2021.

The Company is pursuing Biologics License Application ("BLA") approval for COVAXIN in the United States. The Company has initiated a Phase 2/3 immuno-bridging and broadening clinical trial evaluating COVAXIN for adults ages 18 years and older, pursuant to an Investigational New Drug ("IND") application cleared by the U.S. Food and Drug Administration ("FDA"). The clinical trial, which is currently enrolling and dosing patients, is designed to evaluate whether the immune response observed in participants in a completed Phase 3 clinical trial in India is similar to a demographically representative, adult population in the United States. The Company additionally plans to initiate an adult safety clinical trial this year, subject to discussions with the FDA. The Phase 2/3 immuno-bridging and broadening clinical trial and the safety clinical trial will be used to support a BLA submission. In November 2021, the Company submitted a request to the FDA for Emergency Use Authorization ("EUA") for COVAXIN for pediatric use in ages two to 18 years in the United States, which the FDA declined in March 2022. The Company is continuing to assess the regulatory pathway for the pediatric use of COVAXIN in the United States.

The Company is also pursuing approval to market COVAXIN in Canada and recently expanded its commercialization rights for COVAXIN to include Mexico. In July 2021, the Company completed its rolling submission to Health Canada for COVAXIN. The rolling submission process, which was conducted through the Company's Canadian subsidiary, Vaccigen Ltd. ("Vaccigen"), was recommended and accepted under the Minister of Health's *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* ("Interim Order") and transitioned to a New Drug Submission ("NDS") for COVID-19. In December 2021, Health Canada provided the Company with a Notice of Deficiency ("NOD") on its NDS submission and requested further analyses of the COVAXIN preclinical and clinical data, as well as additional information regarding chemistry, manufacturing, and controls ("CMC"). The Company has responded to and provided proposed resolutions for the deficiencies included in the NOD and has continued discussions with Health Canada regarding the Company's NDS submission. The Company's NOD responses are currently under review by Health Canada. The Comisión Federal para la Protección contra Riesgos Sanitarios ("COFEPRIS") authorized emergency use for COVAXIN in Mexico for adults ages 18 years and older, which remains active. COFEPRIS is currently reviewing the EUA submission for COVAXIN in Mexico for pediatric use in ages two to 18 years.

The Company is evaluating its commercialization strategy for COVAXIN in the United States and Canada, if approved in either jurisdiction, and is actively preparing for commercialization in Mexico. In June 2021, the Company selected Jubilant HollisterStier, with whom the Company expects to enter into a master services agreement, as a manufacturing partner to prepare

for the commercial manufacturing of COVAXIN. In September 2021, the Company entered into a Development and Commercial Supply Agreement (the "Supply Agreement") with Bharat Biotech, pursuant to which Bharat Biotech will supply the Company with clinical trial materials and commercial supplies of COVAXIN finished drug product prior to the completion of a technology transfer. Following the completion of the technology transfer to Jubilant HollisterStier, which is in progress, Bharat Biotech will supply COVAXIN drug product components and continue to supply finished drug product as necessary for the commercial manufacture and supply of COVAXIN.

Modifier Gene Therapy Platform

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

The Company believes that OCU400, its first product candidate being developed with its modifier gene therapy platform, 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 four Orphan Drug Designations ("ODDs") from the FDA for the treatment of certain disease genotypes: nuclear receptor subfamily 2 group E member 3 ("*NR2E3*"), centrosomal protein 290 ("*CEP290*"), rhodopsin ("*RHO*"), and phosphodiesterase 6B ("*PDE6ß*") mutation-associated inherited retinal degenerations. Additionally, OCU400 has received Orphan Medicinal Product Designation ("OMPD") from the European Commission ("EC") based on the recommendation of the European Medicines Agency ("EMA") for RP and LCA.

In November 2021, the Company submitted an IND application to the FDA to initiate a Phase 1/2 clinical trial for OCU400 for the treatment of *NR2E3* and *RHO* mutation associated RP, which was cleared by the FDA in December 2021. The Company has initiated the Phase 1/2 clinical trial, a multicenter, open-label, dose ranging study to assess the safety of unilateral subretinal administration of OCU400 in subjects with *NR2E3* and *RHO*-related RP in the United States. The first patient was dosed in March 2022 and the Company has successfully completed dosing patients in the first of three cohorts. After reviewing the data from the first cohort, the independent Data Safety Monitoring Board ("DSMB") has recommended the Company to proceed with dosing in the second cohort. The Company expects to initiate dosing in the second cohort in August 2022.

The Company's second modifier gene therapy candidate, OCU410, is being developed to utilize the nuclear receptor genes RAR-related orphan receptor A ("*RORA*") for the treatment of dry AMD. The Company is currently executing pre-IND studies consistent with FDA discussions to support a Phase 1/2 clinical trial, which the Company intends to initiate next year. The Company has engaged CanSino Biologics, Inc. ("CanSinoBIO") to manufacture clinical trial materials and be responsible for the CMC development for OCU400 and OCU410. CanSinoBIO will be responsible for the costs associated with such activities.

Novel Biologic Therapy for Retinal Diseases

The Company's biologic product candidate, OCU200, is a novel fusion protein designed to treat severely sight-threatening diseases such as 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") that will manufacture OCU200 clinical trial materials. The Company is currently executing pre-IND studies consistent with FDA discussions and manufacturing the clinical trial material (Good Manufacturing Practice ("GMP") batch) for use in the planned Phase 1/2a clinical trial, which the Company intends to initiate next year.

NeoCart Cell Therapy Platform

NeoCart is a three-dimensional tissue-engineered disc of new cartilage that is manufactured by growing chondrocytes, the cells responsible for maintaining cartilage health, which are derived from the patient on a unique scaffold. The Company believes NeoCart has the potential to accelerate healing and reduce pain by rebuilding a patient's damaged knee cartilage. It treats pain at the source, creating a similar, functional joint surface as it was before the injury. Ultimately, the goal is to prevent a patient's progression to osteoarthritis. NeoCart was acquired in the Company's reverse merger in 2019.

Recently, the FDA granted a Regenerative Medicine Advanced Therapy ("RMAT") designation to NeoCart for the repair of full-thickness lesions of the knee cartilage in adults. The Company is currently working with the FDA to finalize the Phase 3 clinical trial protocol necessary to advance the clinical development of NeoCart for eventual market authorization.

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, debt, and grant proceeds. The Company incurred net losses of approximately $37.5 million and $33.0 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, the Company had an accumulated deficit of $169.2 million and cash and cash equivalents totaling $115.0 million. This amount will not meet the Company's capital requirements over the next 12 months. The Company believes that its cash and cash equivalents will enable it to fund its operations into the second quarter of 2023. 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 financing in the future 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 plans to increase working capital through public and private placements of equity and/or debt, payments from potential strategic research and development arrangements, sales of assets, government grants, licensing and/or collaboration arrangements with pharmaceutical companies or other institutions, or other funding from the government or other third parties. Such financing and funding may not be available at all, or on terms that are favorable to the Company. While management of the Company believes that it has a plan to fund ongoing 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 increase in 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 condensed consolidated financial statements included herein have been prepared in conformity with the accounting principles generally accepted 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, 2021, included in the Company's Annual Report on Form 10-K filed with the SEC on February 28, 2022 (the "2021 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 accounting and fair value measurement of equity instruments.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash equivalents may include bank demand deposits, marketable securities with maturities of three months or less at purchase, and money market funds that invest primarily in certificates of deposit, commercial paper, and U.S. government and U.S. government agency obligations. The Company's restricted cash balance consisted of cash held to collateralize a corporate credit card account.

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

	As of June 30,	
	2022	2021
Cash and cash equivalents	$ 115,005	$ 115,642
Restricted cash	—	151
Total cash, cash equivalents, and restricted cash	$ 115,005	$ 115,793

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.

Operating leases are included in other assets and operating lease obligations in the Company's condensed consolidated balance sheets. Operating lease right-of-use assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. Operating lease payments are recognized as lease expense 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. The Company currently leases real estate classified as operating leases. Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 842, *Leases* 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 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 payments.

Fair Value Measurements

The Company follows the provisions of FASB 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 values due to the short-term nature of these instruments. As of June 30, 2022, the Company believes the fair value using Level 2 inputs of the borrowings under the EB-5 Loan Agreement (as defined in Note 7) approximate their carrying value. See Note 7 for additional information.

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 also accounts for certain issuances of preferred stock and warrants in accordance with ASC 718. ASC 718 requires all stock-based payments, including grants of stock options 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 RSUs 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.

Compensation expense related to stock-based compensation awards granted with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Stock-based compensation awards generally vest over a one to three year requisite service period. Stock options have a contractual term of 10 years. Compensation expense for stock-based compensation awards with performance-based vesting conditions is only recognized when the performance-based vesting condition is deemed probable to occur. 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 November 2021, the FASB issued Accounting Standards Update ("ASU") No. 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*. This standard increases the transparency of transactions with the government that are accounted for by applying a grant or contribution accounting model, and aims to reduce diversity that currently exists in the recognition, measurement, presentation, and disclosure of government assistance received by business entities due to the lack of specific authoritative guidance in GAAP. This standard requires an entity to provide information regarding the nature of the transaction with a government and the related accounting policy used to account for this transaction, the line items on the consolidated balance sheet and consolidated statement of operations and comprehensive loss that are affected by the transaction and the amounts applicable to each financial statement line item, and the significant terms and conditions of the transaction, including commitments and contingencies. The standard was effective for the Company on January 1, 2022. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40)*. This standard clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options, including warrants, that remain equity-classified after modification or exchange. The standard requires an entity to treat a modification or an exchange of a freestanding equity-classified written call option that remains equity-classified after the modification or exchange as an exchange of the original instrument for a new instrument. The standard additionally provides guidance on measuring and

recognizing the effect of a modification or an exchange. The standard was effective for the Company on January 1, 2022. 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 include 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 and 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.

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

3. License and Development Agreement

The Company entered into the Covaxin Agreement with Bharat Biotech to co-develop COVAXIN for the Ocugen Covaxin Territory. The Covaxin Agreement was originally entered into in February 2021 with respect to the U.S. market and was subsequently amended in June 2021 to add rights to the Canadian market, for which the Company paid Bharat Biotech a non-refundable, upfront payment of $15.0 million at the execution of the amendment, which was recognized as research and development expense in the condensed consolidated statements of operations and comprehensive loss during the three and six months ended June 30, 2021. The Company additionally agreed to pay Bharat Biotech $10.0 million within 30 days after the first commercial sale of COVAXIN in Canada. The Covaxin Agreement was amended a second time in April 2022 to add rights to the Mexican market. The Covaxin Agreement is a collaboration arrangement within the scope of ASC 808.

Pursuant to the Covaxin Agreement, the Company obtained an exclusive right and license under certain of Bharat Biotech's intellectual property rights, with the right to grant sublicenses, to develop, manufacture, and commercialize COVAXIN in the Ocugen Covaxin Territory. In consideration of the license and other rights granted to the Company by Bharat Biotech, the parties agreed to share any Operating Profits (as defined in the Covaxin Agreement) generated from the commercialization of COVAXIN in the Ocugen Covaxin Territory, with the Company retaining 45% of such profits, and Bharat Biotech receiving the balance of such profits.

Under the Covaxin Agreement, the Company is collaborating with Bharat Biotech to develop COVAXIN for the respective territories of each party. Except with respect to manufacturing rights under certain circumstances subsequently described, the Company has the exclusive right and is solely responsible for researching, developing, manufacturing, and commercializing COVAXIN for the Ocugen Covaxin Territory. Bharat Biotech is responsible for researching, developing, manufacturing, and commercializing COVAXIN outside of the Ocugen Covaxin Territory. Bharat Biotech has agreed to provide to the Company preclinical and clinical data, and to transfer to the Company certain proprietary technology owned or controlled by Bharat Biotech, that is necessary for the successful commercial manufacture and supply of COVAXIN to support potential commercial sale in the Ocugen Covaxin Territory.

In September 2021, the Company entered into the Supply Agreement with Bharat Biotech, pursuant to which Bharat Biotech will supply the Company with clinical trial materials and commercial supplies of COVAXIN finished drug product prior to the completion of a technology transfer. Following the completion of the technology transfer to Jubilant HollisterStier, which is in progress, Bharat Biotech will supply COVAXIN drug product components and continue to supply finished drug product as

necessary for the commercial manufacture and supply of COVAXIN. In March 2021, the Company issued shares of Series B Convertible Preferred Stock (as defined in Note 8) as an advance payment for the supply of COVAXIN to be provided by Bharat Biotech under the Supply Agreement. See Note 8 for additional information about the Series B Convertible Preferred Stock issuance to Bharat Biotech.

The Covaxin Agreement continues in effect for the commercial life of COVAXIN, subject to the earlier termination of the Covaxin Agreement in accordance with its terms. The Covaxin Agreement also contains customary representations and warranties made by both parties and customary provisions relating to indemnification, limitation of liability, confidentiality, information and data sharing, and other matters. The Supply Agreement expires upon the expiration of the Covaxin Agreement and may be earlier terminated by either party in the event of an uncured material breach or bankruptcy of the other party.

4. 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):

	June 30, 2022	December 31, 2021
Furniture and fixtures	$ 497	$ 284
Machinery and equipment	1,211	855
Leasehold improvements	1,342	167
Construction in progress	625	232
Total property and equipment	3,675	1,538
Less: accumulated depreciation	(522)	(374)
Total property and equipment, net	$ 3,153	$ 1,164

5. Operating Leases

The Company has commitments under operating leases for office, laboratory, and storage space located in Malvern, Pennsylvania. The Company's operating leases have initial terms of approximately seven years and include options to extend the operating 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 components of lease expense were as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Operating lease cost	$ 203	$ 66	$ 382	$ 134
Variable lease cost	26	22	53	52
Total lease cost	$ 229	$ 88	$ 435	$ 186

Supplemental balance sheet information related to leases was as follows (in thousands):

	June 30, 2022	December 31, 2021
Right-of-use assets, net	$ 4,172	$ 1,587
Current lease obligations	$ 314	$ 363
Non-current lease obligations	3,892	1,231
Total lease liabilities	$ 4,206	$ 1,594

Supplemental information related to leases was as follows:

	Six months ended June 30,	
	2022	2021
Weighted-average remaining lease term — operating leases (years)	6.7	6.4
Weighted-average discount rate — operating leases	6.4 %	4.6 %

Future minimum operating lease base rent payments are approximately as follows (in thousands):

For the Years Ending December 31,	Amount
Remainder of 2022	$ 212
2023	762
2024	785
2025	809
2026	833
Thereafter	1,859
Total	$ 5,260
Less: present value adjustment	(1,054)
Present value of minimum lease payments	$ 4,206

6. Accrued Expenses

Accrued expenses are as follows (in thousands):

	June 30, 2022	December 31, 2021
Research and development	$ 818	$ 866
Clinical	233	703
Professional fees	789	747
Employee-related	1,846	1,716
Other	417	293
Total accrued expenses	$ 4,103	$ 4,325

7. Debt

In September 2016, pursuant to the U.S. government's Immigrant Investor Program, commonly known as the EB-5 program, the Company entered into an arrangement (the "EB-5 Loan Agreement") to borrow up to $10.0 million from EB5 Life Sciences, L.P. ("EB-5 Life Sciences") in $0.5 million increments. Borrowings may be limited by the amount of funds raised by EB-5 Life Sciences and are subject to certain job creation requirements by the Company. Borrowings are at a fixed interest rate of 4.0% per annum and are to be utilized in the clinical development, manufacturing, and commercialization of the Company's product candidates and for the general working capital needs of the Company. Outstanding borrowings pursuant to the EB-5 Loan Agreement, including accrued interest, become due upon the seventh anniversary of the final disbursement. Amounts repaid cannot be re-borrowed. The EB-5 Loan Agreement borrowings are secured by substantially all assets of the Company, except for any patents, patent applications, pending patents, patent licenses, patent sublicenses, trademarks, and other intellectual property rights. Under the terms and conditions of the EB-5 Loan Agreement, the Company has borrowed $1.5 million. Issuance costs were recognized as a reduction to the loan balance and are amortized to interest expense over the term of the loan.

The carrying values of the EB-5 Loan Agreement borrowings as of June 30, 2022 and December 31, 2021 are summarized below (in thousands):

	June 30, 2022	December 31, 2021
Principal outstanding	$ 1,500	$ 1,500
Plus: accrued interest	271	241
Less: unamortized debt issuance costs	(21)	(29)
Carrying value, net	$ 1,750	$ 1,712

8. Equity

COVAXIN Preferred Stock Purchase Agreement

On March 1, 2021, the Company entered into a preferred stock purchase agreement, 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 to be provided by Bharat Biotech pursuant to the Supply Agreement. In February 2022, the Company entered into a supply commitment to purchase $14.3 million of COVAXIN drug product components from Bharat Biotech to support the technology transfer from Bharat Biotech to Jubilant HollisterStier. The doses produced using these drug product components are expected to be commercially salable following successful completion of process qualification activities and regulatory approval. The previously issued Series B Convertible Preferred Stock as an advance payment for the supply of COVAXIN to be provided by Bharat Biotech will be applied to this commitment.

Each share of Series B Convertible Preferred Stock is 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. As of June 30, 2022, the conversion condition relating to the delivery of the first 10.0 million doses of COVAXIN had not been met. The conversion rate of the Series B Convertible Preferred Stock is 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 equity during the six months ended June 30, 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 sheets as of June 30, 2022 and 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 incorporates 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.

Offerings of Common Stock

Public Offering

In February 2022, the Company entered into an underwriting agreement with Cantor Fitzgerald & Co., 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 "Public Offering"). Upon the closing of the Public Offering, the Company received net proceeds of $49.8 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

Registered Direct Offerings

In April 2021, the Company entered into a securities purchase agreement with certain institutional investors pursuant to which the Company sold 10.0 million shares of its common stock at an offering price of $10.00 per share in a registered direct offering

(the "April 2021 Registered Direct Offering"). Upon the closing of the April 2021 Registered Direct Offering, the Company received net proceeds of $93.4 million after deducting equity issuance costs of $6.6 million.

In February 2021, the Company entered into a securities purchase agreement with certain institutional investors pursuant to which the Company sold 3.0 million shares of its common stock at an offering price of $7.65 per share in a registered direct offering (the "February 2021 Registered Direct Offering"). Upon the closing of the February 2021 Registered Direct Offering, the Company received net proceeds of $21.2 million after deducting equity issuance costs of $1.7 million.

At-the-Market Offering

During the six months ended June 30, 2021, the Company sold 1.0 million shares of the Company's common stock under an at-the-market offering and received net proceeds of $4.8 million after deducting equity issuance costs of $0.1 million.

9. Warrants

Liminal Warrants

On January 24, 2022 (the "Issuance Date"), the Company entered into a non-binding letter of intent ("LOI") with Liminal Biosciences Inc. ("Liminal") for the acquisition of Liminal's manufacturing site in Belleville, Ontario, Canada for a combination of cash and warrants to purchase the Company's common stock. Pursuant to the LOI, the Company issued warrants to purchase 2.3 million shares of the Company's common stock at an exercise price of $3.76, subject to certain adjustments (the "Liminal Warrants"). The Liminal Warrants vest and become exercisable upon closing of the transactions contemplated by the LOI and terminate on the tenth anniversary of the Issuance Date, unless earlier terminated in accordance with their terms. The Liminal Warrants are cancellable by the Company in the event the transactions contemplated by the LOI are not consummated. As of June 30, 2022, all of the Liminal Warrants were outstanding and unvested. The Liminal Warrants are accounted for in accordance with ASC 718.

Completion of the transaction proposed in the LOI is subject to finalization of due diligence investigations by the parties, the negotiation and execution of definitive transaction agreements, and other customary closing conditions including certain funding requirements. The LOI may be terminated at any time by mutual written consent of the Company and Liminal, among other termination provisions contained in the LOI.

Canada Warrants

In July 2021, the Company entered into a consulting agreement with an individual to provide services to the Company with regard to the Company's Canadian operations (the "Canada Consulting Agreement"). Compensation under the Canada Consulting Agreement includes, among other forms of compensation, 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 upon the achievement of certain milestones related to COVAXIN. The Canada Consulting Agreement terminates in July 2023, unless earlier terminated in accordance with its terms.

The Canada Warrants were issued on July 15, 2021 in a private placement transaction. The warrant holder has the right to exercise the Canada Warrants to purchase up to 0.2 million shares of the Company's common stock at an exercise price of $6.36 per share upon the achievement of certain milestones related to COVAXIN. The Canada Warrants terminate on July 15, 2031, unless earlier terminated in accordance with their terms. As of June 30, 2022 and December 31, 2021, all of the Canada Warrants were outstanding and unvested. The Canada Warrants are accounted for in accordance with ASC 718.

OpCo Warrants

Beginning in 2016, OpCo issued warrants to purchase the Company's common stock (the "OpCo Warrants"). As of June 30, 2022 and December 31, 2021, 0.6 million OpCo Warrants were outstanding. As of June 30, 2022, the outstanding OpCo Warrants had a weighted-average exercise price of $6.23. The outstanding OpCo Warrants expire between 2026 and 2027.

10. 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 June 30,		Six months ended June 30,	
	2022	2021	2022	2021
General and administrative	$ 1,495	$ 1,527	$ 3,711	$ 2,117
Research and development	584	568	1,667	811
Total	$ 2,079	$ 2,095	$ 5,378	$ 2,928

As of June 30, 2022, the Company had $21.9 million of unrecognized stock-based compensation expense related to stock options and RSUs outstanding. This expense is expected to be recognized over a weighted-average period of 2.1 years as of June 30, 2022.

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 June 30, 2022, the 2014 Plan and 2019 Plan authorize for the granting of up to 0.8 million and 19.5 million equity awards with respect to the Company's common stock, respectively. 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.

Options to Purchase Common Stock

The following table summarizes the stock option activity:

	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Options outstanding at December 31, 2021	10,086,167	$ 2.59	8.8	$ 24,664
Granted	5,480,035	$ 3.99		
Exercised	(766,166)	$ 0.77		
Forfeited	(2,375,303)	$ 3.88		
Options outstanding at June 30, 2022	12,424,733	$ 3.08	8.7	$ 5,574
Options exercisable at June 30, 2022	3,396,021	$ 2.32	7.7	$ 2,608

As of June 30, 2022 and December 31, 2021, there were 1.0 million and 1.2 million of stock options with performance-based vesting conditions outstanding, of which 0.7 million and 0.9 million were not yet vested and exercisable, respectively. The weighted-average grant date fair values of stock options granted during the three and six months ended June 30, 2022 were $1.96 and $3.26, respectively. The weighted-average grant date fair values of stock options granted during the three and six months ended June 30, 2021 were $4.98 and $2.60, respectively. The total fair values of stock options vested during the three and six months ended June 30, 2022 were $1.1 million and $4.0 million, respectively. The total fair values of stock options vested during the three and six months ended June 30, 2021 were $0.3 million and $0.6 million, respectively.

RSUs

The following table summarizes the RSU activity:

	Number of Shares	Weighted-Average Grant-Date Fair Value
RSUs outstanding at December 31, 2021	191,811	$ 6.79
Granted	1,217,834	$ 4.28
Vested	(44,156)	$ 6.25
Forfeited	(390,447)	$ 4.64
RSUs outstanding at June 30, 2022	975,042	$ 4.54

11. Net Loss Per Share of Common Stock

The following table sets forth the computation of basic and diluted earnings per share for the three and six months ended June 30, 2022 and 2021 (in thousands, except share and per share amounts):

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Net loss — basic and diluted	$ (19,471)	$ (25,952)	$ (37,490)	$ (33,029)
Shares used in calculating net loss per common share — basic and diluted	215,862,977	195,572,189	210,806,330	190,960,775
Net loss per common share — basic and diluted	$ (0.09)	$ (0.13)	$ (0.18)	$ (0.17)

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 June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Options to purchase common stock	12,424,733	10,378,847	12,424,733	10,378,847
RSUs	975,042	116,701	975,042	116,701
Warrants	3,110,655	774,137	3,110,655	774,137
Series A Convertible Preferred Stock (as converted to common stock)	—	3,115	—	3,115
Series B Convertible Preferred Stock (as converted to common stock)	547,450	547,450	547,450	547,450
Total	17,057,880	11,820,250	17,057,880	11,820,250

12. Commitments and Contingencies

Commitments

The Company has commitments under certain license and development agreements, lease agreements, debt agreements, supply agreements, and consulting 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 licensing agreements are more fully described within Note 3 and within the Company's 2021 Annual Report). Commitments under lease agreements are future minimum lease payments (see Note 5). Commitments under debt agreements are the future payment of principal and accrued interest under the EB-5 Loan Agreement (see Note 7). Commitments under supply agreements are purchases of drug product components to support the technology transfer from Bharat Biotech to Jubilant HollisterStier related to COVAXIN (see Note 8). Commitments under consulting agreements include payments upon the achievement of certain milestones related to COVAXIN (see Note 9).

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 EUA for the vaccine candidate. In July 2021, a second securities class action was filed against the Company and certain of its officers and directors 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 actions and appointed Andre Galan Bernd Benayon to serve as lead plaintiff. The lead plaintiff's amended complaint was filed in June 2022. The Company's motion to dismiss the amended complaint is due in August 2022. The lead plaintiff's opposition to the motion to dismiss is due in October 2022, and the Company's reply in support of its motion to dismiss is due in November 2022.

In August 2021, a stockholder derivative lawsuit was filed derivatively on behalf of the Company against certain of its officers and directors 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 officers and directors 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 have stipulated to the consolidation of the two stockholder derivative lawsuits and also have 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.

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.

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, 2021, included in our 2021 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 2021 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 and vaccines that improve health and offer hope for patients across the globe.

Our cutting-edge technology pipeline includes:

- **COVID-19 Vaccine Candidate** — COVAXIN is a whole-virion inactivated COVID-19 vaccine candidate being developed to prevent COVID-19, caused by SARS-CoV-2, in humans. We are co-developing COVAXIN with Bharat Biotech for the North American market.
- **Modifier Gene Therapy Platform** — Based on NHRs, we believe our modifier gene therapy platform has the potential to address many retinal diseases, including RP, LCA, and dry AMD.
- **Novel Biologic Therapy for Retinal Diseases** — OCU200 is a novel biologic product candidate designed to treat DME, DR, and wet AMD.
- **NeoCart Cell Therapy Platform** — We recently introduced a Phase 3 cell therapy platform technology called NeoCart (autologous chondrocyte-derived neocartilage) to our pipeline, which is being developed for the repair of full-thickness lesions of the knee cartilage in adults.

COVID-19 Vaccine Candidate

In February 2021, we entered into the Covaxin Agreement with Bharat Biotech, pursuant to which we obtained an exclusive right and license under certain of Bharat Biotech's intellectual property rights, with the right to grant sublicenses to develop, manufacture, and commercialize COVAXIN for the prevention of COVID-19 in the United States, its territories, and possessions. In June 2021 and April 2022, we entered into amendments to the Covaxin Agreement, pursuant to which we and Bharat Biotech agreed to expand our rights to develop, manufacture, and commercialize COVAXIN to include Canada and Mexico, respectively, in addition to the United States, its territories, and possessions. COVAXIN is formulated with the inactivated SARS-CoV-2 virus, an antigen, and an adjuvant. COVAXIN utilizes a toll-like receptor 7/8 agonist molecule (IMDG) adsorbed to alum (Algel) as an adjuvant designed to boost COVAXIN's immunogenicity. The adjuvant used in the formulation of COVAXIN is the first adjuvant in an authorized or approved vaccine against an infectious disease to activate toll-like receptor 7/8. COVAXIN requires a two-dose vaccination regimen given 28 days apart and is stored in standard vaccine storage conditions (2-8°C). COVAXIN was granted an EUL by the WHO in November 2021, has been authorized or approved for use in over 25 countries, and is accepted for travel purposes in over 85 countries. Over 350 million doses have been administered to date.

The Phase 3 clinical trial conducted by Bharat Biotech in India in 25,798 adults ages 18 years and older, who were healthy or had stable chronic medical conditions, reported an overall estimated vaccine efficacy of COVAXIN against COVID-19 of 77.8%, with efficacy against severe COVID-19 of 93.4%, and efficacy against asymptomatic COVID-19 of 63.6%. Individuals with asymptomatic infection have a detectable viral load in nasal and saliva swabs and therefore are considered carriers of COVID-19. COVAXIN was generally well tolerated, with no clinically or statistically significant differences in reported adverse events in the vaccine and placebo groups. Additionally, a Phase 2/3 immuno-bridging clinical trial was conducted by Bharat Biotech in India to assess the protective immunity of COVAXIN in children ages two to 18 years. COVAXIN is formulated such that the same dosage can be administered to adults and children alike. The results demonstrated a robust

neutralizing antibody response comparable to that of the adults studied in a Phase 2 clinical trial conducted by Bharat Biotech in India, and that COVAXIN was generally well tolerated. Among the 526 study subjects in the Phase 2/3 pediatric clinical trial, no serious adverse events, such as deaths, hospitalizations, myocarditis, pericarditis, Guillain-Barre syndrome, vaccine-induced thrombotic thrombocytopenia, or anaphylactic reactions were reported. COVAXIN has received EUA approval in India for children ages six to 18 years. Further, data from clinical trials conducted by Bharat Biotech has shown that COVAXIN has neutralizing potential against multiple variants of concern including both the Omicron (B.1.1.529) and Delta (B.1.617.2) variants.

We are pursuing a BLA submission for COVAXIN for adults ages 18 years and older in the United States. We initiated a Phase 2/3 immuno-bridging and broadening clinical trial evaluating COVAXIN for adults ages 18 years and older, pursuant to the IND application cleared by the FDA. The clinical trial, which is currently enrolling and dosing patients, is designed to evaluate whether the immune response observed in participants in the aforementioned completed Phase 3 clinical trial in India is similar to a demographically representative, adult population in the United States. We additionally plan to initiate an adult safety clinical trial this year, subject to discussions with the FDA. The Phase 2/3 immuno-bridging and broadening clinical trial and the safety clinical trial will be used to support a BLA submission. In November 2021, we submitted a request to the FDA for EUA for COVAXIN for pediatric use in ages two to 18 years in the United States, which the FDA declined in March 2022. We are continuing to assess the regulatory pathway for the pediatric use of COVAXIN in the United States.

We are also pursuing approval to market COVAXIN in Canada and recently expanded our commercialization rights for COVAXIN under the Covaxin Agreement to include Mexico. In July 2021, we completed our rolling submission to Health Canada for COVAXIN. The rolling submission process, which was conducted through our Canadian subsidiary, Vaccigen, was recommended and accepted under the Interim Order and transitioned to a NDS for COVID-19. In December 2021, Health Canada provided us with a NOD on our NDS submission and requested further analyses of the COVAXIN preclinical and clinical data, as well as additional information regarding CMC. We have responded to and provided proposed resolutions for the deficiencies included in the NOD and have continued discussions with Health Canada regarding our NDS submission. Our NOD responses are currently under review by Health Canada. COFEPRIS has authorized emergency use for COVAXIN in Mexico for adults ages 18 years and older, which remains active. COFEPRIS is currently reviewing the EUA submission for COVAXIN in Mexico for pediatric use in ages two to 18 years.

We are evaluating our commercialization strategy for COVAXIN in the United States and Canada, if approved in either jurisdiction, and are actively preparing for commercialization in Mexico. In June 2021, we selected Jubilant HollisterStier, with whom we expect to enter into a master services agreement, as our manufacturing partner to prepare for the commercial manufacturing of COVAXIN. In September 2021, we entered into the Supply Agreement with Bharat Biotech, pursuant to which Bharat Biotech will supply us with clinical trial materials and commercial supplies of COVAXIN finished drug product prior to the completion of a technology transfer. Following the completion of the technology transfer to Jubilant HollisterStier, which is in progress, Bharat Biotech will supply COVAXIN drug product components and continue to supply finished drug product as necessary for the commercial manufacture and supply of COVAXIN.

Modifier Gene Therapy Platform

We are developing a modifier gene therapy platform designed to fulfill unmet medical needs in retinal diseases, including IRDs, such as RP and LCA, and dry AMD. Our modifier gene therapy platform is based on 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 to address multiple retinal diseases caused by mutations in multiple genes with one product; and potentially address complex diseases, such as dry AMD, that are potentially caused by imbalances in multiple gene networks.

IRDs, such as RP and LCA, can lead to visual impairment and blindness and affect over two million people worldwide. RP and LCA are rooted in mutations of more than 175 different genes. We believe that OCU400, our first product candidate being developed with our modifier gene therapy platform, has the potential to be broadly effective in restoring retinal integrity and function across a range of IRDs, including RP and LCA. OCU400 has received four ODDs from the FDA for the treatment of certain disease genotypes: *NR2E3*, *CEP290*, *RHO*, and *PDE6ß* mutation-associated inherited retinal degenerations. Additionally, OCU400 has received OMPD from the EC based on the recommendation of the EMA for RP and LCA, which we believe demonstrates that OCU400 has the potential to be a broad-spectrum therapeutic to treat many IRDs.

In November 2021, we submitted an IND application to the FDA to initiate a Phase 1/2 clinical trial for OCU400 for the treatment of *NR2E3* and *RHO* mutation associated RP, which was cleared by the FDA in December 2021. We have initiated the Phase 1/2 clinical trial, a multicenter, open-label, dose ranging study to assess the safety of unilateral subretinal administration of OCU400 in subjects with *NR2E3* and *RHO*-related RP in the United States. The first patient was dosed in March 2022 and

we have successfully completed dosing patients in the first of three cohorts. After reviewing the data from the first cohort, the independent DSMB recommended us to proceed with dosing in the second cohort. We expect to initiate dosing in the second cohort in August 2022.

Our second modifier gene therapy candidate, OCU410, is being developed to utilize the nuclear receptor genes *RORA* for the treatment of dry AMD. We are currently executing pre-IND studies consistent with FDA discussions to support a Phase 1/2 clinical trial, which we intend to initiate next year. We have engaged CanSinoBIO to manufacture clinical trial materials and be responsible for the CMC development for OCU400 and OCU410. CanSinoBIO will be responsible for the costs associated with such activities.

Novel Biologic Therapy for Retinal Diseases

Our biologic product candidate, OCU200, is a novel fusion protein designed to treat severely sight-threatening diseases such as DME, DR, and wet AMD. We have completed the technology transfer of manufacturing processes to our CDMO that will manufacture OCU200 clinical trial materials. We are currently executing pre-IND studies consistent with FDA discussions and manufacturing the clinical trial material (GMP batch) for use in the planned Phase 1/2a clinical trial, which we intend to initiate next year.

NeoCart Cell Therapy Platform

NeoCart is a three-dimensional tissue-engineered disc of new cartilage that is manufactured by growing chondrocytes, the cells responsible for maintaining cartilage health, which are derived from the patient on a unique scaffold. We believe NeoCart has the potential to accelerate healing and reduce pain by rebuilding a patient's damaged knee cartilage. It treats pain at the source, creating a similar, functional joint surface as it was before the injury. Ultimately, the goal is to prevent a patient's progression to osteoarthritis. NeoCart was acquired in our reverse merger in 2019.

Recently, the FDA granted the RMAT designation to NeoCart for the repair of full-thickness lesions of the knee cartilage in adults. We are currently working with the FDA to finalize the Phase 3 clinical trial protocol necessary to advance the clinical development of NeoCart for eventual market authorization.

Impact of COVID-19 on our Business

The COVID-19 pandemic remains ongoing and we continue to closely monitor the situation. Impacts from the COVID-19 pandemic still remain uncertain and are subject to change and, as such, we cannot predict the specific duration or impact that the COVID-19 pandemic may have on our operations going forward, including our preclinical activities, current and future clinical trials, and commercialization activities. The extent to which the COVID-19 pandemic may impact our operations is dependent on future developments, including but not limited to: (i) the duration of the spread of the SARS-CoV-2 virus, including the spread of current and future variants, (ii) the actions taken by governmental authorities and regulators with respect to the COVID-19 pandemic, and (iii) the impact on our partners, collaborators, and suppliers. We will continue to monitor the situation closely as these effects could have a material impact on our operations.

Results of Operations

Comparison of the Three Months Ended June 30, 2022 and 2021

	Three months ended June 30,		
	2022	2021	Change
Operating expenses			
Research and development	$ 9,007	$ 18,853	$ (9,846)
General and administrative	10,558	6,757	3,801
Total operating expenses	19,565	25,610	(6,045)
Loss from operations	(19,565)	(25,610)	6,045
Other income (expense), net	94	(342)	436
Net loss	$ (19,471)	$ (25,952)	$ 6,481

Research and development expense

Research and development expense decreased by $9.8 million for the three months ended June 30, 2022 compared to the three months ended June 30, 2021. The decrease was primarily due to the $15.0 million upfront payment to Bharat Biotech in connection with the amendment to the Covaxin Agreement to add rights to the Canadian market in June 2021, offset by increases of $2.3 million in employee-related expenses as we expand our headcount and continue to provide competitive compensation plans to support our development, commercialization, and business efforts, $1.7 million in COVAXIN preclinical and clinical activities, $0.9 million in OCU200 preclinical activities, and $0.2 million in OCU410 preclinical activities. OCU400 clinical activities increased $0.7 million, which was offset by a decrease in OCU400 preclinical activities of $0.8 million.

General and administrative expense

General and administrative expense increased by $3.8 million for the three months ended June 30, 2022 compared to the three months ended June 30, 2021. The increase was primarily due to increases of $1.2 million in employee-related expenses, $1.1 million in office expenses for our new corporate headquarters, $1.0 million in professional and consulting services, including legal fees, and $0.6 million in pre-commercialization activities. These increases were partially offset by a decrease of $0.5 million in expenses for the annual stockholder meeting and proxy solicitation.

Other income (expense), net

Other income (expense), net increased by $0.4 million for the three months ended June 30, 2022 compared to the three months ended June 30, 2021. The increase was primarily due to a loss of $0.8 million related to the write-off of a note receivable deemed uncollectible, partially offset by a gain on loan extinguishment of $0.4 million for the forgiveness of the Paycheck Protection Program note both during the three months ended June 30, 2021.

Comparison of the Six Months Ended June 30, 2022 and 2021

	Six months ended June 30,		
	2022	2021	Change
Operating expenses			
Research and development	$ 16,922	$ 21,725	$ (4,803)
General and administrative	20,677	10,942	9,735
Total operating expenses	37,599	32,667	4,932
Loss from operations	(37,599)	(32,667)	(4,932)
Other income (expense), net	109	(362)	471
Net loss	$ (37,490)	$ (33,029)	$ (4,461)

Research and development expense

Research and development expense decreased by $4.8 million for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. The decrease was primarily due to the $15.0 million upfront payment to Bharat Biotech in connection with the amendment to the Covaxin Agreement to add rights to the Canadian market in June 2021 offset by increases of $5.1 million in employee-related expenses, including $0.9 million in stock-based compensation expense, $2.9 million in COVAXIN preclinical, clinical, and CMC activities, and $1.7 million in OCU200 preclinical activities. These increases were partially offset by a decrease of $0.5 million in professional services related to COVAXIN, including consulting services. Additionally, OCU400 clinical activities increased $1.2 million, which was offset by a decrease in OCU400 preclinical activities of $1.3 million.

General and administrative expense

General and administrative expense increased by $9.7 million for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. The increase was primarily due to increases of $4.2 million in employee-related expenses, including $1.6 million in stock-based compensation expense, $3.5 million in professional and consulting services, including legal fees, $1.5 million in pre-commercialization activities, $1.2 million in office expenses for our new corporate headquarters,

and $0.6 million in insurance. These increases were partially offset by a decrease of $1.7 million in expenses for the annual stockholder meeting and proxy solicitation.

Other income (expense), net

Other income (expense), net increased by $0.5 million for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. The increase was primarily due to a loss of $0.8 million related to the write-off of a note receivable deemed uncollectible, partially offset by a gain on loan extinguishment of $0.4 million for the forgiveness of the Paycheck Protection Program note both during the six months ended June 30, 2021.

Liquidity and Capital Resources

As of June 30, 2022, we had $115.0 million in cash and cash equivalents. We have not generated significant revenue to date and have primarily funded our operations to date through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes, debt, and grant proceeds. Since our inception and through June 30, 2022, we have raised an aggregate of $270.0 million to fund our operations, of which $257.3 million was from gross proceeds from the sale of our common stock and warrants, $10.3 million was from the issuance of convertible notes, $2.2 million was from debt, and $0.2 million was from grant proceeds.

In June 2022, we entered into an At Market Issuance Sales Agreement ("Sales Agreement") with certain agents, whereby we may, from time to time, offer and sell shares of our common stock having an aggregate gross sales price of up to $160.0 million. The offer and sale of the shares of common stock made pursuant to the Sales Agreement, if any, will be made under our Registration Statement on Form S-3ASR, which was previously filed with the SEC and became automatically effective on March 22, 2021, as supplemented by a prospectus supplement, dated June 10, 2022. We will pay the agents a commission rate of 3.0% of the gross sales price per share of common stock sold through the agents, as well as reimburse certain expenses. No sales of shares of our common stock have been effected pursuant to the Sales Agreement as of June 30, 2022.

In February 2022, we issued and sold 16.0 million shares of our common stock at a public offering price of $3.13 per share pursuant to the underwritten offering. We received net proceeds of $49.8 million, after deducting underwriting discounts and commissions and offering expenses.

Since our inception, we have devoted substantial resources to the research, development, and commercialization of our product candidates and have incurred significant net losses and may continue to incur net losses in the future. We incurred net losses of approximately $37.5 million and $33.0 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $169.2 million. Additionally, we had accounts payable and accrued expenses of $10.0 million and indebtedness of $1.8 million as of June 30, 2022.

The following table shows a summary of our cash flows for the six months ended June 30, 2022 and 2021 (in thousands):

	Six months ended June 30,	
	2022	2021
Net cash used in operating activities	$ (28,863)	$ (27,084)
Net cash used in investing activities	(1,589)	(1,274)
Net cash provided by financing activities	50,338	119,961
Effect of changes in exchange rate on cash, cash equivalents, and restricted cash	10	—
Net increase in cash, cash equivalents, and restricted cash	$ 19,896	$ 91,603

Operating activities

Cash used in operating activities was $28.9 million for the six months ended June 30, 2022 compared to $27.1 million for the six months ended June 30, 2021. The increase in cash used in operating activities was primarily driven by an increase in our operating expenses to continue to support our development, commercialization, and business efforts including development and pre-commercialization expenses for our product candidates, employee-related expenses to offer competitive compensation plans, and professional and consulting services. These increases were offset by a $15.0 million upfront payment to Bharat Biotech in connection with the amendment to the Covaxin Agreement to add rights to the Canadian market in June 2021.

Investing activities

Cash used in investing activities was $1.6 million for the six months ended June 30, 2022 compared to $1.3 million for the six months ended June 30, 2021. The increase in cash used in investing activities was primarily driven by an increase of $1.1 million in purchases of property and equipment during the six months ended June 30, 2022 as compared to the six months ended June 30, 2021, partially offset by the receipt of a note receivable of $0.8 million during the six months ended June 30, 2021.

Financing activities

Cash provided by financing activities was $50.3 million for the six months ended June 30, 2022 compared to $120.0 million for the six months ended June 30, 2021. During the six months ended June 30, 2022, cash provided by financing activities primarily consisted of gross proceeds of $50.0 million received from the underwritten offering that closed in February 2022. During the six months ended June 30, 2021, cash provided by financing activities primarily consisted of gross proceeds of $100.0 million and $22.9 million received from the April 2021 Registered Direct Offering and the February 2021 Registered Direct Offering, respectively.

Contractual Obligations

We have commitments under certain licensing and development agreements, lease obligations, debt agreements, supply agreements, and consulting agreements. There have been no material changes to our contractual obligations as reported in our 2021 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, contract to manufacture our product candidates, prepare for 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 clinical trials for our product candidates;
- the outcome, timing, and cost of the regulatory approval process for our product candidates; including with respect to COVAXIN in the Ocugen Covaxin Territory;
- the costs of manufacturing and commercialization, including with respect to COVAXIN;
- costs related to doing business internationally with respect to our development and commercialization of COVAXIN in Canada and Mexico;
- 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;
- the expenses needed to attract and retain skilled personnel;
- the extent to which we in-license or acquire other products, product candidates, or technologies;
- the impact of the COVID-19 pandemic on our activities; and
- the impact of geopolitical turmoil, including the ongoing invasion of Ukraine by Russia or increased trade restrictions between the United States, Russia, China and other countries, social unrest, political instability, terrorism, or other acts of war.

As of June 30, 2022, we had cash and cash equivalents of approximately $115.0 million. This amount will not meet our capital requirements over the next 12 months. We believe that our cash and cash equivalents will enable us to fund our operations into the second quarter of 2023. 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 future operations until we recognize significant revenue from product sales. Our management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to: public and private placements of equity and/or debt, including sales of common stock through the Sales Agreement, pursuant to which we may, but are not obligated to, issue and sell up to $160.0 million of shares of our common stock, payments from potential strategic research and development arrangements, sales of assets, government grants, licensing and/or collaboration arrangements with pharmaceutical companies or other institutions, or other funding from the government or other third parties. Our ability to secure funding is subject to numerous risks and uncertainties, including the impact of the COVID-19 pandemic and geopolitical turmoil, including related to the ongoing invasion of Ukraine by Russia, 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 increase in spending that will be necessary to continue to research, develop, and commercialize our product candidates, there is substantial doubt about our ability to continue as a going concern within one year after the date that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q are issued.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of financial statements in conformity with GAAP requires us to make judgments, estimates, and assumptions in the preparation of our condensed consolidated financial statements. Actual results could differ from those estimates. There have been no material changes to our critical accounting policies and estimates as reported in our 2021 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.

Other Company Information

None.

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 June 30, 2022. Based upon that 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 disclosure. 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 12 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 in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 (the "First Quarter 10-Q"), there have been no material changes in our risk factors as previously disclosed in our 2021 Annual Report. The risks described in our 2021 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

During the period covered by this Quarterly Report on Form 10-Q, there were no sales by us of unregistered securities 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.

Exhibit	Description
10.1	At Market Issuance Sales Agreement, dated June 10, 2022, by and between the Company, Cantor Fitzgerald & Co., Mizuho Securities USA LLC, H.C. Wainwright & Co., LLC, Roth Capital Partners, LLC, and Chardan Capital Markets, LLC (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K as filed on June 10, 2022, and incorporated herein by reference)
10.2+	First Amendment to Amended and Restated Executive Employment Agreement, dated as of April 27, 2022, by and between the Company and Shankar Musunuri (filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q as filed on May 6, 2022, and incorporated herein by reference)
10.3#	Second Amendment to Co-Development, Supply and Commercialization Agreement, dated as of April 15, 2022, by and between the Company and Bharat Biotech International Limited (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q as filed on May 6, 2022, and incorporated herein by reference)
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 Chief Accounting Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certifications of the Chief Executive Officer and 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.

Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

\+ Indicates a management contract or compensatory plan or arrangement.

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: August 5, 2022

/s/ Shankar Musunuri

Shankar Musunuri, Ph.D., MBA
Chief Executive Officer and Chairman
(Principal Executive Officer)

Dated: August 5, 2022

/s/ Jessica Crespo

Jessica Crespo, CPA
Chief Accounting Officer and Senior Vice President, Finance
(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. 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: August 5, 2022 /s/ Shankar Musunuri, Ph.D., MBA

Shankar Musunuri, Ph.D., MBA
Chief Executive Officer and Chairman
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Jessica Crespo, 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: August 5, 2022 /s/ Jessica Crespo

Jessica Crespo, CPA
Chief Accounting Officer and Senior Vice President, Finance
(Principal Financial Officer and Principal Accounting 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)

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), each of the undersigned officers of Ocugen, Inc. (the Company), does hereby certify, to the best of such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 (the Form 10-Q) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, 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: August 5, 2022 /s/ Shankar Musunuri, Ph.D., MBA

Shankar Musunuri, Ph.D., MBA
Chief Executive Officer and Chairman
(Principal Executive Officer)

Date: August 5, 2022 /s/ Jessica Crespo

Jessica Crespo, CPA
Chief Accounting Officer and Senior Vice President, Finance
(Principal Financial Officer and Principal Accounting 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.