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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, 2022

or

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

Commission File Number: 001-36751

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

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

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

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

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

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of November 1, 2022, there were 218,886,893 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, 2022

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

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

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

The forward-looking statements in this Quarterly Report on Form 10-Q and those contained in (i) our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission ("SEC") on February 28, 2022 (the "2021 Annual Report") and (ii) our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022 filed with the SEC on May 6, 2022 and August 5, 2022, respectively (together with this Quarterly Report on Form 10-Q, the "2022 Quarterly Reports"), include, among other things, statements about:

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

- our ability to comply with regulatory schemes and other regulatory developments applicable to our business in the United States and foreign countries; including the extent to which developments with respect to the COVID-19 pandemic will affect the regulatory pathway available for COVID-19 vaccines in such countries;
- the performance of third-parties upon which we depend, including contract development and manufacturing organizations, suppliers, manufacturers, group purchasing organizations, distributors, and logistics providers;
- the pricing and reimbursement of our product candidates, if commercialized;
- our ability to obtain and maintain patent protection, or obtain licenses to intellectual property and defend our intellectual property rights against third-parties;
- our ability to maintain our relationships, profitability, and contracts with our key collaborators and commercial partners and our ability to establish additional collaborations and partnerships;
- our ability to recruit or retain key scientific, technical, commercial, and management personnel and to retain our executive officers;
- our ability to comply with stringent United States and applicable foreign government regulations with respect to the manufacturing of pharmaceutical products, including current Good Manufacturing Practice compliance, and other relevant regulatory authorities;
- the extent to which health epidemics and other outbreaks of communicable diseases, including the COVID-19 pandemic, geopolitical turmoil, macroeconomic conditions, social unrest, political instability, terrorism, or other acts of war could disrupt our business and operations, including impacts on our development programs, global supply chain, and collaborators and manufacturers; and
- other matters discussed under the heading "Risk Factors" contained in the 2021 Annual Report, the 2022 Quarterly Reports, and in any other documents we file with the SEC.

We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in the 2021 Annual Report and in the 2022 Quarterly Reports, particularly under the sections titled "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations, or investments we may make.

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

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

Solely for convenience, tradenames and trademarks referred to in this Quarterly Report on Form 10-Q appear without the ® or ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert their rights, to these tradenames or trademarks, as applicable. All tradenames, trademarks, and service marks included or incorporated by reference in this Quarterly Report on Form 10-Q are the property of their respective owners. Further, for ease of reference, the name "COVAXIN" is used throughout this Quarterly Report on Form 10-Q to refer to the vaccine candidate, BBV152. The name COVAXIN has not been evaluated or cleared by the FDA or Health Canada.

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

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 101,602	$ 94,958
Prepaid expenses and other current assets	5,895	7,688
Total current assets	107,497	102,646
Property and equipment, net	4,517	1,164
Restricted cash	—	151
Other assets	4,225	1,800
Total assets	$ 116,239	$ 105,761
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 6,460	$ 2,312
Accrued expenses	8,004	4,325
Operating lease obligations	443	363
Total current liabilities	14,907	7,000
Non-current liabilities		
Operating lease obligations, less current portion	3,764	1,231
Long term debt, net	2,265	1,712
Total non-current liabilities	6,029	2,943
Total liabilities	20,936	9,943
Commitments and contingencies (Note 12)		
Stockholders' equity		
Convertible preferred stock; $0.01 par value; 10,000,000 shares authorized at September 30, 2022 and December 31, 2021		
Series A; zero and seven shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	—	—
Series B; 54,745 shares issued and outstanding at September 30, 2022 and December 31, 2021	1	1
Common stock; $0.01 par value; 295,000,000 shares authorized, 216,809,937 and 199,502,183 shares issued, and 216,688,437 and 199,380,683 shares outstanding at September 30, 2022 and December 31, 2021, respectively	2,168	1,995
Treasury stock, at cost, 121,500 shares at September 30, 2022 and December 31, 2021	(48)	(48)
Additional paid-in capital	284,231	225,537
Accumulated other comprehensive income	30	—
Accumulated deficit	(191,079)	(131,667)
Total stockholders' equity	95,303	95,818
Total liabilities and stockholders' equity	$ 116,239	$ 105,761

See accompanying notes to condensed consolidated financial statements.

OCUGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 15,622	$ 6,281	$ 32,544	$ 28,006
General and administrative	7,497	4,508	28,174	15,450
Total operating expenses	23,119	10,789	60,718	43,456
Loss from operations	(23,119)	(10,789)	(60,718)	(43,456)
Other income (expense), net	1,197	(18)	1,306	(380)
Loss before income taxes	(21,922)	(10,807)	(59,412)	(43,836)
Income tax benefit	—	(52)	—	(52)
Net loss	$ (21,922)	$ (10,755)	$ (59,412)	$ (43,784)
Other comprehensive income (loss)				
Foreign currency translation adjustment	20	—	30	—
Comprehensive loss	$ (21,902)	$ (10,755)	$ (59,382)	$ (43,784)
Shares used in calculating net loss per common share — basic and diluted	216,591,011	198,790,980	212,755,746	193,599,525
Net loss per share of common stock — basic and diluted	$ (0.10)	$ (0.05)	$ (0.28)	$ (0.23)

See accompanying notes to condensed consolidated financial statements.

OCUGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share amounts)

(Unaudited)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount					
Balance at December 31, 2021	7	$ —	54,745	$ 1	199,502,183	$ 1,995	$ (48)	$ 225,537	$ —	$ (131,667)	$ 95,818
Stock-based compensation expense	—	—	—	—	—	—	—	3,299	—	—	3,299
Issuance of common stock for stock option exercises	—	—	—	—	277,323	3	—	177	—	—	180
Issuance of common stock for underwritten offering, net	—	—	—	—	15,973,420	160	—	49,691	—	—	49,851
Net loss	—	—	—	—	—	—	—	—	—	(18,019)	(18,019)
Balance at March 31, 2022	7	$ —	54,745	$ 1	215,752,926	$ 2,158	$ (48)	$ 278,704	$ —	$ (149,686)	$ 131,129
Stock-based compensation expense	—	—	—	—	—	—	—	2,079	—	—	2,079
Issuance of common stock for stock option exercises	—	—	—	—	488,843	5	—	404	—	—	409
Issuance of common stock upon restricted stock unit vesting, net	—	—	—	—	26,378	—	—	(48)	—	—	(48)
Series A convertible preferred stock conversion	(7)	—	—	—	3,115	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	10	—	10
Net loss	—	—	—	—	—	—	—	—	—	(19,471)	(19,471)
Balance at June 30, 2022	—	$ —	54,745	$ 1	216,271,262	$ 2,163	$ (48)	$ 281,139	$ 10	$ (169,157)	$ 114,108
Stock-based compensation expense	—	—	—	—	—	—	—	2,495	—	—	2,495
Issuance of common stock for stock option exercises	—	—	—	—	529,833	5	—	607	—	—	612
Issuance of common stock upon restricted stock unit vesting, net	—	—	—	—	8,842	—	—	(10)	—	—	(10)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	20	—	20
Net loss	—	—	—	—	—	—	—	—	—	(21,922)	(21,922)
Balance at September 30, 2022	**—**	**$ —**	**54,745**	**$ 1**	**216,809,937**	**$ 2,168**	**$ (48)**	**$ 284,231**	**$ 30**	**$ (191,079)**	**$ 95,303**

OCUGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (CONTINUED)

(in thousands, except share amounts)

(Unaudited)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount					
Balance at December 31, 2020	7	$ —	—	$ —	184,133,384	$ 1,841	$ (48)	$ 93,059	$ —	$ (73,302)	$ 21,550
Stock-based compensation expense	—	—	—	—	—	—	—	833	—	—	833
Issuance of common stock for stock option exercises	—	—	—	—	157,468	2	—	174	—	—	176
At-the-market common stock issuance, net	—	—	—	—	987,000	10	—	4,839	—	—	4,849
Registered direct offering common stock issuance, net	—	—	—	—	3,000,000	30	—	21,174	—	—	21,204
Series B Convertible Preferred Stock issuance, net	—	—	54,745	1	—	—	—	4,953	—	—	4,954
Net loss	—	—	—	—	—	—	—	—	—	(7,077)	(7,077)
Balance at March 31, 2021	7	$ —	54,745	$ 1	188,277,852	$ 1,883	$ (48)	$ 125,032	$ —	$ (80,379)	$ 46,489
Stock-based compensation expense	—	—	—	—	—	—	—	2,095	—	—	2,095
Issuance of common stock for stock option and warrant exercises	—	—	—	—	538,893	5	—	366	—	—	371
Registered direct offering common stock issuance, net	—	—	—	—	10,000,000	100	—	93,306	—	—	93,406
Net loss	—	—	—	—	—	—	—	—	—	(25,952)	(25,952)
Balance at June 30, 2021	7	$ —	54,745	$ 1	198,816,745	$ 1,988	$ (48)	$ 220,799	$ —	$ (106,331)	$ 116,409
Stock-based compensation expense	—	—	—	—	—	—	—	1,347	—	—	1,347
Issuance of common stock for stock 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**

See accompanying notes to condensed consolidated financial statements.

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

	Nine months ended September 30,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (59,412)	$ (43,784)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	307	151
Non-cash interest expense	58	59
Non-cash lease expense	463	200
Stock-based compensation expense	7,873	4,275
Income tax benefit	—	(52)
Gain on forgiveness of Paycheck Protection Program note	—	(426)
Impairment on note receivable	—	761
Other	(673)	—
Changes in assets and liabilities:		
Prepaid expenses and other assets	1,888	845
Accounts payable and accrued expenses	6,592	2,925
Lease obligations	(261)	(191)
Other assets	—	100
Net cash used in operating activities	(43,165)	(35,137)
Cash flows from investing activities		
Purchases of property and equipment	(2,433)	(747)
Asset acquisition	—	(127)
Issuance of note receivable	—	(750)
Repayment of note receivable	761	—
Net cash used in investing activities	(1,672)	(1,624)
Cash flows from financing activities		
Proceeds from issuance of common stock	51,198	128,606
Tax payments for net share settlement of restricted stock units	(57)	—
Payment of equity issuance costs	(298)	(8,525)
Proceeds from issuance of debt	500	—
Payment of debt issuance costs	(43)	—
Financing lease principal payments	—	(10)
Net cash provided by financing activities	51,300	120,071
Effect of changes in exchange rate on cash, cash equivalents, and restricted cash	30	—
Net increase in cash, cash equivalents, and restricted cash	6,493	83,310
Cash, cash equivalents, and restricted cash at beginning of period	95,109	24,190
Cash, cash equivalents, and restricted cash at end of period	$ 101,602	$ 107,500

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

	Nine months ended September 30,	
	2022	**2021**
Supplemental disclosure of non-cash investing and financing transactions:		
Series B Convertible Preferred Stock issuance	$ —	$ 4,988
Exercise of warrants	$ —	$ 603
Forgiveness of Paycheck Protection Program note	$ —	$ 426
Equity issuance costs	$ 2	$ —
Purchases of property and equipment	$ 1,231	$ 9
Right-of-use asset related to operating leases	$ 2,916	$ 926
Debt issuance costs	$ 19	$ —

See accompanying notes to condensed consolidated financial statements.

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

1. Nature of Business

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

Vaccines

Intramuscular COVID-19 Vaccine Candidate

In February 2021, the Company entered into a Co-Development, Supply and Commercialization Agreement with Bharat Biotech International Limited ("Bharat Biotech"), pursuant to which the Company obtained an exclusive right and license under certain of Bharat Biotech's intellectual property rights, with the right to grant sublicenses to develop, manufacture, and commercialize BBV152, known as COVAXIN, for the prevention of COVID-19 caused by SARS-CoV-2 in the United States, its territories, and possessions. In June 2021 and April 2022, the Company entered into amendments to the Co-Development, Supply and Commercialization Agreement (as so amended, the "Covaxin Agreement"), pursuant to which the parties agreed to expand the Company's rights to develop, manufacture, and commercialize COVAXIN to include Canada and Mexico, respectively, in addition to the United States, its territories, and possessions (the "Ocugen Covaxin Territory"). COVAXIN is a whole-virion inactivated COVID-19 vaccine candidate and is formulated with the inactivated SARS-CoV-2 virus, an antigen, and an adjuvant.

The Company has completed enrollment in a Phase 2/3 immuno-bridging and broadening clinical trial evaluating COVAXIN for adults ages 18 years and older, pursuant to an Investigational New Drug ("IND") application cleared by the U.S. Food and Drug Administration ("FDA"). The clinical trial was designed to evaluate whether the immune response observed in participants in a completed Phase 3 clinical trial in India is similar to a demographically representative, adult population in the United States. The Company intends to work with government agencies in the United States to obtain funding in order to comply with the requirements of a Biologics License Application ("BLA") submission.

Mucosal COVID-19 Vaccine Candidate

In September 2022, the Company entered into an exclusive license agreement ("WU License Agreement") with The Washington University ("Washington University"), pursuant to which the Company obtained the rights to develop, manufacture, and commercialize a mucosal COVID-19 vaccine, OCU500, in the United States, Europe, and Japan (collectively, the "Mucosal COVID-19 Vaccine Territory"). OCU500 is a recombinant, replication-deficient, adenovirus-vectored vaccine with a prefusion stabilized spike protein. As this vaccine can potentially be delivered through the mucosal route (intranasal or inhalation), the Company believes that OCU500 has the potential to generate rapid local immunity in the nose, mouth, upper airways, and lungs where SARS-CoV-2 enters and infects the body, which the Company believes may help reduce or prevent infection and transmission as well as provide protection against new COVID-19 variants. The Company intends to work closely with government agencies in the Mucosal COVID-19 Vaccine Territory to obtain funding to initiate clinical trials and manufacture OCU500.

Modifier Gene Therapy Platform

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

The Company believes that OCU400, its first product candidate being developed with its modifier gene therapy platform, has the potential to be broadly effective in restoring retinal integrity and function across a range of genetically diverse IRDs,

including RP and LCA. OCU400 has received Orphan Drug Designations ("ODDs") from the FDA for the treatment of certain disease genotypes: nuclear receptor subfamily 2 group E member 3 ("*NR2E3*"), centrosomal protein 290 ("*CEP290*"), rhodopsin ("*RHO*"), and phosphodiesterase 6B ("*PDE6ß*") mutation-associated inherited retinal degenerations. Additionally, OCU400 has received Orphan Medicinal Product Designation ("OMPD") from the European Commission ("EC") based on the recommendation of the European Medicines Agency ("EMA") for RP and LCA.

The Company has initiated a Phase 1/2 clinical trial, a multicenter, open-label, dose ranging study to assess the safety of unilateral subretinal administration of OCU400 in subjects with *NR2E3* and *RHO*-related RP in the United States, pursuant to an IND application cleared by the FDA. The first patient was dosed in March 2022 and the Company has completed dosing patients in two out of three cohorts. The Company initiated dosing in the third cohort in October 2022. The Company expects to complete enrollment in the third cohort by the end of 2022. Patients with LCA associated with *CEP290* mutations will be included in the current Phase 1/2 clinical trial.

The Company is also developing OCU410 and OCU410ST to utilize the nuclear receptor genes RAR-related orphan receptor A ("*RORA*") for the treatment of dry AMD and Stargardt disease, respectively. The Company is currently executing IND-enabling studies for OCU410 consistent with FDA discussions. The Company intends to submit IND applications in the second quarter of 2023 to initiate Phase 1/2 clinical trials. The Company has engaged CanSino Biologics, Inc. ("CanSinoBIO") as its manufacturing partner for its modifier gene therapy platform. CanSinoBIO has produced the clinical trial supplies for use in the Phase 1/2 clinical trials.

Novel Biologic Therapy for Retinal Diseases

The Company's biologic product candidate, OCU200, is a novel fusion protein designed to treat severely sight-threatening diseases, such as diabetic macular edema ("DME"), diabetic retinopathy ("DR"), and wet AMD. The Company has completed the technology transfer of manufacturing processes to its contract development and manufacturing organization ("CDMO") and has produced clinical trial supplies to initiate a Phase 1 clinical trial. The Company is currently executing IND-enabling studies consistent with FDA discussions. The Company intends to submit an IND application in the first quarter of 2023 to initiate a Phase 1 clinical trial targeting DME.

Regenerative Medicine – Cell Therapy Platform

NeoCart is a three-dimensional tissue-engineered disc of new cartilage that is manufactured by growing chondrocytes, the cells responsible for maintaining cartilage health. The chondrocytes are derived from the patient on a unique scaffold. The Company believes NeoCart has the potential to accelerate healing and reduce pain by reconstructing a patient's previously damaged knee cartilage. It treats pain at the source, creating a similar, functional joint surface as it was before the injury. Ultimately, the therapy's goal is to prevent a patient's progression toward osteoarthritis, reduce pain, and improve function of the joint. In May 2022, the FDA granted a Regenerative Medicine Advanced Therapy ("RMAT") designation to NeoCart for the repair of knee cartilage injuries in adults. The Company is currently working with the FDA to finalize the Phase 3 clinical trial protocol necessary to advance the clinical development of NeoCart for eventual market authorization.

Going Concern Consideration

The condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") assuming the Company will continue as a going concern. As of September 30, 2022, the Company had cash and cash equivalents of approximately $101.6 million, which the Company believes will enable it to fund its operations into the fourth quarter of 2023. The cash runway is based on management's updated projections, including the removal of external expenditures for COVAXIN beyond the ongoing Phase 2/3 immuno-bridging and broadening clinical trial. The Company anticipates that the continued development of its COVID-19 vaccine candidates will require government funding to support the regulatory pathway of such candidates. There can be no assurance, however, that the Company will be successful in obtaining such funding in sufficient amounts, on terms acceptable to the Company, or at all. As the result of the updated projections, the Company believes that its cash and cash equivalents will enable the funding of its operating expenses and capital expenditure requirements through at least one year from the date the condensed consolidated financial statements are issued.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying unaudited condensed consolidated financial statements included herein have been prepared in conformity with GAAP and under the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim reporting. The accompanying condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, that are necessary to present fairly the Company's financial position, results of operations, and cash flows. The condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosures of the Company normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted under the SEC's rules and regulations. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto for the year ended December 31, 2021, included in the Company's Annual Report on Form 10-K filed with the SEC on February 28, 2022 (the "2021 Annual Report"). The condensed consolidated financial statements include the accounts of Ocugen and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

In preparing the condensed consolidated financial statements in conformity with GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting period. Due to the inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions. These estimates and assumptions include those used in the accounting for research and development contracts, including clinical trial accruals, and the accounting and fair value measurement of equity instruments.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash equivalents may include bank demand deposits, marketable securities with maturities of three months or less at purchase, and money market funds that invest primarily in certificates of deposit, commercial paper, and U.S. government and U.S. government agency obligations. The Company earns interest on its cash equivalents balance which is recorded as interest income in other income (expense), net within the condensed consolidated statements of operations and comprehensive loss. The Company recorded $0.5 million and $0.6 million as interest income for the three and nine months ended September 30, 2022, respectively. The Company's restricted cash balance consisted of cash held to collateralize a corporate credit card account.

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

	As of September 30,	
	2022	2021
Cash and cash equivalents	$ 101,602	$ 107,349
Restricted cash	—	151
Total cash, cash equivalents, and restricted cash	$ 101,602	$ 107,500

Leases

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

Operating leases are included in other assets and operating lease obligations in the Company's condensed consolidated balance sheets. Operating lease right-of-use assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. Operating lease payments are recognized as lease expense on a straight-line basis over the lease term and recognized as research and development expense or general and administrative expense based on the underlying nature of the expense. The Company currently leases real estate classified as operating leases. Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 842, *Leases*, requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. The implicit interest rates were not readily determinable in the Company's current operating leases. As such, the incremental borrowing rates were used based on the information available at the commencement dates in determining the present value of the lease payments.

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

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

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

Fair Value Measurements

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

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

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

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

The carrying value of certain financial instruments, including cash and cash equivalents, accounts payable, and accrued expenses, approximates their fair value due to the short-term nature of these instruments. As of September 30, 2022, the Company believes the fair value using Level 2 inputs of the borrowings under the EB-5 Loan Agreement (as defined in Note 7) approximate their carrying value. See Note 7 for additional information.

Stock-Based Compensation

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

Expense related to stock-based compensation awards granted with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Stock-based compensation awards generally vest over a one to three year requisite service period. Stock options have a contractual term of 10 years. Expense for stock-based compensation awards with performance-based vesting conditions is only

recognized when the performance-based vesting condition is deemed probable to occur. Shares issued upon stock option exercise and RSU vesting are newly-issued common shares.

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

Recently Adopted Accounting Standards

In November 2021, the FASB issued Accounting Standards Update ("ASU") No. 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*. This standard increases the transparency of transactions with the government that are accounted for by applying a grant or contribution accounting model, and aims to reduce diversity that currently exists in the recognition, measurement, presentation, and disclosure of government assistance received by business entities due to the lack of specific authoritative guidance in GAAP. This standard requires an entity to provide information regarding the nature of the transaction with a government and the related accounting policy used to account for this transaction, the line items on the consolidated balance sheet and consolidated statement of operations and comprehensive loss that are affected by the transaction and the amounts applicable to each financial statement line item, and the significant terms and conditions of the transaction, including commitments and contingencies. The standard was effective for the Company on January 1, 2022. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40)*. This standard clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options, including warrants, that remain equity-classified after the modification or exchange. The standard requires an entity to treat a modification or an exchange of a freestanding equity-classified written call option that remains equity-classified after the modification or exchange as an exchange of the original instrument for a new instrument. The standard additionally provides guidance on measuring and recognizing the effect of a modification or an exchange. The standard was effective for the Company on January 1, 2022. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

Recent Accounting Pronouncements

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

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

Exclusive License Agreement with Washington University

In September 2022, the Company entered into the WU License Agreement with Washington University, pursuant to which the Company was granted an exclusive, sublicensable, royalty-bearing license to patent rights for a mucosal COVID-19 vaccine, OCU500, as well as a license to certain tangible research property and technical information necessary to exploit the patent rights within the Mucosal COVID-19 Vaccine Territory. The Company paid Washington University an initial license issuance fee of $1.0 million, which was recognized as research and development expense in the condensed consolidated statement of operations and comprehensive loss during the three and nine months ended September 30, 2022. In addition, the Company is required to pay Washington University an annual license maintenance fee, payments upon the achievement of regulatory and commercial milestones in the aggregate amount of up to $37.0 million, and low single-digit percentage royalties on net sales of licensed products (as defined in the WU License Agreement).

Pursuant to the WU License Agreement, the Company may make, have made, sell, offer for sale, use, market, promote, distribute, export, and import licensed products in the Mucosal COVID-19 Vaccine Territory. The Company will use commercially reasonable efforts to develop, manufacture, promote, and sell the licensed products in the Mucosal COVID-19 Vaccine Territory.

Washington University maintains control of patent preparation, filing, prosecution, and maintenance. The Company is responsible for Washington University's out-of-pocket expenses related to the preparation, filing, prosecution, issuance, and maintenance of the licensed patent rights incurred pursuant to the WU License Agreement.

The WU License Agreement will expire on a country-by-country basis and a licensed product-by-licensed product basis and end, separately in each such country and for each such licensed product, upon the latter of (a) the expiration date of the last valid claim, (b) the fifteenth (15^{th}) anniversary of the date of the first commercial sale of a licensed product, or (c) the expiration of the last form of Market Exclusivity (as defined in the WU License Agreement), subject to the earlier termination of the WU License Agreement in accordance with its terms. In addition, the Company may terminate the WU License Agreement without cause by giving at least ninety days' written notice. The WU License Agreement contains customary termination provisions in the event of an uncured material breach or upon certain corporate actions, including bankruptcy, receivership, or liquidation.

Co-Development, Supply and Commercialization Agreement with Bharat Biotech

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

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

Under the Covaxin Agreement, the Company is collaborating with Bharat Biotech to develop COVAXIN for 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 preclinical and clinical data, and to transfer to the Company certain proprietary technology owned or controlled by Bharat Biotech, that is necessary for the successful commercial manufacture and supply of COVAXIN to support potential commercial sale in the Ocugen Covaxin Territory.

The Company has selected Jubilant HollisterStier as a manufacturing partner to prepare for the commercial manufacturing of COVAXIN. In September 2021, the Company entered into a Development and Commercial Supply Agreement (the "Supply Agreement") with Bharat Biotech, pursuant to which Bharat Biotech will supply the Company with clinical trial materials and commercial supplies of COVAXIN finished drug product prior to the completion of a technology transfer. Following the completion of the technology transfer to Jubilant HollisterStier, Bharat Biotech will supply COVAXIN drug product components and continue to supply finished drug product as necessary for the commercial manufacture and supply of COVAXIN. In March 2021, the Company issued shares of Series B Convertible Preferred Stock (as defined in Note 8) as an advance payment for the supply of COVAXIN to be provided by Bharat Biotech under the Supply Agreement. See Note 8 for additional information about the Series B Convertible Preferred Stock issuance to Bharat Biotech.

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

4. Property and Equipment

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

	September 30, 2022	December 31, 2021
Furniture and fixtures	$ 333	$ 284
Machinery and equipment	1,505	855
Leasehold improvements	1,597	167
Construction in progress	1,660	232
Total property and equipment	5,095	1,538
Less: accumulated depreciation	(578)	(374)
Total property and equipment, net	$ 4,517	$ 1,164

5. Operating Leases

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Operating lease cost	$ 196	$ 66	$ 578	$ 200
Variable lease cost	36	26	89	79
Total lease cost	$ 232	$ 92	$ 667	$ 279

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

	September 30, 2022	December 31, 2021
Right-of-use assets, net	$ 4,040	$ 1,587
Current lease obligations	$ 443	$ 363
Non-current lease obligations	3,764	1,231
Total lease liabilities	$ 4,207	$ 1,594

Supplemental information related to leases was as follows:

	Nine months ended September 30,	
	2022	2021
Weighted-average remaining lease term (years)	6.5	6.2
Weighted-average discount rate	6.4 %	4.6 %

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

For the Years Ending December 31,	Amount
Remainder of 2022	$ 147
2023	762
2024	785
2025	809
2026	833
Thereafter	1,859
Total	$ 5,195
Less: present value adjustment	(988)
Present value of minimum lease payments	$ 4,207

6. Accrued Expenses

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

	September 30, 2022	December 31, 2021
Research and development	$ 1,379	$ 866
Clinical	2,199	703
Professional fees	494	747
Employee-related	2,363	1,716
Other	1,569	293
Total accrued expenses	$ 8,004	$ 4,325

7. Debt

In September 2016, pursuant to the U.S. government's Immigrant Investor Program, commonly known as the EB-5 program, the Company entered into an arrangement (the "EB-5 Loan Agreement") to borrow up to $10.0 million from EB5 Life Sciences, L.P. ("EB-5 Life Sciences") in $0.5 million increments. Borrowings may be limited by the amount of funds raised by EB-5 Life Sciences and are subject to certain job creation requirements by the Company. Borrowings are at a fixed interest rate of 4.0% per annum and are to be utilized in the clinical development, manufacturing, and commercialization of the Company's product candidates and for the general working capital needs of the Company. Outstanding borrowings pursuant to the EB-5 Loan Agreement, including accrued interest, become due upon the seventh anniversary of the final disbursement. Amounts repaid cannot be re-borrowed. The EB-5 Loan Agreement borrowings are secured by substantially all assets of the Company, except for any patents, patent applications, pending patents, patent licenses, patent sublicenses, trademarks, and other intellectual property rights. Under the terms and conditions of the EB-5 Loan Agreement, the Company borrowed $1.5 million prior to 2022 and an additional $0.5 million in September 2022. 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, 2022 and December 31, 2021 are summarized below (in thousands):

	September 30, 2022	December 31, 2021
Principal outstanding	$ 2,000	$ 1,500
Plus: accrued interest	287	241
Less: unamortized debt issuance costs	(22)	(29)
Carrying value, net	$ 2,265	$ 1,712

8. Equity

COVAXIN Preferred Stock Purchase Agreement

On March 1, 2021, the Company entered into a preferred stock purchase agreement with Bharat Biotech, pursuant to which the Company agreed to issue and sell 0.1 million shares of the Company's Series B Convertible Preferred Stock, par value $0.01 per share (the "Series B Convertible Preferred Stock"), at a price per share equal to $109.60, to Bharat Biotech. On March 18, 2021, the Company issued the Series B Convertible Preferred Stock as an advance payment of $6.0 million for the supply of COVAXIN 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, which the Company received in April 2021, and (ii) the Company's receipt of shipments by Bharat Biotech of the first 10.0 million doses of COVAXIN manufactured by Bharat Biotech pursuant to the Supply Agreement, and further on the terms and subject to the conditions set forth in the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock. As of September 30, 2022, the conversion condition relating to the delivery of the first 10.0 million doses of COVAXIN had not been met. The conversion rate of the Series B Convertible Preferred Stock is subject to adjustment in the event of a stock dividend, stock split, reclassification, or similar event with respect to the Company's common stock.

The Company accounted for the issuance of the Series B Convertible Preferred Stock in accordance with ASC 718 and recorded its grant date fair value of $5.0 million within equity during the nine months ended September 30, 2021, with a corresponding short-term asset for the advanced payment for the supply of COVAXIN included in prepaid expenses and other current assets in the condensed consolidated balance sheet as of December 31, 2021. The Company utilized the traded common stock price, adjusted by the Conversion Ratio, to value the Series B Convertible Preferred Stock and the Finnerty model to estimate a 15% discount rate for the lack of marketability of the instrument. The valuation incorporated Level 3 inputs in the fair value hierarchy, including the estimated time until the instrument's liquidity and the estimated volatility of the Company's common stock as of the grant date.

As of September 30, 2022 and December 31, 2021, the remaining balance of the short-term asset for the advanced payment for the supply of COVAXIN was $4.1 million and $5.0 million, respectively. The reduction in the advanced payment resulted from the Company's receipt of COVAXIN drug product components from Bharat Biotech, which the Company utilized to produce the demonstration batch at Jubilant HollisterStier during the three months ended September 30, 2022. In February 2022, the Company entered into a supply commitment to purchase $14.3 million of COVAXIN drug product components from Bharat Biotech to utilize in the Process Performance Qualification ("PPQ") runs. The doses produced in the PPQ runs, if successfully completed, are expected to be commercially salable following regulatory approval. Subsequent to September 30, 2022, the Company withdrew this supply commitment as a result of the deficiencies identified in an inspection conducted by the World Health Organization ("WHO").

Offerings of Common Stock

Public Offering

In February 2022, the Company entered into an underwriting agreement with Cantor Fitzgerald & Co., pursuant to which the Company sold 16.0 million shares of its common stock at a public offering price of $3.13 per share (the "Public Offering"). Upon the closing of the Public Offering, the Company received net proceeds of $49.8 million, after deducting equity issuance costs payable by the Company.

Registered Direct Offerings

In April 2021, the Company entered into a securities purchase agreement with certain institutional investors pursuant to which the Company sold 10.0 million shares of its common stock at an offering price of $10.00 per share in a registered direct offering (the "April 2021 Registered Direct Offering"). Upon the closing of the April 2021 Registered Direct Offering, the Company received net proceeds of $93.4 million after deducting equity issuance costs of $6.6 million.

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

At-the-Market Offering

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

9. Warrants

Liminal Warrants

On January 24, 2022, the Company entered into a non-binding letter of intent ("LOI") with Liminal Biosciences Inc. ("Liminal") for the acquisition of Liminal's manufacturing site in Belleville, Ontario, Canada for a combination of cash and warrants to purchase the Company's common stock. Pursuant to the LOI, the Company issued warrants to purchase 2.3 million shares of the Company's common stock at an exercise price of $3.76 per share, subject to certain adjustments (the "Liminal Warrants"). As of September 30, 2022, the Liminal Warrants were cancelled as a result of the termination of the LOI.

Canada Warrants

In July 2021, the Company entered into a consulting agreement with an individual to provide services to the Company with regard to the Company's Canadian operations (the "Canada Consulting Agreement"). Compensation under the Canada Consulting Agreement includes, among other forms of compensation, the issuance of warrants to purchase up to 0.2 million shares of the Company's common stock (the "Canada Warrants") and cash payments of up to $3.0 million upon the achievement of certain milestones related to COVAXIN. The Canada Consulting Agreement terminates in July 2023, unless earlier terminated in accordance with its terms.

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

OpCo Warrants

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

10. Stock-Based Compensation

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
General and administrative	$ 2,057	$ 840	$ 5,769	$ 2,957
Research and development	438	507	2,104	1,318
Total	$ 2,495	$ 1,347	$ 7,873	$ 4,275

As of September 30, 2022, the Company had $18.0 million of unrecognized stock-based compensation expense related to stock options and RSUs outstanding, which is expected to be recognized over a weighted-average period of 2.0 years.

Equity Plans

The Company maintains two equity compensation plans, the 2014 Ocugen OpCo, Inc. Stock Option Plan (the "2014 Plan") and the Ocugen, Inc. 2019 Equity Incentive Plan (the "2019 Plan", collectively with the 2014 Plan, the "Plans"). As of September 30, 2022, the 2014 Plan and the 2019 Plan authorize for the granting of up to 0.8 million and 19.5 million equity awards with respect to the Company's common stock, respectively. In addition to stock options and RSUs granted under the Plans, the Company has granted certain stock options and RSUs as material inducements to employment in accordance with Nasdaq Listing Rule 5635(c)(4), which were granted outside of the Plans.

Stock 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)
Stock options outstanding at December 31, 2021	10,086,167	$ 2.59	8.8	$ 24,664
Granted	5,809,257	$ 3.90		
Exercised	(1,295,999)	$ 0.93		
Forfeited	(2,872,488)	$ 4.10		
Stock options outstanding at September 30, 2022	11,726,937	$ 3.06	8.5	$ 2,448
Stock options exercisable at September 30, 2022	2,982,799	$ 2.56	7.5	$ 1,089

As of September 30, 2022 and December 31, 2021, there were 0.9 million and 1.2 million of stock options with performance-based vesting conditions outstanding, of which 0.7 million and 0.9 million were not yet vested and exercisable, respectively. The weighted-average grant date fair values of stock options granted during the three and nine months ended September 30, 2022 were $2.01 and $3.19, respectively. 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 total fair values of stock options vested during the three and nine months ended September 30, 2022 were $0.6 million and $4.6 million, respectively. 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.

RSUs

The following table summarizes the RSU activity:

	Number of Shares	Weighted-Average Grant-Date Fair Value
RSUs outstanding at December 31, 2021	191,811	$ 6.79
Granted	1,304,902	$ 4.16
Vested	(56,807)	$ 6.42
Forfeited	(507,027)	$ 4.75
RSUs outstanding at September 30, 2022	932,879	$ 4.24

11. Net Loss Per Share of Common Stock

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Net loss — basic and diluted	$ (21,922)	$ (10,755)	$ (59,412)	$ (43,784)
Shares used in calculating net loss per common share — basic and diluted	216,591,011	198,790,980	212,755,746	193,599,525
Net loss per common share — basic and diluted	$ (0.10)	$ (0.05)	$ (0.28)	$ (0.23)

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,	
	2022	2021	2022	2021
Options to purchase common stock	11,726,937	10,518,263	11,726,937	10,518,263
RSUs	932,879	179,051	932,879	179,051
Warrants	798,352	946,179	798,352	946,179
Series A Convertible Preferred Stock (as converted to common stock)	—	3,115	—	3,115
Series B Convertible Preferred Stock (as converted to common stock)	547,450	547,450	547,450	547,450
Total	14,005,618	12,194,058	14,005,618	12,194,058

12. Commitments and Contingencies

Commitments

The Company has commitments under certain license and development agreements, lease agreements, debt agreements, and consulting agreements. Commitments under certain license and development agreements include annual payments, payments upon the achievement of certain milestones, and royalty payments based on net sales of licensed products (commitments under the Company's licensing agreements are more fully described within Note 3 and within the Company's 2021 Annual Report). Commitments under lease agreements are future minimum lease payments (see Note 5). Commitments under debt agreements are the future payment of principal and accrued interest under the EB-5 Loan Agreement (see Note 7). Commitments under consulting agreements include payments upon the achievement of certain milestones related to COVAXIN (see Note 9). The Company previously entered into a supply commitment in February 2022 for the purchase of COVAXIN drug product components from Bharat Biotech which was withdrawn by the Company subsequent to September 30, 2022 (see Note 8).

Contingencies

In June 2021, a securities class action lawsuit was filed against the Company and certain of its agents in the U.S. District Court for the Eastern District of Pennsylvania ("Court") (Case No. 2:21-cv-02725) that purported to state a claim for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, based on statements made by the Company concerning the announcement of the Company's decision to pursue the submission of a BLA in the United States for COVAXIN for adults ages 18 years and older rather than pursuing emergency use authorization ("EUA") for the vaccine candidate. In July 2021, a second securities class action was filed against the Company and certain of its agents in the Court (Case No. 2:21-cv-03182) that also purported to state a claim for alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, based on the same statements as the first complaint. The complaints seek unspecified damages, interest, attorneys' fees, and other costs. In March 2022, the Court consolidated these two related securities class action lawsuits and appointed Andre Galan Bernd Benayon to serve as lead plaintiff. The lead plaintiff's amended complaint was filed in June 2022. The Company filed a motion to dismiss the amended complaint in August 2022. The lead plaintiff's opposition to the motion to dismiss was filed in October 2022. The Company will file its reply in support of its motion to dismiss by November 10, 2022.

In August 2021, a stockholder derivative lawsuit was filed derivatively on behalf of the Company against certain of its agents and the nominal defendant Ocugen in the Court (Case No. 2:21-cv-03876) that purported to state a claim for breach of fiduciary duty and contribution for violations of Sections 10(b) and 21(d) of the Exchange Act, based on facts and circumstances relating to the securities class action lawsuits and seeking contribution and indemnification in connection with claims asserted in the securities class action lawsuits. In September 2021, a second stockholder derivative lawsuit was filed derivatively on behalf of the Company against certain of its agents and the nominal defendant Ocugen in the Court (Case No. 2:21-cv-04169) that purported to state a claim for breach of fiduciary duties, unjust enrichment, abuse of control, waste of corporate assets, and contribution for violations of Sections 10(b) and 21(d) of the Exchange Act, based on the same allegations as the first complaint. The parties to both stockholder derivative lawsuits have stipulated to the consolidation of the two stockholder derivative lawsuits and also have submitted to the Court in each action a proposed order requesting a stay of the litigation pending a decision on any motion to dismiss filed in the securities class action lawsuits, which the Court entered in April 2022.

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

13. Subsequent Events

Subsequent to September 30, 2022, the Company sold 2.1 million shares of its common stock under an At Market Issuance Sales Agreement ("Sales Agreement"), which the Company entered into in June 2022 with certain agents, pursuant to which the Company may, from time to time, offer and sell shares of its common stock having an aggregate gross sales price of up to $160.0 million. The offer and sale of the shares of common stock made pursuant to the Sales Agreement were made under the Company's Registration Statement on Form S-3ASR, which was previously filed with the SEC and became automatically effective on March 22, 2021, as supplemented by a prospectus supplement, dated June 10, 2022. The Company received net proceeds of $3.6 million after deducting equity issuance costs of $0.3 million.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements for the year ended December 31, 2021, included in our 2021 Annual Report. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and related financing, include forward-looking statements that involve risks, uncertainties, and assumptions. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. Except as required by law, we undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events, or otherwise. You should read the "Risk Factors" section included in our 2021 Annual Report and the "Risk Factors" and "Disclosure Regarding Forward-Looking Statements" sections of this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

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

Our cutting-edge technology pipeline includes:

- **COVID-19 Vaccine Candidates** — COVAXIN is a whole-virion inactivated intramuscular COVID-19 vaccine candidate being developed to prevent COVID-19, caused by SARS-CoV-2, in humans. We are co-developing COVAXIN with Bharat Biotech for the North American market. In addition, the Company recently obtained rights from Washington University to develop, manufacture, and commercialize a mucosal COVID-19 vaccine candidate, OCU500, in the United States, Europe, and Japan.
- **Modifier Gene Therapy Platform** — Based on NHRs, we believe our modifier gene therapy platform has the potential to address many retinal diseases, including RP, LCA, dry AMD, and Stargardt disease.
- **Novel Biologic Therapy for Retinal Diseases** — OCU200 is a novel biologic product candidate designed to treat DME, DR, and wet AMD.
- **Regenerative Medicine – Cell Therapy Platform** — Our Phase 3 cell therapy platform technology, NeoCart (autologous chondrocyte-derived neocartilage), is being developed for the repair of knee cartilage injuries in adults.

Vaccines

Intramuscular COVID-19 Vaccine Candidate

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

The Phase 3 clinical trial conducted by Bharat Biotech in India in 25,798 adults ages 18 years and older, who were healthy or had stable chronic medical conditions, reported an overall estimated vaccine efficacy of COVAXIN against COVID-19 of 77.8%, with efficacy against severe COVID-19 of 93.4%, and efficacy against asymptomatic COVID-19 of 63.6%. Cross variant protection was also demonstrated with a vaccine efficacy of 65.2% against the Delta variant (B.1.617.2). Individuals with asymptomatic infection have a detectable viral load in nasal and saliva swabs and therefore are considered carriers of

COVID-19. COVAXIN was generally well tolerated, with no clinically or statistically significant differences in reported adverse events in the vaccine and placebo groups. Additionally, a Phase 2/3 immuno-bridging clinical trial was conducted by Bharat Biotech in India to assess the protective immunity of COVAXIN in children ages two to 18 years. COVAXIN is formulated such that the same dosage can be administered to adults and children alike. The results demonstrated a robust neutralizing antibody response comparable to that of the adults studied in a Phase 2 clinical trial conducted by Bharat Biotech in India, and that COVAXIN was generally well tolerated. Among the 526 study subjects in the Phase 2/3 pediatric clinical trial, no serious adverse events, such as deaths, hospitalizations, myocarditis, pericarditis, Guillain-Barre syndrome, vaccine-induced thrombotic thrombocytopenia, or anaphylactic reactions were reported. COVAXIN has received EUA approval in India for children ages six to 18 years. Further, data from clinical trials conducted by Bharat Biotech has shown that COVAXIN has neutralizing potential against multiple variants including both the Omicron (B.1.1.529) and Delta (B.1.617.2) variants.

We are currently dosing patients in a Phase 2/3 immuno-bridging and broadening clinical trial evaluating COVAXIN for adults ages 18 years and older, pursuant to an IND application cleared by the FDA. The clinical trial, which completed enrollment with over 400 patients, was designed to evaluate whether the immune response observed in participants in the aforementioned completed Phase 3 clinical trial in India is similar to a demographically representative, adult population in the United States. No safety concerns have been identified in the Phase 2/3 immuno-bridging and broadening clinical trial to date. We expect to release top line data in early 2023. We additionally plan to initiate an adult safety clinical trial, subject to discussions with the FDA, and intend to work with government agencies in the United States to obtain funding. Data from the Phase 2/3 immuno-bridging and broadening clinical trial and a safety clinical trial will be utilized to support a BLA submission.

We also have rights to commercialize COVAXIN in Canada and Mexico. In July 2021, we completed our rolling submission to Health Canada for COVAXIN. The rolling submission process, which was conducted through our Canadian subsidiary, Vaccigen Ltd., 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 and transitioned to a New Drug Submission ("NDS") for COVID-19. In August 2022, we withdrew our NDS based on discussions with Health Canada and are evaluating the requirements for resubmitting an updated NDS. The Comisión Federal para la Protección contra Riesgos Sanitarios authorized emergency use for COVAXIN in Mexico for adults ages 18 years and older, which remains active. We are in discussions with Consejo Nacional de Ciencia y Tecnología in Mexico regarding our submission for emergency use authorization for COVAXIN for pediatric use in ages five to 18 years.

We are evaluating our commercialization strategy for COVAXIN in the Ocugen Covaxin Territory. We have selected Jubilant HollisterStier as a manufacturing partner to prepare for the commercial manufacturing of COVAXIN. In September 2021, we entered into the Supply Agreement with Bharat Biotech, pursuant to which Bharat Biotech will supply us with clinical trial materials and commercial supplies of COVAXIN finished drug product prior to the completion of a technology transfer. Following the completion of the technology transfer to Jubilant HollisterStier, Bharat Biotech will supply COVAXIN drug product components and continue to supply finished drug product as necessary for the commercial manufacture and supply of COVAXIN.

Mucosal COVID-19 Vaccine Candidate

In September 2022, we entered into the WU License Agreement with Washington University, pursuant to which we obtained the rights to develop, manufacture, and commercialize a mucosal COVID-19 vaccine, OCU500, in the Mucosal COVID-19 Vaccine Territory. OCU500 is a recombinant, replication-deficient, adenovirus-vectored vaccine with a prefusion stabilized spike protein. As this vaccine can potentially be delivered through the mucosal route (intranasal or inhalation), we believe that OCU500 has the potential to generate rapid local immunity in the nose, mouth, upper airways, and lungs where SARS-CoV-2 enters and infects the body, which we believe may help reduce or prevent infection and transmission as well as provide protection against new COVID-19 variants. We intend to work closely with government agencies in the Mucosal COVID-19 Vaccine Territory to obtain funding to initiate clinical trials and manufacture OCU500.

Modifier Gene Therapy Platform

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

IRDs, such as RP and LCA, can lead to visual impairment and blindness and affect over two million people worldwide. RP and LCA are rooted in more than 175 different gene mutations. 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. OCU400 has received ODDs from the FDA for the treatment of certain disease genotypes: *NR2E3*, *CEP290*, *RHO*, and *PDE6ß* mutation-associated inherited retinal degenerations. Additionally, OCU400 has received OMPD from the EC based on the recommendation of the EMA for RP and LCA, which we believe demonstrates that OCU400 has the potential to be a broad-spectrum therapeutic to treat multiple IRDs.

We have initiated a Phase 1/2 clinical trial, a multicenter, open-label, dose ranging study to assess the safety of unilateral subretinal administration of OCU400 in subjects with *NR2E3* and *RHO*-related RP in the United States, pursuant to an IND application cleared by the FDA. The first patient was dosed in March 2022 and we have completed dosing patients in two out of three cohorts. After reviewing the data from the second cohort, an independent Data Safety and Monitoring Board recommended us to proceed with dosing in the third cohort. We initiated dosing in the third cohort in October 2022. We expect to complete enrollment in the third cohort by the end of 2022. Patients with LCA associated with *CEP290* mutations will be included in the current Phase 1/2 clinical trial.

We are also developing OCU410 and OCU410ST to utilize the nuclear receptor genes *RORA* for the treatment of dry AMD and Stargardt disease, respectively. We are currently executing IND-enabling studies for OCU410 consistent with FDA discussions. We intend to submit IND applications in the second quarter of 2023 to initiate Phase 1/2 clinical trials. We have engaged CanSinoBIO as our manufacturing partner for our modifier gene therapy platform. CanSinoBIO has produced the clinical trial supplies for use in the Phase 1/2 clinical trials.

Novel Biologic Therapy for Retinal Diseases

Our biologic product candidate, OCU200, is a novel fusion protein designed to treat severely sight-threatening diseases, such as DME, DR, and wet AMD. We have completed the technology transfer of manufacturing processes to our CDMO and have produced clinical trial supplies to initiate a Phase 1 clinical trial. We are currently executing IND-enabling studies consistent with FDA discussions. We intend to submit an IND application in the first quarter of 2023 to initiate a Phase 1 clinical trial targeting DME.

Regenerative Medicine – Cell Therapy Platform

NeoCart is a three-dimensional tissue-engineered disc of new cartilage that is manufactured by growing chondrocytes, the cells responsible for maintaining cartilage health. The chondrocytes are derived from the patient on a unique scaffold. We believe NeoCart has the potential to accelerate healing and reduce pain by reconstructing a patient's previously damaged knee cartilage. It treats pain at the source, creating a similar, functional joint surface as it was before the injury. Ultimately, the therapy's goal is to prevent a patient's progression toward osteoarthritis, reduce pain, and improve function of the joint. In May 2022, the FDA granted a RMAT designation to NeoCart for the repair of knee cartilage injuries in adults. We are currently working with the FDA to finalize the Phase 3 clinical trial protocol necessary to advance the clinical development of NeoCart for eventual market authorization.

Impact of the COVID-19 Pandemic

The COVID-19 pandemic remains ongoing. 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 any current or future variants, (ii) future actions taken by governmental authorities and regulators with respect to the COVID-19 pandemic including restrictions and available funding for COVID-19 vaccines, and (iii) the impact on our partners, collaborators, and suppliers. To date, the COVID-19 pandemic has not had a material adverse impact on our business operations, and we currently do not expect that it will have a material adverse impact on our operations in the future. However, we continue to monitor the situation for any new developments that could potentially have a material adverse impact on our operations.

Results of Operations

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

The following table summarizes the results of our operations for the three months ended September 30, 2022 and 2021 (in thousands):

	Three months ended September 30,		
	2022	2021	Change
Operating expenses			
Research and development	$ 15,622	$ 6,281	$ 9,341
General and administrative	7,497	4,508	2,989
Total operating expenses	23,119	10,789	12,330
Loss from operations	(23,119)	(10,789)	(12,330)
Other income (expense), net	1,197	(18)	1,215
Loss before income taxes	(21,922)	(10,807)	(11,115)
Income tax benefit	—	(52)	52
Net loss	$ (21,922)	$ (10,755)	$ (11,167)

Research and development expense

Research and development expense increased by $9.3 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021. The increase was primarily due to increases of $5.4 million related to COVAXIN, driven by clinical and chemistry, manufacturing, and controls ("CMC") activities; $1.1 million in employee-related expenses as we expand our headcount to support our research and development initiatives; $1.2 million related to OCU200, driven by preclinical activities; and $1.0 million related to the initial license issuance fee to Washington University for the rights to develop, manufacture, and commercialize OCU500 in the Mucosal COVID-19 Vaccine Territory.

General and administrative expense

General and administrative expense increased by $3.0 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021. The increase was primarily due to $2.1 million in employee-related expenses, including $1.2 million in stock-based compensation expense.

Other income (expense), net

Other income (expense), net increased by $1.2 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021. The increase was primarily due to the collection of $0.8 million related to a note receivable that was previously impaired and $0.5 million in interest earned on our cash and cash equivalents balance.

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes the results of our operations for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine months ended September 30,		
	2022	2021	Change
Operating expenses			
Research and development	$ 32,544	$ 28,006	$ 4,538
General and administrative	28,174	15,450	12,724
Total operating expenses	60,718	43,456	17,262
Loss from operations	(60,718)	(43,456)	(17,262)
Other income (expense), net	1,306	(380)	1,686
Loss before income taxes	(59,412)	(43,836)	(15,576)
Income tax benefit	—	(52)	52
Net loss	$ (59,412)	$ (43,784)	$ (15,628)

Research and development expense

Research and development expense increased by $4.5 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021. The increase was primarily due to increases of $7.9 million related to COVAXIN, driven by clinical and CMC activities; $6.2 million in employee-related expenses; $2.9 million related to OCU200 and $1.2 million related to OCU410, both of which are driven by preclinical activities; and $1.0 million related to the initial license issuance fee to Washington University for rights to develop, manufacture, and commercialize OCU500 in the Mucosal COVID-19 Vaccine Territory. These increases are offset 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 and an overall decrease of $0.4 million related to OCU400, which is driven by an increase in clinical activities and a decrease in preclinical activities.

General and administrative expense

General and administrative expense increased by $12.7 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021. The increase was primarily due to $6.3 million in employee-related expenses, including $2.8 million in stock-based compensation expense; $3.7 million in professional and consulting services, including legal fees; $1.9 million in pre-commercialization activities; $0.9 million in insurance expense; and $0.9 million in office expenses for our new corporate headquarters. These increases were partially offset by a decrease of $1.9 million in expenses for the annual stockholder meeting and proxy solicitation.

Other income (expense), net

Other income (expense), net increased by $1.7 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021. The increase was primarily due to the collection of $0.8 million during the nine months ended September 30, 2022 related to a note receivable that was previously impaired during the nine months ended September 30, 2021 and $0.6 million in interest earned on our cash and cash equivalents balance. These increases were partially offset by a gain on loan extinguishment of $0.4 million for the forgiveness of the Paycheck Protection Program note during the nine months ended September 30, 2021.

Liquidity and Capital Resources

As of September 30, 2022, we had $101.6 million in cash and cash equivalents. We have not generated significant revenue to date and have primarily funded our operations to date through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes, debt, and grant proceeds. Since our inception and through September 30, 2022, we have raised an aggregate of $271.2 million to fund our operations, of which $258.0 million was from gross proceeds from the sale of our common stock and warrants, $10.3 million was from the issuance of convertible notes, $2.7 million was from debt, and $0.2 million was from grant proceeds.

In June 2022, we entered into the Sales Agreement with certain agents, whereby we may, from time to time, offer and sell shares of our common stock having an aggregate gross sales price of up to $160.0 million. Subsequent to September 30, 2022, we sold 2.1 million shares of our common stock and received net proceeds of $3.6 million after deducting equity issuance costs of $0.3 million.

In February 2022, we issued and sold 16.0 million shares of our common stock at a public offering price of $3.13 per share pursuant to an underwritten offering. We received net proceeds of $49.8 million, after deducting equity issuance costs.

Since our inception, we have devoted substantial resources to the research, development, and pre-commercialization activities of our product candidates and have incurred significant net losses and may continue to incur net losses in the future. We incurred net losses of approximately $59.4 million and $43.8 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of $191.1 million. Additionally, we had accounts payable and accrued expenses of $14.5 million and indebtedness of $2.3 million as of September 30, 2022.

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

	Nine months ended September 30,	
	2022	2021
Net cash used in operating activities	$ (43,165)	$ (35,137)
Net cash used in investing activities	(1,672)	(1,624)
Net cash provided by financing activities	51,300	120,071
Effect of changes in exchange rate on cash, cash equivalents, and restricted cash	30	—
Net increase in cash, cash equivalents, and restricted cash	$ 6,493	$ 83,310

Operating activities

Cash used in operating activities was $43.2 million for the nine months ended September 30, 2022 compared to $35.1 million for the nine months ended September 30, 2021. The increase in cash used in operating activities was primarily driven by an increase in our operating expenses to continue to support our development, commercialization, and business efforts including development and pre-commercialization expenses for our product candidates, employee-related expenses, including an increase in headcount to support our operations, and professional and consulting services, including legal fees. These increases were offset by a $15.0 million upfront payment to Bharat Biotech in connection with the amendment to the Covaxin Agreement to add rights to the Canadian market in June 2021.

Investing activities

Cash used in investing activities was $1.7 million for the nine months ended September 30, 2022 compared to $1.6 million for the nine months ended September 30, 2021. The increase in cash used in investing activities was primarily driven by an increase of $1.7 million in purchases of property and equipment during the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021. This increase was partially offset by the collection of a note receivable of $0.8 million during the nine months ended September 30, 2022 that was issued during the nine months ended September 30, 2021.

Financing activities

Cash provided by financing activities was $51.3 million for the nine months ended September 30, 2022 compared to $120.1 million for the nine months ended September 30, 2021. During the nine months ended September 30, 2022, cash provided by financing activities primarily consisted of gross proceeds of $50.0 million received from our underwritten offering that closed in February 2022. 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 an at-the-market offering, partially offset by payments of equity issuance costs of $8.5 million.

Contractual Obligations

We have commitments under certain licensing and development agreements, lease obligations, debt agreements, and consulting agreements. We previously entered into a supply commitment in February 2022 to purchase $14.3 million of COVAXIN drug product components from Bharat Biotech, which was withdrawn by us subsequent to September 30, 2022 as a result of the deficiencies identified in an inspection conducted by the WHO. In addition, we entered into the WU License Agreement in September 2022. Our obligations pursuant to the WU License Agreement are further described in Note 3. Except for the withdrawal of the supply commitment with Bharat Biotech and our obligations pursuant to the WU License Agreement, there have been no material changes to our contractual obligations as reported in our 2021 Annual Report.

Funding requirements

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

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

- the initiation, progress, timing, costs, and results of clinical trials for our product candidates;
- the outcome, timing, and cost of the regulatory approval process for our product candidates;
- the costs of manufacturing and commercialization;
- the costs related to doing business internationally with respect to the development and commercialization of our product candidates;
- the cost of filing, prosecuting, defending, and enforcing our patent claims and other intellectual property rights;
- the costs 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 costs involved in recruiting and retaining skilled personnel;
- the extent to which we in-license or acquire other products, product candidates, or technologies; and
- the impact of geopolitical turmoil, macroeconomic conditions, social unrest, political instability, terrorism, or other acts of war.

Although we believe our cash and cash equivalents will enable us to fund our operating expenses and capital requirements through at least one year from the date the condensed consolidated financial statements included in this report are issued, our management plans to continue to raise additional capital to support the development and commercialization of our product candidates through public and private placements of equity and/or debt, including sales of common stock through the Sales Agreement, pursuant to which we may, but are not obligated to, issue and sell up to $160.0 million of shares of our common stock, for which we have received net proceeds of $3.6 million to date, payments from potential strategic research and development arrangements, sales of assets, licensing and/or collaboration arrangements with pharmaceutical companies or other institutions, funding from the government, particularly for the adult safety clinical trial for COVAXIN and for the development of OCU500, or funding from other third parties. Our ability to secure funding is subject to numerous risks and uncertainties, including the impact of the COVID-19 pandemic, geopolitical turmoil, and macroeconomic conditions, and as a result, there can be no assurance that these funding efforts will be successful. If we cannot obtain the necessary funding, we will need to delay, scale back, or eliminate some or all of our research and development programs and commercialization efforts; consider other various strategic alternatives, including a merger or sale; or cease operations. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition, and results of operations could be materially adversely affected.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

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

Recently Adopted Accounting Pronouncements

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

Other Company Information

None.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of September 30, 2022. Based upon this evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

For a discussion of legal proceedings, see Note 12 in the notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors.

Except as set forth in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 (the "First Quarter 10-Q"), there have been no material changes in our risk factors as previously disclosed in our 2021 Annual Report. The risks described in our 2021 Annual Report and our First Quarter 10-Q are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, or future results.

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

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

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit	Description
10.1*#	Exclusive License Agreement by and between Ocugen, Inc. and The Washington University, dated as of September 23, 2022
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Chief Accounting Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certifications of the Chief Executive Officer and Chief Accounting Officer as required by 18 U.S.C. 1350
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from this Quarterly Report on Form 10-Q, formatted in Inline XBRL

* Filed herewith.

** Furnished herewith.

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

SIGNATURES

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

Ocugen, Inc.

Dated: November 8, 2022

/s/ Shankar Musunuri

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

Dated: November 8, 2022

/s/ Jessica Crespo

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

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and the registrant customarily and actually treats as private and confidential.

Exhibit 10.1

EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement ("Agreement") is made and entered into as of the date of the last signature below (the "Effective Date") by and between: The Washington University, a corporation established by special act of the Missouri General Assembly approved February 22, 1853 and acts amendatory thereto, through its Office of Technology Management having its principal offices at 4240 Duncan Avenue, Suite 110, St. Louis, MO 63110 (hereinafter referred to as "WU"); and Ocugen, Inc., a corporation organized and existing under the laws of the State of Delaware, having its principal offices at 11 Great Valley Parkway, Malvern, PA 19355 and its Affiliates (hereinafter and collectively referred to as "Licensee").

RECITALS

A. WU possesses certain Patent Rights (as defined below), Technical Information (as defined below), and Tangible Research Property (as defined below).

B. Licensee shall develop within [***] days of the Effective Date a Development Plan (as defined below) to develop, test, manufacture, market, and/or sell products based on the Patent Rights, the Technical Information, and/or the Tangible Research Property.

C. Licensee possesses or plans to obtain the knowledge, expertise, experience, and resources to carry out the Development Plan, to meet the milestones set forth in Summary of Terms hereto, and to otherwise use Commercially Reasonable Efforts to manufacture, market, and commercialize products based on the Patent Rights, Tangible Research Property, and/or the Technical Information.

D. Licensee desires to obtain from WU certain licenses to the Tangible Research Property, Technical Information and Patent Rights and WU desires to grant such licenses to Licensee. The Tangible Research Property includes certain materials ("Penn Materials") sourced from the Trustees of the University of Pennsylvania ("Penn") as set forth in Schedule C. WU and Penn have entered into an Inter-institutional Agreement (IIA) dated 07/09/2020 that permits WU to provide Penn Materials to the Licensee pursuant to the terms of this Agreement.

SUMMARY OF TERMS

The terms set forth below shall apply to this Agreement, and shall be interpreted in accordance with **Schedules A – E** appended hereto. This Agreement includes and hereby expressly incorporates **Schedules A – E** appended hereto.

- Field: vaccines for humans
- Territory: US, Europe, and Japan
- License Issue Fee: $1,000,000
- License Maintenance Fee: $[***]
- Patent Royalty Rate: [***]%
- Non-Patent Royalty Rate: [***]%

- Diligence Milestones and Payments:
    - Diligence Milestones – Technical

Milestone		Date
a.	[***]	Within [***] months from the Effective Date
b.	[***]	Within [***] months from the Effective Date
c.	[***]	Within [***] months from the Effective Date
d.	[***]	Within [***] months from the Effective Date

-
    - Milestone Payments

Payment	Payment Due
Upon dosing the first human subject in a licensing enabling clinical trial (the results of which are the basis of a registration and regulatory approval in the Territory)	[***]
First Commercial Sale of a Licensed Product	[***]
Upon first achieving the cumulative Net Sales of $[***] in the Territory	[***]
Upon first achieving the cumulative Net Sales of $[***] in the Territory	[***]
Upon first achieving the cumulative Net Sales of $[***] in the Territory	[***]
Upon first achieving the cumulative Net Sales of $[***] in the Territory	[***]

- Minimum Royalty: $[***]
- Sublicensing Revenue Percentage: [***] %

[*The signature page follows*]

The signatures of the undersigned indicate that they have read, understand, and agree with the terms of this Agreement, including its appended **Schedules A - E**, and have the authority to execute this Agreement on behalf of and to bind their represented party.

THE WASHINGTON UNIVERSITY		**LICENSEE**	
Signature:	/s/ Nicole Mercier	Signature:	/s/ Shankar Musunuri
Name:	Nichole Mercier, PhD.	Name:	Dr. Shankar Musunuri
Title:	Assistant Vice Chancellor & Managing Director	Title:	Chairman and CEO
Date:	September 22, 2022	Date:	September 23, 2022

SCHEDULE A

TERMS AND CONDITIONS

1. Definitions.

1.1. "Affiliate" means an entity that now or hereafter, directly or indirectly, controls or is controlled by or is under common control with a party to this Agreement whether by beneficial ownership, contract, or otherwise. Control means (i) the direct or indirect ownership of at least 50% of voting securities (or the equivalent) of the entity, or (ii) having the majority power to govern the financial and operating policies of the entity, or (iii) the power to appoint the management of the entity.

1.2. "Calendar Half" means each six-month period of a calendar year, or portion thereof, beginning on January 1 or July 1.

1.3. "Combination Product" means a collection or group of products sold together (such as in a kit or package) that contains (a) a Licensed Product and (b) one or more other functional products ("Other Products") that has been sold separately for use without the Licensed Product and which is not essential to the use or operation of the Licensed Product.

1.4. "Commercially Reasonable Efforts" means the efforts and resources that a similarly situated biopharmaceutical company would use to develop and commercialize its own internally discovered technology of similar commercial potential at a similar stage of development. Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the Licensee (a) promptly assign responsibility for such obligation to specific employee(s) who are accountable for progress and monitor such progress on an on-going basis, (b) set annual objectives for carrying out such obligations, and (c) allocate resources designed to advance progress with respect to such objectives. For clarity, Commercially Reasonable Efforts will not mean that the Licensee guarantees that it will actually accomplish the applicable task or objective.

1.5. "Development Plan" means Licensee's plan to develop, test, manufacture, market, and/or sell Licensed Products, which plan is attached hereto as **Schedule B**.

1.6. "Diligence Milestones" means the activities outlined in the Summary of Terms above, which Licensee shall perform for the purpose of developing and commercializing the first Licensed Product.

1.7. "Field" means the field, as described in the Summary of Terms, in which Licensee is authorized to use the Patent Rights, Technical Information, and Tangible Research Property under this Agreement.

1.8. "First Commercial Sale" means the earliest date on which a Sale of a Licensed Product is consummated pursuant to this Agreement.

1.9. [Reserved]

1.10. "Licensed Product" means (a) any product or service that is covered by a Valid Claim; (b) any product or service that uses a method, or any product that is produced using a method, which is covered by a Valid Claim; and/or (c) any product that is developed using, made using, derived from, and/or requires the use of, in whole or in part, Technical Information and/or Tangible Research Property.

1.11. "Market Exclusivity" means, with respect to any country or other jurisdiction in the Territory, any additional market protection, other than Patent Rights protection, granted by a regulatory authority in such country or other jurisdiction which confers an exclusive commercialization period during which Licensee or Sublicensees have the exclusive right to market and sell a Licensed Product in such country or other jurisdiction through a regulatory exclusivity right (e.g., new molecular or chemical entity exclusivity, new use or indication exclusivity,

new formulation exclusivity, orphan drug exclusivity, unmet medical need exclusivity, pediatric exclusivity, or any applicable data exclusivity).

1.12. "Milestone Payments" means the payments outlined in the Summary of Terms above, which shall be paid to WU within [***] days after the achievement of the milestone indicated for each payment.

1.13. "Net Sales" means the gross value of all forms of consideration received from Sales of Licensed Products, less the Permissible Deductions.

1.14. "Patent Rights" means the patents and patent applications listed in **Schedule C**; all continuation, divisional, and continuation-in-part applications (excluding all claims that are not supported by the disclosures contained in the patents and patent applications listed in **Schedule C** as of the Effective Date) that claim priority (directly or indirectly) to the patents and patent applications listed in **Schedule C**; all reexaminations, reissues, and foreign counterparts thereof; and all patents that issue from any and all of the foregoing applications.

1.15. "Patent Royalty Rate" means the royalty rate, in the amount listed in the Summary of Terms, which shall apply to Net Sales of Licensed Products that are made, sold, used, or transferred to a customer located within a country in which a patent or patent application is then subsisting that contains at least one Valid Claim.

1.16. "Non-Patent Royalty Rate" means the royalty rate, in the amount listed in the Summary of Terms, which shall apply to Net Sales of Licensed Products that are not otherwise subject to the Patent Royalty Rate.

1.17. "Permissible Deductions" means [***]

1.18. [Reserved]

1.19. [Reserved]

1.20. "Sale" means any transaction in which a Licensed Product is sold, exchanged, provided, or transferred to an unrelated third party (that is not an Affiliate or Sublicensee of Licensee or an Affiliate of Sublicensee) for any value, payment, or compensation of any type or kind. Sales shall not include transfers by Licensee, its Affiliates, its Sublicensees, or Sublicensee's Affiliates to others (i) as samples, (ii) for charitable or benevolent purposes (including, but not limited to, early access programs, named patient sales, and compassionate use), provided no consideration is received or the Licensed Product is provided at-cost, (iii) for use in non-clinical or clinical trials, (iv) for use in any tests or studies reasonably necessary to comply with any applicable laws, rules, or regulations, and (v) for the purpose of researching, developing, or testing a Licensed Product, provided that Licensee receives no value, payment, or compensation for such Licensed Product in excess of the fully-burdened (i.e., direct and indirect) costs for producing and transporting such Licensed Product.

1.21. "Sublicensing Revenue" means all value, payments, and compensation of any type or kind, other than earned royalties on Net Sales, received by Licensee from or through its Sublicensees for licensing, cross-licensing, and/or granting of rights to the Patent Rights, regardless of whether such licenses and rights are granted in the form of a collaboration, co-development, profit sharing, research, or option agreement. Sublicensing Revenue shall include without limitation all fees, milestone payments, cash equivalents, securities, equipment, property, and/or anything else of value received by Licensee, from or for the benefit of any Sublicensee, in consideration for such licenses and rights to the Patent Rights, but shall exclude any amount received from any Sublicensee as (a) support of Licensee's research and development directly relating to the Licensed Products as evidenced by detailed research and budget proposals provided to WU prior to Licensee's receipt of such funding, or (b) the portion of the purchase price for Licensee's debt or equity securities that reflect the then current market value of such securities or, if such securities are not publicly traded, the then current market value of such securities.

1.22. "Tangible Research Property" means the materials and other property that WU provides to Licensee pursuant to this Agreement, including without limitation the materials listed in **Schedule C,** and any progeny, derivatives and modifications of such materials made by or on behalf of Licensee, its Affiliates, or Sublicensees.

1.23. "Technical Information" means all know-how, information, protocols, and/or data developed by WU by or under the direction of Drs. David Curiel and Michael Diamond before the Effective Date that has been provided to or accessed by the Licensee, which are necessary or useful for the discovery, development, manufacture, use, marketing, sale, distribution, or other commercial exploitation of a Licensed Product, including without limitation (a) all know-how, information, and data disclosed in any of the Patent Rights or (b) any reports or disclosures concerning research or inventions provided or disclosed to, or otherwise received by, the Licensee. Technical Information includes without limitation the information set forth in **Schedule C** hereto.

1.24. "Territory" means the countries and other territories listed in the Summary of Terms, but excluding those countries and territories to which export of technology or goods is prohibited by applicable U.S. export control laws or regulations.

1.25. "Valid Claim" means a claim (a) of a pending patent application, within the Patent Rights, which has been pending for no longer than [***] years after its earliest priority date; and/or (b) of an issued and unexpired patent within the Patent Rights, provided that such claim has not been (i) held invalid or unenforceable by a court or other governmental agency of competent jurisdiction in a decision or order that is not subject to appeal or a decision which has not been timely appealed, (ii) cancelled, (iii) disclaimed, or (iv) abandoned in accordance with, or as permitted by the terms of this Agreement or by mutual written agreement of WU and Licensee.

2. <u>License Grants and Restrictions</u>.

2.1 Subject to the terms and conditions of this Agreement, WU hereby grants to Licensee, and Licensee hereby accepts, a non-transferable (subject to Section 15.5), sublicensable (in accordance with Section 2.8), exclusive (subject to Section 2.3 below), royalty-bearing license under the Patent Rights, in the Field and in the Territory, for the Term of this Agreement, to make, have made, sell, offer for sale, use, market, promote, distribute, export, and import Licensed Products.

2.2 Subject to the terms and conditions of this Agreement, WU hereby grants to Licensee, and Licensee hereby accepts, a non-transferable (subject to Section 15.5), sublicensable (in accordance with Section 2.8), non-exclusive license, in the Field and in the Territory, for the Term of this Agreement, to use the Technical Information and Tangible Research Property solely for the purpose of exploiting the license granted to Licensee in Section 2.1 above.

2.3 WU retains the right to use the Patent Rights, Technical Information, and Tangible Research Property for research and educational purposes.

2.4 Licensee agrees and acknowledges that: (a) in accordance with Public Laws 96-517, 97-256, and 98-620, codified at 35 U.S.C. §§ 200-212, the United States government retains certain rights to inventions arising from federally supported research or business; (b) under such laws and implementing regulations, the government may impose requirements on such inventions; (c) Licensed Products embodying inventions subject to such laws and regulations sold in the United States must be substantially manufactured in the United States; and (d) the license rights granted in this Agreement are expressly made subject to such laws and regulations as amended from time to time. Licensee agrees to abide by all such laws and regulations. Upon Licensee's request, and at Licensee's expense, WU agrees to cooperate with Licensee in connection with attempting to secure a waiver of such obligations.

2.5 WU retains all ownership rights in the Patent Rights, Technical Information, and Tangible Research Property (except for certain Tangible Research Property that will remain the sole and exclusive property of WU and Penn). Licensee agrees that it will not do any act or thing which would in any way contest WU's or Penn's ownership in, or otherwise derogate from the ownership by WU or Penn, of any rights in the Patent Rights, Tangible Research Property, and/or Technical Information, as applicable.

2.6 To the extent applicable, Licensee shall ensure that all Licensed Products (or their packaging, as appropriate) sold by or on behalf of Licensee are marked with the appropriate patent numbers, in accordance with each country's patent laws.

2.7 Licensee hereby grants to WU and WU hereby accepts, a non-transferable, non-exclusive, perpetual, irrevocable, fully paid-up license for research and education purposes only, under any and all applicable patents, copyright registrations or other intellectual property rights, to make and use any and all inventions, discoveries or improvements conceived of or reduced to practice by Licensee during the Term of this Agreement and relating to the Patent Rights, Tangible Research Property or Technical Information. For the avoidance of doubt, the rights under this Section 2.7 do not include any right to make, use, sell or offer to sell any products or services for any commercial purpose.

2.8 Licensee shall have the right to sublicense the rights and licenses granted in Sections 2.1 and 2.2 to third parties in accordance with the provisions of **Schedule D**.

2.9 [Reserved]

2.10 The license and rights granted in this Agreement shall not be construed to confer any rights upon Licensee by implication, estoppel, or otherwise to any other technology and/or intellectual property not specifically identified in this Agreement.

3. Development Plan.

3.1 Licensee represents and warrants that it shall develop within [***] days of the Effective Date a Development Plan that contains Licensee's good faith, bona fide plans for commercializing Licensed Products using its Commercially Reasonable Efforts. Licensee represents and warrants that it has or plans to obtain the knowledge, expertise, experience and resources to fully carry out such plans.

3.2 Licensee agrees to use Commercially Reasonable Efforts to meet any and all Diligence Milestones set forth in the Summary of Terms above and in the Development Plan on or before the times set forth in the Development Plan including, without limitation, the development milestones for each Licensed Product.

3.3 Licensee will deliver to WU written reports on Licensee's progress against the Development Plan no later than [***], and no later than [***]. Each such report will set forth Licensee's progress against the Development Plan in reasonable detail including, without limitation, the progress achieved and any problems encountered in the development, prototyping, evaluation, testing, manufacture, Sale, and/or marketing of, as applicable, each Licensed Product. Each such report will identify in detail any financial investment, grant or other source of funding awarded or provided to Licensee that is used, in part or in whole, to develop, evaluate, test, manufacture, sell and/or market a Licensed Product and including, but not limited to, the items outlined in **Schedule E**. Upon reasonable request by WU from time-to-time, Licensee will meet with WU to consult with WU about Licensee's then-current progress against the Development Plan.

3.4 Licensee shall provide each significant amendment, change, or other modification to the Development Plan to WU for review, discussion, and comment, shall respond to all reasonable questions of WU with respect to the proposed modification, and shall obtain WU's consent prior to implementing any such significant modification. For purposes of this section, significant shall refer to any change or modification that causes a delay in the development timeline.

4. Diligence.

4.1 Licensee shall exercise Commercially Reasonable Efforts, itself or through its Affiliates, Sublicensees, or contractors, to fully satisfy all of the Diligence Milestones set forth in the Summary of Terms. Licensee will deliver to WU detailed written updates on Licensee's progress towards achieving such Diligence Milestones within each report that is provided to WU pursuant to Section 3.3. Each report will include sufficient detail to enable WU to assess whether Licensee is making reasonable progress towards each Diligence Milestone. In the event that a report does not, in WU's sole and reasonable discretion, contain sufficient information, within forty-five (45) days from WU notifying Licensee of such deficiency, Licensee shall provide the additional information that WU requests under this Section 4.1.

4.2 After fully satisfying the Diligence Milestones under Section 4.1, Licensee will continue to exercise Commercially Reasonable Efforts to develop, manufacture, promote, and sell Licensed Products in the countries in which Patent Rights exist for the duration of the Term.

4.3 Should WU conclude, in its reasonable judgment, that Licensee has failed to meet the diligence requirements set out in this Section 4, WU may notify Licensee of its conclusions and the basis therefor. The parties shall then undertake to resolve WU's concerns through good faith negotiations for a period of [***] days. Should such negotiations fail to result in (i) Licensee achieving a level of diligence consistent with its obligations under this Section 4, (ii) Licensee presenting a plan reasonably designed to meet the diligence requirements set out in this Section 4, or (iii) Licensee and WU mutually agreeing to adjust a Diligence Milestone or extend the date for achievement of a Diligence Milestone, in WU's sole and reasonable discretion, then WU may exercise its right to terminate this Agreement as provided in Section 13 below, provided that the parties have exhausted the dispute resolution provisions in Section 15.18.

5. Fees, Payments, Royalties.

5.1 Within [***] days after the Effective Date, Licensee agrees to pay the License Issue Fee to WU. Such License Issue Fee shall be non-refundable and shall not be credited against any other payments that may be due hereunder.

5.2 On or before every anniversary of the Effective Date and until the First Commercial Sale of a Licensed Product that occurs in a primary country designated in the Development Plan, Licensee agrees to pay the License Maintenance Fee to WU. All License Maintenance Fees shall be non-refundable and shall not be credited against any other payments that may be due hereunder.

5.3 Licensee will pay WU the Patent Royalty Rate of Net Sales, for those Sales that are subject to the Patent Royalty Rate. Licensee will pay WU the Non-Patent Royalty Rate of Net Sales, for those Sales that are subject to the Non-Patent Royalty Rate. A Sale of a Licensed Product will be deemed to have been made at the time Licensee first invoices, ships, recognizes, or receives value for a Licensed Product.

5.4 If rights under any intellectual property owned by any third party is needed to practice, use, make, sell, offer to sell, or import any Licensed Product, then royalties payable to WU with respect to such Licensed Product under Section 5.3 may be reduced by Licensee dollar for dollar in an amount up to [***] percent ([***]%) of any royalty payable by Licensee to any such third party for such right. However, in no event shall the effective Patent Royalty Rate be reduced below [***]% as a result of the royalty reductions permitted under this Section 5.4 and Section 5.5 below. The royalty deductions permitted under this Section 5.4 shall only be applicable for third party licenses needed to provide freedom-to-operate under the Patent Rights (and do not apply to other licenses or permissions that Licensee may obtain to develop, produce, or market a Licensed Product, including third party formulation technology).

5.5 In the event that a Licensed Product is sold as part of a Combination Product, Net Sales generated from Combination Products shall be determined by multiplying the Net Sales of such Combination Product by the fraction (C/(C+D)), where C is the total gross invoice price of the Licensed Product when sold separately and D is the total gross invoice price of the Other Products when sold separately.

5.6 The royalties owed to WU will be paid by Licensee within [***] days after the end of each Calendar Half in which the Sales of the applicable Licensed Products occur.

5.7 Licensee shall not consummate a Sale of a Licensed Product for an amount that is less than the fair market value of the Licensed Product, except in connection with the launch of a Licensed Product and a related introductory pricing strategy.

5.8 Commencing after the Calendar Half in which the First Commercial Sale occurs and continuing thereafter throughout the Term of this Agreement, Licensee agrees to pay WU the Minimum Royalty set forth in the

Summary of Terms above, for each Calendar Half as an advance against the royalties due under this Agreement, including this Section 5 and Schedule D. Such Minimum Royalties shall be due on January 31 and July 31 of each Calendar Half.

5.9 Licensee agrees to pay WU Milestone Payments in the amounts set forth in the Summary of Terms above within [***] days after the date that the applicable Milestone Payment is due.

5.10 For the avoidance of doubt, multiple royalties will not be owed to WU if a Licensed Product, or the manufacture, use, Sale or importation thereof, is covered by more than one Valid Claim (or more than one patent or patent application within the Patent Rights).

5.11 In the event that a court or a governmental agency of competent jurisdiction requires Licensee, its Affiliates, or its Sublicensees to grant a compulsory license to a third party permitting such third party to make and sell a Licensed Product in a country in the Territory, Licensee and WU shall meet to discuss and negotiate in good faith appropriate treatment and pro-rata reductions for any royalties arising in connection with such compulsory license.

6. Payments, Records, and Audits.

6.1 All dollar ($) amounts referred to in this Agreement are expressed in United States dollars. All payments to WU shall be made in United States dollars by check or electronic transfer payable to "Washington University." Any Sales revenues for Licensed Products in currency other than United States dollars shall be converted to United States dollars at the applicable monthly average conversion rate (or as mutually agreed upon) for the foreign currency as published in the Eastern edition of *The Wall Street Journal* in the United States (or any other mutually agreed upon source). All payments (including the License Issue Fee, License Maintenance Fees, royalties, and Milestone Payments) paid to WU under this Agreement are non-refundable and shall not be credited against any other payments that may be due from Licensee under this Agreement or any other agreement unless it can be shown to both parties satisfaction that Licensee mistakenly overpaid any such fees, royalties, milestone payments, and/or other amounts, such overpayments will then be applicable to future payments as mutually agreed. All payments shall include or reference the WU Contract Number listed herein, to ensure accurate crediting to Licensee's account. Electronic transfers shall be made to a bank account designated in writing by WU, and Licensee shall pay for all bank charges for the wire transfer of funds and shall not the deduct bank charges from the total amount due to WU. All checks shall be sent to:

Washington University
Office of Technology Management
Attn: Accounting Dept.
660 S. Euclid, Campus Box 8013
St. Louis, MO 63110

6.2 Within [***] days after the end of each Calendar Half in which a Sale of a Licensed Product is made, Licensee shall deliver to WU a written report setting forth the calculation of all amounts due to Licensee for such Calendar Half. Each report will show, at a minimum, (a) the number of Licensed Products sold, by country, during such Calendar Half; (b) the gross receipts for Sales of Licensed Products, by country, during such Calendar Half, including total amounts invoiced and received; (c) the amount of any Permissible Deductions for such Calendar Half; and (d) the amount of Net Sales of Licensed Products, by country, for such Calendar Half.

6.3 Licensee shall maintain complete and accurate books of account and records that would enable an independent auditor to verify the amounts paid as royalties and other amounts under this Agreement. The books and records must be maintained for at least [***] years following each Calendar Half. Upon not less than [***] days' prior written notice by WU, Licensee must give WU (or an independent accountant mutually acceptable to Licensee and WU and who enters into a non-disclosure agreement with Licensee) access to all books and records relating to

Sales of Licensed Products by Licensee to conduct, at WU's expense, an audit or review of those books and records. This access must be available at least once every [***] months, during regular business hours, during the Term of this Agreement and for the [***] calendar years following the year in which termination or expiration of this Agreement occurs. No accounting period shall be subject to audit more than one time hereunder. If any such audit or review determines that Licensee has underpaid royalties by [***] percent ([***]%) or more for any Calendar Half, Licensee shall (a) reimburse WU for the costs and expenses of the accountant and auditors in connection with the review and audit and (b) immediately pay WU the amount of such underpayment along with interest on the past due amount as provided in Section 6.4 below.

6.4 Any amounts not paid by Licensee to WU when due shall accrue interest, from the date [***] days after the balance is due at an interest rate of [***]% per month. In addition, Licensee will reimburse WU for all reasonable costs and expenses incurred (including reasonable attorneys' fees) in collecting any overdue amounts.

6.5 Payments shall be paid to WU free and clear of all foreign taxes. If laws, rules or regulations require withholding of income taxes of other rates imposed upon payments set forth in this Agreement, Licensee shall make such withholding payments as required and without subtracting such withholding payments from such payments to WU. Licensee shall submit appropriate proof of payment of the withholding rates to WU within a reasonable period of time. Licensee shall use efforts consistent with its usual business practices to minimize the extent of any withholding taxes imposed under the provisions of the current or any future double taxation treaties or agreement between foreign countries, and the parties shall cooperate with each other with respect thereto, with the appropriate party under the circumstances providing the documentation required under such treaty or agreement to claim benefits thereunder.

7. Confidentiality.

7.1 The parties acknowledge that, prior to and during the Term of this Agreement, the parties may disclose to one another scientific, technical, business, or other information which is treated by the disclosing party as confidential or proprietary, including but not limited to unpublished Patent Rights, Technical Information, Tangible Research Property, and reports provided by Licensee to WU under this Agreement (hereinafter referred to as "Confidential Information"). Both parties agree that in order to ensure that each party understands which information is deemed to be confidential, all Confidential Information will be in written form and clearly marked as "Confidential" by the disclosing party, and if the Confidential Information is initially disclosed in oral or some other non-written form, it will be confirmed and summarized in writing and clearly marked as "Confidential" by the disclosing party within [***] days of disclosure; provided, however, that Confidential Information shall include information, whether marked or unmarked and whether reduced to writing or not, otherwise reasonably expected to be treated in a confidential manner under the circumstances of disclosure under this Agreement or by the nature of the information itself. The receiving party shall hold such Confidential Information in confidence, shall use it solely as necessary to exercise its rights or perform its obligations under this Agreement, and shall treat such information in the same manner as it treats its own confidential information but not less than with a reasonable degree of care. In recognition that WU is a non-commercial, academic institution, Licensee agrees to limit to the extent possible the delivery of Licensee Confidential Information to WU. WU retains the right to refuse to accept any such information or data from Licensee which it does not consider to be essential to this Agreement or which it reasonably believes to be improperly delivered, but such refusal shall not eliminate the obligation of the individual making such determination from treating such information as Confidential Information hereunder where such information has been disclosed to such individual. The Confidential Information provided to the receiving party will remain the property of the disclosing party. Notwithstanding any preceding sentence to the contrary, Licensee may disclose WU Confidential Information to those affiliates, directors, officers, employees, agents, counsel, and consultants of Licensee who need to know such information to enable Licensee to fulfill its obligations under this Agreement and who are subject to restrictions on use and disclosure at least as restrictive as those set forth in this Agreement, and then only to the extent necessary to enable Licensee to fulfill its obligations under this Agreement. The parties agree that no indirect or consequential damages, or damages based on loss of profits or lost market share, are contemplated or recoverable for breach of the confidentiality obligations of this Agreement.

Notwithstanding the foregoing, Licensee may disclose the terms of this Agreement to the extent required by securities or other applicable laws, or rules of any recognized stock exchange, to existing or prospective investors, acquirers, partners, collaborators, licensees, contractors, and to Licensee's accountants, attorneys and other professional advisors, in each case on a need-to-know basis and subject to customary confidentiality restrictions.

7.2 Confidential Information does not include information that (a) was known to the receiving party without any limitation on use or disclosure prior to receipt from the disclosing party as evidenced by the receiving party's records; (b) is or becomes part of the public domain through no act or omission by or on behalf of the receiving party; (c) is lawfully received by the receiving party from a third party in possession of such information who is not under obligation to the disclosing party not to disclose the information, and/or (d) comprises identical subject matter to that which had been originally and independently developed by the receiving party personnel without knowledge of, use of, access to, or reliance upon any Confidential Information as evidenced by the receiving party's records.

Specific information shall not be deemed to be within any of the foregoing exclusions set out in clauses (a) through (d) above merely because it is or may be within the scope of more general information which falls within any one or more of the foregoing exclusions.

7.3 In the event that a court or an agency of a competent jurisdiction legally compels the receiving party to disclose the disclosing party's Confidential Information in accordance with a judicial or other governmental order, the receiving party may disclose such Confidential Information provided that the receiving party either (a) gives the disclosing party prompt written notice (to the extent reasonably practicable and legally permissible) prior to such disclosure to allow the disclosing party a reasonable opportunity to seek a protective order or equivalent, or (b) obtains written assurance from the applicable judicial or governmental entity that it will afford the Confidential Information the highest level of protection afforded under applicable law or regulation.

In the event that such an assurance of the highest level of protection or a protective order or other remedy is not obtained, the receiving party shall furnish only that portion of the disclosing party's Confidential Information which in the opinion of the receiving party's counsel is legally required and shall exercise commercially reasonable efforts to obtain a protective order or other reliable assurance that confidential treatment shall be accorded to the disclosing party's Confidential Information.

In the case of disclosures required by securities laws, rules, regulations, or orders or the rules of any securities exchange or market on which a receiving party's securities are listed or traded, the receiving party shall take reasonable steps, upon the advice of securities counsel, to limit disclosure of or seek confidential treatment for such Confidential Information.

7.4 Licensee may, to the extent necessary, use and disclose the Confidential Information of WU (a) to secure governmental approval to clinically test or market a Licensed Product, (b) if applicable, to secure patent protection for an invention within the Patent Rights, (c) in connection with the sale of all, or substantially all, of the Licensee's assets to which this Agreement relates, (d) to actual or potential Sublicensees or contractors performing services with respect to Licensed Products, and their respective directors, officers, employees, advisors, and consultants, provided such actual or potential Sublicensees or contractors first agree in writing to be bound by terms of confidentiality that are at least as restrictive as the terms of confidentiality set forth in this Agreement, or (e) to actual or potential investors, lenders or other financing sources, licensees, sublicensees and acquirers, and their respective directors, officers, employees, advisors, and consultants, provided such actual or potential investors, lenders or other financing sources, licensees, sublicensees and acquirers first agree in writing to be bound by terms of confidentiality that are at least as restrictive as the terms of confidentiality set forth in this Agreement. Licensee will, in any such event, take all reasonably available steps to maintain the confidentiality of the disclosed Confidential Information and to guard against any further disclosure.

8. Representations and Warranties.

8.1 Each of WU and Licensee represents and warrants to the other that (a) this Agreement has been duly executed and delivered and constitutes a valid and binding agreement enforceable against such party in accordance with its terms, (b) no authorization or approval from any third party is required in connection with such party's execution, delivery, or performance of this Agreement, and (c) the execution, delivery, and performance of this Agreement does not violate the laws of any jurisdiction or the terms or conditions of any other agreement to which it is a party or by which it is otherwise bound.

8.2 Licensee represents and warrants that it will (a) use the Patent Rights, Tangible Research Property, and Technical Information only in accordance with the provisions of this Agreement and with such laws, rules, regulations, government permissions and standards as may be applicable thereto in the Territory and in the Field, and (b) otherwise comply with all laws, rules, regulations, government permissions and standards as may be applicable to Licensee in the Territory with respect to the performance by Licensee of its obligations hereunder. Licensee further represents and warrants that (i) it has obtained the insurance coverage required by Section 12 below, and (ii) there is no pending litigation and, to its knowledge, no threatened claims against it that could impair its ability or capacity to perform and fulfill its duties and obligations under this Agreement. Licensee warrants that all reports and/or statements provided by Licensee hereunder are true and correct and are certified true and correct by Licensee upon delivery to WU.

8.3 WU represents that to the best of its knowledge (a) as of the Effective Date, there is no known pending litigation against WU relating to the Patent Rights, and it has received no notice of any third party claims against WU challenging WU's ownership or control of the Patent Rights, Technical Information, and Tangible Research Property; (b) it has obtained assignments from all WU inventors named in patent applications and patents within the Patent Rights, which assign to WU all of their right, title and interest in and to the Patent Rights, and (c) it has the right to provide Penn Materials to Licensee pursuant to the terms of this Agreement. WU further represents to the best of its knowledge that as of the Effective Date, it has not received a notice from any third party of any potential patent infringement for any Licensed Products.

9. Patent Rights.

9.1 WU will have the sole right to control the preparation, filing, prosecution, and maintenance of Patent Rights. Subject to compliance by Licensee to the terms and conditions of this Agreement, WU will (a) prosecute and maintain the applications and patents within the Patent Rights and (b) prepare, file and prosecute additional applications within the Patent Rights as Licensee may reasonably request, in WU's name at Licensee's sole cost and expense. WU will select qualified patent counsel and corresponding foreign associates reasonably acceptable to Licensee to prepare, file, prosecute and maintain patents and patent applications within the Patent Rights. WU will consult with Licensee regarding the prosecution of Patent Rights, including providing Licensee with a reasonable opportunity to review and comment on proposed substantive correspondence with any patent office.

Notwithstanding the foregoing provisions of this Section 9.1, after the first anniversary of the Effective Date, Licensee shall have the right, but not the obligation, to negotiate with WU to assume responsibility for and control of the prosecution and maintenance of the Patent Rights throughout the Territory in WU's name.

9.2 Licensee will reimburse WU for all costs and expenses associated with the preparation, filing, prosecution, issuance, and/or maintenance of patents and applications within the Patent Rights, provided that such costs and expenses are incurred after the Effective Date and during the Term of this Agreement. Licensee will pay WU the amount of any such reimbursement within [***] days after receipt by Licensee of documentation for any such costs and expenses, which WU may provide to Licensee from time-to-time. In the event that Licensee fails to timely pay WU the amounts owed under this Section 9.2, WU shall have the option, but not the obligation, to immediately suspend WU's obligations under Section 9.1 until such amounts are fully paid to WU (and WU shall not be responsible or liable for any Patent Rights that may be abandoned or otherwise compromised as a result of such suspension). WU's rights to suspend such obligations shall be in addition to those rights afforded to WU under Section 13.

9.3 Licensee may elect not to reimburse WU for amounts due under this Section 9 in respect to one or more Patent Rights, only by giving WU notice of such election at least [***] days before the date on which the applicable cost or expense is to be incurred by WU (each an "Election Notice"). For purposes of this Section, a cost or expense shall be deemed to be incurred by WU on the earlier of (a) the date WU actually pays the cost or expense, or (b) the date WU becomes obligated to pay the cost or expense (which, for example, shall be the date WU engages a third party to perform any service which gives rise to any such cost or expense). Any such Election Notice shall specify the Patent Rights to which such Election Notice relates ("Elected Patent Rights"). In the event any Election Notice is given by Licensee, (i) the term "Patent Rights" shall be modified to exclude, as applicable, such Elected Patent Rights, (ii) the term "Technical Information" shall be modified to exclude any research and business information, unpatented inventions, know-how, data, methods, and information that is no longer necessary for the exploitation of the license granted to the remaining Patent Rights, and (iii) the term "Tangible Research Property" shall be modified to exclude any and all research tools and other materials that WU may have provided to Licensee that are no longer necessary for the exploitation of the license granted to the remaining Patent Rights, in each instance as of the date the Election Notice is given. As of the date of the Election Notice, the license to the Elected Patent Rights, the applicable Technical Information, and the applicable Tangible Research Property granted to Licensee under this Agreement will terminate, and WU shall be free, without any further obligation to Licensee whatsoever, to abandon the applications or patents subject to the Election Notice, or to continue prosecution or maintenance of such applications or patents for WU's sole use and benefit, or to license such applications or patents to unrelated third parties, at WU's option. Licensee will deliver to WU, along with any Election Notice, all Technical Information and Tangible Research Property to which such Election Notice relates.

9.4 The parties desire to avail themselves to the maximum extent possible of all applicable legal privileges. The parties intend that information regarding the preparation, filing, prosecution, and maintenance of the applications and patents within the Patent Rights ("Shared Information") that would otherwise be subject to one or more legal privileges or protections is and shall be subject to those same privileges and protections, despite the fact that it has been developed by or exchanged between or among them and/or their joint or independent counsel. The parties further intend that Shared Information is and shall be subject to the joint defense doctrine and common interest/community of interest doctrine. The parties acknowledge that the legal privileges and protections pertaining to Shared Information are held jointly by all parties, and that no individual party is authorized to waive any such privilege or protection. Further, this Agreement shall not affect the ethical, fiduciary, or other obligations inherent in those attorney-client relationships, other than to extend the cloak of confidentiality and privilege to the Shared Information as provided herein.

10. Infringement, Enforcement, and Defense.

10.1 Throughout the Term of this Agreement, each of WU and Licensee agree to give the other prompt notice of (a) any known or suspected infringement of the Patent Rights or unauthorized use or disclosure of the Technical Information and/or Tangible Research Property in the Territory, and (b) any claim that a Licensed Product infringes the intellectual property rights of a third party.

10.2 Licensee will have the right, but not the obligation, at its sole expense, to promptly stop any infringement of the Patent Rights in the Territory and in the Field. Upon receipt of WU's written consent, such consent not to be unreasonably withheld, Licensee may initiate and prosecute actions in its own name or, if required by law, in WU's name against third parties for infringement of the Patent Rights in the Territory and in the Field through outside counsel of Licensee's choice who are reasonably acceptable to WU. Licensee shall consult with WU prior to and in conjunction with all significant issues, shall keep WU informed of all proceedings, and shall provide copies to WU of all pleadings, legal analyses, and other papers related to such actions. WU will provide reasonable assistance to Licensee in prosecuting any such actions, at Licensee's sole cost and expense.

If Licensee fails or declines to take any action under this Section within a reasonable time after learning of the infringement of the Patent Rights, WU shall have the right (but not the obligation) to take appropriate actions including, without limitation, filing its own action. Licensee will provide reasonable assistance to WU in prosecuting, resolving and/or settling any such actions, at WU's sole cost and expense. Any recovery obtained by WU as a result of such proceeding or other actions, whether obtained by settlement or otherwise, shall be allocated

in the following order of priority until all of the recovery has been allocated: (1) reasonable expenses incurred by WU, including costs and reasonable attorneys' fees; (2) reasonable expenses incurred by Licensee in assisting in such action (including reasonable attorneys' fees); and (3) the remainder to WU.

10.3 In the event that Licensee or its Affiliate challenges the validity or enforceability of any of the Licensed Patents in any forum through any means, or otherwise indicate the payment of any royalty due under this Agreement is made under protest or with any objection, Licensee agrees that WU shall have the right, but not the obligation, in addition to any other remedy it may have available to it at law and/or in equity, to terminate this Agreement upon providing thirty (30) days prior written notice of the same to Licensee, during which time Licensee or its Affiliate may remediate the challenge. WU in response to such challenge by Licensee may seek redress in any court of competent jurisdiction in its sole discretion notwithstanding Section 10 or any other provision of this Agreement.

10.4 Notwithstanding anything in this Agreement to the contrary, Licensee may not, without the advanced written consent of WU (such consent not to be unreasonably withheld, conditioned, or delayed), settle, compromise, or otherwise enter into any form of settlement (or other similar agreement) regarding any claim or action brought under this Section that either (a) admits liability on the part of WU; (b) negatively affects the rights of WU or imposes any liability, restrictions, or obligation upon WU; (c) requires any financial payment by WU; and/or (d) grants rights or concessions to a third party to the Patent Rights or any Licensed Products.

10.5 WU shall have the exclusive right (but not the obligation) to institute legal action against any third party arising out of such third party's actual or threatened infringement or misappropriation of the Technical Information, and WU shall retain any and all proceeds from any such actions. Licensee shall have no right to make any demands or claims, bring suit, effect any settlements or take any other action with respect to any such infringement or misappropriation without the prior written consent of WU.

10.6 If Licensee obtains any value, payment, or compensation of any type or kind, including all forms of non-cash consideration, as a result of any claim brought by Licensee pursuant to this Section, Licensee shall pay to WU, after first deducting its costs, such as attorneys' fees and expert witness fees, a percentage of the remainder of any such proceeds equal to the Patent Royalty Rate of any such value, payment, and compensation, including the fair market value of any non-cash forms of consideration.

11 <u>Indemnification</u>.

Licensee shall indemnify, defend, reimburse and hold harmless WU, WU personnel, WU's Affiliates, Penn, Penn personnel, Penn's Affiliates and each of their respective trustees, faculty, staff, employees, students, directors, officers, agents, contractors, successors and assigns (altogether the "Indemnitees") from, for and against any and all judgments, settlements, losses, expenses, damages and/or liabilities and any and all court costs, reasonable attorneys' fees, and expert witness fees and expenses that an Indemnitee may incur from any and all allegations, claims, suits, actions or proceedings (the "Claims") to the extent arising out of, relating to, or incidental to Licensee's breach of this Agreement or its use, development, commercialization, or other exploitation of Licensed Products, Patent Rights, Tangible Research Property and/or Technical Information, whether by or through Licensee, and including all Claims for infringement, injury to business, personal injury, and product liability, except to the extent such Claims are adjudicated by a court of competent jurisdiction to arise out of the gross negligence or willful misconduct of an Indemnitee or WU's breach of this Agreement. The obligations set forth in this Section shall survive termination of this Agreement and shall continue even after assignment of rights and responsibilities.

Indemnitees seeking indemnification under this Agreement shall: (a) give Licensee prompt written notice of the Claim; (b) cooperate with the Licensee in connection with the defense and settlement of the Claim; and (c) permit Licensee to control the defense, settlement, or compromise of such Claim, including the right to select defense counsel. In no event, however, may Licensee compromise or settle any claim or suit in a manner under this Section 11 which (1) admits fault or negligence on the part of Penn, WU, or any other Indemnitees; (2) commits Penn, WU, or any other Indemnitees to take, or forbear to take, any action, without the prior written consent of the

applicable party, or (3) grant rights or concessions to a third party to the Patent Rights, Tangible Research Property, Technical Information, or any Licensed Products.

12 Insurance.

12.1 Throughout the Term of this Agreement and for a period of [***] years thereafter, Licensee shall obtain and maintain comprehensive general liability and product liability insurance, providing WU and Penn with additional insured status, with carrier(s) having at least A.M. Best ratings/class sizes of A/VII and in the following minimum annual limits:

[***]

[***]

12.2 Licensee's insurance will:

- Be issued by an insurance carrier with an A.M. Best rating of "A" or better;

- Provide for thirty (30) day advance written notice to WU or Penn of any modification;

- State that Penn and WU are endorsed as an additional insureds with respect to the coverages in Section 12.1; and

- Include a provision that the coverages will be primary and will not participate with nor will be excess over any valid and collective insurance or program of self-insurance carried or maintained by WU or Penn.

12.3 Licensee will provide WU and Penn with (i) a certificate of insurance evidencing compliance with all the requirements of this Agreement and (ii) additional insured endorsements for Licensee's applicable policies naming "The Trustees of the University of Pennsylvania" and "Washington University" as additional insureds, each within thirty days of execution of this Agreement and annually thereafter. The certificates must provide that Licensee's insurer will notify WU and Penn in writing at least thirty (30) days prior to cancellation or material change in coverage. The specified minimum insurance coverage and limits do not constitute a limitation on Licensee's liability or obligation to indemnify or defend under this Agreement.

13 Term and Termination.

13.1 The term of this Agreement will commence on the Effective Date and continue on a country-by-country and Licensed Product-by-Licensed Product basis and end, separately in each such country and for each such Licensed Product, upon the latter of (a) the last day that at least one Valid Claim exists, (b) the fifteenth (15^{th}) anniversary of the day of the First Commercial Sale, or c) the expiration of the last form of Market Exclusivity (the "Term"), unless terminated earlier in accordance with the provisions of this Agreement.

13.2 Licensee may terminate this Agreement without cause by giving at least ninety (90) days' written notice thereof to WU. Licensee shall pay WU all amounts due and owing to WU under this Agreement as of the date of termination, including the above mentioned ninety (90) day notice period, within [***] days after receipt of an invoice from WU for such amounts. Licensee may also terminate this Agreement by giving written notice thereof to WU in the event WU commits a breach of any provision of this Agreement and fails to cure such breach within [***] days after the day that Licensee gives notice to WU of such breach.

13.3 WU may terminate this Agreement by giving written notice thereof to Licensee in the event Licensee commits a material breach of any provision of this Agreement and fails to cure such breach within [***] days after the day that WU gives Licensee written notice of such breach, provided that the parties have exhausted the dispute resolution provisions in Section 15.18. Licensee agrees and acknowledges that Licensee's failure to (a) fully satisfy any of the Diligence Milestones set forth in this Agreement (as may be adjusted or extended by mutual

agreement by the parties); and/or (b) timely pay WU the amounts owed under Sections 5 and 9 will be considered a breach of this Agreement. In addition, WU may immediately terminate this Agreement by giving written notice thereof to Licensee in the event that Licensee (i) becomes insolvent, bankrupt, or is otherwise unable to pay its debt(s) to WU by the due date(s), (ii) suffers the appointment of a receiver, receiver and manager, or administrative receiver of the whole or any part of its assets or undertaking, (iii) a resolution is passed, for its winding up (other than for the purpose of amalgamation or reconstruction), or (iv) it enters into any arrangement with its creditors or suffers any distress or execution to be levied on its goods.

13.4 On the date of earlier termination of this Agreement, all license rights granted to Licensee under Section 2 shall terminate. Licensee agrees to, promptly upon the earlier termination of this Agreement, deliver to WU all originals, copies, reproductions and summaries of all Tangible Research Property, Technical Information and Confidential Information, in each instance in the format in which it exists at the time of the earlier termination of this Agreement, or in another mutually agreed format. The expiration or earlier termination of this Agreement shall not relieve Licensee of its obligation to account for and make payment to WU of any amount due hereunder including, without limitation, under Sections 5 and 9. Licensee may, upon prior written consent from WU, which shall not be unreasonably withheld, request a wind down period not to exceed [***] months following the date of such earlier termination, which will allow the Licensee to continue selling Licensed Product for the duration of the agreed upon wind down period, provided that Licensee pays to WU the applicable royalty or other amounts due on such Sales of Licensed Product in accordance with the terms and conditions of this Agreement. In the event that the Licensee terminates this Agreement under Section 13.2 or Section 13.4, the parties agree Licensee's obligation under Section 5.3 to pay Non-Patent Royalty Rate on Net Sales, for those Sales of Licensed Product by Licensee and its Affiliates for the applicable term set forth therein shall survive such termination for the remainder of the term as set forth in 13.1.

14 Disclaimer and Limitation of Liability.

NOTWITHSTANDING ANYTHING HEREIN TO THE CONTRARY, EVERYTHING PROVIDED BY WU UNDER THIS AGREEMENT IS UNDERSTOOD TO BE EXPERIMENTAL IN NATURE, MAY HAVE HAZARDOUS PROPERTIES, AND IS PROVIDED WITHOUT ANY WARRANTY OF ANY KIND, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, OR NON-INFRINGEMENT OF ANY THIRD-PARTY PATENT, TRADEMARK, COPYRIGHT OR ANY OTHER THIRD-PARTY RIGHT. WU AND PENN MAKES NO REPRESENTATIONS OR WARRANTIES REGARDING THE QUALITY, ACCURACY, COMMERCIAL VIABILITY, OR ANY OTHER ASPECT OF ITS PERFORMANCE PURSUANT TO THIS AGREEMENT OR REGARDING THE PERFORMANCE, VALIDITY, SAFETY, EFFICACY, OR COMMERCIAL VIABILITY OF ANYTHING PROVIDED BY WU UNDER THIS AGREEMENT. WITH THE EXCEPTION OF LICENSEE'S INDEMNIFICATION OBLIGATIONS UNDER THIS AGREEMENT, IN NO EVENT SHALL WU OR LICENSEE OR PENN BE LIABLE FOR ANY INDIRECT, SPECIAL, OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS AGREEMENT, WHETHER IN BREACH OF CONTRACT, TORT OR OTHERWISE, EVEN IF SUCH PARTY IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. WITH THE EXCEPTION OF LICENSEE'S INDEMNIFICATION OBLIGATIONS UNDER THIS AGREEMENT, EACH PARTY'S AGGREGATE LIABILITY TO THE OTHER UNDER THIS AGREEMENT SHALL NOT EXCEED THE PAYMENTS MADE OR PAYMENTS DUE UNDER THIS AGREEMENT.

15 General Provisions.

15.1 In performing their respective obligations under the Agreement, the parties will comply with United States export control and asset control laws, regulations, and orders, as they may be amended from time to time, applicable to the export or re-export of goods or services, including software, processes, or technical data. WU is providing no representation or warranty regarding the export control status or classification of any information or materials provided hereunder.

15.2 This Agreement embodies the entire understanding of the parties with respect to the subject matter hereof and supersedes all other past and present communications and agreements relating to the subject matter. No amendment or modification of this Agreement shall be valid unless made in writing and signed by authorized representatives of both parties.

15.3 This Agreement shall be governed by and construed in accordance with the laws of the State of Missouri, without regard to its rules or procedures involving conflicts of laws. All actions relating to this Agreement shall be brought exclusively in the United States District Court for the Eastern District of Missouri or the Circuit Court of St. Louis County, Missouri, if no federal subject matter jurisdiction exists. The parties irrevocably waive all present and future objections to personal jurisdiction, forum or venue in such courts.

15.4 Each provision of this Agreement that would by its nature or terms survive, shall survive any termination or expiration of this Agreement, regardless of the cause. Such provisions include, without limitation, Sections 5.3, 6, 7, 11, 12, 13, 14, and 15.

15.5 This Agreement shall be personal to Licensee, and it is not assignable by Licensee to any other person or entity without the prior written consent of WU, such consent to be in WU's sole discretion. Notwithstanding the foregoing, Licensee shall be free to assign this Agreement and its rights and obligations hereunder without WU's consent (a) to any Affiliate or (b) in connection with any sale of substantially all of Licensee's assets or business (or that portion of its assets or business related to the subject matter of this Agreement), merger, acquisition, consolidation, reorganization, or other similar transaction, provided that (i) Licensee shall not be released of its obligations existing at the time of such assignment and (ii) the assignee or successor to this Agreement confirms, in writing, that it will be subject to and must comply with all terms, conditions, and obligations of this Agreement.

15.6 Each party is an independent contractor and not a partner or agent of the other party. This Agreement will not be interpreted or construed as creating or evidencing any partnership or agency between the parties or as imposing any partnership or agency obligation or liability upon either party. Further, neither party is authorized to, and will not, enter into or incur any agreement, contract, commitment, obligation or liability in the name of or otherwise on behalf of the other party.

15.7 If any provision in this Agreement is held invalid, illegal, or unenforceable in any respect, such holding shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if it had never contained the invalid, illegal, or unenforceable provisions.

15.8 The failure of either party to insist upon or enforce strict performance by the other party of any provision of this Agreement, or to exercise any right or remedy under this Agreement will not be interpreted or construed as a waiver or relinquishment of that party's right to assert or rely upon any such provision, right or remedy in that or any other instance; rather, the same will be and remain in full force and effect. All rights and remedies under this Agreement are cumulative of every other such right or remedy and may be exercised concurrently or separately from time-to-time.

15.9 Neither party nor Penn may use the trademarks or name of the other party or Penn or its employees for any commercial, advertisement, or promotional purposes without the prior written consent of an authorized corporate officer of the other party or Penn, as applicable. If either party or Penn is required by law, governmental regulation, or its own authorship or conflict of interest policies to disclose its relationship with the other party or Penn, including, but not limited to, in SEC filings, scientific publications or grant submissions, it shall provide the other party or Penn, as applicable with a copy of the disclosure. If the disclosure is substantially similar to prior disclosures made by the party and for which the obligations of this section have been satisfied, the disclosing party need not share such disclosure ahead of it being made. Notwithstanding the provisions of this Section 15.9, either party or Penn may publicize the existence of, and the parties to, this Agreement, provided, however, that WU and Penn shall not publicize the existence of, or the parties to, this Agreement before Licensee discloses such information by way of required SEC disclosure filing.

15.10 Neither WU nor Licensee will be liable for failure of or delay in performing obligations set forth in this Agreement, and neither will be deemed in breach of its obligations, other than for payments, if such failure or delay is due to natural disasters or other causes reasonably beyond the control of a party and reasonable notice of the delay is provided to the other party.

15.11 Licensee agrees that for all WU faculty or staff members who serve Licensee in the capacity of consultant, officer, employee, board member, advisor, or otherwise through a personal relationship with Licensee (a "Consultant") (a) such Consultant shall serve the Licensee in his or her individual capacity, as an independent contractor, and not as an agent, employee or representative of WU; (b) WU exercises no authority or control over such Consultant while acting in such capacity; (c) WU receives no benefit from such activity; (d) neither Licensee nor the Consultant may use WU resources in the course of such service; (e) WU makes no representations or warranties regarding such service and otherwise assumes no liability or obligation in connection with any such work or service undertaken by such Consultant; and (f) any breach, error, or omission by a Consultant acting in the capacity set forth in this Section shall not be imputed or otherwise attributed to WU, and shall not constitute a breach of this Agreement by WU.

15.12 Each party shall, at the reasonable request of the other, execute and deliver to the other such instruments and/or documents and shall take such actions as may be required to more effectively carry out the terms of this Agreement.

15.13 Licensee acknowledges (a) that WU is exempt from federal income tax under Section 501(c) (3) of the Internal Revenue Code, (b) that maintenance of such exempt status is of critical importance to WU and to its members, and (c) that WU has entered into this Agreement with the expectation that there will be no adverse impact on its tax exempt status. As such, and if it becomes necessary, the parties agree to amend, modify or reform this Agreement as necessary (i) in order to ensure that there is no material adverse impact on WU's tax exempt status, and (ii) in a manner that preserves the economic terms of the Agreement as such are set forth in this Agreement.

15.14 Notices pursuant to this Agreement shall be to the following contacts and are effective when sent if sent by a commercial carrier's overnight delivery service or when received if sent otherwise:

To WU:

Office of Technology Management
Attention: Asst. Vice Chancellor / Director
Washington University in St. Louis
660 South Euclid Avenue, CB 8013
St. Louis, MO 63100

To Licensee:

Ocugen, Inc.
11 Great Valley Parkway
Malvern, PA 19355
Attn: Dr. Shankar Musunuri

With a copy to:
11 Great Valley Parkway
Malvern, PA 19355
Attn: General Counsel

15.15 This Agreement may be executed in counterparts, each of which shall be deemed an original and as executed shall constitute one agreement, binding on both parties, even though both parties do not sign the same counterpart.

15.16 The parties agree that any photocopy or facsimile copy of this fully-executed Agreement shall have the same force and effect as any copy bearing original signatures of the parties. Each party agrees that the respective signatures of the parties hereto may be delivered by facsimile, electronic mail (including .pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com), or other transmission method and that the parties may rely on a signature so delivered as an original, duly and validly delivered, and valid and effective for all purposes.

15.17 Third Party Beneficiary. Penn is not a party to this Agreement and has no liability to Licensee or any user of anything covered by this Agreement, but the parties expressly agree that Penn is an intended third-party beneficiary of this Agreement and certain provisions are for the benefit of Penn and are enforceable by Penn in its own name, including Sections 11, 12, 15.9, and the requirement that Sublicenses include terms and conditions to the benefit of Penn described in Schedule D.

15.18 Dispute Resolution. As a condition precedent to WU exercising its right to terminate this Agreement as contemplated in Section 4.3 and provided in Section 13, the parties shall attempt to resolve such dispute according to the following procedure:

(i) The parties shall negotiate in good faith to resolve the dispute between them regarding this Agreement.

(ii) If such negotiations do not resolve the dispute to the satisfaction of the parties within thirty (30) days (or such longer period as required under this Agreement), either party may elect to present the dispute to the Chief Executive Officer of Licensee and to WU's Managing Director of the Office of Technology Management, who shall meet and confer within thirty (30) days of either party's decision that the recourse provided by Section 15.18(i) above is unlikely to result in satisfaction, in an effort to resolve the dispute.

(iii) In the event the dispute cannot be resolved to the satisfaction of both parties despite efforts in compliance with Sections 15.18(i) and 15.18(ii), then the parties shall consider arbitration or another neutral third party means of resolving the outstanding dispute. The parties will have a period of 10 business days after exhausting the procedures described in Sections 15.18(i) and 15.18(ii) to mutually agree on the use of arbitration or another neutral third party means acceptable to both parties to resolve the dispute. If the parties do not mutually agree to arbitration or neutral third party means after [***] days, then the parties shall have exhausted the dispute resolution provisions in this Section.

SCHEDULE B

Initial Development Plan

[***]

SCHEDULE C

- **Patent Rights**

[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]

- **Tangible Research Property**

[***]

[***]

- **Technical Information**

SCHEDULE D

Sublicensing Rights

1. Licensee may grant sublicenses under the rights granted in Sections 2.1 and 2.2 to third parties by entering into a written agreement with any such third party (each such agreement shall be referred to herein as a "Sublicense" and each such third party shall be referred to herein as a "Sublicensee"). Only Licensee (and not any Sublicensee) may enter into a Sublicense, and each Sublicense shall expressly prohibit the Sublicensee from granting further sublicenses.

2. Licensee will pay WU a running royalty based on Sales of Licensed Products by Sublicensees (a "Sublicensee Running Royalty"). The Sublicensee Running Royalty will be calculated as follows:

- Licensee will pay WU the Patent Royalty Rate of Net Sales, for those Sales by Sublicensees that are subject to the Patent Royalty Rate.
- Licensee will pay WU the Non-Patent Royalty Rate of Net Sales, for those Sales by Sublicensees that are not otherwise subject to the Patent Royalty Rate.

3. A Sale of a Licensed Product will be deemed to have been made at the time Sublicensee first invoices, ships, recognizes or receives value for a Licensed Product. The royalties owed to WU will be paid by Licensee within [***] days after the end of each Calendar Half in which the Sales of the applicable Licensed Products occur.

4. Licensee shall pay to WU the Sublicensing Revenue Percentage (as listed in the Summary of Terms above) of all Sublicensing Revenue within [***] days of the end of the Calendar Half in which Licensee receives the Sublicensing Revenue.

5. Licensee agrees that it will require all Sublicensees to comply with the terms and conditions set forth in this Agreement as applicable to Sublicensee. In furtherance of the foregoing but without limiting the generality thereof, each Sublicense shall, for the express benefit of WU, bind the Sublicensee to terms and conditions no less favorable to WU than those between WU and Licensee contained in this Agreement. To the extent that any term, condition, or limitation of any Sublicense is inconsistent with the terms, conditions and limitations contained in this Agreement, such term, condition, and/or limitation shall be null and void against WU.

6. Licensee will be primarily liable to WU for all acts, errors or omissions of a Sublicensee. Any act, error or omission of a Sublicensee that would be a breach of this Agreement if imputed to Licensee will be deemed to be a breach of this Agreement by Licensee.

7. At Licensee's written request, any Sublicense granted by Licensee under this Agreement will remain in effect in the event that this Agreement is terminated prior to expiration. Any such Sublicensee will automatically become a direct licensee of WU under the rights originally sublicensed to it by Licensee provided the Sublicensee did not cause the termination of this Agreement and the Sublicensee agrees to comply with the terms of this Agreement and to fulfill all the responsibilities of Licensee hereunder. In the event that this Agreement is terminated, all amounts subsequently owed to Licensee with respect to any Sublicense granted under this Agreement shall become paid directly by Sublicensee to WU following the date of termination.

8. Within [***] days after the effective date of any Sublicense, Licensee shall provide WU a complete and accurate copy of the Sublicense, without any redactions, including without limitation any and all exhibits and/or attachments thereto. If the Sublicense is written in a language other than English, the copy of the Sublicense shall be accompanied by a complete translation written in English. Upon delivery of such translation to WU, Licensee shall be deemed to represent and warrant to WU that such translation is a true and accurate translation of the Sublicense.

9. Without in any way narrowing or limiting the scope of the foregoing provisions, all Sublicenses shall contain the terms and conditions set forth below:

a. Sublicensee agrees to indemnify, defend, and hold harmless Indemnitees to the same extent and under terms no less favorable to Indemnitees as Licensee's obligations under Section 11 of this Agreement.

b. Sublicensee agrees to maintain insurance for WU's and Penn's benefit to the same extent and under terms no less favorable to WU and Penn as Licensee's obligations under Section 12 of this Agreement.

c. Sublicensee agrees to maintain books and records and allow audits for WU's benefit to the same extent and under terms no less favorable to WU as Licensee's obligations under this Agreement.

d. If Licensee enters bankruptcy or receivership, voluntarily or involuntarily, Sublicensee Running Royalty and Sublicensing Revenue then or thereafter due to Licensee will, upon notice from WU to any Sublicensee, become directly due and owing to WU for the account of Licensee.

e. Sublicensee shall not consummate a Sale of a Licensed Product for an amount that is less than the fair market value of the Licensed Product.

f. Washington University is a third party beneficiary of the Sublicense, and Penn is a third party beneficiary of the Sublicense with respect to the conditions of subparagraphs 9.a., 9.b., and 9.g.

g. Sublicensee may not use the trademarks or name of WU or Penn for any commercial, advertisement, or promotional purposes without the prior written consent of an authorized officer of WU or Penn, as applicable.

10. In the event that Licensee sublicenses any of the rights or licenses granted in Sections 2.1 and 2.2, in combination with any rights or licenses to any other patents, patent applications, or other forms of intellectual property that are owned or controlled by Licensee and/or any third party (referred to herein as "non-WU IP"), Licensee shall confer with WU and the parties shall agree upon the relative value that will be assigned to (a) the sublicense under the rights and licenses granted in Sections 2.1 and 2.2 of this Agreement and (b) the non-WU IP. The agreed upon relative valuation will then be used to properly calculate the amount of Sublicensing Revenue that will be owed to WU under this Schedule D.

SCHEDULE E

Diligence and Progress Reports

[***]

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 8, 2022 /s/ Shankar Musunuri, Ph.D., MBA

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

Exhibit 31.2

CERTIFICATION

I, Jessica Crespo, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2022 /s/ Jessica Crespo

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

Exhibit 32.1

Certification

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

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

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Ocugen, Inc. (the Company), does hereby certify, to the best of such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 (the Form 10-Q) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2022 /s/ Shankar Musunuri, Ph.D., MBA

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

Date: November 8, 2022 /s/ Jessica Crespo

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

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