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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

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.)

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

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	**OCGN**	**The Nasdaq Stock Market LLC (The Nasdaq Capital Market)**

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

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

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

Large accelerated filer	☐	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 7(a)(2)(B) of the Securities Act. ☐

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

As of November 2, 2021, there were 199,185,877 outstanding shares of the registrant's common stock, $0.01 par value per share.

OCUGEN, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2021

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 contained in our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission (“SEC”) on March 19, 2021 (the "2020 Annual Report") include, among other things, statements about:

- our estimates regarding expenses, future revenue, capital requirements, and timing and availability of and the need for additional financing;
- our ability to obtain sufficient additional capital to continue to advance our product candidates and our preclinical programs;
- our activities with respect to BBV152, known as COVAXIN outside the United States, 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, if authorized or approved in the United States and Canada;
- our submission of a request to the U.S. Food and Drug Administration (the “FDA”) for Emergency Use Authorization for COVAXIN for pediatric use in children ages two to 18 years in the United States, which was based on the results of a Phase 2/3 immuno-bridging pediatric clinical trial conducted by Bharat Biotech in India;
- our plans regarding the submission of a Biologics License Application ("BLA") to the FDA for COVAXIN for ages 18 years and older, including the need for a Phase 3 immuno-bridging study to support a BLA submission as well as a safety-bridging study if required by the FDA;
- our ability to successfully obtain adequate supply of COVAXIN from Bharat Biotech and to complete a technology transfer to Jubilant HollisterStier or another third-party manufacturer and engage such manufacturer on commercially acceptable terms;
- anticipated market demand for COVAXIN in the United States or Canada, including for both the pediatric and adult population;
- the extent to which health epidemics and other outbreaks of communicable diseases, including the COVID-19 pandemic, could disrupt our business and operations;
- the uncertainties associated with the clinical development and regulatory authorization or approval of our product candidates, including potential delays in the commencement, enrollment, and completion of clinical trials;
- our ability to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of 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 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, and other foreign countries; including the extent to which developments with respect to the COVID-19 pandemic will affect the regulatory pathway available for vaccines in the United States, Canada, or other jurisdictions;
- the performance of third-parties upon which we depend, including third-party contract development and manufacturing organizations, and third-party suppliers, manufacturers, group purchasing organizations, distributors, and logistics providers;

- the pricing and reimbursement of our product candidates, if authorized or approved;
- 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; including with Bharat Biotech, and our ability to establish additional collaborations and/or partnerships;
- our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers;
- our ability to comply with stringent U.S., Canada, and other foreign government regulation in the manufacture of pharmaceutical products, including Good Manufacturing Practice compliance and other relevant regulatory authorities;
- the impact of the COVID-19 pandemic on our development programs, global supply chain, and collaborators and manufacturers, including Bharat Biotech; and
- other matters discussed under the heading “Risk Factors” contained in this Quarterly Report on Form 10-Q, the 2020 Annual Report, 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 this Quarterly Report on Form 10-Q and in the 2020 Annual Report, 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 that 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 TM 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 its 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.

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

	September 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 107,349	$ 24,039
Advance for COVAXIN supply	4,988	—
Prepaid expenses and other current assets	1,113	1,839
Total current assets	113,450	25,878
Property and equipment, net	1,052	633
Restricted cash	151	151
Other assets	1,659	714
Total assets	$ 116,312	$ 27,376
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,095	$ 395
Accrued expenses and other current liabilities	3,962	2,941
Short-term debt, net	—	234
Operating lease obligation	172	44
Total current liabilities	6,229	3,614
Non-current liabilities		
Operating lease obligation, less current portion	1,280	389
Long term debt, net	1,693	1,823
Total non-current liabilities	2,973	2,212
Total liabilities	9,202	5,826
Commitments and contingencies (Note 13)		
Stockholders' equity		
Convertible preferred stock; $0.01 par value; 10,000,000 shares authorized at September 30, 2021 and December 31, 2020		
Series A; seven issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Series B; 54,745 and zero issued and outstanding at September 30, 2021 and December 31, 2020, respectively	1	—
Common stock; $0.01 par value; 295,000,000 and 200,000,000 shares authorized, 199,049,329 and 184,133,384 shares issued, and 198,927,829 and 184,011,884 shares outstanding at September 30, 2021 and December 31, 2020, respectively	1,990	1,841
Treasury stock, at cost, 121,500 shares at September 30, 2021 and December 31, 2020	(48)	(48)
Additional paid-in capital	222,253	93,059
Accumulated deficit	(117,086)	(73,302)
Total stockholders' equity	107,110	21,550
Total liabilities and stockholders' equity	$ 116,312	$ 27,376

See accompanying notes to condensed consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenues				
Collaboration revenue	$ —	$ —	$ —	$ 43
Total revenues	—	—	—	43
Operating expenses				
Research and development	6,281	1,478	28,006	4,760
In-process research and development	—	7,000	—	7,000
General and administrative	4,508	1,704	15,450	5,760
Total operating expenses	10,789	10,182	43,456	17,520
Loss from operations	(10,789)	(10,182)	(43,456)	(17,477)
Other income (expense)				
Interest income	5	—	15	—
Interest expense	(19)	(292)	(59)	(555)
Other income (expense)	(4)	—	(336)	—
Total other income (expense)	(18)	(292)	(380)	(555)
Loss before income taxes	(10,807)	(10,474)	(43,836)	(18,032)
Income tax benefit	(52)	—	(52)	—
Net loss and comprehensive loss	$ (10,755)	$ (10,474)	$ (43,784)	$ (18,032)
Deemed dividend related to Warrant Exchange	—	—	—	(12,546)
Net loss to common stockholders	$ (10,755)	$ (10,474)	$ (43,784)	$ (30,578)
Shares used in calculating net loss per common share — basic and diluted	198,790,980	141,591,218	193,599,525	92,764,157
Net loss per share of common stock — basic and diluted	$ (0.05)	$ (0.07)	$ (0.23)	$ (0.33)

See accompanying notes to condensed consolidated financial statements.

OCUGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(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 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 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 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
Stock-based compensation expense	—	—	—	—	—	—	—	1,347	—	1,347
Issuance of common stock for option exercises	—	—	—	—	232,584	2	—	107	—	109
Net loss	—	—	—	—	—	—	—	—	(10,755)	(10,755)
Balance at September 30, 2021	**7**	**$ —**	**54,745**	**$ 1**	**199,049,329**	**$ 1,990**	**$ (48)**	**$ 222,253**	**$ (117,086)**	**$ 107,110**

OCUGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (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 Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2019	7	$ —	—	$ —	52,746,728	$ 528	$ (48)	$ 62,019	$ (51,480)	$ 11,019
Stock-based compensation expense	—	—	—	—	—	—	—	222	—	222
Net loss	—	—	—	—	—	—	—	—	(3,944)	(3,944)
Balance at March 31, 2020	7	$ —	—	$ —	52,746,728	$ 528	$ (48)	$ 62,241	$ (55,424)	$ 7,297
Stock-based compensation expense	—	—	—	—	—	—	—	149	—	149
Warrant Exchange	—	—	—	—	21,920,820	219	—	(5,197)	—	(4,978)
Issuance of common stock for subscription agreements and warrant exercises	—	—	—	—	1,328,405	13	—	319	—	332
At-the-market common stock issuance, net	—	—	—	—	59,132,191	591	—	14,846	—	15,437
Net loss	—	—	—	—	—	—	—	—	(3,614)	(3,614)
Balance at June 30, 2020	7	$ —	—	$ —	135,128,144	$ 1,351	$ (48)	$ 72,358	$ (59,038)	$ 14,623
Stock-based compensation expense	—	—	—	—	—	—	—	126	—	126
At-the-market common stock issuance, net	—	—	—	—	27,019,829	270	—	9,876	—	10,146
Net loss	—	—	—	—	—	—	—	—	(10,474)	(10,474)
Balance at September 30, 2020	**7**	**$ —**	**—**	**$ —**	**162,147,973**	**$ 1,621**	**$ (48)**	**$ 82,360**	**$ (69,512)**	**$ 14,421**

See accompanying notes to condensed consolidated financial statements.

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

	Nine months ended September 30,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (43,784)	$ (18,032)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	151	58
Non-cash interest expense	59	555
Non-cash lease expense	200	143
In-process research and development expense	—	7,000
Stock-based compensation expense	4,275	497
Income tax benefit	(52)	—
Gain on forgiveness of PPP Note	(426)	—
Impairment on note receivable	761	—
Other non-cash	—	(166)
Changes in assets and liabilities:		
Prepaid expenses and other assets	845	796
Accounts payable and accrued expenses	2,925	(1,133)
Other assets	100	—
Lease obligations	(191)	(144)
Net cash used in operating activities	(35,137)	(10,426)
Cash flows from investing activities		
Purchase of property and equipment	(747)	(56)
Asset acquisition	(127)	—
Issuance of note receivable	(750)	—
Net cash used in investing activities	(1,624)	(56)
Cash flows from financing activities		
Proceeds from issuance of common stock	128,606	26,693
Payment of equity issuance costs	(8,525)	(1,084)
Proceeds from issuance of debt	—	921
Payments of debt issuance costs	—	(6)
Repayments of debt	—	(4,362)
Financing lease principal payments	(10)	(18)
Net cash provided by financing activities	120,071	22,144
Net increase in cash, cash equivalents, and restricted cash	83,310	11,662
Cash, cash equivalents, and restricted cash at beginning of period	24,190	7,595
Cash, cash equivalents, and restricted cash at end of period	$ 107,500	$ 19,257

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

	Nine months ended September 30,	
	2021	2020
Supplemental disclosure of non-cash investing and financing transactions:		
Exercise of warrants	$ 603	$ —
Series B Convertible Preferred Stock issuance	$ 4,988	$ —
Forgiveness of PPP Note	$ 426	$ —
Purchase of property and equipment	$ 9	$ —
Right-of-use asset related to operating leases	$ 926	$ —
Issuance of Warrant Exchange Promissory Notes	$ —	$ 5,625
Obligation settled with common stock	$ —	$ 331
Equity issuance costs	$ —	$ 25

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 biopharmaceutical company focused on developing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19. The Company is headquartered in Malvern, Pennsylvania, and manages its business as one operating segment.

COVID-19 Vaccine

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 outside the United States, for the prevention of COVID-19 caused by SARS-CoV-2 in humans in the United States, its territories, and possessions. In June 2021, the Company entered into an amendment 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 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 requires a two-dose vaccination regimen given 28 days apart and is stored in standard vaccine storage conditions (2-8°C). COVAXIN has been authorized for emergency use in India for ages 18 years and older. In November 2021, COVAXIN was awarded an Emergency Use Listing ("EUL") by the World Health Organization ("WHO").

In July 2021, the Company announced that COVAXIN demonstrated an overall vaccine efficacy against COVID-19 disease of 77.8%, with efficacy against severe COVID-19 disease of 93.4%, and efficacy against asymptomatic COVID-19 disease of 63.6% in the Phase 3 clinical trial conducted by Bharat Biotech in India. Adverse events in the COVAXIN and control arms of the Phase 3 clinical trial were observed in 12.4% of subjects, with less than 0.5% of subjects experiencing serious adverse side effects. The majority of the symptomatic cases identified in aggregate in the COVAXIN and control arms in the Phase 3 clinical trial were COVID-19 variants, the majority of which were identified to be the Delta variant, B.1.617.2. Subjects vaccinated with COVAXIN in the Phase 3 clinical trial showed protection against the Delta variant, B.1.617.2, showing a vaccine efficacy of 65.2%. Additionally, in in-vitro studies conducted by the Indian Council of Medical Research ("ICMR") — National Institute of Virology, COVAXIN demonstrated potential effectiveness against the Zeta variant, B.1.1.28.2, the Alpha variant, B.1.1.7, and the Beta variant, B.1.351.

In June 2021, the U.S. Food and Drug Administration (the "FDA") provided feedback to the Company regarding the data and information contained in a "Master File" that was previously submitted to the FDA and recommended that the Company pursue a Biologics License Application ("BLA") submission instead of an Emergency Use Authorization ("EUA") application for COVAXIN for ages 18 years and older in the United States. As part of the feedback provided by the FDA regarding the "Master File," the FDA also requested additional information and data. The Company has continued discussions with the FDA regarding the appropriate regulatory pathway for COVAXIN for ages 18 years and older in the United States as well as the data requirements for COVAXIN under a BLA submission. In October 2021, the Company filed an Investigational New Drug ("IND") application with the FDA to initiate a Phase 3 immuno-bridging study evaluating COVAXIN for ages 18 years and older. The Company will also initiate a safety-bridging study under the IND, if required by the FDA, to support a BLA submission. The Company anticipates filing a BLA submission with the FDA by the end of 2022.

In November 2021, the Company submitted a request to the FDA for EUA for COVAXIN for pediatric use in children ages two to 18 years in the United States. The EUA submission was based on the results of a Phase 2/3 immuno-bridging pediatric clinical trial conducted by Bharat Biotech in India.

The Company is also pursuing approval for COVAXIN in Canada. In July 2021, the Company announced it had completed its rolling submission to Health Canada for COVAXIN. The rolling submission process, which permits companies to submit safety and efficacy data and information as they become available, 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* (the "Interim Order") and transitioned to a New Drug Submission ("NDS") for COVID-19. The submission was conducted through the

Company's Canadian affiliate, Vaccigen, Ltd. ("Vaccigen"). The Interim Order expired on September 16, 2021. The expiration of the Interim Order has not impacted the Company's NDS.

The Company is evaluating its commercialization strategy for COVAXIN in the United States and Canada, if authorized or approved in either jurisdiction. In June 2021, the Company selected Jubilant HollisterStier as its manufacturing partner for COVAXIN to prepare for the potential commercial manufacturing for the Ocugen Covaxin Territory. The Company expects to enter into a master services agreement with Jubilant HollisterStier for the manufacture of COVAXIN and the technology transfer process to Jubilant HollisterStier has been initiated.

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 the Company’s technology transfer to Jubilant HollisterStier. Following the completion of the Company’s technology transfer to Jubilant HollisterStier, Bharat Biotech will supply COVAXIN drug product components and continue to supply finished drug product as necessary for commercial manufacture and supply of COVAXIN subsequent to a regulatory authorization or approval.

Modifier Gene Therapy Platform

The Company is developing a breakthrough modifier gene therapy platform to generate therapies designed to fulfill unmet medical needs in the area of retinal diseases, including inherited retinal diseases ("IRDs") 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. Unlike single-gene replacement therapies, which only target one genetic mutation, the Company believes that its gene therapy platform, through its use of NHRs, represents a novel approach in that it may address multiple retinal diseases with one product.

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 retinitis pigmentosa ("RP") and leber congenital amaurosis ("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. In November 2021, the Company filed an IND application with the FDA for OCU400 for the treatment of the *NR2E3* and *RHO* disease genotypes. The Company is planning to initiate a Phase 1/2 clinical trial for OCU400 for the treatment of the *NR2E3* and *RHO* disease genotypes in the United States near the end of 2021. OCU400 additionally 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, which the Company believes further supports the potential broad spectrum application of OCU400 to treat many IRDs. The Company is currently evaluating options to commence OCU400 clinical trials in Europe in 2022. The Company's second 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 IND-enabling preclinical studies to support a Phase 1/2 clinical trial. The Company has engaged CanSino Biologics, Inc. ("CanSinoBIO") to manufacture clinical supplies and be responsible for the chemistry, manufacturing, and controls ("CMC") development for OCU400 and OCU410. See Note 3 for additional information about the Company's collaboration with CanSinoBIO.

Novel Biologic Therapy for Retinal Diseases

The Company's biologic product candidate, OCU200, is a novel fusion protein being developed to treat diabetic macular edema ("DME"), diabetic retinopathy ("DR"), and wet AMD. The Company is currently executing IND-enabling preclinical studies to support a Phase 1 clinical trial. The Company has completed the technology transfer of manufacturing processes to the Company's contract development and manufacturing organization ("CDMO") that will manufacture OCU200 clinical supplies.

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 $43.8 million and $18.0 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, the Company had an accumulated deficit of $117.1 million and cash, cash equivalents, and restricted cash totaling $107.5 million.

The Company has a limited operating history and its prospects are 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 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 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, 2020, included in the Company's Annual Report on Form 10-K filed with the SEC on March 19, 2021 (the "2020 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. Certain prior period amounts have been reclassified to conform with current period presentation.

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 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 primarily include those used in the accounting for research and development accruals, the fair value measurement of equity instruments, and the collectibility of the note receivable.

Collaboration Arrangements

The Company assesses whether collaboration agreements are subject to Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 808, *Collaborative Arrangements* ("ASC 808"), based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of ASC 808, the Company assesses whether the payments between the Company and the collaboration partner are subject to other accounting literature. If payments from the collaboration partner represent consideration from a customer, the Company accounts for those payments within the scope of FASB ASC Topic 606, *Revenue from Contracts with Customers*. However, if the Company concludes that its collaboration partner is not a customer, the Company will record royalty payments received as collaboration revenue in the period in which the underlying sale occurs and record expenses and expense reimbursements as either research and

development expense or general and administrative expense, or a reduction thereof, based on the underlying nature of the expense or expense reimbursement. During the nine months ended September 30, 2020, the Company recorded collaboration revenue from an agreement accounted for as a collaborative arrangement within the scope of ASC 808. No collaboration revenue was recorded during the nine months ended September 30, 2021.

Exit and Disposal Activities

The Company records liabilities for one-time termination benefits in accordance with FASB ASC Topic 420, *Exit and Disposal Cost Obligations* ("ASC 420"). In accordance with ASC 420, an arrangement for one-time termination benefits exists at the date the plan of the termination meets the following criteria: (i) management commits to a plan of termination, (ii) the plan identifies the impacted employees and expected completion date, (iii) the plan identifies the terms of the benefits arrangement, (iv) it is unlikely significant changes to the plan will be made or the plan will be withdrawn, and (v) the plan has been communicated to employees. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits, are recognized ratably over the future service period.

The Company records liabilities for employee termination benefits covered by ongoing benefit arrangements in accordance with FASB ASC Topic 712, *Compensation — Nonretirement Postemployment Benefits* ("ASC 712"). In accordance with ASC 712, costs for termination benefits under ongoing benefits arrangements are recognized when management has committed to a plan of termination and the costs are probable and estimable.

Severance-related charges, once incurred, are recognized as either research and development expense or general and administrative expense within the condensed consolidated statements of operations and comprehensive loss depending on the job function of the former employee.

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 September 30, 2021, the Company believes the fair value using Level 2 inputs of the borrowings under the EB-5 Loan Agreement (as defined in Note 8) approximate their carrying value. See Note 8 for additional information.

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 consists 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 September 30,	
	2021	2020
Cash and cash equivalents	$ 107,349	$ 19,106
Restricted cash	151	151
Total cash, cash equivalents, and restricted cash	$ 107,500	$ 19,257

Property and Equipment, Net

Property and equipment is recorded at historical cost. Significant additions or improvements are capitalized, and expenditures for repairs and maintenance are charged to expense as incurred. Gains and losses on disposal of assets are included in the condensed consolidated statements of operations and comprehensive loss. Depreciation is calculated using the straight-line method and is recognized over the expected useful life of the underlying asset. The Company's property and equipment currently includes furniture and fixtures, machinery and equipment, leasehold improvements, and construction in progress. The Company's furniture and fixtures have an expected useful life of three to seven years. The Company's machinery and equipment have an expected useful life of five to seven years. Leasehold improvements are amortized over the shorter of their expected useful lives or the remaining lease term. If a leasehold improvement transfers ownership to the Company at the end of the lease term, the leasehold improvement is amortized over its expected useful life. Construction in progress is not depreciated until such time that the asset is completed and placed into service. Once placed into service, the asset is depreciated over its expected useful life.

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 current and historical 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. FASB ASC Topic 842, *Leases* ("ASC 842") requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. The implicit interest rate was not readily determinable in the Company’s current and historical operating leases, therefore the incremental borrowing rate was used based on the information available at the commencement date 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.

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 at 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 and have a contractual term of 10 years. To the extent a stock-based compensation award is subject to performance-based vesting conditions, the amount of compensation expense recorded reflects an assessment of the probability of achieving the performance conditions. 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.

Asset Held for Sale

During 2019, the Company had an intangible asset held for sale that was carried at its original fair value less cost to sell of $7.0 million. The Company concluded during the three and nine months ended September 30, 2020, that a sale of the intangible asset was no longer probable to be completed within one year from the date the intangible asset was initially recorded as held for sale. As such, the carrying value of the intangible asset was reduced to zero with the corresponding charge of $7.0 million recognized as in-process research and development expense in the condensed consolidated statements of operations and comprehensive loss during the three and nine months ended September 30, 2020 as the in-process research and development did not have an alternative future use.

Recently Adopted Accounting Standards

In December 2019, the FASB issued Accounting Standards Update ("ASU") No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This standard removes certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocations, and calculating income taxes in interim periods. This standard also adds guidance to reduce complexity in certain areas, including recognizing franchise tax, recognizing deferred taxes for the tax basis of goodwill, allocating taxes to the members of a consolidated group, and recognizing the effect of enacted changes in tax laws or rates during an interim period. This standard was effective for the Company on January 1, 2021. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

Recent Accounting Pronouncements

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 will have an effective and transition date of January 1, 2022. 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 Company does not currently expect the adoption of this standard to have a material impact on the Company's condensed consolidated financial statements.

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 Agreements

Co-Development, Supply and Commercialization Agreement with Bharat Biotech

The Company entered into the Covaxin Agreement with Bharat Biotech to co-develop COVAXIN, a whole-virion inactivated COVID-19 vaccine being developed to prevent COVID-19 infection, for the U.S. and Canadian markets. 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. 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 by Bharat Biotech to the Company, the parties agreed to share any profits 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. In consideration of the expansion of the Ocugen Covaxin Territory to include Canada, the Company paid Bharat Biotech a non-refundable, upfront payment of $15.0 million in June 2021, which was recognized as research and development expense in the condensed consolidated statements of operations and comprehensive loss during the nine months ended September 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 is a collaboration arrangement within the scope of ASC 808.

Under the Covaxin Agreement, the Company and Bharat Biotech will collaborate to develop COVAXIN for their respective territories. 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 all 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 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 the Company’s technology transfer to Jubilant HollisterStier. Following the completion of the Company’s technology transfer to Jubilant HollisterStier, Bharat Biotech will supply COVAXIN drug product components and continue to supply finished drug product as necessary for commercial manufacture and supply of COVAXIN subsequent to a regulatory authorization or approval. The technology transfer process to Jubilant HollisterStier has been initiated. In March 2021, the Company issued shares of Series B Convertible Preferred Stock (as defined in Note 9) as an advance payment for the supply of COVAXIN to be provided by Bharat Biotech under the Supply Agreement. See Note 9 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 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.

Co-Development and Commercialization Agreement with CanSinoBIO

In 2019, the Company entered into a co-development and commercialization agreement with CanSinoBIO with respect to the development and commercialization of OCU400. The co-development and commercialization agreement was subsequently amended in September 2021 (as so amended, the "CanSinoBIO Agreement"), whereby OCU410 was added to the Company's existing collaboration with CanSinoBIO. Pursuant to the CanSinoBIO Agreement, the Company and CanSinoBIO will collaborate on the development of OCU400 and OCU410 and CanSinoBIO will be responsible for the CMC development and manufacture of clinical supplies of such products and be responsible for the costs associated with such activities. CanSinoBIO will have an exclusive option to obtain a non-exclusive license from the Company to manufacture OCU400 and OCU410 for commercial sale by the Company. CanSinoBIO has an exclusive license to develop, manufacture, and commercialize OCU400 and OCU410 in and for China, Hong Kong, Macau, and Taiwan (the “CanSinoBIO Territory”), and the Company maintains exclusive development, manufacturing, and commercialization rights with respect to OCU400 and OCU410 outside the CanSinoBIO Territory (the “Company Territory”).

CanSinoBIO will pay to the Company an annual royalty between mid- and high-single digits based on Net Sales (as defined in the CanSinoBIO Agreement) of OCU400 and OCU410 in the CanSinoBIO Territory. The Company will pay to CanSinoBIO an annual royalty between low- and mid-single digits based on Net Sales (as defined in the CanSinoBIO Agreement) of OCU400 and OCU410 in the Company Territory.

Unless earlier terminated in accordance with its terms, the CanSinoBIO Agreement will continue in force on a country-by-country and product-by-product basis until the later of (a) the expiration of the last valid claim of patent rights of the Company covering such products and (b) the 10th anniversary of the first commercial sale of such products in such country.

4. Notes Receivable

On April 13, 2021, the Company received a promissory note in the principal amount of $0.8 million from a company in connection with a potential collaboration. The promissory note bore interest at a rate per annum of 5% and the outstanding principal balance of the promissory note plus any accrued and unpaid interest thereon was payable in full on April 13, 2022 (the "Maturity Date"). Effective July 2021, the Company accepted an amended and restated promissory note (as so amended and restated, the "Promissory Note") pursuant to which the parties agreed to extend the Maturity Date of the Promissory Note to June 30, 2022 and increase the interest rate per annum to 9% with quarterly interest payments. The Promissory Note may be prepaid in whole or in part at any time, together with accrued and unpaid interest. The Promissory Note contains customary covenants and events of default, including, among others, failure to make payment, breach of agreement, and bankruptcy.

The Company evaluated the probability of collecting the full principal and accrued interest balance under the terms of the Promissory Note and determined that collection was not probable. During the nine months ended September 30, 2021, the Company wrote off the full principal and accrued interest balance of the Promissory Note and recorded the write-off as a loss within other income (expense) within the condensed consolidated statements of operations and comprehensive loss.

5. Property and Equipment

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

	September 30, 2021	December 31, 2020
Furniture and fixtures	$ 322	$ 166
Machinery and equipment	856	452
Leasehold improvements	167	177
Construction in progress	41	—
Financing lease right-of-use asset	—	64
Total property and equipment	1,386	859
Less: accumulated depreciation	(334)	(226)
Total property and equipment, net	$ 1,052	$ 633

The Company recognized depreciation expense of $0.1 million and $0.2 million during the three and nine months ended September 30, 2021, respectively. The Company recognized depreciation expense of $19.8 thousand and $0.1 million during the three and nine months ended September 30, 2020, respectively.

6. Operating Leases

The Company has commitments under an operating lease for certain facilities used in its operations including for the use of laboratory, office, and storage space located in Malvern, Pennsylvania (the “Lease Agreement”). The Lease Agreement was determined to have two lease components per ASC 842, a laboratory space lease component (the "Initial Premises") and an office, storage, and future expanded laboratory space lease component (the "Expansion Premises"), with varying commencement dates. The Initial Premises commencement date occurred in December 2020 and the Expansion Premises commencement date occurred in January 2021. The Lease Agreement has an initial term of seven years and the Company has the option to extend the Lease Agreement for one additional five-year term. The option for extension has been excluded from the lease term (and lease liability) for the Lease Agreement as it is not reasonably certain that the Company will exercise such option. The Company terminated a former lease agreement for its previous office space with the same landlord without penalty upon the commencement of the Expansion Premises in January 2021.

The components of lease expense were as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Operating lease cost	$ 66	$ 48	$ 200	$ 143
Variable lease cost	26	21	79	62
Total lease cost	$ 92	$ 69	$ 279	$ 205

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

	September 30, 2021	December 31, 2020
Right-of-use assets, net	$ 1,430	$ 434
Current lease obligations	$ 172	$ 44
Non-current lease obligations	1,280	389
Total lease liabilities	$ 1,452	$ 433

Supplemental information related to leases was as follows:

	Nine months ended September 30,	
	2021	2020
Weighted-average remaining lease term — operating leases (years)	6.2	1.4
Weighted-average discount rate — operating leases	4.6 %	7.6 %

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

For the Years Ending December 31,	Amount
Remainder of 2021	$ 41
2022	252
2023	261
2024	269
2025	277
Thereafter	578
Total	$ 1,678
Less: present value adjustment	(226)
Present value of minimum lease payments	$ 1,452

Subsequent to September 30, 2021, the Company entered into a lease agreement for additional office space located in Malvern, Pennsylvania. See Note 14 for additional information.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities are as follows (in thousands):

	September 30, 2021	December 31, 2020
Research and development	$ 1,100	$ 512
Clinical	585	117
Professional fees	610	405
Employee-related	1,155	963
Severance-related (1)	90	712
Other	422	232
Total accrued expenses and other current liabilities	$ 3,962	$ 2,941

(1) In June 2020, the Company communicated notice to five employees of the termination of their employment as a result of the discontinuation of a product candidate. This reduction represented one-third of the Company's workforce at the time of communication. All terminations were "without cause" and each employee received termination benefits upon departure. The termination dates varied for each employee and ranged from June 30, 2020 to December 31, 2020.

The Company recognized no severance-related charges and a de minimis amount of severance-related charges during the three and nine months ended September 30, 2021, respectively. The Company recognized severance-related charges of $0.4 million and $1.1 million during the three and nine months ended September 30, 2020, respectively. For the three months ended September 30, 2020, the Company recognized a de minimis amount of severance-related charges within general and administrative expense and $0.4 million of severance-related charges within research and development expense. For the nine months ended September 30, 2020, the Company recognized $0.2 million of severance-related charges within general and administrative expense and $0.9 million of severance-related charges within research and development expense.

The Company made severance payments of $0.1 million and $0.6 million during the three and nine months ended September 30, 2021, respectively. The Company made severance payments of $0.2 million during the three and nine months ended September 30, 2020. The Company expects to pay the remaining severance benefits of $0.1 million throughout the remainder of 2021.

8. Debt

The following table provides a summary of the carrying values for the components of debt as reflected on the condensed consolidated balance sheets (in thousands):

	September 30, 2021	December 31, 2020
PPP Note	$ —	$ 421
EB-5 Loan Agreement	1,693	1,636
Total carrying value of debt, net	$ 1,693	$ 2,057

PPP Note

In April 2020, the Company was granted a loan from Silicon Valley Bank ("SVB"), in the amount of $0.4 million, pursuant to the Paycheck Protection Program (the “PPP”) of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the “CARES Act”). Under the PPP, the loan was eligible for forgiveness to the extent the funds received were used for qualifying expenses as described by the CARES Act. The loan was in the form of a promissory note dated April 30, 2020 in favor of SVB (the "PPP Note"). The PPP Note had a maturity date of April 30, 2022 and bore interest at a rate of 1.0% per annum. The Company did not provide any collateral or guarantees for the loan, nor did the Company pay any facility charge to obtain the loan. The PPP Note provided for customary events of default, including, among others, failure to make payment, bankruptcy, breaches of representations, and material adverse events. In May 2021, the Company received notice from the Small Business Administration that the PPP Note was forgiven in its entirety, including both principal and accrued interest. The Company recognized a $0.4 million gain on loan extinguishment within other income (expense) for the forgiveness of the PPP Note within the condensed consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2021.

EB-5 Loan Agreement

In September 2016, pursuant to the U.S. government’s Immigrant Investor Program, commonly known as the EB-5 program (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 borrowed $1.0 million in 2016 and an additional $0.5 million in March 2020. 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 September 30, 2021 and December 31, 2020 are summarized below (in thousands):

	September 30, 2021	December 31, 2020
Principal outstanding	$ 1,500	$ 1,500
Plus: accrued interest	226	181
Less: unamortized debt issuance costs	(33)	(45)
Carrying value	$ 1,693	$ 1,636

9. 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 for the supply of COVAXIN to be provided by Bharat Biotech pursuant to the Supply Agreement.

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 and (ii) the Company's receipt of shipments by Bharat Biotech of the first 10.0 million doses of COVAXIN manufactured by Bharat Biotech pursuant to the Supply Agreement, and further on the terms and subject to the conditions set forth in the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (the "Certificate of Designation"). In April 2021, the Company's stockholders approved an increase in the number of the Company's authorized shares of common stock from 200.0 million to 295.0 million. As of September 30, 2021, 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.

Bharat Biotech is entitled to receive dividends on the Series B Convertible Preferred Stock equal (on an as-converted to common stock basis) to and in the same form as dividends actually paid on shares of common stock, when and if such dividends are paid. Except as provided by law and certain protective provisions set forth in the Certificate of Designation, the Series B Convertible Preferred Stock has no voting rights. Upon a liquidation or dissolution of the Company, holders of Series B Convertible Preferred Stock would be entitled to receive the same amount that a holder of common stock would receive if the Series B Convertible Preferred Stock were fully converted to common stock.

The Company accounted for the issuance of the Series B Convertible Preferred Stock in accordance with ASC 718 and recorded the fair value of $5.0 million within equity during the nine months ended September 30, 2021, with a corresponding short-term asset for the advanced payment for the doses of COVAXIN. 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.

Registered Direct Offerings

On April 23, 2021, the Company entered into a securities purchase agreement with certain institutional investors pursuant to which the Company agreed to issue and sell in a registered direct offering (the "April 2021 Registered Direct Offering") an aggregate of 10.0 million shares of the Company's common stock at an offering price of $10.00 per share. The closing of the April 2021 Registered Direct Offering occurred on April 27, 2021 and the Company received net proceeds of $93.4 million after deducting equity issuance costs of $6.6 million.

On February 7, 2021, the Company entered into a securities purchase agreement with certain institutional investors pursuant to which the Company agreed to issue and sell in a registered direct offering (the "February 2021 Registered Direct Offering") an aggregate of 3.0 million shares of the Company's common stock at an offering price of $7.65 per share. The closing of the February 2021 Registered Direct Offering occurred on February 10, 2021 and the Company received net proceeds of $21.2 million after deducting equity issuance costs of $1.7 million.

At-the-Market Offerings

The Company commenced three separate at-the-market offerings (each an "ATM", and collectively, the "ATMs") in May 2020, June 2020, and August 2020. The offerings were made pursuant to the Company's effective "shelf" registration statement on Form S-3 filed with the SEC on March 27, 2020, the base prospectus contained therein dated May 5, 2020, and the prospectus supplements related to the offerings dated May 8, 2020, June 12, 2020, and August 17, 2020. During the nine months ended September 30, 2021, the Company sold 1.0 million shares of the Company's common stock under the August 2020 ATM and received net proceeds of $4.8 million after deducting equity issuance costs of $0.1 million. During the three and nine months

ended September 30, 2020, the Company sold an aggregate of 27.0 million and 86.2 million shares of the Company's common stock under the ATMs, respectively. During the three months ended September 30, 2020, the Company received net proceeds of $10.1 million after deducting equity issuance costs of $0.4 million. During the nine months ended September 30, 2020, the Company received net proceeds of $25.6 million after deducting equity issuance costs of $1.1 million.

Subscription Agreements

In June 2020, the Company entered into a subscription agreement with an accredited investor for the issuance of 1.3 million shares of the Company's common stock in a private placement. The shares of common stock were issued as part of a transaction in settlement of an outstanding obligation of the Company to the accredited investor, in which (i) the Company agreed to make certain cash payments, (ii) the Company issued the 1.3 million shares of the Company's common stock in exchange for the accredited investor's agreement to cancel $0.3 million of the outstanding obligation, and (iii) the accredited investor agreed to cancel an additional portion of the amount owed by the Company representing a discount of $0.2 million.

In April 2020, the Company entered into a subscription agreement with an accredited investor for the issuance of 1,000 shares of the Company's common stock in a private placement for an aggregate offering price of $395 (the "April 2020 Subscription Agreement").

10. Warrants

Canada Warrants

On July 15, 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 on July 15, 2023, unless earlier terminated in accordance with its terms.

The Canada Warrants were issued on July 15, 2021 in a private placement transaction. The warrantholder 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 September 30, 2021, all of the Canada Warrants were outstanding and unvested. The Canada Warrants are accounted for in accordance with ASC 718.

SPA Warrants

In October 2019, the Company issued three series of warrants to purchase shares of the Company’s common stock (the “Series A Warrants,” the “Series B Warrants”, and the “Series C Warrants” and collectively, the “SPA Warrants”) under a securities purchase agreement with certain accredited investors. In April 2020, the Company entered into the April 2020 Subscription Agreement, as discussed within Note 9, which represented a dilutive issuance as defined by the Series A Warrants and resulted in adjustments to the number of issuable Series A Warrants and the exercise price of the Series A Warrants. Immediately prior to the Company entering into the April 2020 Subscription Agreement, 8.8 million Series A Warrants, 1,000 Series B Warrants, and 1,000 Series C Warrants were outstanding.

Contemporaneously with the April 2020 Subscription Agreement, the Company and OpCo entered into Amendment and Exchange Agreements (each an "Exchange Agreement" and collectively, the "Exchange Agreements") with the accredited investors. Pursuant to the Exchange Agreements, the Company, OpCo, and the accredited investors agreed, among other things, after giving effect to the dilutive issuance, to amend the Series A Warrants to provide for an adjustment to the number of common stock issuable upon the exercise of the Series A Warrants. Concurrently with such amendments, the accredited investors exchanged the Series A Warrants for (i) an aggregate of 21.9 million shares of the Company's common stock and (ii) promissory notes of $5.6 million (the "Warrant Exchange Promissory Notes" and collectively with the common stock issued, the "Warrant Exchange"). During the three and nine months ended September 30, 2020, the Company made payments to the Warrant Exchange Promissory Notes holders of $3.2 million and $4.4 million, respectively. As of December 31, 2020, the Warrant Exchange Promissory Notes had been repaid in full. Immediately following the consummation of the Warrant Exchange and the concurrent exercise of the remaining Series B Warrants and Series C Warrants, there were no SPA Warrants outstanding.

The Company accounted for the Warrant Exchange by recognizing the fair value of the consideration transferred in excess of the carrying value of the Series A Warrants as a reduction of additional paid-in capital. The fair value of the Series A Warrants immediately prior to the Warrant Exchange was $1.1 million, which was estimated using a Black-Scholes valuation model utilizing Level 3 inputs. The fair value of the consideration transferred to settle the Series A Warrants was approximately $13.6 million, comprised of $8.6 million in shares of the Company's common stock and the fair value of the Warrant Exchange Promissory Notes of $5.0 million. The fair value of consideration transferred to settle the Series A Warrants was in excess of the fair value of the Series A Warrants immediately prior to the Warrant Exchange by approximately $12.5 million. The excess consideration was accounted for as a deemed dividend to the Series A Warrant holders and was reflected as an additional net loss to common stockholders in the calculation of basic and diluted net loss per common share for the nine months ended September 30, 2020.

OpCo Warrants

Beginning in 2016, OpCo issued warrants to purchase the Company's common stock (the "OpCo Warrants") to investors of the Company pursuant to a stockholders' agreement and to two employees of the Company pursuant to their respective employment agreements. As of September 30, 2021 and December 31, 2020, 0.8 million and 0.9 million OpCo Warrants were outstanding, respectively. As of September 30, 2021 the outstanding OpCo Warrants had a weighted-average exercise price of $4.97. The outstanding OpCo Warrants expire between 2026 and 2027.

11. Stock-Based Compensation

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
General and administrative	$ 840	$ 101	$ 2,957	$ 248
Research and development	507	25	1,318	249
Total	$ 1,347	$ 126	$ 4,275	$ 497

Stock-based compensation expense during the three and nine months ended September 30, 2021 included $41.3 thousand and $1.1 million of expense related to stock options with performance-based vesting conditions, respectively. No stock-based compensation expense during the three and nine months ended September 30, 2020 was related to stock options with performance-based vesting conditions.

As of September 30, 2021, the Company had $13.9 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 2.2 years as of September 30, 2021.

Equity Plans

The Company maintains two equity compensation plans, the 2014 Ocugen OpCo, Inc. Stock Option Plan (the “2014 Plan”) and the Ocugen, Inc. 2019 Equity Incentive Plan (the “2019 Plan”, collectively with the 2014 Plan, the "Plans"). As of September 30, 2021, the 2014 Plan and 2019 Plan authorize for the granting of up to 0.8 million and 11.5 million equity awards in 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 (years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2020	4,224,433	$ 0.84	8.9	$ 5,496
Granted	7,469,300	$ 3.33		$ —
Exercised	(901,250)	$ 0.73		$ 8,042
Forfeited	(274,220)	$ 2.96		$ 1,146
Options outstanding at September 30, 2021	10,518,263	$ 2.56	9.0	$ 49,552
Options exercisable at September 30, 2021	991,429	$ 1.71	7.8	$ 5,629

Stock options not yet exercisable as of September 30, 2021 includes 1.5 million stock options with performance-based vesting conditions. There were no stock options with performance-based vesting conditions as of December 31, 2020. The weighted-average grant date fair values of stock options granted during the three and nine months ended September 30, 2021 were $5.97 and $2.77, respectively. The weighted-average grant date fair value of stock options granted during both the three and nine months ended September 30, 2020 was $0.34 per share. The total fair values of stock options vested during the three and nine months ended September 30, 2021 were $0.1 million and $0.7 million, respectively. The total fair values of stock options vested during the three and nine months ended September 30, 2020 were $0.1 million and $0.3 million, respectively.

RSUs

The following table summarizes the RSU activity:

	Number of Shares	Weighted-Average Grant-Date Fair Value	Aggregate Intrinsic Value (in thousands)
RSUs outstanding at December 31, 2020	—	$ —	$ —
Granted	179,951	$ 6.69	$ 1,280
Forfeited	(900)	$ 8.75	$ 6
RSUs outstanding at September 30, 2021	179,051	$ 6.68	$ 1,286

12. 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 nine months ended September 30, 2021 and 2020 (in thousands, except share and per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Net loss — basic and diluted	$ (10,755)	$ (10,474)	$ (43,784)	$ (18,032)
Deemed dividend related to Warrant Exchange	—	—	—	(12,546)
Net loss to common stockholders	$ (10,755)	$ (10,474)	$ (43,784)	$ (30,578)
Shares used in calculating net loss per common share — basic and diluted	198,790,980	141,591,218	193,599,525	92,764,157
Net loss per common share — basic and diluted	$ (0.05)	$ (0.07)	$ (0.23)	$ (0.33)

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Options to purchase common stock	10,518,263	4,268,277	10,518,263	4,268,277
RSUs	179,051	—	179,051	—
Warrants	946,179	870,017	946,179	870,017
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	—
Total	12,194,058	5,138,294	12,194,058	5,138,294

13. Commitments and Contingencies

Commitments

The Company has commitments under certain license agreements, lease agreements, debt agreements, separation agreements, and consulting agreements. Commitments under certain license agreements primarily 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 2020 Annual Report. Commitments under lease agreements are future minimum lease payments for operating leases. See Note 6 and Note 14 for additional information about commitments under lease agreements. Commitments under debt agreements are the future payment of principal and accrued interest under the EB-5 Loan Agreement. See Note 8 for additional information about commitments under debt agreements. Commitments under separation agreements are severance payments to be paid throughout the remainder of 2021 as a result of the reduction in force in connection with the Company's discontinuation of a product candidate. See Note 7 for additional information about commitments under separation agreements. Commitments under consulting agreements include payments upon the achievement of certain milestones related to COVAXIN. See Note 10 for additional information about commitments under consulting agreements.

Contingencies

On June 17, 2021, a securities class action lawsuit was filed against the Company and certain of its officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (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 ages 18 years and older rather than pursuing EUA for the vaccine candidate. On July 16, 2021, a second securities class action was filed against the Company and certain of its officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (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.

On August 30, 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 U.S. District Court for the Eastern District of Pennsylvania (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. On September 22, 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 U.S. District Court for the Eastern District of Pennsylvania (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 remains pending before each court, and this status could change.

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

14. Subsequent Events

On October 15, 2021, the Company entered into a lease agreement for additional office space located in Malvern, Pennsylvania. The lease has an expected commencement date in 2022 and has an initial term of seven years. The aggregate estimated base rent payments due over the initial seven year term are $3.8 million. Additionally, the Company will be responsible for the operating expenses and utilities associated with the leased premises. The Company has the option to extend the lease agreement for two additional five year terms, provided the Company is not under an event of default pursuant to the terms of the lease agreement.

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, 2020, included in our 2020 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 2020 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 biopharmaceutical company focused on developing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19.

Our technology pipeline includes:

- **COVID-19 Vaccine** — COVAXIN is a whole-virion inactivated COVID-19 vaccine candidate being developed to prevent COVID-19 infection in humans. We are co-developing COVAXIN with Bharat Biotech for the U.S. and Canadian markets.
- **Modifier Gene Therapy Platform** — Based on NHRs, we believe our gene therapy platform has the potential to address many retinal diseases, including RP, LCA, and dry AMD.
- **Novel Biologic Therapy for Retinal Diseases** — We are developing OCU200, a novel biologic product candidate, to treat DME, DR, and wet AMD.

COVID-19 Vaccine

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 humans in the United States, its territories, and possessions. The Covaxin Agreement was subsequently amended in June 2021 by which we and Bharat Biotech agreed to expand our rights to develop, manufacture, and commercialize COVAXIN to include Canada in addition to the United States, its territories, and possessions.

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 requires a two-dose vaccination regimen given 28 days apart and is stored in standard vaccine storage conditions (2-8°C). COVAXIN has been authorized for emergency use in India for ages 18 years and older and the Subject Expert Committee has recommended the Drugs Controller General of India authorize COVAXIN for emergency use in India for children ages two years and older. In November 2021, COVAXIN was awarded an EUL by the WHO. Over 98.0 million doses of COVAXIN globally have been administered to date.

In July 2021, we announced that COVAXIN demonstrated an overall vaccine efficacy against COVID-19 disease of 77.8%, with efficacy against severe COVID-19 disease of 93.4%, and efficacy against asymptomatic COVID-19 disease of 63.6% in the Phase 3 clinical trial conducted by Bharat Biotech in India. The aforementioned efficacy results represent point estimates of vaccine efficacy with a 95% confidence interval of 65.2% to 86.4% against COVID-19 disease, 57.1% to 99.8% against severe COVID-19 disease, and 29.0% to 82.4% against asymptomatic COVID-19 disease. The Phase 3 clinical trial enrolled 25,798 participants over the age of 18 in India, including 10.7% of participants over the age of 60 and 27.5% of participants with at least one pre-existing condition. Adverse events in the COVAXIN and control arms of the Phase 3 clinical trial were observed in 12.4% of subjects, with less than 0.5% of subjects experiencing serious adverse side effects. The majority of the symptomatic cases identified in aggregate in the COVAXIN and control arms in the Phase 3 clinical trial were COVID-19 variants, the majority of which were identified to be the Delta variant, B.1.617.2. Subjects vaccinated with COVAXIN in the Phase 3 clinical trial showed protection against the Delta variant, B.1.617.2, showing a vaccine efficacy of 65.2%, which represents a point estimate of vaccine efficacy with a 95% confidence interval of 33.1% to 83.0%. Additionally, in in-vitro studies conducted by

the ICMR — National Institute of Virology, COVAXIN demonstrated potential effectiveness against the Zeta variant, B.1.1.28.2, the Alpha variant, B.1.1.7, and the Beta variant, B.1.351.

In June 2021, the FDA provided feedback to us regarding the data and information contained in the "Master File" that was previously submitted to the FDA and recommended that we pursue a BLA submission instead of an EUA application for COVAXIN for ages 18 years and older in the United States. As part of the feedback provided by the FDA regarding the "Master File," the FDA also requested additional information and data. We have continued discussions with the FDA regarding the appropriate regulatory pathway for COVAXIN for ages 18 years and older in the United States as well as the data requirements for COVAXIN under a BLA submission. In October 2021, we filed an IND application with the FDA to initiate a Phase 3 immuno-bridging study evaluating COVAXIN for ages 18 years and older. We will also initiate a safety-bridging study under the IND, if required by the FDA, to support a BLA submission. We anticipate filing a BLA submission with the FDA by the end of 2022.

In November 2021, we submitted a request to the FDA for EUA for COVAXIN for pediatric use in children ages two to 18 years in the United States. The EUA submission was based on the results of a Phase 2/3 immuno-bridging pediatric clinical trial conducted by Bharat Biotech in India.

We are pursuing approval for COVAXIN in Canada. In July 2021, we announced that we had completed our rolling submission to Health Canada for COVAXIN. The rolling submission process, which permits companies to submit safety and efficacy data and information as they become available, was recommended and accepted under the Interim Order and transitioned to an NDS for COVID-19. The submission was conducted through our Canadian affiliate, Vaccigen. The Interim Order expired on September 16, 2021. The expiration of the Interim Order has not impacted our NDS.

We are evaluating our commercialization strategy for COVAXIN in the United States and Canada, if authorized or approved in either jurisdiction. In June 2021, we selected Jubilant HollisterStier as our manufacturing partner for COVAXIN to prepare for the potential commercial manufacturing for the Ocugen Covaxin Territory. We expect to enter into a master services agreement with Jubilant HollisterStier for the manufacture of COVAXIN and the technology transfer process to Jubilant HollisterStier has been initiated.

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 our technology transfer to Jubilant HollisterStier. Following the completion of our technology transfer to Jubilant HollisterStier, Bharat Biotech will supply COVAXIN drug product components and continue to supply finished drug product as necessary for commercial manufacture and supply of COVAXIN subsequent to a regulatory authorization or approval.

Modifier Gene Therapy Platform

We are developing a breakthrough modifier gene therapy platform to generate therapies designed to fulfill unmet medical needs in the area of retinal diseases, including IRDs 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 gene therapy platform, through its use of NHRs, represents a novel approach in that it may address multiple retinal diseases with one product. IRDs such as RP, a group of rare genetic disorders that involve a breakdown and loss of cells in the retina and can lead to visual impairment and blindness, affect over 2.0 million people worldwide. Over 150 gene mutations have been associated with RP and this number represents only 60% of the RP population. The remaining 40% of RP patients cannot be genetically diagnosed, making it difficult to develop individual treatments.

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 genetically diverse IRDs, including RP and LCA. For example, we believe OCU400 has the potential to eliminate the need for developing more than 150 individual products and provide one treatment option for all RP patients. 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. In November 2021, we filed an IND application with the FDA for OCU400 for the treatment of the *NR2E3* and *RHO* disease genotypes. We are planning to initiate a Phase 1/2 clinical trial for OCU400 for the treatment of the *NR2E3* and *RHO* disease genotypes in the United States near the end of 2021. OCU400 additionally has received OMPD from the EC, based on the recommendation of the EMA, for RP and LCA, which we believe further supports the potential broad spectrum application of OCU400 to treat many IRDs. We are currently evaluating options to commence OCU400 clinical trials in Europe in 2022. Our second gene therapy candidate, OCU410, is being developed to utilize the nuclear receptor genes *RORA* for the treatment of dry AMD. We are currently executing IND-enabling preclinical studies to support a Phase 1/2 clinical trial. In 2019, we entered

into the CanSinoBIO Agreement with respect to the development and commercialization of OCU400, which was subsequently amended in September 2021, pursuant to which OCU410 was added to our existing collaboration with CanSinoBIO. CanSinoBIO will be responsible for the CMC development and manufacture of clinical supplies for OCU400 and OCU410 and 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 being developed to treat DME, DR, and wet AMD. We are currently executing IND-enabling preclinical studies to support a Phase 1 clinical trial. We have completed the technology transfer of manufacturing processes to our CDMO that will manufacture OCU200 clinical supplies.

Product Candidate for the Treatment of Ocular Graft-Versus-Host Disease

We were developing OCU300, a small molecule therapeutic for the treatment of symptoms associated with ocular graft-versus-host disease. The Phase 3 clinical trial for OCU300 was discontinued in 2020 based on the results of a pre-planned interim sample size analysis conducted by an independent Data Monitoring Committee, which indicated the trial was unlikely to meet its co-primary endpoints upon completion.

Impact of COVID-19 on our Business

The COVID-19 pandemic is continually evolving and we are closely monitoring the situation. Impacts from the COVID-19 pandemic remain highly uncertain and subject to change and, as such, we cannot predict the specific duration or impact that the COVID-19 pandemic may have on our operations including our preclinical activities, future clinical trials, and potential commercialization. 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 variants, (ii) the future 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.

Financial Operations Overview

We have no products approved for commercial sale and have not generated significant revenue to date. We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of approximately $43.8 million and $18.0 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $117.1 million and a cash, cash equivalents, and restricted cash balance of $107.5 million.

Research and development expense

Research and development costs are expensed as incurred. These costs consist of internal and external expenses, as well as depreciation on assets used within our research and development activities. Internal expenses include the cost of salaries, benefits, severance, and other related costs, including stock-based compensation, for personnel serving in our research and development functions, as well as allocated rent and utilities expenses. External expenses include development, clinical trials, patent costs, and regulatory compliance costs incurred with research organizations, contract manufacturers, and other third-party vendors. License fees paid to acquire access to proprietary technology are expensed to research and development unless it is determined that the technology is expected to have an alternative future use. All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred to research and development expense due to the uncertainty about the recovery of the expenditure. We record costs for certain development activities, such as preclinical studies and clinical trials, based on our evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the condensed consolidated financial statements as prepaid or accrued research and development expense, as applicable. Our recording of costs for certain development activities requires us to use estimates. We believe our estimates and assumptions are reasonable under the current conditions; however, actual results may differ from these estimates.

Research and development expenses account for a significant portion of our operating expenses. We plan to incur research and development expenses for the foreseeable future as we expect to continue the development of our product candidates. We anticipate that our research and development expenses will be higher in 2021 and subsequent periods as compared to prior periods as we evaluate the regulatory and commercialization path for COVAXIN in the United States and Canada as well as conduct preclinical and clinical activities with respect to our product candidates.

Our research and development expenses are not currently tracked on a program-by-program basis for indirect and overhead costs. We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying, developing, and commercializing product candidates.

At this time, due to the inherently unpredictable nature of preclinical and clinical developments as well as regulatory approval (or authorization) and commercialization, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in our continued development and commercialization efforts. As a result of these uncertainties, successful development and completion of clinical trials as well as regulatory approval (or authorization) and commercialization are uncertain and may not result in approved (or authorized) and commercialized products. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. We will continue to make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to our ability to enter into collaborations with respect to each product candidate, the scientific and clinical success of each product candidate as well as ongoing assessments as to the commercial potential of each product candidate.

General and administrative expense

General and administrative expense consists primarily of personnel expenses, including salaries, benefits, severance, insurance, and stock-based compensation expense, for employees in executive, accounting, commercialization, human resources, and other administrative functions. General and administrative expense also includes corporate facility costs, including allocated rent and utilities, insurance premiums, legal fees related to corporate matters, and fees for auditing, accounting, and other consulting services.

We anticipate that our general and administrative expenses will be higher in 2021 as compared to prior periods as a result of higher corporate infrastructure costs including, but not limited to, accounting, legal, human resources, consulting, investor relations, and public company insurance fees. Additionally, we anticipate an increase in general and administrative expenses as we prepare to support the potential commercialization of COVAXIN, if authorized or approved.

Severance-related expense

In June 2020, we communicated notice to five employees of the termination of their employment as a result of the discontinuation of a product candidate. This reduction represented one-third of our workforce at the time of communication. All terminations were “without cause” and each employee received termination benefits upon departure. The termination dates varied for each employee and ranged from June 30, 2020 to December 31, 2020. As a result of the workforce reduction, we expect to pay severance benefits of $0.1 million throughout the remainder of 2021. We made severance payments of $0.1 million and $0.6 million during the three and nine months ended September 30, 2021, respectively. We made severance payments of $0.2 million during the three and nine months ended September 30, 2020.

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 were no material changes to our critical accounting policies and estimates as reported in our 2020 Annual Report.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

The following table summarizes the results of our operations for the three months ended September 30, 2021 and 2020 (in thousands):

	Three months ended September 30,		
	2021	2020	Change
Operating expenses			
Research and development	$ 6,281	$ 1,478	$ 4,803
In-process research and development	—	7,000	(7,000)
General and administrative	4,508	1,704	2,804
Total operating expenses	10,789	10,182	607
Loss from operations	(10,789)	(10,182)	(607)
Other income (expense)			
Interest income	5	—	5
Interest expense	(19)	(292)	273
Other income (expense)	(4)	—	(4)
Total other income (expense)	(18)	(292)	274
Loss before income taxes	(10,807)	(10,474)	(333)
Income tax benefit	(52)	—	(52)
Net loss	$ (10,755)	$ (10,474)	$ (281)

Research and development expense

Research and development expense increased by $4.8 million for the three months ended September 30, 2021 compared to the three months ended September 30, 2020. The increase was primarily due to increases of $1.6 million in COVAXIN development and regulatory activities, $1.4 million in OCU400 preclinical and clinical activities, $1.1 million in employee-related expenses, and $0.5 million in stock-based compensation expense.

In-process research and development

In-process research and development expense decreased by $7.0 million for the three months ended September 30, 2021 compared to the three months ended September 30, 2020. The decrease was due to the write-off of an intangible asset held for sale during the three months ended September 30, 2020 as a sale of the intangible asset was deemed not probable to be completed within one year from the date the intangible asset was initially recorded as held for sale.

General and administrative expense

General and administrative expense increased by $2.8 million for the three months ended September 30, 2021 compared to the three months ended September 30, 2020. The increase was primarily due to increases of $0.8 million in employee-related expenses, $0.7 million in stock-based compensation expense, and $0.7 million in professional fees.

Interest expense

Interest expense decreased by $0.3 million for the three months ended September 30, 2021 compared to the three months ended September 30, 2020. Interest expense during the three months ended September 30, 2021 primarily includes debt coupon interest and amortization of debt issuance costs. Interest expense during the three months ended September 30, 2020 primarily related to the accretion of the debt discount on the Warrant Exchange Promissory Notes.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table summarizes the results of our operations for the nine months ended September 30, 2021 and 2020 (in thousands):

	Nine months ended September 30,		
	2021	2020	Change
Revenues			
Collaboration revenue	$ —	$ 43	$ (43)
Total revenues	—	43	(43)
Operating expenses			
Research and development	28,006	4,760	23,246
In-process research and development	—	7,000	(7,000)
General and administrative	15,450	5,760	9,690
Total operating expenses	43,456	17,520	25,936
Loss from operations	(43,456)	(17,477)	(25,979)
Other income (expense)			
Interest income	15	—	15
Interest expense	(59)	(555)	496
Other income (expense)	(336)	—	(336)
Total other income (expense)	(380)	(555)	175
Loss before income taxes	(43,836)	(18,032)	(25,804)
Income tax benefit	(52)	—	(52)
Net loss	$ (43,784)	$ (18,032)	$ (25,752)

Research and development expense

Research and development expense increased by $23.2 million for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. The increase 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 as well as increases of $2.9 million in OCU400 preclinical and clinical activities, $2.5 million in COVAXIN development and regulatory activities, $1.4 million in employee-related expenses, $1.1 million in stock-based compensation expense, and $1.0 million in OCU200 preclinical activities. The increases were partially offset by a $1.1 million decrease for the discontinuation of OCU300 clinical trial activities in 2020.

In-process research and development

In-process research and development expense decreased by $7.0 million for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. The decrease was due to the write-off of an intangible asset held for sale during the nine months ended September 30, 2020 as a sale of the intangible asset was deemed not probable to be completed within one year from the date the intangible asset was initially recorded as held for sale.

General and administrative expense

General and administrative expense increased by $9.7 million for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. The increase was primarily due to increases of $3.1 million in expenses for stockholder meetings and proxy solicitation, $2.7 million in stock-based compensation expense, $1.5 million in professional fees, and $1.3 million in employee-related expenses.

Interest expense

Interest expense decreased by $0.5 million for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. Interest expense during the nine months ended September 30, 2021 primarily includes debt coupon interest

and amortization of debt issuance costs. Interest expense during the nine months ended September 30, 2020 primarily related to the accretion of the debt discount on the Warrant Exchange Promissory Notes.

Other income (expense)

Other income (expense) increased by $0.3 million for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020. The increase was primarily due to $0.8 million related to a loss on the write-off of the Promissory Note deemed uncollectible, partially offset by a gain on loan extinguishment of $0.4 million for PPP Note forgiveness obtained in May 2021.

Liquidity and Capital Resources

As of September 30, 2021, we had $107.5 million in cash, cash equivalents, and restricted cash. 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 September 30, 2021, we have raised an aggregate of $218.9 million to fund our operations, of which $206.3 million was from gross proceeds from the sale of our common stock and warrants, $10.3 million was from the issuance of convertible notes, $2.1 million was from debt, and $0.2 million was from grant proceeds.

In April 2021, we issued and sold 10.0 million shares of our common stock at an offering price of $10.00 per share in the April 2021 Registered Direct Offering pursuant to a securities purchase agreement with certain institutional investors. We received net proceeds of $93.4 million. In February 2021, we issued and sold 3.0 million shares of our common stock at an offering price of $7.65 per share in the February 2021 Registered Direct Offering pursuant to a securities purchase agreement with certain institutional investors. We received net proceeds of $21.2 million. For additional information about the April 2021 Registered Direct Offering and the February 2021 Registered Direct Offering, see Note 9 in the notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Additionally, during the nine months ended September 30, 2021, we sold 1.0 million shares of our common stock under the August 2020 ATM and received net proceeds of $4.8 million. The offering was made pursuant to our effective "shelf" registration statement on Form S-3 filed with the SEC on March 27, 2020, the base prospectus contained therein dated May 5, 2020, and the prospectus supplement related to the offering dated August 17, 2020.

Since our inception, we have devoted substantial resources to research and development and have incurred significant net losses and may continue to incur net losses in the future. We incurred net losses of approximately $43.8 million and $18.0 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $117.1 million.

The following table shows a summary of our cash flows for the nine months ended September 30, 2021 and 2020 (in thousands):

	Nine months ended September 30,	
	2021	2020
Net cash used in operating activities	$ (35,137)	$ (10,426)
Net cash used in investing activities	(1,624)	(56)
Net cash provided by financing activities	120,071	22,144
Net increase in cash, cash equivalents, and restricted cash	$ 83,310	$ 11,662

Operating activities

Cash used in operating activities was $35.1 million for the nine months ended September 30, 2021 compared to $10.4 million for the nine months ended September 30, 2020. The increase in cash used in operating activities was primarily driven by 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, an increase in our research and development expenses for our product candidates, an increase in employee-related expenses as we expand our headcount to support our development, commercialization, and business efforts, and an increase in expenses for stockholder meetings and proxy solicitation.

Investing activities

Cash used in investing activities was $1.6 million for the nine months ended September 30, 2021 compared to $0.1 million for the nine months ended September 30, 2020. The increase in cash used in investing activities was primarily driven by the receipt of the Promissory Note of $0.8 million in April 2021, an increase of $0.7 million in purchases of property and equipment, and the acquisition of an intangible asset of $0.1 million.

Financing activities

Cash provided by financing activities was $120.1 million for the nine months ended September 30, 2021 compared to $22.1 million for the nine months ended September 30, 2020. During the nine months ended September 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, and gross proceeds of $5.0 million received under the August 2020 ATM, partially offset by payments of equity issuance costs of $8.5 million. During the nine months ended September 30, 2020, cash provided by financing activities primarily consisted of gross proceeds of $26.7 million received under the ATMs and $0.9 million in proceeds from the issuance of debt, partially offset by payments of equity issuance costs of $1.1 million and repayments of debt of $4.4 million.

Indebtedness

In September 2016, pursuant to the EB-5 program, we entered into the EB-5 Loan Agreement to borrow up to $10.0 million from EB-5 Life Sciences in $0.5 million increments. 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 our product candidates and for our general working capital needs. Outstanding borrowings pursuant to the EB-5 Program become due upon the seventh anniversary of the final disbursement. Amounts repaid cannot be re-borrowed. As of September 30, 2021, there was $1.5 million of principal outstanding under the EB-5 Loan Agreement.

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 potential commercialization of our product candidates, add operational, financial, and information systems to execute our business plan, maintain, expand, and protect our patent portfolio, expand headcount to support our development, commercialization, and business efforts, and operate as a public company.

For additional information regarding our commitments and contingencies, see Note 13 in the notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. 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, including the need for a Phase 3 immuno-bridging study to support a BLA submission for COVAXIN for ages 18 years and older as well as a safety-bridging study if required by the FDA;
- the outcome, timing, and cost of the regulatory authorization or approval process for our product candidates; including with respect to COVAXIN in the United States and Canada;
- the costs of manufacturing and commercialization, including with respect to COVAXIN, if authorized or approved;
- costs related to doing business internationally with respect to our proposed development and commercialization of COVAXIN in Canada;
- 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; and
- the impact of the COVID-19 pandemic.

As of September 30, 2021, we had $107.5 million in cash, cash equivalents, and restricted cash. This amount will not meet our capital requirements over the next 12 months. 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, 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. 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; 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 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. See Note 1 to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information.

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.

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 September 30, 2021. 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 13 in the notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors.

Except as set forth below and in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2021 and June 30, 2021, there have been no material changes in our risk factors as previously disclosed in our 2020 Annual Report. The risks described in our 2020 Annual Report, our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2021 and June 30, 2021, and this Quarterly Report on Form 10-Q are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, or future results.

We have submitted an EUA application for COVAXIN for pediatric use. The FDA may not grant us the EUA for pediatric use, and, even if they do, absent supplemental Biologics License Application approval for that indication, such EUA would be revoked when the COVID-19 emergency terminates, and, prior to that time, we would face significant competition from other pharmaceutical and biotechnology companies, and may not be able to compete effectively.

In November 2021, we submitted a request to the FDA for EUA for COVAXIN for pediatric use in children ages two to 18 years in the United States. The EUA submission was based on the results of a Phase 2/3 immuno-bridging pediatric clinical trial conducted by Bharat Biotech in India.

The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. Generally, EUAs for unapproved products require that manufacturers distribute factsheets for healthcare providers, addressing significant known and potential benefits and risks, and the extent to which benefits and risks are unknown, and the fact that the FDA has authorized emergency use; and, distribution of factsheets for recipients of the product, addressing significant known and potential benefits and risks, and the extent to which benefits and risks are unknown, the option to accept or refuse the product, the consequences of refusing, available alternatives, and the fact that FDA has authorized emergency use.

EUAs for unapproved products also include requirements for adverse event monitoring and reporting, and other recordkeeping and reporting requirements. In addition, the FDA may include various requirements in an EUA as a matter of discretion as deemed necessary to protect the public health, including restrictions on which entities may distribute the product, and how to perform distribution (including requiring that distribution be limited to government entities), restrictions on who may administer the product, requirements for collection and analysis of safety and effectiveness data, waivers of Current Good Manufacturing Practice, and restrictions applicable to prescription drugs or restricted devices (including advertising and promotion restrictions).

As of the date of this Quarterly Report on Form 10-Q, we have not received any correspondence from the FDA regarding the EUA, other than an acknowledgement of the submission. Therefore, the timing of a potential grant of EUA for pediatric use, if at all, is currently unknown. In addition, there can be no guarantee that the data and results from the preclinical and clinical studies of COVAXIN, which have been conducted by Bharat Biotech in India, will be accepted by the FDA or otherwise sufficient to support our EUA submission.

If we are granted an EUA by the FDA for COVAXIN for pediatric use, we would be able to commercialize it for that use without FDA approval. However, the FDA may revoke the EUA where it is determined that the COVID-19 public health emergency no longer exists or warrants such authorization, and we cannot predict how long, if ever, an EUA would remain in place. Such revocation could adversely impact our business in a variety of ways including if we, Bharat Biotech, and our manufacturing partners have invested in the supply chain to provide COVAXIN for pediatric use under an EUA in the United States. In addition, the FDA may revoke or terminate the EUA sooner if, for example, we fail to comply with the conditions of authorization or other terms of the EUA or if COVAXIN is determined to be less effective or safe than it was initially believed to be. We cannot predict how long, if ever, an EUA for the pediatric use of COVAXIN would remain in place.

Furthermore, many biotechnology and pharmaceutical companies are developing treatments for COVID-19 or vaccines against SARS-CoV-2, the virus that causes COVID-19. Many of these companies, which include large pharmaceutical companies, have greater resources for development and established commercialization capabilities than us. In addition, some of these companies

have already received regulatory approval or a grant of EUA for their respective products, some of which include authorization for the administration of COVID-19 vaccines in certain pediatric patient populations. Given the products currently approved or authorized for use as well as those in development by others, even if our EUA is approved for pediatric use, we will face significant competition. If existing vaccines in the market or if competitors develop and commercialize additional COVID-19 vaccines before we can complete regulatory review and obtain an EUA for pediatric use or regulatory approval for COVAXIN, or if they develop and commercialize one or more COVID-19 vaccines that are safer, more effective, have fewer or less severe side effects, have broader market acceptance, are more convenient, or are less expensive than COVAXIN, our business, financial condition, and results of operations would be materially adversely affected.

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

On July 15, 2021, we entered into the Canada Consulting Agreement with an individual to provide services to us with regard to our Canadian operations. In connection therewith, we issued to such individual the Canada Warrants to purchase up to 0.2 million shares of our 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.

The Canada Warrants were issued on July 15, 2021 in a private placement transaction pursuant to Rule 4(a)(2) of the Securities Act. We did not receive any proceeds from the issuance of the Canada Warrants. See Note 10 in the notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

Not Applicable.

Item 6. Exhibits.

	Description
	Development and Commercial Supply Agreement, dated September 29, 2021, by and between the Registrant and Bharat Biotech International Limited
	First Amendment to the Co-Development and Commercialization Agreement, dated September 30, 2021, by and between the Registrant and CanSino Biologics, Inc.
	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350
	Inline XBRL Instance Document
	Inline XBRL Taxonomy Extension Schema Document
	Inline XBRL Taxonomy Extension Calculation Linkbase Document
	Inline XBRL Taxonomy Extension Definition Linkbase Document
	Inline XBRL Taxonomy Extension Label Linkbase Document
	Inline XBRL Taxonomy Extension Presentation Linkbase Document
	The cover page from this Quarterly Report on Form 10-Q, formatted in Inline XBRL

* Filed herewith.

** Furnished herewith.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Ocugen, Inc.

Dated: November 9, 2021

/s/ Shankar Musunuri

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

Dated: November 9, 2021

/s/ Sanjay Subramanian

Sanjay Subramanian
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Certain portions of this document have been omitted pursuant to Item 601(b)(10) of Regulation S-K and, where applicable, have been marked with "[***]" to indicate where omissions have been made. The marked information has been omitted because it is (i) not material and (ii) the type that the registrant treats as private or confidential. The registrant hereby undertakes to provide further information regarding such marked information to the Securities and Exchange Commission upon request.

Exhibit 10.1

DEVELOPMENT AND COMMERCIAL SUPPLY AGREEMENT

This **DEVELOPMENT AND COMMERCIAL SUPPLY AGREEMENT** (this "**Agreement**") is made and entered into as of the 29th day of September, 2021 (the "**Effective Date**") by and between Bharat Biotech International Limited, whose registered office address is at Genome Valley, Shameerpet, Hyderabad – 500 078 Telangana India (together with its Affiliates, subsidiaries, successors and permitted assigns, "**BBIL**"), and Ocugen, Inc., with an address at 263 Great Valley Parkway, Malvern, PA 19355, USA (together with its Affiliates, subsidiaries, successors and permitted assigns, "**Ocugen**").

WHEREAS, Ocugen and BBIL are parties to that certain Co-Development, Supply and Commercialization Agreement, dated as of January 31, 2021 (the "**Co-Development Agreement**"), pursuant to which BBIL granted Ocugen the exclusive right to Develop, Manufacture and Commercialize the Product for use in the Field in and for the Ocugen Territory;

WHEREAS, pursuant to Section 7.1(a) of the Co-Development Agreement, BBIL has agreed to Manufacture and supply all of the Clinical Trial Materials required for Ocugen's non-clinical and clinical Development of the Product in the Field in and for the Ocugen Territory (including the performance of the Ocugen Development Activities), subject to and in accordance with the terms of this Agreement;

WHEREAS, pursuant to Section 7.2(a) of the Co-Development Agreement, BBIL has also agreed to Manufacture and supply all of Ocugen's requirements of commercial quantities of the Product for Ocugen's use and Commercialization of the Product in the Field in and for the Ocugen Territory, subject to and in accordance with the terms of this Agreement until such time as the Initial Technology Transfer has been completed;

WHEREAS, Ocugen desires that BBIL Manufacture and supply Ocugen's requirements of COVAXIN™ Drug Substance and Drug Product Components necessary for Ocugen's Commercialization of the Product in the Field in and for the Ocugen Territory, and BBIL desires to Manufacture and supply such COVAXIN™ Drug Substance and Drug Product Components, subject to and in accordance with the terms of this Agreement during the Term; and

WHEREAS, capitalized terms that are not defined in this Agreement shall have the meanings ascribed to such terms in the Co-Development Agreement.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and promises set forth herein, the Parties hereby agree as follows:

1. Definitions. For the purposes of this Agreement, unless this Agreement expressly provides otherwise or unless the context otherwise requires, the following initially capitalized terms in this Agreement, whether used in the singular or plural, will have the respective meanings set forth below:

1.1 "**Aluminum Hydroxide/TLR Complex**" has the meaning set forth in Exhibit A.

1.2 "Adjuvant" means the BBIL proprietary adjuvant **aluminum hydroxide + IMDG** used for manufacture of the Product.

1.3 "**BBIL Indemnitees**" has the meaning set forth in Section 11.2.

1.4 "**Cell Banks**" has the meaning set forth in Exhibit A.

1.5 "**Certificate of Analysis**" means a document signed by an authorized representative of BBIL, describing the testing methods applied to the Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, and the results of testing.

1.6 "**Certificate of Compliance**" means a document signed by an authorized representative of BBIL, certifying that a particular batch of the Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, was manufactured in accordance with cGMP, Applicable Laws, and the Specifications therefor.

1.7 "**cGMP**" means then current Good Manufacturing Practices as described in 21 CFR Parts 210 and 211, and such other FDA, EMA and International Conference on Harmonisation (ICH) guidance, directives, rules, orders and documents pertaining to manufacturing and quality control practice, all as updated, amended and/or revised from time to time.

1.8 [***]

1.9 "**COVAXIN™ Drug Substance**" has the meaning set forth in Exhibit A.

1.10 "**Critical Reagents**" has the meaning set forth in Exhibit A.

1.11 [***]

1.12 [***]

1.13 "**Drug Product Components**" means the intermediate raw materials and formulation and other components necessary to Manufacture and supply the Product (prior to the performance of fill and finish activities), including without limitation, Aluminum Hydroxide/TLR Complex, IMDG, Cell Banks, Virus Seed, Reference Standards and any other Critical Reagents necessary to Manufacture and supply the Product (prior to the performance of fill and finish activities).

1.14 "**Facility**" means the BBIL facility located at Hyderabad, India.

1.15 "**IMDG**" has the meaning set forth in Exhibit A.

1.16 "**Initial Technology Transfer**" means the technology transfer described in Section 7.3(a) of the Co-Development Agreement as it relates to the Product (in finished form after the performance of all fill and finish activities).

1.17 "**Inspection Period**" has the meaning set forth in Section 4.5(a).

1.18 "**Latent Defect**" means a failure of the Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, to comply with cGMP or the Specifications therefor that could not reasonably have been identified through Ocugen's review of the applicable Records or the initial testing and inspection of the Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable.

1.19 "**Losses**" has the meaning set forth in Section 11.1.

1.20 "**Ocugen Indemnitee**" has the meaning set forth in Section 11.1.

1.21 "**Parties**" means Ocugen and BBIL together.

1.22 "**Party**" means either Ocugen or BBIL, as the context requires.

1.23 "**Quality Agreement**" means the separate agreement which applies to the Services to be performed under cGMP requirements, signed by each of the Parties and setting forth the mutual responsibilities of the Parties with respect to quality assurance and cGMP guidelines

applicable to the Services performed by BBIL hereunder. Such responsibilities of BBIL and Ocugen are as defined in the Quality Agreement.

1.24 "**Recalls**" has the meaning set forth in Section 4.8.

1.25 "**Records**" has the meaning set forth in Section 3.1.

1.26 "**Reference Standards**" has the meaning set forth in Exhibit A.

1.27 "**Secondary Technology Transfer**" means the technology transfer described in Section 7.3(b) of the Co-Development Agreement, as it relates to COVAXIN™ Drug Substance and Drug Product Components. For clarity, in addition to the technical assistance and cooperation described in Section 7.3(c) of the Co-Development Agreement, any such Secondary Technology Transfer shall include the provision by BBIL to Ocugen or its designee of any quality assistance for process and methods of manufacture that Ocugen may reasonably require in order to effectuate such Secondary Technology Transfer and support the successful commercial Manufacture of the Product by Ocugen for commercial sale by Ocugen of the Product in the Field in and for the Ocugen Territory.

1.28 "**Services**" has the meaning set forth in Section 2.2.

1.29 "**Specifications**" means the specifications, quality standards, formulas, requirements, quality assurance standards, processes, and all modifications or improvements of such specifications, quality standards, formulas, requirements, quality assurance standards and processes for the Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, that are set forth in **Exhibit A** attached hereto or that are otherwise mutually agreed to by the Parties in writing.

1.30 "**Term**" has the meaning set forth in Section 8.1.

1.31 "**Third Party**" means any Person other than the Parties and their respective Affiliates.

1.32 "**Virus Seed**" has the meaning set forth in Exhibit A.

2. The Services.

2.1 Supply and Purchase of Adjuvants, Clinical Trial Materials, Product, COVAXIN™ Drug Substance and Drug Product Components.

(a) Subject to the terms and conditions set forth herein, prior to the completion of the Initial Technology Transfer, BBIL shall exclusively Manufacture and supply to Ocugen, and Ocugen shall purchase from BBIL, such form and quantity of Adjuvants, Clinical Trial Materials as Ocugen reasonably requires to conduct the Ocugen Development Activities and carry out Clinical Trials necessary to seek and obtain Regulatory Approval of the Product in the Field in and for the Ocugen Territory;

(b) Subject to the terms and conditions set forth herein, prior to completion of the Initial Technology Transfer, BBIL shall Manufacture and supply to Ocugen, and Ocugen shall purchase from BBIL, all of Ocugen's requirements of commercial quantities of the Product for Ocugen's use and Commercialization of the Product in the Field in and for the Ocugen Territory, subject to any reasonable limitations on BBIL's capacity, after Ocugen's receipt of EUA, BLA or Regulatory Approval for the Product in the Ocugen Territory; and

(c) Subject to the terms and conditions set forth herein, after completion of the Initial Technology Transfer and even following the completion of the Secondary Technology Transfer, BBIL shall Manufacture and supply to Ocugen, and Ocugen shall purchase from BBIL such quantities of the COVAXIN™ Drug Substance and Drug Product Components and exclusively purchase such quantities of Adjuvant from BBIL as are reasonably necessary or useful to support the successful commercial Manufacture of the Product for commercial sale of the Product in the Field in and for the Ocugen Territory after Ocugen's receipt of EUA, BLA or other Regulatory Approval for the Product in the Ocugen Territory.

2.2 Release and Stability Testing. Subject to the terms and conditions set forth herein, BBIL shall perform release and stability testing of the Clinical Trial Materials, Product, COVAXIN™ Drug Substance and Drug Product Components, as applicable, for use in the Field in the Ocugen Territory in accordance with FDA requirements, Applicable Laws, and the terms of the Quality Agreement (such activities under Section 2.1 and this Section 2.2, the "**Services**"). Notwithstanding the foregoing, Ocugen shall take commercially reasonable steps to promptly qualify an alternative supplier of the Product, COVAXIN™ Drug Substance and Drug Product Components after the Effective Date to cover limited events of supply failure where, for some reason, BBIL is unable to Manufacture and supply the Product, COVAXIN™ Drug Substance or Drug Product Components for/to Ocugen pursuant to the terms and conditions of this Agreement.

2.3 Communications. Each Party will appoint a representative who will have primary responsibility for day-to-day interactions with the other Party's representative concerning the Services. Either Party may appoint a substitute or successor representative by providing written notice thereof to the other Party.

2.4 Subcontracting. Upon the prior written agreement of Ocugen, BBIL may subcontract the performance of certain of its obligations under this Agreement to its Affiliates or to qualified Third Parties, provided that such Affiliates or Third Parties execute an agreement containing provisions that that (a) are consistent with the cooperation, records and reports, ownership, confidentiality and intellectual property provisions set forth in this Agreement, and (b) assign any and all intellectual property rights discovered or invented by the Third Party contractor thereunder to BBIL or Ocugen, as applicable. BBIL will remain liable for the actions or inactions of any Third Party with whom it contracts for any obligations under this Agreement.

2.5 Quality Agreement. Within [***] days after the Effective Date and prior to BBIL conducting any Services that are subject to cGMP requirements, the Parties will enter into the Quality Agreement to establish the Parties' respective quality assurance responsibilities relating to the Services. Following execution of the Quality Agreement, in the event of a conflict between the terms of the Quality Agreement and this Agreement, the terms of the Quality Agreement will govern or control with respect to all quality control and quality assurance matters, and this Agreement will govern or control with respect to all other matters.

3. Records; Personnel and Inspection.

3.1 Records. BBIL will keep complete and accurate records of all Manufacturing and testing by BBIL in the course of its performance of the Services and with respect to the Specifications in sufficient detail to permit Ocugen to confirm that the Services are or have been performed in compliance with this Agreement and Applicable Laws, and to verify the amounts that Ocugen has paid BBIL for the performance of such Services (the "**Records**"). While in the possession or control of BBIL, the Records will be made available for inspection, examination and copying by or on behalf of Ocugen and at Ocugen's expense; *provided*, *however*, that BBIL may exclude or redact from such Records any confidential or proprietary information of Third Parties. Upon the expiration or termination of this Agreement, BBIL will transfer to Ocugen, at Ocugen's expense, the Records; *provided*, *however*, that BBIL may (a) retain one copy of

such Records solely for the purposes of internal record-keeping, and monitoring its obligations under this Agreement and as required by Applicable Laws and (b) exclude or redact from such Records any confidential or proprietary information of Third Parties.

3.2 Inspections, Visits, and Audits.

(a) Inspections and Visits. Ocugen or its duly designated representative will have the right, upon at least [***] prior written notice without cause, to have [***] Ocugen employees or representatives, during normal business hours, at Ocugen's cost, to (i) observe the Manufacturing of the Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, at the Facility; (ii) review the Records; and (iii) otherwise inspect the relevant portions of the Facility during the performance of the Services.

(b) Audits. Ocugen or its duly designated representative that is reasonably acceptable to BBIL will have the right, at Ocugen's cost, upon [***] prior written notice, and no more than [***] every Calendar Year unless for cause, in which case, as frequently as necessary to audit the Facility and Records to ascertain compliance by BBIL with the terms of this Agreement, the Quality Agreement, Applicable Laws, and the Specifications.

(c) Ocugen employees and representatives who inspect, visit, or audit BBIL's Facility and Records will do so during normal business hours and at all times comply with BBIL's rules, regulations and SOPs relating to inspections and visits to the Facility, and Ocugen retains full responsibility and liability for the presence and actions of its employees on BBIL's premises. Any representative conducting any inspection, visit or audit hereunder shall be subject to confidentiality obligations no less restrictive than those set forth in this Agreement.

(d) Each Party shall bear its own costs associated with all such inspections, visits and audits under this Section 3.2, unless provided otherwise in this Section 3.2.

4. Minimum 2021 Supply Commitment; Forecasts; Purchase Orders; Shipping; Acceptance.

4.1 Minimum 2021 Supply Commitment. Notwithstanding the consummation of the Initial Technology Transfer, for and during Calendar Year 2021, BBIL shall Manufacture and supply to Ocugen, its Affiliates or Sublicensees, not less than (*i.e.*, at least) [***] doses of finished commercial Product (sufficient for a minimum of [***] patients) for Ocugen's, its Affiliates' and Sublicensees' use in the Field in and for the Ocugen Territory. Notwithstanding the foregoing, in the event that Ocugen's receipt of an EUA and/or BLA for the Product in the Field in and for the Ocugen Territory is delayed beyond [***], the Parties shall discuss in good faith and use best efforts to revise the quantities of finished commercial Product to be Manufactured and supplied by BBIL for and during Calendar Year 2021, such that BBIL shall remain obligated to Manufacture [***] doses of finished commercial Product for and during the remainder of Calendar Year 2021, provided, however, in no event shall BBIL's monthly supply commitment during such period exceed [***] doses per [***], with supply of such finished commercial Product to commence during July 2021 and continue through December 2021.

4.2 Forecasts. Commencing upon the Effective Date and on a [***] basis thereafter until the termination or expiration of this Agreement, Ocugen will provide to BBIL a rolling [***] forecast of its, its Affiliates' or Sublicensees' pre-clinical, clinical and commercial requirements for the Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance and Drug Product Components (separately identifying its, its Affiliates' or Sublicensees' pre-clinical, clinical and commercial requirements of Aluminum Hydroxide/TLR Complex, IMDG, Cell Banks, Virus Seed, Reference Standards and any other Critical

Reagents), as applicable (the "**Forecast**"). The first [***] of each Forecast will be considered the firm order period and will be binding on the Parties (the "**Binding Forecast**") and the following [***] will be a non-binding, good faith estimate. Forecasts will be updated by Ocugen to BBIL in writing on a [***] basis, with each subsequent [***] forecast adding an additional [***] to the firm period (e.g., a rolling [***] firm period). Notwithstanding the foregoing, during Calendar Year 2021 the Parties will collaborate, discuss in good faith and mutually agree upon each Forecast.

4.3 Purchase Orders. Together with each Forecast, Ocugen will submit firm, non-cancellable purchase orders for Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance and/or Drug Product Components, as applicable, under the applicable Binding Forecast. All purchase orders for Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance and/or Drug Product Components shall state the quantities of Clinical Trial Materials, Product, COVAXIN™ Drug Substance and/or Drug Product Components (separately specifying the Aluminum Hydroxide/TLR Complex, IMDG, Cell Banks, Virus Seed, Reference Standards and any other Critical Reagents) to be purchased pursuant to such purchase orders, the requested delivery dates, and shipping instructions. Purchase orders for Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance and/or Drug Product Components (separately specifying the IMDG, Aluminum Hydroxide/TLR Complex, Virus Seed, Cell Banks, and any other Critical Reagents) shall state the ordered quantity, including with respect to the Product, in increments of full batches. For clarity, each purchase order placed by Ocugen will be deemed as accepted by BBIL to the extent that it is consistent with the Binding Forecast. BBIL may, in writing, object within [***] after submission by Ocugen, to any purchase order that is inconsistent with the Binding Forecast by more than a [***] variance. BBIL will have [***] after its receipt of a purchase order to accept such purchase order, which will become firm upon its acceptance by BBIL. If the quantity of Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components (separately specifying the Aluminum Hydroxide/TLR Complex, IMDG, Cell Banks, Virus Seed, Reference Standards and any other Critical Reagents), as applicable, ordered in a purchase order exceeds [***] of the applicable Binding Forecast related to such Clinical Trial Materials, Adjuvant, Product, COVAXIN™ Drug Substance or Drug Product Components (separately specifying the Aluminum Hydroxide/TLR Complex, IMDG, Cell Banks, Virus Seed, Reference Standards and any other Critical Reagents), as applicable, BBIL will use commercially reasonable efforts to accommodate the excess quantity thereof so ordered by Ocugen. Notwithstanding the foregoing, during Calendar Year 2021, the Parties shall abide by the mutually agreed terms with respect to forecast and accommodation for the excess quantity.

4.4 Shipping; Storage. Shipments of the Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance and Drug Product Components shall be made EXW (as defined in Incoterms 2020) from the Facility. Title to same and risk of loss or damage shall pass to Ocugen accordingly after the Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, is loaded onto the carrier's vehicle for shipment at the EXW point. All shipping instructions of Ocugen will be accompanied by the name and address of the recipient and the shipping date and any costs and insurance associated with shipping will be borne by Ocugen. BBIL must provide all required documentation, including without limitation a Certificate of Analysis and Certificate of Compliance, and the Records including analytical testing data, if any, for each lot of Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, certifying conformity with the Specifications, Applicable Laws, and cGMP. In addition, BBIL must provide all product/process documentation and analytical raw data of each lot, as well as supplementing documentation as requested (e.g., for regulatory filings). Should Ocugen require special handling, packaging or services, then the cost of such special handling, packaging or services will be borne entirely by Ocugen at BBIL's prevailing rates. On Ocugen's written request, and at Ocugen's cost and expense, BBIL will store Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product

Components, as applicable, for up to an additional [***] following an initial period of [***] which shall also be at Ocugen's cost following the release of such Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components by Ocugen. Such additional storage will be subject to storage fees to be mutually agreed upon by the Parties.

4.5 Inspection and Rejection.

(a) Inspection. BBIL will ship the Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, in accordance with Section 4.4 upon successful completion of the release testing required to be performed thereon by BBIL. Ocugen will have [***] after receipt (the "**Inspection Period**") to inspect and test the Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, in accordance with Applicable Laws, the terms of this Agreement, the Quality Agreement, and the Specifications. Prior to the expiration of the Inspection Period for a shipment of Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, Ocugen will provide prompt written notice to BBIL if any such Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components does not comply with Applicable Laws, the terms of the Agreement (including the Quality Agreement), and/or the Specifications. Such notice will specify the nature of the Adjuvant, Clinical Trial Materials', Product's, COVAXIN™ Drug Substance's or Drug Product Components' non-compliance. Subject to Section 4.5(b), failure by Ocugen to provide such notice within the applicable Inspection Period will be deemed an acceptance of such Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components by Ocugen.

(b) Latent Defect. Ocugen may, no later than [***] after Ocugen's acceptance of a batch of Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components under Section 4.5(a), reject such Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components if it discovers that such Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components has a Latent Defect. Ocugen must notify BBIL of such Latent Defect in writing within [***] after its first discovery of such Latent Defect. Such notice will state in a reasonably sufficient detail the reason for the Latent Defect, if known.

4.6 Referee Laboratory. In case of any disagreement between the Parties as to whether any Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components conforms to the applicable Specifications, the Parties shall attempt, in good faith, to resolve such dispute. If Ocugen and BBIL cannot resolve such dispute, a representative sample of such Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, will be submitted to an independent testing laboratory mutually agreed upon by the Parties ("**Referee Lab**") for tests and final determination of whether such Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, conforms to such Specifications. The Referee Lab must meet the requirements of cGMP, be of recognized standing in the industry, and consent to the appointment of such laboratory, which will not be unreasonably withheld, conditioned or delayed by either Party. The Referee Lab will use the test methods contained in the applicable Specifications. The determination of conformance by the Referee Lab with respect to all or part of such Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, will be final and binding on the Parties. The fees and expenses of the Referee Lab incurred in making such determination will be paid by the Party against whom the determination is made.

4.7 Remedies. If BBIL agrees or the Referee Lab determines that Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as applicable, do not conform to the applicable Specifications as a result of BBIL's (i) failure to follow Applicable Laws, (ii) breach of this Agreement or the Quality Agreement, or (iii) negligence or willful misconduct, then Ocugen will have the right to reject such non-conforming Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components. Ocugen will promptly return any such rejected Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components to BBIL, or at BBIL's direction dispose of such Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components at BBIL's expense. BBIL will replace such non-conforming Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components with Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components that conforms to the applicable Specifications as soon as reasonably practicable after receipt of notice of rejection thereof. BBIL will bear all reasonable costs directly related to the replacement of the non-conforming Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components. If the Parties, through their Quality Assurance groups, agree in writing, the replacement of the non-conforming Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components can be satisfied through reprocessing or reworking the non-conforming Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components.

4.8 Recalls. The handling of field alerts, recalls and market withdrawals (collectively, "**Recalls**") of the Product, to the extent the Product is then being Commercialized in the Field in and for the Ocugen Territory, will be within the sole discretion of Ocugen, and Ocugen will notify BBIL promptly of any such Recall of Product. Notification to any Regulatory Authority and the conduct of such Recall will be the sole responsibility of Ocugen. BBIL will (a) cooperate fully with Ocugen in the event of any such Recall and (b) provide such assistance in connection with the Recall as Ocugen may reasonably request. Ocugen will bear all expenses of any such Recall and BBIL's assistance unless and to the extent such Recall directly results from BBIL's (i) negligence or willful misconduct, (ii) failure to comply with its obligations under this Agreement in respect of the Product that is subject to Recall, or (iii) breach of any representation, warranty or covenant contained herein with respect to the Product that is subject to Recall, whereupon in each case BBIL will (A) bear the actual, documented and reasonable expenses of the Parties in carrying out the Recall and (B) replace the Product subject to such Recall with conforming Product as soon as reasonably practicable at BBIL's expense.

5. Price and Payments.

5.1 Price. Ocugen will pay BBIL the purchase price for the Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance and Drug Product Components (separately specifying the purchase price for the Aluminum Hydroxide/TLR Complex, IMDG, Cell Banks, Virus Seed, Reference Standards and any other Critical Reagents) as set forth in **Exhibit B** attached hereto (the "**Purchase Price**"), which **Exhibit B** shall be updated by the Parties at the appropriate time to reflect the actual Purchase Price paid by Ocugen to BBIL for the Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components (separately specifying the Purchase Price actually paid for the Aluminum Hydroxide/TLR Complex, IMDG, Cell Banks, Virus Seed, Reference Standards and any other Critical Reagents), as applicable. Notwithstanding the foregoing, the maximum Purchase Price payable by Ocugen for Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or any Drug Product Component Manufactured and supplied hereunder shall be at such price as is mutually agreed in writing by the Parties.

5.2 Payments. BBIL will invoice Ocugen upon release of each batch of Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components, as

applicable, by BBIL's Quality Department. Payment of undisputed amounts of invoices will be due thirty (30) days after the date each invoice is received by Ocugen. Ocugen shall pay all undisputed fees, expenses and other charges as and when due. The Parties shall use good faith efforts to resolve any disputed amounts within [***] and if the dispute is not resolved within such [***], the Parties reserve all rights respecting the disputed amount. Interest on unpaid balances shall accrue at the rate of [***] from the date payment is due, provided that interest on amounts that Ocugen had timely disputed shall not begin to run until [***] after the date the payment is due, and provided further that such interest shall not be payable on any invoice or portion of an invoice which is determined to not be due to BBIL, but where determined to be due to BBIL, the interest period shall run from the date when originally due.

5.3 Invoices. All payments hereunder will be made in United States Dollars. Ocugen will make all payments pursuant to this Agreement by wire transfer to a bank account designated in writing by BBIL.

5.4 Taxes. Any use, sales, excise or value added tax, duty, custom, inspection or testing fee, or any other tax, fee or charge of any nature whatsoever imposed by any governmental authority on or measured by the transaction between BBIL and Ocugen (other than BBIL's income tax), will be paid by Ocugen in addition to the prices quoted or invoiced by BBIL. In the event BBIL is required to pay any such tax, fee, or charge, Ocugen will reimburse BBIL for such payment, or in lieu of such payment, Ocugen will provide BBIL at the time the order is submitted an exemption certificate or other document acceptable to the authority imposing the tax, fee or charge.

6. Representations and Warranties.

6.1 By Both Parties. BBIL and Ocugen each represents and warrants to the other that:

(a) It is, and will remain, a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization.

(b) The execution and delivery of this Agreement has been authorized by all requisite corporate action. This Agreement is and will remain a valid and binding obligation of the executing Party, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors.

(c) It is under no contractual or other obligation or restriction that is inconsistent with its execution or performance of this Agreement.

(d) It will comply with cGMP and all Applicable Laws while performing its obligations hereunder.

6.2 By BBIL. BBIL represents and warrants to Ocugen that:

(a) The Services will be performed (i) in a professional and workmanlike manner using only properly qualified and trained personnel, and (ii) in accordance with Applicable Laws and cGMP, and, upon delivery, the Clinical Trial Materials, Product, COVAXIN™ Drug Substance and Drug Product Components, as applicable, will meet the Specifications therefor.

(b) Title to any Adjuvant, Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components provided to Ocugen under this Agreement shall pass as provided in this Agreement, free and clear of any security interest, lien or other encumbrance.

(c) BBIL will promptly notify Ocugen in writing should it become aware of any claim asserting that the use of BBIL Technology in the performance of the Services infringes the intellectual property rights of any Third Party.

(d) Neither BBIL nor any of its employees providing the Services has been debarred, or convicted, or is subject to a pending debarment or conviction, pursuant to section 306 of the United States Food, Drug, and Cosmetic Act, 21 U.S.C. § 335a, the Generic Drug Enforcement Act of 1992, 21 U.S.C. Sec. 335a, or any foreign equivalent hereto related to the transactions contemplated by this Agreement.

(e) BBIL has all appropriate training, registrations, licenses and other governmental authorizations required to carry out its obligations under this Agreement.

6.3 By Ocugen: Ocugen represents and warrants to BBIL that:

(a) It shall maintain the COVAXIN™ Drug Substance, Drug Product Components and Product in a facility that is properly equipped to store the COVAXIN™ Drug Substance, Drug Product Components and Product and have in place appropriate product security measures in accordance with Applicable Law.

(b) In the event Ocugen uses the COVAXIN™ Drug Substance supplied by BBIL hereunder in a Product and packages such Product for use in Ocugen Development Activities, it shall do so, and shall distribute such Product, in accordance with all Applicable Laws.

(c) Neither Ocugen nor any of its employees performing Ocugen's obligations under this Agreement has been debarred, or convicted, or is subject to a pending debarment or conviction, pursuant to section 306 of the United States Food, Drug, and Cosmetic Act, 21 U.S.C. § 335a, the Generic Drug Enforcement Act of 1992, 21 U.S.C. Sec. 335a, or any foreign equivalent thereto.

(d) Ocugen or its personnel with responsibilities related to this Agreement, as applicable, have all appropriate training, registrations, licenses and/or other governmental authorizations required to carry out its/their obligations under this Agreement.

6.4 DISCLAIMER. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

7. Government Approvals. As more fully described in the Co-Development Agreement, Ocugen will be responsible for obtaining, at its expense, all regulatory and governmental approvals and permits necessary for Ocugen to use and Commercialize the Product in the Field, in and for the Ocugen Territory that is provided to Ocugen by BBIL under this Agreement, including without limitation, all submissions filed with the FDA or other Regulatory Authorities.

8. Expiration, Initial Technology Transfer and Termination.

8.1 Expiration. This Agreement will become effective as of the Effective Date. Unless earlier terminated in accordance with this Section 8, this Agreement will be and remain effective until the expiration or termination of the Co-Development Agreement (such period, the "**Term**").

8.2 Effects of Initial Technology Transfer. Upon completion of the Initial Technology Transfer:

(a) Ocugen shall be responsible, at its sole cost and expense, for the Manufacture and supply of the finished Product in its commercial packaging presentation, for use and Commercialization by Ocugen in the Field in and for the Ocugen Territory, except that BBIL shall continue to Manufacture and supply Adjuvant, COVAXIN™ Drug Substance and Drug Product Components after the completion of the Secondary Technology Transfer to Ocugen for the remainder of the Term to the extent forecasted and ordered by Ocugen pursuant to the terms of the Agreement and consistent with Section 7.2(b) of the Co-Development Agreement, provided however that notwithstanding anything to the contrary contained in this Agreement, BBIL shall not be required to and shall not transfer any technology related to the Adjuvant to Ocugen and Ocugen shall only be entitled to supplies of Adjuvant from BBIL on a long term basis;

(b) notwithstanding Ocugen's exclusive right to Manufacture the Product in and for the Ocugen Territory, BBIL shall continue to be a back-up supplier of the Product for Ocugen, its Affiliates or Sublicensees, as applicable, in and for the Ocugen Territory, provided that the purchase price payable by Ocugen for any such back-up supply shall be negotiated between the Parties within a reasonable period of time prior to BBIL manufacturing such supply for Ocugen;

(c) BBIL shall continue to have a non-exclusive right to Manufacture the Product in the BBIL Territory for the use and Commercialization of such Product by Ocugen, its Affiliates or Sublicensees in the Field in and for the Ocugen Territory, solely as may be requested by Ocugen, its Affiliates or Sublicensees pursuant to and in accordance with the terms of this Agreement, provided that, after the completion of the Initial Technology Transfer, Ocugen shall have and retain, except as otherwise set forth in this Agreement, the sole and exclusive right to Manufacture the Product in the Field in and for the Ocugen Territory, subject only to the limitations described in this Section 8.2(c); and

(d) the technology for the COVAXIN™ Drug Substance and Drug Product Components shall have been fully transferred to Ocugen, provided not withstanding such transfer, Ocugen shall have the right to request that BBIL supply, on an as-needed basis, the Aluminum Hydroxide/TLR Complex to Ocugen for the Manufacture and supply by Ocugen of the Product in the Field in and for the Ocugen Territory. For clarity, all costs related to the Initial Technology Transfer shall be for the account of and shall be paid by Ocugen.

8.3 Termination for Breach or Bankruptcy. Either Party will have the right to terminate this Agreement in accordance with Sections 12.2(a)(i) or 12.2(a)(iii), but subject to Section 12.2(b), of the Co-Development Agreement as if such provisions were contained in and applied to the Parties under this Agreement.

8.4 Obligations on Termination.

(a) Of BBIL. Upon termination of this Agreement pursuant to this Section 8, BBIL will suspend work as early as possible and:

(i) perform only those Services and other activities mutually agreed upon by Ocugen and BBIL as being necessary or advisable;

(ii) use commercially reasonable efforts to cancel any Third Party obligations;

(iii) promptly deliver to Ocugen all materials ordered by BBIL for Ocugen after receipt of undisputed amounts applicable to such materials by Ocugen; and

(iv) promptly return all Confidential Information of Ocugen that it has received pursuant to this Agreement.

(b) Of Ocugen. Upon termination of this Agreement pursuant to this Section 8, Ocugen will:

(i) promptly pay BBIL any undisputed monies due and owing BBIL, up to the time of termination, for Services actually performed, all authorized expenses actually incurred and, except for any termination by Ocugen under Section 8.1 or Section 8.3, any uncancellable commitments made by BBIL in connection with the Services; and

(ii) promptly return all Confidential Information of BBIL that it has received pursuant to this Agreement.

8.5 Surviving Terms. Expiration or termination of this Agreement for any reason will not affect and rights or obligation of either Party that accrued prior to such expiration or termination. Further, the rights and obligations of the Parties under the following provisions of this Agreement will survive in accordance with their terms: Sections 1, 4.7, 4.8, 5.2, 5.4, 6, 7, 8.2, 8.3, 8.4, 8.5, 11.3 through 11.11 and 12.

9. Force Majeure. In the event of any Force Majeure hereunder, the Parties shall approach and resolve the matter in accordance with Section 14.1 of the Co-Development Agreement, and the provisions of such Section 14.1 of the Co-Development Agreement shall apply in interpreting this Agreement *mutatis mutandis*, as if the same was incorporated herein.

10. Confidential Information. With respect to confidentiality and publicity, the terms of Article XI of the Co-Development Agreement shall apply *mutatis mutandis* to this Agreement, as if the same was incorporated herein.

11. Indemnification; Limited Liability.

11.1 Indemnification by BBIL. BBIL will indemnify, defend and hold harmless Ocugen, its Affiliates and Sublicensees, and its and their respective directors, officers, employees, and agents, and their respective successors, heirs and assigns (collectively, the "**Ocugen Indemnitees**") against any and all damages, liabilities, losses and expenses, including reasonable attorneys' fees and expenses of litigation (collectively "**Losses**") incurred by or imposed upon the Ocugen Indemnitees, or any of them, including as a direct result of Claims of Third Parties, including personal injury and product liability claims (collectively "**Ocugen Indemnity Claims**"), to the extent arising out of: (a) any breach of this Agreement by BBIL or any of its Affiliates or agents, including its representations, warranties and covenants; or (b) the gross negligence or willful misconduct of or fraud by any BBIL Indemnitee or agent of BBIL, excluding any BBIL Indemnity Claim or Losses for which Ocugen has an obligation to indemnify BBIL Indemnitees pursuant to Section 11.2, as to which Claims or Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.

11.2 Indemnification by Ocugen. Ocugen will indemnify, defend and hold harmless BBIL and its Affiliates, and its and their respective directors, officers, employees, and agents, and their respective successors, heirs and assigns (collectively, the "**BBIL Indemnitees**") against all Losses incurred by or imposed upon the BBIL Indemnitees, or any of them, including as a direct result of Claims of Third Parties, including personal injury and product liability claims (collectively, "**BBIL Indemnity Claims**"), to the extent arising out of: (a) the Development, Manufacture or Commercialization of the Product by Ocugen or any of its agents in the Field in and for the Ocugen Territory; (b) any breach of this Agreement by Ocugen or any of its Affiliates or Sublicensees, and its and their respective agents, including its representations, warranties and covenants; or (c) the gross negligence or willful misconduct of or fraud by any

Ocugen Indemnitee or agent of Ocugen, excluding any Ocugen Indemnity Claim or Losses for which BBIL has an obligation to indemnify Ocugen Indemnitees pursuant to Section 11.1, as to which Claims or Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.

11.3 Conditions to Indemnification. A Person seeking indemnification under this Section 11 (the "**Indemnified Party**") in respect of a BBIL Indemnity Claim or an Ocugen Indemnity Claim, as applicable (each, an "**Indemnity Claim**") shall give prompt written notice of such Indemnity Claim to the Party from whom indemnification is sought (the "**Indemnifying Party**"); provided, that the Indemnifying Party is not contesting its obligation under this Section 11, and shall permit the Indemnifying Party to control the investigation, defense and settlement of such Indemnity Claim; and further provided, that the Indemnifying Party shall (a) act reasonably and in good faith with respect to all matters relating to the settlement or disposition of such Indemnity Claim as the settlement or disposition relates to such Indemnified Party and (b) not settle or otherwise resolve such Indemnity Claim without the prior written consent of such Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). Each Indemnified Party shall cooperate with the Indemnifying Party in its investigation, defense and settlement of any such Indemnity Claim in all reasonable respects and shall have the right to be present in person or through counsel at all legal proceedings with respect to such Indemnity Claim. If the Indemnifying Party does not assume and conduct the defense of the Indemnity Claim as provided above, (i) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Indemnity Claim in any manner the Indemnified Party may deem appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (ii) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Section 11. The Indemnifying Party shall have no liability for any settlement of Indemnity Claims entered into by the Indemnified Party without the prior written consent of the Indemnifying Party.

11.4 Limited Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES OR ITS SUBLICENSEES FOR ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS OR LOST REVENUES, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER SECTIONS 11.1 OR 11.2, FOR DAMAGES AVAILABLE FOR A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OR A BREACH OF CONFIDENTIALITY OBLIGATION UNDER SECTION 10.

11.5 Insurance. Each Party shall procure and maintain insurance in accordance with Section 13.5 of the Co-Development Agreement, and the provisions of such Section 13.5 of the Co-Development Agreement shall apply in interpreting this Agreement *mutatis mutandis*, as if the same were incorporated herein.

11.6 Maximum Liability. Except to the extent of a Party's gross negligence or willful misconduct in the performance of this Agreement, or to the extent any BBIL Indemnity Claim or Losses in respect of a BBIL Indemnity Claim relates to or arises from or is in any way connected to the Ocugen Territory (the liability of Ocugen thereto being uncapped), the maximum aggregate liability of either Party in respect of any Claim, including an Indemnity Claim, under this Agreement, notwithstanding anything to the contrary contained in this Agreement shall not exceed an amount equal to [***] preceding the date on which the action or omission alleged to have caused such Claim or Indemnity Claim occurred.

11.7 Otherwise Compensated. If the Indemnifying Party makes any payment by way of Losses in respect of a Claim under this Agreement ("**Damages Payment**") and the Indemnified Party

subsequently receives any monetary payment (exclusive of payments from the Indemnifying Party), which payment compensates the Indemnified Party for the same Loss as the Damages Payment, the Indemnified Party shall, once it has received such monetary payment, forthwith repay (net of any taxes actually paid or withheld with respect thereto) to the Indemnifying Party an amount equal to the amount (if any) by which the amount of the Damages Payment, aggregated with the amount of such monetary payment, exceeds the total amount of the Losses suffered by the Indemnified Party in respect of such Claim.

11.8 No Double Recovery. No Indemnified Party shall be entitled to recover damages or obtain payment, reimbursement, restitution or indemnity more than once for the same loss, damage, deficiency or breach whether under this Agreement or the Co-Development Agreement.

11.9 Mitigation Not Affected. Both Parties shall procure that commercially reasonable steps are taken and commercially reasonable assistance is given to avoid or mitigate any Losses which, in the absence of mitigation, might give rise to a liability in respect of any Claim.

11.10 Time Limitation for Claims. BBIL shall not be liable for any Claim unless a notice of the Claim is given by Ocugen to BBIL specifying the matters set out in Section 11.11 and in the case of any Claims of Third Parties, including personal injury and product liability claims, within twelve (12) months from the expiry date of the shelf life of the applicable Clinical Trial Materials, Product, COVAXIN™ Drug Substance or Drug Product Components supplied by BBIL under this Agreement.

11.11 Notification of Claims. Notice of any Claim shall be given by Ocugen to BBIL within the time limits specified in Section 11.10 and shall not be valid unless it specifies full information (to the extent available) in relation to the legal and factual basis of the Claim and the evidence on which Ocugen is making such Claim relies (including, where the Claim is the result of or in connection with a Third Party Claim, evidence of the Third Party Claim) and setting out Ocugen's good faith estimate of the amount of Losses which are, or are to be, the subject of the Claim (including any Losses which are contingent on the occurrence of any future event).

12. Miscellaneous.

12.1 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder, either in whole or in part, without the prior written consent of the other Party. Notwithstanding the foregoing, either Party may assign this Agreement without the other Party's consent to one or more of its Affiliates, to any person or entity into which the assigning Party has merged, or to any person or entity which has otherwise succeeded to all or substantially all of the assigning Party's business and assets to which this Agreement pertains, whether such succession results from sale of assets, stock, merger, consolidation, reorganization or otherwise. The assigning Party shall provide the other Party with prompt written notice of any such assignment. Any permitted assignee shall assume all obligations of its assignor under this Agreement, and no permitted assignment shall relieve the assignor of liability for its obligations hereunder. Any attempted or purported assignment in violation of this section shall be null and void. This Agreement, and each Party's rights and obligations hereunder will bind and inure to the benefit of its respective successors, heirs, executors, administrators, and permitted assigns.

12.2 Severability. Each provision in this Agreement is independent and severable from the others, and no provision will be rendered unenforceable because any other provision is found by a proper authority to be invalid or unenforceable in whole or in part. If any provision of this Agreement is found by such an authority to be invalid or unenforceable in whole or in part, such provision will be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision and the intent of the Parties, within the limits of Applicable Laws.

12.3 Notices. All notices which either Party is required or may desire to give hereunder shall be provided in accordance with Section 14.4 of the Co-Development Agreement.

12.4 Choice of Law and Jurisdiction. The validity, construction and performance of this Agreement shall be governed by and construed in accordance with the laws of the United Kingdom, without regard to the application of principles of conflicts of law.

12.5 Dispute Resolution. In respect of any dispute concerning this Agreement, the Parties shall resolve the matter in accordance with Section 14.6 of the Co-Development Agreement, and the provisions of such Section 14.6 of the Co-Development Agreement shall apply in interpreting this Agreement *mutatis mutandis*, as if the same was incorporated herein.

12.6 Entire Agreement; Amendment. This Agreement constitutes the final, complete and exclusive statement of the terms between Ocugen and BBIL with respect to the subject matter hereof and supersedes and terminates any and all prior agreements and understandings (other than the Co-Development Agreement), whether written or oral, between the Parties with respect to the subject matter hereof.

12.7 Conflicts. If there is any conflict, discrepancy, or inconsistency between the terms of this Agreement and any purchase order hereunder or other form used by the Parties, the terms of this Agreement will control. If there is conflict, discrepancy, or inconsistency between the terms of this Agreement and the Co-Development Agreement, the terms of the Co-Development Agreement will control.

12.8 Headings; Construction. The Section headings are intended for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. Both Parties have participated equally in the formation of this Agreement and the language of this Agreement will not be presumptively construed against either Party.

12.9 No Partnership or Employment Relationship. All Services will be rendered by BBIL as an independent contractor for federal, state and local income tax purposes and for all other purposes. BBIL will not in any way represent itself to be a partner or joint venturer of or with Ocugen. This Agreement does not create an employer-employee relationship between Ocugen on the one hand and BBIL or any employee, subcontractors, Affiliate of BBIL, or any BBIL personnel on the other. BBIL is acting under this Agreement as an independent contractor with full power and authority to determine the means, manner and method of performance of BBIL's duties. Each Party will be responsible for and will withhold and/or pay any and all applicable federal, state or local taxes, payroll taxes, workers' compensation contributions, unemployment insurance contributions, or other payroll deductions from the compensation of such Party's employees and other personnel. Each Party understands and agrees that it is solely responsible for such matters and that it will indemnify the other Party and hold the other Party harmless from all claims and demands in connection with such matters.

12.10 Waiver. No term or condition of this Agreement shall be deemed to have been waived, nor shall there be any estoppel against the enforcement of any provision of this Agreement, except by a written instrument signed by the Party against whom enforcement of such waiver or estoppel is sought. No such written waiver shall be deemed a continuing waiver unless specifically stated therein, and each such waiver shall operate only as to the specific term or condition waived and shall not constitute a waiver of such term or condition for the future or as to any act other than that specifically waived.

12.11 Amendments or Modifications. This Agreement cannot be amended or modified except in a writing executed by both Parties.

12.12 Survival. Any covenant or provision of this Agreement which by its express terms is required to be observed, kept or performed after expiration or termination hereof, or which by its

nature and effect is intended to survive expiration or termination of this Agreement shall so survive.

12.13 Further Assurances. The Parties hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

12.14 Counterparts. This Agreement and any amendments hereof may be executed in counterparts and by original, facsimile, PDF or other electronic signatures.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives, effective as of the Effective Date.

OCUGEN, INC.		**BHARAT BIOTECH INTERNATIONAL LIMITED**	
By:	/s/ Sanjay Subramanian	By:	/s/ V. Krishna Mohan
Name:	Sanjay Subramanian	Name:	Dr. V. Krishna Mohan
Title:	CFO	Title:	Whole-time Director
Date:	9/29/2021	Date:	9/29/2021

EXHIBIT A

SPECIFICATIONS

[***]

EXHIBIT B

PURCHASE PRICE

[***]

Certain portions of this document have been omitted pursuant to Item 601(b)(10) of Regulation S-K and, where applicable, have been marked with "[***]" to indicate where omissions have been made. The marked information has been omitted because it is (i) not material and (ii) the type that the registrant treats as private or confidential. The registrant hereby undertakes to provide further information regarding such marked information to the Securities and Exchange Commission upon request.

Exhibit 10.2

1st Amendment to the CO-DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This **1st Amendment** to the CO-DEVELOPMENT AND COMMERCIALIZATION AGREEMENT ("**Amendment**") by and between Ocugen, Inc. previously having a place of business at 5 Great Valley Parkway, Suite 160, Malvern, PA 19355, now with an address at 263 Great Valley Parkway, Malvern, PA 19355, USA ("**Ocugen**") and CanSino Biologics, Inc., whose registered office address is at 185 South Ave, TEDA West District, Tianjin, 300457, China ("**CanSino**") is made and effective as of the last date of signature below ("**Effective Date**").

Ocugen and **CanSino** hereinafter also individually referred to as "**Party**", and collectively referred to as the "**Parties**".

RECITALS

WHEREAS, the Parties have entered into a CO-DEVELOPMENT AND COMMERCIALIZATION AGREEMENT effective as of September 27, 2019 ("**Original Collaboration Agreement**"), under which Ocugen and CanSino has established co-development and commercialization relationship on the gene therapy product of OCU400;

WHEREAS, the Parties agree that the **Original Collaboration Agreement** is still in full force and effect;

WHEREAS, Ocugen is willing to establish additional co-development and commercialization relationship with CanSino on the other gene therapy product known as OCU410 for use in the Field of OCU410 under the **Original Collaboration Agreement**;

WHEREAS, CanSino, representing itself and its Affiliates, wishes to obtain the exclusive right regarding Ocugen Technology and Ocugen Patent Rights of OCU410 to collaborate and cooperate with Ocugen to co-development and commercialization under the **Original Collaboration Agreement**; and

WHEREAS, pursuant to Section 11.2, the **Parties** desire to amend the **Original Collaboration Agreement** as provided for herein.

NOW, THEREFORE, in consideration of the premises and mutual covenants, agreements and provisions herein contained, and intending to be legally bound, the Parties have entered into the present Amendment as follows:

1. Definitions

1.1. Unless otherwise established herein, the terms that are in bold letters or capitalized and defined and/or used in the Original Collaboration Agreement shall have the same meanings set out in this Amendment.

1.2. In the **Original Collaboration Agreement**, Section 1 “Definitions” is amended to include the following new terms:

CanSino Development Activities of OCU410:	shall mean All Development activities to be conducted by or on behalf of CanSino with respect to the Development Program of OCU410 as specified in the Development Plan pursuant to this **Amendment.**
Clinical Data of OCU410:	shall mean any and all data (together with all clinical trial reports and the result of analyses thereof) derived or generated from any Clinical Trial involving OCU410 Product conducted by or on behalf of a Party or from the testing of subjects or the analysis of samples used in any such Clinical Trial.
Development Plan of OCU410:	Ocugen Development Activities and the CanSino Development Activities regarding to OCU410 to be carried out by the Parties as set forth in the Appendix A under this Amendment.
Field of OCU410:	shall mean the treatment of the following diseases in humans: Dry Age-Related Macular Degeneration.
OCU410:	shall mean the novel gene therapy known as OCU410 consisting of an adeno-associated virus serotype 5-based vector containing the human RORA gene in an expression cassette comprised of: a) AAV2 inverted terminal repeat (AAV2 ITR); b) the cytomegalovirus (CMV) enhancer; c) the chicken beta actin (CBA) promoter; d) chimeric intron; e) the cloned cDNA coding for human RORA (Retinoic Acid Receptor-Related Orphan Receptor Alpha) protein; f) the SV40 polyadenylation (PolyA) region; and g) inverted AAV2 ITR.

1.3. In the **Original Collaboration Agreement**, Section 1 “Definitions” is amended to include the following new terms:

Confidential Information:	shall mean all (a) documents and information provided by or on behalf of one Party to the other Party in connection with or in furtherance of this Agreement, including at any meeting of the JSC, (b) the terms of this Agreement, and (c) all Ocugen Technology, Ocugen Patent Rights, Joint Program Technology, and Ocugen Technology and Ocugen Patent Rights, including but not limited to information related to OCU400 and OCU410 **Products**, Joint Program Patent Rights and Joint Program Materials and that are disclosed or provided by or on behalf of a Party to the other Party, or to any of its employees, consultants or Affiliates during the Term.

	The term **Confidential Information** shall not include **Information** that (a) are within the public domain or enters into the public domain, through no act or omission of the receiving party; or (b) comes within the possession of the receiving party by disclosure from a third party having a legal right to disclose the **Information**, but only to the extent allowed by such a third party; or (c) was already in the receiving party's possession prior to receipt from the disclosing party; or (d) is independently developed by the receiving party without reference to the **Information** of the disclosing party. The **Parties** further agree that no portion of **Information** shall be construed as coming within exceptions (a) through (d) of this definition, solely on the basis that more generalized information embracing such portion of **Information** falls within any of the exceptions or on the basis that elements of such portion of the **Information** are independently within any of the exceptions.
Ocugen Patent Rights:	shall mean the Patent Rights that contain one or more claims to the Ocugen Technology, which as of the Effective Date are set forth in Schedule 1 of the **Original Collaboration Agreement** and as set forth in **Appendix B** of this **Amendment** including, but not limited to, any claims contained in any patents and/or patent applications related to OCU400 and/or OCU410.
Ocugen Technology:	Any Technology that (a) is necessary for the conduct of the Development Program for OCU400 and OCU410, and (b) (i) is Controlled by Ocugen or its Affiliates as of the Effective Date of the **Original Collaboration Agreement** or Effective Date of this **Amendment** or (ii) is Controlled by Ocugen or its Affiliates during the Term and conceived or first reduced to practice by Ocugen or its Affiliates or employees or subcontractors of, consultants to, or collaborators with Ocugen or its Affiliates outside of the conduct of the Development Program, or that otherwise relates to a Product (including its composition of matter, formulation, method of delivery or use, and/or its Manufacture). For clarity, Ocugen Technology shall exclude any Joint Program Technology.
Product(s):	shall mean in any country of the Territory, any biopharmaceutical preparation, substance, formulation or product comprised, in whole or in part, of OCU400 and/or OCU410 including any modification or derivative thereof.

2. Amendment to Section 2.1 "**Grant of Rights**" in the **Original Collaboration Agreement**

2.1. The Parties hereby agree to expand the granted rights scope to OCU410 based on the OCU400 according to section 2 of the **Original Collaboration Agreement**, including:

(a) an exclusive, non-sub-licensable, royalty-bearing license to use, research, Develop, Manufacture and Commercialize Products in the Field of OCU410 in and for the CanSino Territory;

(b) an exclusive, royalty-bearing license, including the right to grant sublicenses solely as provided in Section 2.3 of the **Original Collaboration Agreement**, under Ocugen's rights in the Joint Program

Technology and Joint Program Patent Rights, to use, research, Develop, Manufacture and Commercialize Products in the Field of OCU410 in and for the CanSino Territory;

(c) an exclusive Option on OCU410 as set forth in the **Original Collaboration Agreement**.

2.2. All clauses under section 2 of the **Original Collaboration Agreement** shall applied to the expanded scope as above mentioned.

3. **Section 3 "Co-Development of Products"** in the **Original Collaboration Agreement** shall be amended by adding the following addendum:
Consistent with the remaining terms and requirements of the Original Collaboration Agreement, the Parties agree to use their Commercially Reasonable Efforts to conduct the their respective Development Activities as set forth in the Appendix A Development Plan of OCU410 and the cost of such Development shall be borne by CanSino or Ocugen based on their responsibilities in the Appendix A according to clause 3.3 under the Original Collaboration Agreement.

4. **Section 4 "Commercialization"** in the **Original Collaboration Agreement** shall be amended by adding the following addendum:
Consistent with the remaining terms and requirements of the Original Collaboration Agreement, besides the Commercialization of Products of OCU400, each Party shall be solely responsible for Commercialization of Products of OCU410 in the Field of OCU410 in its Territory.

5. **Section 5 "Payment/Consideration"** in the **Original Collaboration Agreement** shall be amended by adding the following addendum:
In consideration for the licenses granted under section 2 of this Amendment and the rights of each Party to Commercialize Products of OCU410 in its Territory, each Party agrees to pay the other Party royalties with the same procedures and requirements as section 5 under the Original Collaboration Agreement but the percentage of the royalties should be adjusted as following:
(a) On a Product-by-Product and country-by-country basis, Ocugen will pay CanSino a royalty equal to [***] of the cumulative Net Sales of such Products of OCU410 in such country in the Ocugen Territory in a given calendar year (or partial calendar year), commencing with the First Commercial Sale of such Product of OCU410 in such country and ending upon the last day of the Term in such country pursuant to Section 7 below; and
(b) On a Product-by-Product and country-by-country basis, CanSino will pay Ocugen a royalty equal to [***] of the cumulative Net Sales of such Product in such country in the CanSino Territory in a given calendar year (or partial calendar year), commencing with the First Commercial Sale of such Product of OCU410 in such country and ending upon the last day of the Term in such country pursuant to Section 7 below.
Payments of OCU400 remains applicable according to the Original Collaboration Agreement.

6. **Section 6 "Intellectual Property"** in the **Original Collaboration Agreement** shall be amended by adding the following addendum:

6.1. As between the Parties, Ocugen shall have sole and exclusive Control of all right, title and interest on a worldwide basis in and to any and all Ocugen Technology and Ocugen Patent Rights including, but not limited to, those related to OCU410, subject to the licenses provided to CanSino pursuant to this Agreement. The Parties shall jointly Control all right, title and interest on a worldwide basis in and to any and all Joint Program Technology, Joint Program Patent Rights and Joint Program Materials including OCU410.

6.2. The management, including filing, prosecution and maintenance, enforcement and defense, and infringement settlement regarding Products of OCU410 shall be the same as the section 6 of the Original Collaboration Agreement.

7. **Section 9 "Term and Termination"** in the **Original Collaboration Agreement** shall be amended as follows:

7.1. Paragraph 9.1 of the **Original Collaboration Agreement** shall be replaced by the following rewritten paragraph 9.1:

9.1. This Agreement, and the licenses granted hereunder, shall come into effect on the Effective Date and, unless terminated earlier in accordance with this Section 9, shall continue in force on a country-by-country and Product-by-Product basis until the later of:

(a) the expiration of the last Valid Claim included within the Ocugen Patent Rights regarding to OCU400 and OCU410 claiming or Covering such Product that, but for this Agreement, would be infringed by such Product, as applicable, in such country; and

(b) the tenth (10th) anniversary of the First Commercial Sale of such Product of OCU410 in such country (the "Term"), and on such date this Agreement and the licenses granted hereunder shall terminate automatically by expiry with respect to such Product in such country.

To avoid any doubts, according to Section 5 of the Original Collaboration Agreement, the royalties of Product OCU400 shall be paid commencing with the First Commercial Sale of such Product in such country and ending upon the last day of the tenth (10th) anniversary of the First Commercial Sale of such Product of OCU400 in such country unless the Agreement terminated earlier based on (a) of this clause.

Notwithstanding the foregoing, this Agreement shall terminate contemporaneously upon any termination of the SERI Agreement, provided, that if at the time of such termination CanSino is not in breach or default of this Agreement, CanSino shall have the right to request conversion of this Agreement to an agreement/license directly between SERI and CanSino, and SERI shall not unreasonably withhold its acceptance of such conversion if CanSino agrees to be bound by all of the provisions of the SERI Agreement."

7.2. Paragraph 9.4 (d) of the **Original Collaboration Agreement** shall be replaced by the following rewritten paragraph 9.4(d):

"(d)Effective upon such termination and request by Ocugen for such license, CanSino hereby grants to Ocugen a perpetual, irrevocable, exclusive (even as to CanSino, except with respect to Manufacturing if a supply agreement between the Parties is then in effect in accordance with Section 9.4(e)) license, with the right to grant sublicenses, under CanSino's rights in the Joint Program Technology and Joint Program Patent Rights, used in the Development, Manufacture or Commercialization of Products on the date of termination, solely to continue to Develop, Manufacture (subject to Section 9.4(e)) and/or Commercialize Products in the Field in the CanSino Territory. The foregoing license shall be royalty-bearing as follows: (i) Ocugen shall pay CanSino a royalty of [***] of the Net Sales of Products by Ocugen or its sublicensees (to the extent such Products are thereafter Commercialized by Ocugen or its sublicensees) until such time as the amounts paid under this Section 9.4(d) equals the sum of the actual documented and audited out-of-pocket expenses paid by CanSino to conduct CanSino Development Activities and other Develop Products in the Field in and for the CanSino Territory as part of the Development Program (the "CanSino Development Costs"); and (ii) Sections 5.2, 5.3, 5.4 and 5.5 shall apply mutatis mutandis to Ocugen's payment of such royalties. Thereafter, the license granted under this Section 9.4(d) shall be a fully paid-up, non-royalty bearing, perpetual, non-exclusive license in and for the CanSino Territory."

7.3. Paragraph 9.5 (a) of the **Original Collaboration Agreement** shall be replaced by the following rewritten paragraph 9.5(a):

"(a) The licenses granted to CanSino under Section 2.1(a) and Section 2.1(b) shall continue to be valid in accordance with this Agreement, and to the extent permitted by the SERI Agreement and Applicable Laws. The foregoing license shall be royalty-bearing as follows: (i) CanSino shall pay Ocugen a royalty of [***] of the Net Sales of Products by CanSino or its sublicensees (to the extent such Products are thereafter Commercialized by CanSino or its sublicensees) for the balance of the Term; and (ii) Sections 5.2, 5.3, 5.4 and 5.5 shall apply mutatis mutandis to CanSino's payment of such royalties."

8. Section 11.5 "Notices" in the **Original Collaboration Agreement** shall be amended by updating the address and emails for both Parties as follows:

The address and emails of CanSino shall be entirely replaced by the following:

Name: Dongxu Qiu

Title: Executive Director

Address: 185 South Avenue, West District of TEDA, Tianjin, China
Tel: [***]
Email: [***]

with a copy to:

Name: Yuan Zhou
Title: Legal Manager
Address: 185 South Avenue, West District of TEDA, Tianjin, China
Tel: [***]
Email: [***]

The address and emails of Ocugen shall be entirely replaced by the following:

Shankar Musunuri
Chairman, CEO and Co-Founder
Ocugen, Inc.
263 Great Valley Parkway
Malvern, PA 19355, USA
Tel: (610) 590-2140
Email: shankar.musunuri@ocugen.com

with a copy to:

Ocugen, Inc.
263 Great Valley Parkway
Malvern, PA 19355
Attn: Legal Department

9. Miscellaneous

9.1. All Ocugen's Warranties under the Original Collaboration Agreement shall be applicable to OCU410 according this Amendment. Within [***] after the Effectiveness of this Amendment the Parties should conclude into a quality agreement on the Product of OCU410.

9.2. This Amendment shall take effectiveness upon the Effective Date.

9.3. In the event of any discrepancies between this **Amendment** and the **Original Collaboration Agreement**, the **Amendment** will prevail. Matters not expressly covered in this **Amendment** shall be referred to the **Original Collaboration Agreement**.

[*remainder of this page intentionally left blank*]

IN WITNESS WHEREOF, the Parties have caused their duly authorized representatives to execute this Amendment as of the Effective Date.

Ocugen, Inc.	**CanSino Biologics Inc.**
/s/ Shankar Musunuri	/s/ Tao Zhu
Signature	Signature
Dr. Shankar Musunuri	Tao Zhu
Print name	Print name
Chairman and CEO	Chief Scientific Officer
Title	Title
9/30/2021	9/30/2021
Date	Date

Appendix A

[***]

Appendix B

[***]

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: November 9, 2021 /s/ Shankar Musunuri, Ph.D., MBA

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

Exhibit 31.2

CERTIFICATION

I, Sanjay Subramanian, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2021 /s/ Sanjay Subramanian

Sanjay Subramanian
Chief Financial Officer
(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 September 30, 2021 (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: November 9, 2021 /s/ Shankar Musunuri, Ph.D., MBA

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

Date: November 9, 2021 /s/ Sanjay Subramanian

Sanjay Subramanian
Chief Financial Officer
(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.