

**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, 2019

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
(State or other jurisdiction of
incorporation or organization)

04-3522315
(I.R.S. Employer
Identification No.)

5 Great Valley Parkway, Suite 160
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	OCGN	The Nasdaq Stock Market LLC (The Nasdaq Capital Market)

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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

As of November 7, 2019, there were 16,003,916 outstanding shares of the registrant's common stock, \$0.01 par value per share.

OCUGEN, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2019

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As previously announced, on September 27, 2019, Ocugen, Inc. (formerly known as Histogenics Corporation), completed its reverse merger with Ocugen Opco, Inc. (formerly known as Ocugen, Inc.) ("Former Ocugen"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of April 5, 2019, as amended, by and among Ocugen, Former Ocugen and a wholly owned subsidiary of Ocugen ("Merger Sub") (the "Merger Agreement"), pursuant to which Merger Sub merged with and into Former Ocugen, with Former Ocugen surviving as a wholly owned subsidiary of Ocugen (the "Merger").

For accounting purposes, the Merger is treated as a "reverse asset acquisition" under generally acceptable accounting principles in the United States ("U.S. GAAP") and Former Ocugen is considered the accounting acquirer. Accordingly, Former Ocugen's historical results of operations will replace the Company's historical results of operations for all periods prior to the Merger and, for all periods following the Merger, the results of operations of the combined company will be included in the Company's financial statements.

This quarterly report on Form 10-Q relates to the Company's quarter ended September 30, 2019, which includes the date of the completion of the Merger and is therefore the Company's first periodic report that includes results of operations for the combined company, including Former Ocugen.

Unless the context otherwise requires, references to the "Company," the "combined company" "we," "our" or "us" in this report refer to Ocugen, Inc. (formerly known as Histogenics Corporation) and its subsidiaries, references to "Ocugen" refer to the Company following the completion of the Merger, references to "Histogenics" refer to the Company prior to the completion of the Merger and references to "OpCo" refer to Ocugen OpCo, Inc., the Company's wholly owned subsidiary following the Merger.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), about Ocugen and its subsidiaries. These forward-looking statements are intended to be covered by the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact, and can be identified by the use of forward-looking terminology such as “believes”, “expects”, “may”, “will”, “could”, “should”, “projects”, “plans”, “goal”, “targets”, “potential”, “estimates”, “pro forma”, “seeks”, “intends” or “anticipates” or the negative thereof or comparable terminology. Forward-looking statements include discussions of strategy, financial projections, guidance and estimates (including their underlying assumptions), statements regarding plans, objectives, expectations or consequences of various transactions, and statements about the future performance, operations, products and services of Ocugen and its subsidiaries. We caution our stockholders and other readers not to place undue reliance on such statements.

You should read this report and the documents filed by the Company with the SEC completely and with the understanding that our actual future results may be materially different from what we currently expect. Our business and operations are and will be subject to a variety of risks, uncertainties and other factors. Consequently, actual results and experience may materially differ from those contained in any forward-looking statements. Such risks, uncertainties and other factors that could cause actual results and experience to differ from those projected include, but are not limited to: (i) the risk that Ocugen continues to incur significant losses from operations and continues to incur net losses; (ii) the risk that as a new business, Ocugen may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors; (iii) the risk that as a result of adjustments to or exercise of the Pre-Merger Financing Warrants, stockholders of the combined company could be substantially and materially diluted; (iv) the uncertainties associated with the clinical development and regulatory approval of product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; (v) risks related to the inability of the Company to obtain sufficient additional capital to continue to advance these product candidates and its preclinical programs; (vi) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (vii) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market and the risk that products will not achieve broad market acceptance; and (viii) the other risk factors discussed under the heading “Risk Factors” contained in this report and in any other documents Ocugen files with the SEC.

You should assume that the information appearing in this report is accurate as of its date only. Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. All written or oral forward-looking statements attributable to us or any person acting on our behalf made after the date of this report are expressly qualified in their entirety by the risk factors and cautionary statements contained in this report. Unless legally required, we do not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date of this report or to reflect the occurrence of unanticipated events.

OCUGEN, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	\$ 15,301,082	\$ 1,628,136
Prepaid expenses and other current assets	517,562	313,499
Asset held for sale	7,000,000	—
Total current assets	<u>22,818,644</u>	<u>1,941,635</u>
Property and equipment, net	213,229	245,788
Restricted cash	150,910	150,477
Other assets	436,094	116,333
Total assets	<u>\$ 23,618,877</u>	<u>\$ 2,454,233</u>
Liabilities and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	\$ 5,791,298	\$ 3,277,525
Accrued expenses	1,301,304	1,402,750
Short-term debt, net	—	7,483,847
Derivative liabilities	—	1,741,222
Operating lease obligation	151,530	—
Financing lease obligation	19,838	20,442
Short-term warrant liability	27,964,986	—
Deferred grant proceeds	183,800	183,800
Total current liabilities	<u>35,412,756</u>	<u>14,109,586</u>
Non-current liabilities		
Deferred rent	—	3,739
Operating lease obligation, less current portion	223,853	—
Financing lease obligation, less current portion	17,339	33,720
Long term debt, net	1,058,191	1,016,727
Total non-current liabilities	<u>1,299,383</u>	<u>1,054,186</u>
Total liabilities	<u>36,712,139</u>	<u>15,163,772</u>
Commitments and contingencies (Note 10)		
Stockholders' deficit		
Convertible preferred stock, \$0.01 par value, 10,000,000 shares authorized, 7.0 and zero issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, 200,000,000 (\$0.01 par value) authorized and 10,013,605 and 4,960,552 issued and outstanding at September 30, 2019 and December 31, 2018	100,136	49,606
Accumulated other comprehensive income	—	451
Additional paid-in capital	50,668,493	18,477,598
Accumulated deficit	<u>(63,861,891)</u>	<u>(31,237,194)</u>
Total stockholders' deficit	<u>(13,093,262)</u>	<u>(12,709,539)</u>
Total liabilities and stockholders' deficit	<u>\$ 23,618,877</u>	<u>\$ 2,454,233</u>

See accompanying notes to condensed consolidated financial statements.

OCUGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND
COMPREHENSIVE LOSS

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Operating expenses				
Research and development	\$ 1,305,461	\$ 1,561,286	\$ 6,338,530	\$ 7,405,472
General and administrative	1,408,350	843,165	3,544,847	3,045,562
Total operating expenses	2,713,811	2,404,451	9,883,377	10,451,034
Loss from operations	(2,713,811)	(2,404,451)	(9,883,377)	(10,451,034)
Other income (expense)				
Change in fair value of derivative liabilities	(18,512,204)	1,461,872	(19,896,626)	1,208,525
Loss on debt conversion	—	—	(341,136)	—
Interest income	136	3,762	1,107	17,393
Interest expense	(796,141)	(1,001,545)	(1,753,172)	(3,035,350)
Other income (expense)	(751,261)	7,755	(751,493)	(2,413)
Total other income (expense)	(20,059,470)	471,844	(22,741,320)	(1,811,845)
Net loss	\$ (22,773,281)	\$ (1,932,607)	\$ (32,624,697)	\$ (12,262,879)
Other comprehensive income (loss)				
Foreign currency translation adjustment	—	(133)	(451)	391
Comprehensive loss	\$ (22,773,281)	\$ (1,932,740)	\$ (32,625,148)	\$ (12,262,488)
Net loss per share of common stock — basic and diluted	\$ (3.55)	\$ (0.39)	\$ (5.59)	\$ (2.47)
Weighted average shares outstanding — basic and diluted	6,411,308	4,960,552	5,839,840	4,960,552

See accompanying notes to condensed consolidated financial statements.

OCUGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(Unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	—	\$ —	4,960,552	\$ 49,606	\$ 18,477,598	\$ 451	\$ (31,237,194)	\$ (12,709,539)
Stock-based compensation expense	—	—	—	—	415,202	—	—	415,202
Foreign currency translation adjustment	—	—	—	—	—	(282)	—	(282)
Net loss	—	—	—	—	—	—	(6,312,606)	(6,312,606)
Balance at March 31, 2019	—	\$ —	4,960,552	\$ 49,606	\$ 18,892,800	\$ 169	\$ (37,549,800)	\$ (18,607,225)
Stock-based compensation expense	—	—	—	—	111,807	—	—	111,807
Foreign currency translation adjustment	—	—	—	—	—	(169)	—	(169)
Net loss	—	—	—	—	—	—	(3,538,810)	(3,538,810)
Conversion of debt	—	—	1,125,673	11,257	13,959,622	—	—	13,970,878
Equity transactions	—	—	157,743	1,577	1,956,218	—	—	1,957,796
Balance at June 30, 2019	—	\$ —	6,243,968	\$ 62,440	\$ 34,920,447	\$ —	\$ (41,088,610)	\$ (6,105,723)
Issuance of stock for reverse asset acquisition, net of \$5.0 million of costs	7	—	1,576,655	15,766	2,325,284	—	—	2,341,050
Issuance of common stock under Pre-Merger Financing, net of \$1.8 million of costs	—	—	2,192,982	21,930	13,229,757	—	—	13,251,687
Stock-based compensation expense	—	—	—	—	193,005	—	—	193,005
Net loss	—	—	—	—	—	—	(22,773,281)	(22,773,281)
Balance at September 30, 2019	7	\$ —	10,013,605	\$ 100,136	\$ 50,668,493	\$ —	\$ (63,861,891)	\$ (13,093,262)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2017	4,960,552	\$ 49,606	\$ 17,402,911	\$ —	\$ (13,017,530)	\$ 4,434,987
Stock-based compensation expense	—	—	258,682	—	—	258,682
Foreign currency translation adjustment	—	—	—	(34)	—	(34)
Net loss	—	—	—	—	(5,039,026)	(5,039,026)
Balance at March 31, 2018	4,960,552	\$ 49,606	\$ 17,661,593	\$ (34)	\$ (18,056,556)	\$ (345,391)
Stock-based compensation expense	—	—	261,185	—	—	261,185
Foreign currency translation adjustment	—	—	—	558	—	558
Net loss	—	—	—	—	(5,291,246)	(5,291,246)
Balance at June 30, 2018	4,960,552	\$ 49,606	\$ 17,922,778	\$ 524	\$ (23,347,802)	\$ (5,374,894)
Stock-based compensation expense	—	—	226,216	—	—	226,216
Foreign currency translation adjustment	—	—	—	(133)	—	(133)
Net loss	—	—	—	—	(1,932,607)	(1,932,607)
Balance at September 30, 2018	4,960,552	\$ 49,606	\$ 18,148,994	\$ 391	\$ (25,280,409)	\$ (7,081,418)

See accompanying notes to condensed consolidated financial statements.

OCUGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30,	
	2019	2018
Cash flows from operating activities		
Net loss	\$ (32,624,697)	\$ (12,262,879)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	34,626	35,053
Non-cash interest expense	1,718,546	2,825,669
Change in fair value of derivative liability	19,896,626	(1,208,525)
Stock-based compensation expense	720,014	746,083
Loss on debt conversion	341,136	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(315,612)	(390,541)
Other assets	34,774	(4,203)
Accounts payable and accrued expenses	2,045,228	1,413,621
Deferred rent	—	1,210
Net cash used in operating activities	(8,149,359)	(8,844,512)
Cash flows from investing activities		
Purchase of property and equipment	(2,067)	(77,414)
Payment of reverse asset acquisition costs	(2,334,063)	—
Net cash used in investing activities	(2,336,130)	(77,414)
Cash flows from financing activities		
Financing lease principal payments	(16,985)	(4,782)
Payment of debt issuance costs	(122,262)	—
Proceeds from issuance of convertible debt	6,800,000	6,000,000
Repayment of convertible debt	(5,290,000)	—
Payment of equity issuance costs	(649,254)	(741,178)
Proceeds from Pre-Merger Financing	22,437,537	—
Proceeds from stock subscription	999,832	—
Net cash provided by financing activities	24,158,868	5,254,040
Effect of changes in exchange rate on cash	—	391
Net increase (decrease) in cash, cash equivalents and restricted cash	13,673,379	(3,667,495)
Cash, cash equivalents and restricted cash at beginning of period	1,778,613	6,301,572
Cash, cash equivalents and restricted cash at end of period	\$ 15,451,992	\$ 2,634,077
Supplemental disclosure of non-cash transactions:		
Purchase of fixed assets by entering into capital lease (Note 10)	—	\$ 63,817
Conversion of convertible notes (Note 9)	\$ 13,061,029	—
Conversion of convertible promissory note (Note 9)	\$ 907,502	—
Equity issuance costs (Note 4)	\$ 1,150,000	\$ 598,286
Right-of-use asset related to operating leases (Note 10)	\$ 363,093	—
Reverse asset acquisition costs (Note 4)	\$ 2,711,431	—

See accompanying notes to condensed consolidated financial statements.

OCUGEN, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Nature of Business

Ocugen, Inc. (formerly known as Histogenics Corporation), together with its wholly owned subsidiaries (“Ocugen” or the “Company”), is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies to address rare and underserved eye diseases. The Company is located in Malvern, Pennsylvania.

Ocugen is developing a modifier gene therapy platform for unmet medical needs in the area of retinal diseases, including inherited retinal diseases (“IRDs”). Ocugen’s modifier gene therapy platform is novel in that it targets nuclear hormone receptor (“NHR”) genes which have the potential to restore homeostasis to the retina and may target multiple genes that are associated with a range of IRDs. Unlike single-gene replacement therapies, which only target one genetic mutation, the Company believes that its gene therapy platform, through its targeting of NHRs, may impact multiple genes that are associated with a range of genetically diverse diseases. Ocugen’s first gene therapy candidate, OCU400, has received two Orphan Drug Designation (“ODD”) from the Food and Drug Administration (“FDA”), for the treatment of *NR2E3* mutation-associated retinal diseases and CEP290 mutation-associated retinal diseases. OCU400 uses an adeno-associated virus vector (“AAV”). Ocugen’s second gene therapy product candidate, OCU410, is targeted for dry age-related macular degeneration (“dry AMD”). Currently, there are no FDA-approved therapies to treat this disease.

Ocugen has a late-stage, Phase 3 program, OCU300, which has also received ODD from the FDA. OCU300 is a small molecule therapeutic currently in Phase 3 clinical development for patients with ocular graft-versus-host disease (“oGVHD”). Ocugen is the first and only company to receive ODD for the treatment of oGVHD and is the only company conducting Phase 3 studies in this patient population. OCU300 is formulated using the Company’s proprietary nanoemulsion technology, OcuNanoE — Ocugen’s ONE Platform™ (“OcuNanoE™”).

Ocugen is also developing OCU200, a novel fusion protein for the treatment of wet age-related macular degeneration (“wet AMD”), diabetic retinopathy (“DR”) and diabetic macular edema (“DME”).

Merger with Histogenics

On September 27, 2019, the Company completed its reverse merger with Ocugen, OpCo Inc. (formerly known as Ocugen, Inc. (“Former Ocugen”)) in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of April 5, 2019, by and among Histogenics, Former Ocugen and Restore Merger Sub, Inc., a wholly owned subsidiary of Histogenics (“Merger Sub”), as amended (the “Merger Agreement”), pursuant to which Merger Sub merged with and into Former Ocugen, with Former Ocugen surviving as a wholly owned subsidiary of Histogenics (the “Merger”). Immediately after completion of the Merger, Histogenics changed its name to Ocugen, Inc. and the business conducted by Ocugen, Inc. became the business conducted by Former Ocugen. Former Ocugen is deemed to be the accounting acquirer. Accordingly, the historical financial statements of Former Ocugen became the Company’s historical financial statements, including the comparative prior periods. See Note 4 for additional information.

Reverse Stock Split

In connection with, and immediately prior to the completion of the Merger, Histogenics effected a reverse stock split of the common stock, at a ratio of 1-for-60 (the “Reverse Stock Split”). Under the terms of the Merger Agreement, the Company issued common stock to Former Ocugen’s stockholders at an exchange rate of 0.4794 shares of common stock, after taking into account the Reverse Stock Split, for each share of Former Ocugen’s common stock outstanding immediately prior to the Merger.

The capital structure, including the number of shares of common stock issued appearing in the condensed consolidated balance sheets for the periods presented, reflects that of Ocugen. All references in the condensed consolidated financial statements to the number of shares and per-share amounts of common stock have been retroactively restated to reflect the exchange rate.

Going Concern

The Company has incurred recurring losses and negative cash flows from operations since inception and has funded its operating losses through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes, and debt. The Company incurred net losses of approximately \$32.6 million and \$12.3 million for the nine months ended September 30, 2019 and 2018, respectively, and had an accumulated deficit of \$63.9 million as of September 30, 2019. As of September 30, 2019, the Company had cash, cash equivalents and restricted cash totaling \$15.5 million.

The Company has a limited operating history and its prospects are subject to risks, expenses and uncertainties frequently encountered by companies in its industry. The Company intends to continue its research and development efforts for its product candidates, which will require significant funding. If the Company is unable to obtain additional financing in the future or research and development efforts require higher than anticipated capital, there may be a negative impact on the financial viability of the Company. The Company plans to increase working capital by raising additional capital through either private or public equity or debt financing. Such financing may not be available at all, or on terms that are favorable to the Company. While management of the Company believes that it has a plan to fund ongoing operations, its plan may not be successfully implemented. Failure to generate sufficient cash flows from operations, raise additional capital through one or more financings, or appropriately manage certain discretionary spending could have a material adverse effect on the Company's ability to achieve its intended business objectives.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements included herein have been prepared in conformity with accounting principles generally accepted in the United States ("GAAP") and under the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim reporting. The accompanying 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 note 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 of Former Ocugen for the year ended December 31, 2018. The balance sheet data as of December 31, 2018 was derived from the Company's audited financial statements for the year ended December 31, 2018.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Ocugen, Inc. and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

Foreign Currency Translation and Transactions

The assets and liabilities of the Company's foreign subsidiary are translated into U.S. dollars based on exchange rates in effect at the end of each period. Revenues and expenses are translated at average exchange rates during the periods. Currency transaction gains or losses are included in other expenses. Gains or losses from balance sheet translation are included in accumulated other comprehensive income.

Use of Estimates

In preparing condensed consolidated financial statements in conformity with GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting period. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions. These estimates and assumptions include those used in the valuation of share-based payment arrangements, warrants, and embedded conversion features on the convertible notes.

Asset Held for Sale

An asset is considered to be held for sale when all of the following criteria are met: (i) management commits to a plan to sell the asset; (ii) it is unlikely that the disposal plan will be significantly modified or discontinued; (iii) the asset is available for immediate sale in its present condition; (iv) actions required to complete the sale of the asset have been initiated; (v) sale of the asset is probable and the completed sale is expected to occur within one year; and (vi) the asset is actively being marketed for sale at a price that is reasonable given its current market value.

A long-lived asset classified as held for sale is measured at the lower of its carrying amount or fair value less cost to sell. If the long-lived asset is newly acquired, the carrying amount of the long-lived asset is established based on its fair value less cost to sell at the acquisition date. A long-lived asset is not depreciated or amortized while it is classified as held for sale.

As of September 30, 2019, Ocugen had an intangible asset held for sale acquired from Histogenics with a fair value less cost of sell of \$7.0 million. See Notes 4 and 12 for additional information.

Fair Value Measurements

The company follows the provisions of the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") Topic 820, *Fair Value Measurements* ("ASC 820"), which defines fair value as used in numerous accounting pronouncements, establishes a framework for measuring fair value and expands disclosure of fair measurements.

The estimated fair value of certain financial instruments, cash and cash equivalents, accounts payable, and accrued expenses are carried at historical cost basis, which approximates their fair values because of the short-term nature of these instruments.

ASC 820 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 company has derivative instruments that are fair valued on a recurring basis using Level 3 inputs.

Financial Instruments Indexed to and Potentially Settled in Common Stock

The Company accounts for warrants in accordance with ASC Topic 815-40, *Derivatives and Hedging — Contracts in Entity’s Own Equity* (“ASC 815-40”), which is the authoritative guidance on accounting for derivative financial instruments indexed to and potentially settled in a company’s own stock. To determine whether a contract is considered indexed to the issuer’s own equity, the Company performs a two-step analysis:

Step 1 — Evaluate whether the contract contains any exercise contingencies and, if so, whether they disqualify the contract from being classified as equity, and

Step 2 — Assess whether the settlement terms are consistent with equity classification.

The Company classifies the liability-designated warrants on its condensed consolidated balance sheet as a derivative liability which is recognized at fair value at each reporting period subsequent to the initial issuance. Changes in the fair value of derivatives are recognized as other income (expense) in the condensed consolidated statements of operations and comprehensive loss.

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 and cash equivalents 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 United States government and United States government agency obligations. The Company’s restricted cash balance consists of cash held to collateralize a corporate credit card account.

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

	As of September 30,	
	2019	2018
Cash, cash equivalents and restricted cash reconciliation:		
Cash and cash equivalents	\$ 15,301,082	\$ 2,483,749
Restricted cash	150,910	150,328
Total cash, cash equivalents and restricted cash	<u>\$ 15,451,992</u>	<u>\$ 2,634,077</u>

3. Recent Accounting Pronouncements**Recently Adopted Accounting Standards**

In February 2016, the FASB issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases (Topic 842)* (“ASC 842”). In July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842, Leases* (“ASU 2018-10”), which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU No. 2018-11, *Leases (Topic 842)—Targeted Improvements* (“ASU 2018-11”), which addressed implementation issues related to the new lease standard. These and certain other lease-related ASUs have generally been codified in ASC 842. ASC 842 supersedes the lease accounting requirements in ASC Topic 840, *Leases* (“ASC 840”). ASC 842 establishes a right-of-use model that requires a lessee to record a right-of-use (“ROU”) asset and a lease liability on the balance sheet for all leases. Under ASC 842, leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The standard also requires disclosures to help investors and other financial statement users better understand the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 was effective for annual reporting periods beginning after December 15, 2018 and interim periods within that reporting period. The Company adopted ASC 842 on January 1, 2019 using the effective date transition method. Prior period results continue to be presented under ASC 840 based on the accounting standards originally in effect for such periods.

The Company has elected certain practical expedients permitted under the transition guidance within ASC 842 to leases that commenced before January 1, 2019, including the package of practical expedients. The election of the package of practical expedients resulted in the Company not reassessing prior conclusions under ASC 840 related to lease identification, lease classification and initial direct costs for expired and existing leases prior to January 1, 2019. The Company did not elect the practical expedient to not record short-term leases on its consolidated balance sheet. The adoption of ASU 2016-02 did not have a significant impact on the Company's consolidated results of operations or cash flows. Upon adoption, the Company recognized an ROU asset and lease liability of \$0.4 million and \$0.4 million, respectively. See Note 10 for additional information.

4. Merger and Financing

Pre-Merger Financing

In June 2019, Former Ocugen and Histogenics entered into a Securities Purchase Agreement (as amended, the "Financing SPA") with certain accredited investors (the "Investors"). Pursuant to the Financing SPA, among other things, (i) immediately prior to the Merger, Former Ocugen issued 4,574,272 shares of common stock to the Investors (the "Initial Shares" and, as converted pursuant to the exchange rate in the Merger into the right to receive approximately 2.2 million shares the Company's common stock, the "Converted Initial Shares"), (ii) immediately prior to the Merger, Former Ocugen issued and deposited 4,574,272 shares of common stock into escrow on behalf of the Investors (the "Additional Shares" and, as converted pursuant to the exchange rate in the Merger, into the right to receive approximately 2.2 million shares of the Company's common stock, the "Converted Additional Shares") and (iii) the Company agreed to issue, on the fifth trading day following the consummation of the Merger, three series of warrants to purchase shares of the Company's common stock (the "Series A Warrants," the "Series B Warrants" and the "Series C Warrants" and collectively, the "Pre-Merger Financing Warrants") in exchange for an aggregate purchase price of \$25.0 million ("Pre-Merger Financing").

Approximately \$2.5 million of the \$25.0 million Pre-Merger Financing was utilized to pay transaction costs related to the Merger and the Pre-Merger Financing in the form of equity. In addition, the Company utilized \$5.3 million of the Pre-Merger Financing for the repayment of the Senior Secured Notes, as defined in Note 9. As a result, the Company received total net proceeds of \$17.2 million from the Pre-Merger Financing. The Company incurred \$1.8 million in equity issuance costs related to the Pre-Merger Financing, of which \$0.6 million was paid in cash and \$1.2 million was paid with equity as of September 30, 2019. Approximately \$1.0 million of equity issuance costs was allocated to the Series A Warrants and Series C Warrants and is included in additional paid-in capital. Approximately \$0.8 million of issuance costs allocated to the Series B Warrant liability were expensed and are reflected in other income (expense) on the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2019.

Merger with Histogenics

On September 27, 2019, the Company completed the Merger in accordance with the terms of the Merger Agreement. The Merger was structured as a stock-for-stock transaction whereby all of Former Ocugen's outstanding shares of common stock and securities convertible into or exercisable for Former Ocugen's common stock were converted into the right to receive Histogenics' common stock and securities convertible into or exercisable for Histogenics' common stock. Immediately following the Merger, the former equity holders of Former Ocugen owned 84.25% of the outstanding capital stock of the Company, and the equity holders of the Company immediately before the Merger owned 15.75% of the outstanding capital stock of the Company, including the Initial Shares but excluding the Additional Shares and the Pre-Merger Financing Warrants pursuant to the Financing SPA.

In accordance with ASC Topic 805, *Business Combinations* ("ASC 805"), the Company concluded that, while Histogenics is the legal acquirer, Former Ocugen is the accounting acquirer due to the fact that (i) Former Ocugen's shareholders have the majority of the voting rights in Ocugen, (ii) Former Ocugen holds all of the board seats of the combined company and (iii) Former Ocugen management holds all key positions in the management of the combined company. The Company has further concluded that Histogenics does not meet the definition of a business under ASC 805 due to the fact that substantially all of the fair value of the gross assets disposed of is concentrated in a single identifiable asset or a group of similar identifiable assets. Therefore, the Merger will be accounted for as a reverse asset acquisition. The Company incurred \$5.0 million in transaction costs related to the Merger, of which \$2.3 million was paid in cash and \$2.3 million was paid with equity as of September 30, 2019.

Assets and liabilities of Histogenics on September 27, 2019 were as follows (in thousands):

	September 27, 2019
Cash and cash equivalents	\$ 291
Asset held for sale	7,000
Accounts payable	(1,162)
Net assets acquired	<u>\$ 6,129</u>

Asset Held for Sale

In connection with the Merger, on May 8, 2019, Histogenics entered into an asset purchase agreement (the “Asset Purchase Agreement”) with Medavate Corp., a Colorado corporation (“Medavate”), pursuant to which Histogenics agreed to sell substantially all of its assets relating to its NeoCart™ program, including, without limitation, intellectual property, business and license agreements and clinical trial data (the “Assets”) in return for a cash payment of \$6.5 million. On September 26, 2019, the parties entered into an amendment to the Asset Purchase Agreement whereby the closing date was amended to October 4, 2019. On October 4, 2019, the parties entered into a second amendment (the “Second Amendment”) to the Asset Purchase Agreement whereby the purchase price was increased to \$7.0 million under the Asset Purchase Agreement and the closing date of the Asset Purchase Agreement was revised from October 4, 2019 to two business days after Medavate obtains financing in an amount no less than the purchase price (the “Closing Date”). The Second Amendment further provides that if the Closing Date does not occur on or prior to October 31, 2019, Ocugen may choose to terminate the Asset Purchase Agreement without recourse and, if Ocugen does not terminate the Asset Purchase Agreement, the purchase price shall increase 10% per month (or any portion thereof) between October 31, 2019 and the Closing Date. The NeoCart™ asset qualifies as held for sale as of the date of the reverse asset acquisition and is carried at a fair value less cost to sell on the condensed consolidated balance sheet as of September 30, 2019. The Closing Date did not occur as of October 31, 2019 and Ocugen did not terminate the agreement. See Note 12 for additional information.

Medinet Agreement

In December 2017, Histogenics entered into the License and Commercialization Agreement (the “License Agreement”) with MEDINET Co., Ltd. (“MEDINET”) to grant MEDINET a license under certain patents, patent applications, know-how, and technology to develop and commercialize certain therapeutic products related to the NeoCart™ program. As consideration for the granting of the license, MEDINET agreed to pay Histogenics a non-refundable upfront cash payment of \$10.0 million which was received in January 2018. Based on the results of the NeoCart™ research, Histogenics suspended the NeoCart™ program. Subsequently, since MEDINET relied on the NeoCart™ product to supply clinical trial patients, MEDINET suspended the development of its clinical trial. As of September 30, 2019, the contract with MEDINET was wholly unperformed. As a result of the expected sale of the NeoCart™ asset, the Company does not expect to retain any future obligations related to the MEDINET agreement.

The NeoCart™ asset held for sale was valued based on a quoted price of \$7.0 million, which is an observable Level 2 fair value input.

5. 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, 2019 and 2018:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Net loss	\$ (22,773,281)	\$ (1,932,607)	\$ (32,624,697)	\$ (12,262,879)
Weighted average shares of common stock outstanding	6,411,308	4,960,552	5,839,840	4,960,552
Net loss per shares of common stock—basic and diluted	<u>\$ (3.55)</u>	<u>\$ (0.39)</u>	<u>\$ (5.59)</u>	<u>\$ (2.47)</u>

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,	
	2019	2018	2019	2018
Options to purchase common stock	500,933	473,647	500,933	473,647
Warrants(1)	870,020	870,020	870,020	870,020
Series A Warrants	8,771,928	—	8,771,928	—
Series B Warrants(2)	8,007,461	—	8,007,461	—
Series C Warrants	50,000,000	—	50,000,000	—
Total	<u>68,150,342</u>	<u>1,343,667</u>	<u>68,150,342</u>	<u>1,343,667</u>

(1) With the exception of the application of the exchange rate of 0.4794 to the outstanding options and warrants, the terms and conditions related to the options and warrants existing prior to the Merger were not revised.

(2) Warrants do not include additional Series B Warrants that are contingent upon reset pricing as discussed in Note 11.

Subsequent to September 30, 2019, the Pre-Merger Financing Warrants were amended to reduce the number of Series C Warrants, among other things. See Note 12 for additional information.

6. License and Collaboration Agreements

Collaboration Agreement with CanSino Biologics

On September 27, 2019, Ocugen entered into a co-development and commercialization agreement (the “CanSinoBIO Agreement”) with CanSino Biologics Inc. (“CanSinoBIO”) with respect to the development and commercialization of the gene therapy product candidate, OCU400, for the treatment of NR2E3 Mutation-Associated Retinal Degeneration, Leber Congenital Amaurosis, Bardet-Biedl Syndrome and Rhodopsin Mutation-Associated Retinal Degeneration.

CanSinoBIO will be responsible for all the costs for chemistry, manufacturing and control development and manufacture of clinical supplies of OCU400 for all territories. CanSinoBIO will be solely responsible for all other costs and expenses of its development activities in the CanSinoBIO territory (Greater China, Hong Kong, Macao, and Taiwan) and Ocugen will be responsible for all other costs and expenses of its development activities in the Ocugen territory (outside of CanSinoBIO territory). CanSinoBIO will pay to Ocugen an annual royalty between mid to high-single digits based on net sales of products in the CanSinoBIO territory, and Ocugen will pay to CanSinoBIO an annual royalty between low to mid-single digits based on net sales of products in the Ocugen territory.

Unless terminated earlier, the CanSinoBIO Agreement will continue in force on a country-by-country and product-by-product basis until the later of (a) the expiration of the last valid claim of patent rights of Ocugen covering such product and (b) the tenth (10th) anniversary of the first commercial sale of such product in such country. The CanSinoBIO Agreement will also terminate upon the termination of the Exclusive License Agreement, dated December 19, 2017, between Ocugen and Schepens Eye Research Institute, Inc. The CanSinoBIO Agreement may be terminated by either party in its entirety upon (a) a material breach of the Agreement by the other party, (b) a challenge by the other party or any of its affiliates of any intellectual property controlled by the terminating party or (c) bankruptcy or insolvency of the other party. Within forty-five (45) days after such termination, CanSinoBIO shall provide Ocugen with a statement of the CanSinoBIO development costs and, within one (1) year after receipt of such report, Ocugen shall reimburse CanSinoBIO all such CanSinoBIO development costs.

7. Balance Sheet Detail

Accrued Expenses are as follows:

	September 30, 2019	December 31, 2018
Accrued expenses:		
Research and development	\$ 60,315	\$ 705,436
Clinical	243,461	469,473
Consulting	85,508	86,619
Employee-related	531,078	123,372
Legal	380,942	17,850
Total	<u>\$ 1,301,304</u>	<u>\$ 1,402,750</u>

8. Equity Transactions

On April 5, 2019, Former Ocugen entered into a Stock Subscription Agreement (“Subscription Agreement”) with existing investors for the sale of 80,572 shares of common stock for \$1.0 million, or \$12.41 per share. This capital raise triggered the conversion features on the convertible debt described below.

On December 13, 2018, Former Ocugen entered into a service agreement with a financial advisor. Pursuant to this agreement, in June 2019, 77,171 shares of common stock of Former Ocugen were issued at \$12.41 per share for services rendered. These services totaling \$1.0 million are related to the Merger and are therefore reflected in the supplemental disclosure of non-cash transactions included in the condensed consolidated statements of cash flows.

9. Debt

EB-5 Loan

In September 2016, pursuant to the U.S. government’s Immigrant Investor Program, commonly known as the EB-5 program (the “EB-5 Program”), the Company entered into an arrangement (the “EB-5 Loan Agreement”) to borrow up to \$10.0 million from EB5 Life Sciences, L.P. (the “Lender”) in \$0.5 million increments. Borrowing may be limited by the amount of funds raised by the Lender 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 products and for the general working capital needs of the Company. Outstanding borrowings pursuant to the EB-5 Program become due upon the seventh anniversary of the final disbursement. Amounts repaid cannot be re-borrowed. The EB-5 note is secured by substantially all assets of the Company, except for any patents, patent applications, pending patents, patent license, patent sublicense, trademarks, and other intellectual property rights.

In September 2016, \$0.5 million was borrowed by the Company followed by another borrowing of \$0.5 million in December 2016. Issuance costs for these borrowings totaled \$103,887. Amortization of debt issuance costs amounted to approximately \$3,710 for the three months ended September 30, 2019 and 2018, and approximately \$11,131 for the nine months ended September 30, 2019 and 2018, and is included in interest expense.

At September 30, 2019, there is \$1.0 million of principal outstanding which has accrued interest of approximately \$10,000 during the three months ended September 30, 2019 and 2018, respectively, and \$30,000 during the nine months ended September 30, 2019 and 2018. As of September 30, 2019, total accrued interest is approximately \$118,000. As of September 30, 2019, and December 31, 2018, the Company believes the fair value of the EB-5 note approximates its carrying value due to the nature of the loan and the similarity between the interest rate on the Note and prevailing interest rates.

Convertible Notes

During the year ended December 31, 2018, the Company issued convertible notes (the “Notes”) to new and existing stockholders in the Company, including Notes in the aggregate principal amount of \$3.35 million to members of the Board of Directors. As of September 30, 2019, all Notes had been converted and were no longer outstanding.

At issuance, the following amounts were recorded:

Note Issuance Date	Note Principal Amount	Fair Value of Conversion Feature	Fair Value of Change in Control Feature	Debt Issuance Costs	Carrying Amount of the Note	Maturity Date
January 2018	\$ 5,000,000	\$ (2,579,074)	\$ (78,637)	\$ (35,969)	\$ 2,306,320	July 2019
June 2018	1,000,000	(714,041)	(10,175)	(3,000)	272,784	Dec. 2019
November 2018	1,150,400	—	(21,127)	(50,646)	1,078,627	May 2020
December 2018	150,000	—	(2,857)	(14,310)	132,833	May 2020
Total	\$ 7,300,400	\$ (3,293,115)	\$ (112,796)	\$ (103,925)	\$ 3,790,564	

During the nine months ended September 30, 2019, the Company issued additional Notes to new and existing stockholders in the Company, including a Note in the principal amount of \$0.1 million to a member of the Board of Directors. At issuance, the following amounts were recorded:

Note Issuance Date	Note Principal Amount	Fair Value of Conversion Feature	Fair Value of Change in Control Feature	Debt Issuance Costs	Carrying Amount of the Note	Maturity Date
January 2019	\$ 450,000	\$ (172,227)	\$ (10,655)	\$ (29,358)	\$ 237,760	May 2020
February 2019	1,000,000	(284,448)	(17,931)	(55,875)	641,746	June 2020
Total	\$ 1,450,000	\$ (456,675)	\$ (28,586)	\$ (85,233)	\$ 879,506	

All Notes accrued interest at a rate of 5% per annum and had scheduled maturity dates on the eighteenth month anniversary of the date of the issuance of the Notes (the "Maturity Date"). If prior to the Maturity Date, there is a consummation of the sale of all or substantially all of the assets of the Company, change in control or event of default, the Notes become due and payable at an amount equal to 1.5 times the principal amount of the Notes together with all accrued interest (the "Change in Control Feature").

With regard to the Notes issued in January 2018 and June 2018, if the Company receives equity financing from the issuance of stock of the Company from an investor or group of investors in a transaction or series of related transactions resulting in gross proceeds to the Company of at least \$15.0 million, including the conversion of outstanding indebtedness under these Notes, the principal amount and all interest accrued but not paid through the closing date of the qualified equity financing shall automatically convert into the same class of equity securities as those issued in the qualified equity financing at a price per share equal to a 30% discount to the lowest price per share being paid by investors in the qualified equity financing.

With regard to the Notes issued in November 2018 and December 2018, if the Company receives equity financing from the issuance of stock of the Company from an investor or group of investors in a transaction or series of related transactions resulting in gross proceeds to the Company of at least \$4.0 million, including the conversion of outstanding indebtedness under these Notes, the principal amount and all interest accrued but not paid through the closing date of the qualified equity financing shall automatically convert into the same class of equity securities as those issued in the qualified equity financing at a price per share equal to the lowest price per share being paid by investors in the qualified equity financing.

With regard to the notes issued in January 2019 and February 2019, if the Company receives equity financing from the issuance of stock of the Company from an investor or group of investors in a transaction or series of related transactions resulting in gross proceeds to the Company of at least \$10.0 million, including the conversion of outstanding indebtedness under these Notes, the principal amount and all interest accrued but not paid through the closing date of the qualified equity financing shall automatically convert into the same class of equity securities as those issued in the qualified equity financing at a price per share equal to a 15% discount to the lowest price per share being paid by investors in the qualified equity financing.

The Company bifurcated the conversion feature upon a qualified equity financing for the January 2018, June 2018, January 2019, and February 2019 notes and classified it as a derivative liability because the conversion feature does not have a fixed conversion price and conversion will be settled in a variable number of shares of common stock. There is no bifurcated conversion feature for the November 2018 and December 2018 notes as there is no discount to the lowest equity price triggering conversion.

The Company also bifurcated the Change in Control Feature for all of the Notes because it was determined to be a redemption feature not clearly and closely related to the debt host. The fair value of both of the embedded features was accounted for as a derivative liability and was recorded as a discount on the Notes. Inputs used in valuation are unobservable and therefore considered Level 3 in the fair value hierarchy. The debt discount is accreted into interest

expense over the expected time until conversion of the Notes. The accretion amounted to zero and \$0.9 million in the three months ended September 30, 2019 and 2018, and \$0.5 million and \$2.8 million, in the nine months ended September 30, 2019 and 2018, respectively.

The fair value of the embedded features was classified as a liability in the Company's condensed consolidated balance sheets at issuance, with subsequent changes in fair value during the three and nine months ended September 30, 2019 and 2018 recorded on the Company's condensed consolidated statements of operations and comprehensive loss as a change in fair value of derivative liabilities.

	Conversion feature	Change in Control feature
Balance at January 1, 2019	\$ 1,623,009	\$ 118,213
Fair value at issuance — January 2019 notes	172,227	10,655
Fair value at issuance — February 2019 notes	284,448	17,931
Change in fair value of embedded derivatives	1,531,221	(146,799)
Balance at April 5, 2019	<u>\$ 3,610,905</u>	<u>\$ —</u>

The Company considered several possible outcomes in the likelihood and timing of a qualified equity financing and/or a change in control occurring that would trigger conversion or redemption and believes the amounts disclosed above based on inputs utilized in the valuation are the best estimates at each valuation date.

As a result of the Subscription Agreement transaction (Note 8), the triggers for conversion were met for the Notes. On April 5, 2019, the Notes converted with a discount of 30%, which is consistent with the terms of the Notes issued in January 2018 and June 2018, but differs from the 0% discount per the terms of the November 2018, December 2018, January 2019, and February 2019 Notes and the 15% discount per the terms of the January 2019 and February 2019 Notes. The Notes were modified to change the discount percentage from 0% and 15% to 30% at the time of conversion. The Company issued 1,052,358 shares of common stock at 30% discount at \$8.69 per share on the date of conversion to extinguish the debt, which resulted in a loss of \$0.3 million. This non-cash transaction also resulted in an increase of \$13.0 million in additional paid-in capital, which was based on the principal balance outstanding and the unpaid interest upon conversion.

Convertible Promissory Notes

On April 4, 2019, the Company issued the convertible promissory note (the "Promissory Note") to existing stockholder for \$900,000 at 5% interest rate per annum. As of September 30, 2019, the Promissory Note had been converted and was no longer outstanding.

The Promissory Note matured at the earlier of (a) a sale of substantially all of the assets of the Company, (b) the consummation of a reorganization, merger, or consolidation of the Company with another entity or a person, (c) upon a change in control, or (d) July 30, 2019. The Promissory Note also provided the holder an option to convert the Promissory Note into common stock at a price per share equal to \$12.41.

The Company bifurcated the embedded redemption feature, which allows for redemption upon a change in control at 1.5 times principal and unpaid interest, as it was determined to be a redemption feature not clearly and closely related to the debt host. The redemption feature was classified it as a derivative liability and recognized at fair value.

For purposes of estimating the fair market value of the derivative liability, the Company used a with and without model. The Company considered several possible outcomes in the likelihood and timing of and/or a change in control occurring that would trigger redemption and believes the amounts utilized in the valuation are the best estimates of such amounts at each valuation date. The possible outcomes are impacted by the Company's current capital raising plans and its need for additional funding to continue its development efforts. The inputs used in valuation are unobservable and classified as Level 3 inputs in the fair value hierarchy.

At issuance, the following amounts were recorded:

<u>Note Issuance Date</u>	<u>Note Principal Amount</u>	<u>Fair Value of Redemption Feature</u>	<u>Carrying Amount of the Note</u>	<u>Conversion Date</u>
April 2019	\$ 900,000	\$ (18,053)	\$ 881,947	May 2019

On May 16, 2019, the Promissory Note was converted into equity. Former Ocugen issued 73,315 shares of common stock at the conversion date to extinguish the debt at \$12.41 per share. This non-cash transaction resulted in an increase of \$0.9 million in additional paid-in capital, which was based on the principal balance outstanding and the unpaid interest upon conversion.

Senior Secured Convertible Notes

On May 21, 2019, the Company issued senior secured convertible notes to certain Investors for \$2.4 million at an original issue discount of \$0.5 million, and on June 28, 2019, the Company entered into an agreement to issue additional senior secured convertible notes to the Investors for \$2.9 million with an original issue discount of \$0.4 million (together "Senior Secured Notes").

The Senior Secured Notes were secured by the intellectual property of the Company. Immediately prior to the Merger completed on September 27, 2019, the Investors offset \$5.3 million from the amount to be received under the Pre-Merger Financing and the Senior Secured Notes were deemed to have been repaid and cancelled.

The holders also had an option to convert Senior Secured Notes into common stock at a price per share equal to \$10.80 per share at any time after the issuance date. The conversion amount includes unpaid principal, interest and any late fees. The Company assessed the conversion feature and determined that the related value associated with the conversion feature was immaterial.

The Company bifurcated the redemption feature, which allowed for redemption upon default at 1.35 times principal and unpaid interest, and classified it as a derivative liability recognized at fair value.

For purposes of estimating the fair value of the embedded redemption feature, the Company used a with and without model. The inputs used in valuation are unobservable and are considered Level 3 fair value inputs, and include the likelihood and timing of a qualified financing and/or a default occurring that would trigger redemption.

At issuance, the following amounts were recorded:

<u>Note Issuance Date</u>	<u>Note Principal Amount</u>	<u>Fair Value of Redemption Feature</u>	<u>Original Issue Discount</u>	<u>Debt Issuance Costs</u>	<u>Carrying Amount of the Note</u>	<u>Maturity Date</u>
May 2019	\$ 2,415,000	\$ (41,398)	\$ (465,000)	\$ (13,969)	\$ 1,894,633	Sept 2019
June 2019	2,875,000	(22,949)	(375,000)	—	2,477,051	Sept 2019
Total	\$ 5,290,000	\$ (64,347)	\$ (840,000)	\$ (13,969)	\$ 4,371,684	

The accretion of the original issue discount amounted to \$0.7 million and \$0.8 million during the three and nine months ended September 30, 2019, respectively.

10. Commitments

Operating 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 has lease agreements which include lease and non-lease components, which the Company has elected to account for as a single lease component for all classes of underlying assets. Lease expense for variable lease components are recognized when the obligation is probable.

Operating leases are included in other assets and lease obligations on the Company's consolidated balance sheets. Operating lease ROU assets and liabilities are recognized at 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. The Company primarily leases buildings (real estate) which are classified as operating leases. ASC 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. As an implicit interest rate is not readily determinable in the Company's leases, the incremental borrowing rate is used based on the information available at commencement date in determining the present value of lease payments.

The lease term for all of the Company's leases includes the non-cancellable period of the lease plus any additional periods covered by either a Company 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. Options for lease renewals have been excluded from the lease term (and lease liability) for the majority of the Company's leases as the reasonably certain threshold is not met.

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

Variable lease payments not dependent on a rate or index associated with the Company's leases are recognized when the event, activity, or circumstance in the lease agreement on which those payments are assessed as probable. Variable lease payments are presented as operating expenses in the Company's income statement in the same line item as expense arising from fixed lease payments.

The Company has commitments under operating leases for certain facilities used in its operations. The Company's leases have initial lease terms ranging from one to five years. Certain lease agreements contain provisions for future rent increases.

The components of lease expense were as follows:

	<u>Three Months Ended September 30, 2019</u>	<u>Nine Months Ended September 30, 2019</u>
Operating lease cost	\$ 47,696	\$ 202,665
Variable lease cost	21,284	58,163
Total lease cost	<u>\$ 68,980</u>	<u>\$ 260,828</u>

Supplemental balance sheet information related to leases was as follows:

	<u>September 30, 2019</u>
Right-of-use assets, net	<u>\$ 385,094</u>
Current lease obligations	\$ 151,530
Non-current lease obligations	223,853
Total lease liabilities	<u>\$ 375,383</u>

Supplemental cash flow information and other information related to leases was as follows:

	Nine Months Ended September 30, 2019
Cash paid for amounts included in measurement of liabilities:	
Operating cash flows from operating leases	\$ 260,828
Right-of-use assets obtained in exchange for new operating liabilities	\$ 245,974
Weighted-average remaining lease terms—operating leases (years)	2.25
Weighted-average discount rate—operating leases	7.6%

Future minimum operating minimum lease payments for all leases, exclusive of taxes and other carrying charges, are approximately as follows:

For the Years Ending December 31,	Amount
Remainder of 2019	\$ 47,052
2020	191,555
2021	165,574
2022	22,707
Total	\$ 426,888
Less: present value adjustment	(51,505)
Present value of minimum lease payments	\$ 375,383

The Company does not have any leases that have not yet commenced which are significant.

Financing Leases

In June 2018, the Company leased specialized research equipment under a lease classified as a financing lease. The leased equipment is amortized on a straight-line basis over five years. Total accumulated amortization related to the leased equipment is \$15,954 at September 30, 2019, of which \$3,191 and \$9,573 were recognized in the three and nine months ended September 30, 2019. The following is a schedule showing the future minimum lease payments under financing leases by years and the present value of the minimum lease payments as of September 30, 2019. The interest rate related to the lease obligation is 7.6 percent and the maturity date is July 2021.

Future minimum lease payments for all financing leases, exclusive of taxes and other carrying charges, are approximately as follows:

For the Years Ending December 31,	Amount
Remainder of 2019	\$ 5,964
2020	23,856
2021	11,929
Total	\$ 41,749
Less: present value adjustment	(4,572)
Present value of minimum lease payments	\$ 37,177

11. Pre-Merger Financing Warrants

On September 27, 2019, Ocugen completed the Merger with Former Ocugen. Immediately prior to the Merger, Ocugen and Former Ocugen completed a previously announced private placement transaction with certain Investors pursuant to the Financing SPA, whereby, among other things, (i) Former Ocugen issued to the Investors shares of Former Ocugen's common stock, (ii) Former Ocugen issued and deposited additional shares of Former Ocugen's

common stock into escrow, and (iii) the Company agreed to issue on the fifth trading day following the consummation of the Merger, Series A Warrants, Series B Warrants, and Series C Warrants.

The Pre-Merger Financing Warrants are subject to blocker provisions which restricts the exercise of the Pre-Merger Financing Warrants if, as a result of such exercise, the holder, together with its affiliates would beneficially own in excess of 4.99% or 9.99% of the outstanding common stock, including the common shares issuable upon such exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Merger Financing Warrants.

If Ocugen fails to issue to a holder of the Pre-Merger Financing Warrants the number of shares of common stock to which such holder is entitled upon such holder's exercise of the such warrants, then Ocugen shall be obligated to pay the holder on each day while such failure is continuing an amount equal to 2.0% of the market value of the undelivered shares determined using any trading price of the common stock selected by the holder while the failure is continuing and if the holder purchases shares of common stock in connection with such failure, then Ocugen must, at the holder's discretion, reimburse the holder for the cost of such shares or deliver the owed shares and reimburse the holder for the difference between the price such holder paid for the shares and the market price of such shares, measured at any time of the holder's choosing while the delivery failure was continuing.

Series A Warrants

The Series A Warrants have an initial exercise price per share of \$7.13, were exercisable upon issuance and have a term of 60 months from the date of issuance. The Series A Warrants are exercisable for an amount of Ocugen common stock up to the amount issuable upon consummation of the Merger in exchange for 200% of the sum of (i) the number of Converted Initial Shares and (ii) the number of Converted Additional Shares without giving effect to any limitation on delivery contained in the Finance SPA, purchased by the holder.

The Series A Warrants have an anti-dilution adjustment whereby if Ocugen issues or sells, enters into a definitive, binding agreement pursuant to which Ocugen is required to issue or sell or is deemed, pursuant to the provisions of the Series A Warrants, to have issued or sold, any common stock for a price per share lower than the exercise price then in effect (a "Dilutive Issuance"), subject to certain limited exceptions, then (i) the exercise price of the Series A Warrants shall be reduced to such lower price per share and (ii) the number of shares issuable upon exercise of the Series A Warrants shall be increased to the number of shares of common stock determined by multiplying (a) the exercise price in effect immediately prior to such Dilutive Issuance by (b) the number of shares of common stock issuable upon exercise of the Series A Warrants immediately prior to such Dilutive Issuance (without giving effect to any limitation on exercise contained therein), and dividing the product thereof by the exercise price resulting from such Dilutive Issuance.

Series B Warrants

The Series B Warrants have an exercise price of \$0.01, were exercisable upon issuance and will expire on the day following the later to occur of (i) the 45th trading day immediately following the earlier to occur of (a) the first date on which the holders can sell all the shares issuable upon exercise of the Series A Warrants and Series B Warrants without restriction or limitation pursuant to Rule 144 under the Securities Act, and without the requirement to be in compliance with Rule 144(c)(1) and (b) October 4, 2020, and (ii) the date on which the Series B Warrants have been exercised in full (without giving effect to any limitation on exercise contained therein) and no shares remain issuable thereunder. The Series B Warrants will be initially exercisable by a holder for an amount of Ocugen common stock equal to the number (if positive) obtained by subtracting (i) the sum of (a) the number of Converted Initial Shares and (b) the number of Converted Additional Shares delivered or deliverable to the holder pursuant to the Financing SPA, from (ii) the quotient determined by dividing (a) the pro rata portion of the purchase price paid by such holder by (b) greater of (x) 80% of the sum of the volume-weighted average prices of a share of Ocugen common stock on the Nasdaq Capital Market ("Nasdaq") for the first three trading days immediately following the closing date of the Pre-Merger Financing divided by three and (y) \$1.00.

Additionally, every ninth trading day up to and including the 45th trading day (each, a "Reset Date") following (i) each date on which a registration statement registering any registrable securities for resale by a holder of Purchased Securities is declared effective and/or is available for use, (ii) if there is no effective registration statement

that is available for use registering all of the shares issuable upon exercise of the Series A Warrants and the Series B Warrants, the earlier to occur of (a) the first date on which the holders can sell all the shares issuable upon exercise of the Series A Warrants and the Series B Warrants without restriction or limitation pursuant to Rule 144 under the Securities Act, and (b) April 4, 2020 (such earlier date, the “Six Month Reset Date”) and (iii) in the event of a Public Information Failure (as defined in the Financing SPA) at any time following the Six Month Reset Date, then the earlier to occur of (a) the date the Public Information Failure is cured and no longer prevents the holder from selling all of the shares issuable upon exercise of the Series A Warrants and the Series B Warrants pursuant to Rule 144 without restriction or limitation, (b) the first date on which the holders can sell all the shares issuable upon exercise of the Series A Warrants and the Series B Warrants without restriction or limitation pursuant to Rule 144 under the Securities Act and without the requirement to be in compliance with Rule 144(c)(1), and (c) October 4, 2020 (such 45 trading day period, the “Reset Period” and each such 45th trading day after (i), (ii), or (iii), the “End Reset Date”), the number of shares issuable upon exercise of the Series B Warrants shall be increased to the number (if positive) obtained by subtracting (i) the sum of (a) the number of Converted Initial Shares and (b) the number of Converted Additional Shares delivered or deliverable to the holder pursuant to the Securities Purchase Agreement, from (ii) the quotient determined by dividing (a) the pro rata portion of the purchase price paid by such holder, by (b) the greater of (y) 80% of the arithmetic average of the two lowest dollar volume-weighted average prices of a share of Ocugen common stock on Nasdaq during the applicable Reset Period immediately preceding the applicable Reset Date to date and (z) \$1.00 (which amount shall not be adjusted for reverse stock splits or other similar events).

Series C Warrants

The Series C Warrants are exercisable upon issuance for up to 50.0 million shares of common stock at an exercise price of \$7.13 per share and will expire upon the 45th trading day immediately following the earlier to occur of (i) the date the holder can sell all shares issuable upon exercise of the Series C Warrants pursuant to Rule 144 without restriction or limitation and without the requirement to be in compliance with Rule 144(c)(1) and (ii) October 4, 2020, provided that if such date falls on a day other than a business day or on which trading does not take place on Nasdaq (a “Holiday”), the next day that is not a Holiday. If the volume-weighted average trading price of a share of Ocugen common stock on Nasdaq is less than or equal to \$1.20 per share on any five trading days following the date of issuance and prior to the expiration date of the Series C Warrants, the holder may, in lieu of making any cash payment in connection with the exercise of the Series C Warrants, elect to receive a number of shares of common stock equal to the number of Series C Warrants. Subsequent to September 30, 2019, the Pre-Merger Financing Warrants were amended to, among other things, reduce the number of Series C Warrants from 50.0 million to 20.0 million.

Accounting for the Pre-Merger Financing Warrants

As of September 30, 2019, the Series A Warrants and Series C Warrants are classified as equity and the Series B Warrants are classified as a liability on the condensed consolidated balance sheet.

The Series B Warrants are classified as a liability as they do not meet the derivative scope exception to be accounted for within stockholders’ equity. The Series B Warrants do not qualify for criteria related to equity indexation because the reset date is triggered based on effective date of the S-3 Registration Statement (as defined in Note 12) and the timing of when a registration statement for the underlying shares is available is not an input in an option pricing model. Series B Warrants were treated as a derivative liability in the condensed consolidated balance sheet, measured at fair value and marked to market each reporting period.

The fair value of the Series B Warrants was calculated using Monte Carlo simulation while estimating the stock price during the 45-day reset period, based on the terms described within the Financing SPA. Key fair value inputs included the starting stock price, expected stock volatility during the 45-day reset period, and additional shares issued from escrow. The methodology for measuring fair value is sensitive to the expected stock volatility assumption input mentioned above. The volatility used in the fair value estimate was 96.0% and 97.0% as of September 27, 2019 and September 30, 2019, respectively. Inputs used in the valuation are unobservable and are therefore classified as Level 3 fair value inputs.

The following table provides a reconciliation of Series B Warrant liability measured at fair value using Level 3 significant unobservable inputs:

	September 30, 2019
Balance at January 1, 2019	\$ —
Fair value at issuance — September 27, 2019	9,387,760
Change in fair value of embedded derivatives	18,577,226
Balance at September 30, 2019	\$ 27,964,986

Although the Pre-Merger Financing Warrants were issued on October 4, 2019, the agreement for issuance of the Pre-Merger Financing Warrants was a firm commitment reached between Ocugen and the Investors as part of the Financing SPA upon the closing of the Merger. Therefore, the derivative liability related to the Series B Warrants was valued as of the date of the Merger and subsequently remeasured as of September 30, 2019.

12. Subsequent Events

Warrant Issuance

The Series A, B, and C Warrants were issued on October 4, 2019 as follows:

- The Series A Warrants were issued at an initial exercise price of \$7.13, were immediately exercisable upon issuance. The Series A Warrants are exercisable for 8,771,928 common stock in the aggregate.
- The Series B Warrants were issued at an exercise price of \$0.01 and were immediately exercisable upon issuance. The Series B Warrants are initially exercisable for 8,007,461 common stock subject to adjustment based on reset provision in the warrant agreement. After factoring this initial issuance, the potential maximum additional warrants issuable under the Series B Warrants, during the reset period, is 12.6 million warrants.
- The Series C Warrants were issued at an initial exercise price of \$7.13, were immediately exercisable upon issuance. The Series C Warrants were exercisable for up to 50.0 million shares of common stock prior to the Warrant Amendments, as defined below.

Issuance of Converted Additional Shares from Escrow

On October 4, 2019, the Converted Additional Shares were released from escrow to the investors because, as determined at the close of business on October 2, 2019, 80% of the volume-weighted average trading price of a share of Ocugen's common stock as quoted on Nasdaq for the first three trading days immediately following the closing date of the Pre-Merger Financing was lower than the price paid by the Investors for the Initial Shares.

NeoCart™ Intangible Asset Held for Sale

As described in Note 4, Histogenics entered into the Asset Purchase Agreement with Medavate, the closing of which was subject to and conditioned upon the consummation of the Merger. On September 26, 2019, the parties entered into an amendment to the Asset Purchase Agreement whereby the closing date was amended to October 4, 2019. On October 4, 2019, the parties entered into the Second Amendment to the Asset Purchase Agreement whereby the purchase price was increased to \$7.0 million under the Asset Purchase Agreement and the Closing Date of the Asset Purchase Agreement was revised from October 4, 2019 to two business days after Medavate obtains financing in an amount no less than the purchase price. The Second Amendment further provides that if the Closing Date does not occur on or prior to October 31, 2019, Ocugen may choose to terminate the Asset Purchase Agreement and, if Ocugen does not terminate the Asset Purchase Agreement, the purchase price shall increase 10% per month (or any portion thereof) between October 31, 2019 and the Closing Date. Ocugen has not terminated the Asset Purchase Agreement and as of November 1, 2019, the purchase price has increased to \$7.7 million.

Form S-3 Registration Statement

Registration statement number 333-234127 filed on Form S-3 by Ocugen (the "Registration Statement") became effective on November 5, 2019. The Registration Statement relates solely to the resale by certain investors listed therein (in the section titled "Selling Stockholders"), of up to 111,540,825 shares of the Company's common stock.

Share Repurchase

On October 9, 2019, Ocugen announced that its Board of Directors unanimously approved a share repurchase program authorizing the repurchase of up to \$2.0 million in value of the outstanding common stock. Pursuant to this repurchase program, Ocugen plans to repurchase the common stock provided that the timing, actual number and price per share of the common stock to be purchased will be subject to management discretion and board guidance, market conditions, applicable legal requirements, including Rule 10b-18 of the Exchange Act and various other factors.

Warrant Amendments

On November 5, 2019, the Company entered into an agreement with each Investor that amends the terms of each of the Pre-Merger Financing Warrants held by each such Investor (collectively, the “Warrant Amendments”). Pursuant to the Warrant Amendments, the Company and each Investor agreed, among other things, to the following:

- The Series C Warrants were amended such that they are exercisable, in the aggregate for up to 20 million shares of common stock. They had previously been exercisable for up to 50 million shares of common stock.
- Each of the Series C Warrants was also amended to permit the Investors, in lieu of making any cash payment otherwise contemplated to be made to the Company upon the exercise of the Series C Warrant, to elect instead to receive upon such exercise up to 20 million shares of common stock. Prior to the Warrant Amendments, the Series C Warrants had permitted the exercise without any cash payment of up to 50.0 million shares of common stock in the event that the volume weighted-average price of the common stock on Nasdaq was less than or equal to \$1.20 per share on any five trading days following the issuance of the Series C Warrants.
- Each Series A Warrant was amended such that an equity financing involving a research or non-profit foundation or organization qualified under Section 501(c) of the Internal Revenue Code of 1986, as amended, in an amount of gross proceeds not to exceed \$10,000,000 and closing on or prior to May 31, 2020, will be excluded from the anti-dilution adjustment, as set forth in the Series A Warrant.

Concurrently with the effectiveness of the Warrant Amendments, the Investors exercised an aggregate of 3,797,329 Series C Warrants each for one share of common stock.

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, 2018, included in our Form 8-K/A filed with the SEC on October 7, 2019. 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. 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” 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

Ocugen is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies, including gene therapies and biologicals, to address rare and underserved eye diseases.

Ocugen is developing a modifier gene therapy platform for unmet medical needs in the area of retinal diseases, including inherited retinal diseases (“IRDs”). Ocugen’s modifier gene therapy platform is novel in that it targets nuclear hormone receptor (“NHR”) genes, which have the potential to restore homeostasis to the retina and may target multiple genes that are associated with a range of IRDs. Unlike single-gene replacement therapies, which only target one genetic mutation, Ocugen believes that its gene therapy platform, through its targeting of NHRs, may impact multiple genes that are associated with a range of genetically diverse diseases. Ocugen’s first gene therapy candidate, OCU400 has received two Orphan Drug Designation (“ODD”), from the Food and Drug Administration (the “FDA”), for the treatment of *NR2E3* mutation-associated retinal disease and *CEP290* mutation-associated retinal disease. OCU400 uses an adeno-associated virus vector (“AAV”). Ocugen is planning to initiate a Phase 1/2a clinical trial for OCU400 in 2021. Ocugen’s second gene therapy product candidate, OCU410, is targeted for dry age-related macular degeneration (“dry AMD”). Currently, there are no approved FDA therapies to treat this disease.

OCU300, a late-stage product candidate, has also received ODD from the FDA. OCU300 is a small molecule therapeutic currently in Phase 3 clinical development for patients with ocular graft-versus-host disease (“oGVHD”). Ocugen is the first and only company to receive ODD for the treatment of oGVHD and the only company conducting Phase 3 studies in this patient population. Ocugen estimates the prevalence of patients suffering from oGVHD in the United States will be approximately 63,000 by 2020. The final manufacturing processes for OCU300 has been scaled up by Ocugen’s existing contract manufacturer at a cGMP facility located in the United States to support potential commercialization, and chemistry, manufacturing and control (“CMC”) development is ongoing.

OCU300 is formulated using Ocugen’s proprietary nanoemulsion technology, OcuNanoE—Ocugen’s ONE Platform™ (“OcuNanoE™”). Ocugen is the first and only company to use nanoemulsion technology in the ophthalmology space, and Ocugen believes that OcuNanoE™ provides additional protection to the ocular surface in connection with the delivery of therapies for certain retinal disease. Ocugen’s technology delivers the active drug with the use of defined narrow-range globules with an average diameter of less than 100 nanometers. Ocugen believes this provides the potential for enhanced efficacy compared to traditional formulations.

Ocugen has completed a Phase 3 clinical trial for OCU310 and although the study showed that OCU310 is well tolerated, as demonstrated by no adverse events regarding as “severe”, it did not meet its co-primary endpoints for symptoms and signs.

Ocugen is developing OCU200, a novel fusion protein, which is currently in preclinical development for treating wet age-related macular degeneration (“wet AMD”). Ocugen expects to initiate a Phase 1/2 clinical trial for OCU200

within the next two years. In addition, Ocugen plans to expand the therapeutic applications of OCU200 beyond wet AMD to potentially include diabetic retinopathy (“DR”), diabetic macular edema (“DME”), macular edema following retinal vein occlusion (“RVO”), and myopic choroidal neovascularization (“mCNV”). Ocugen’s novel biologic, OCU100 for the treatment of retinitis pigmentosa (“RP”) has received ODD in the United States and the European Union.

To date, Ocugen has viewed its operations and manages its business as one operating segment. As of September 30, 2019, all of Ocugen’s assets were located in the United States. Its headquarters and operations are located in Malvern, Pennsylvania.

Financial Operations Overview

Research and development expense

Research and development costs are expensed as incurred. These costs consist of internal and external expenses. Internal expenses include the cost of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in Ocugen’s product development functions, as well as allocated rent and utilities expenses. External expenses include development, clinical trials, patent costs and regulatory compliance costs incurred with research organizations and other third-party vendors. License fees paid to acquire access to proprietary technology are expensed to research and development unless it is determined that the technology is expected to have an alternative future use. All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred to research and development expense due to the uncertainty about the recovery of the expenditure. Ocugen records costs for certain development activities, such as clinical trials, based on its evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to Ocugen by Ocugen’s vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expense, as the case may be.

Ocugen plans to incur research and development expenses for the foreseeable future as it expects to continue development and eventual commercialization of one or more of its product candidates, if approved. Ocugen anticipates that its research and development expenses will increase substantially as compared to prior periods as it completes its Phase 3 trial with respect to OCU300 and prepares to commence Phase 1 trials with respect to OCU400 and OCU200, and otherwise develops and prepares for commercialization of its product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development, Ocugen is unable to estimate with any certainty the costs it will incur and the timelines it will require in its continued development efforts.

As a result of the uncertainties discussed above, successful development and completion of clinical trials is uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each future product candidate and are difficult to predict. Ocugen will continue to make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to its ability to enter into collaborations with respect to each product candidate, the scientific and clinical success of each product candidate as well as ongoing assessments as to the commercial potential of each product candidates.

General and administrative expense

General and administrative expense consists primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for employees in executive, accounting and other administrative functions. General and administrative expense also includes corporate facility costs, including rent and utilities, as well as legal fees related to corporate matters and fees for accounting and other consulting services.

Ocugen anticipates that its general and administrative expense will increase as a result of an expanded infrastructure and an increased headcount. Ocugen anticipates higher corporate infrastructure costs including, but not limited to

accounting, legal, human resources, consulting and investor relations fees, as well as increased director and officer insurance premiums, associated with becoming a public company. Additionally, if and when Ocugen believes a regulatory approval of a product candidate appears likely, it anticipates an increase in payroll and expense as a result of its preparation for commercial operations, especially as it relates to the sales and marketing of its product candidates.

Change in fair value of derivative liabilities

Change in fair value of derivative liabilities includes the change in fair value each reporting period of the conversion and change in control features embedded in certain of the outstanding convertible promissory notes, which was required to be bifurcated and recognized at fair value. There are no such embedded derivatives valued as of September 30, 2019, due to either the payment or conversion of the related notes. For the three and nine months ended September 30, 2019, the change in fair value of derivative liabilities also includes the change in fair value of the Series B Warrant which was estimated using a Monte Carlo simulation model.

Other income (expense)

Other income (expense) consists primarily of interest expense, including the amortization of debt issuance costs related to Ocugen's debt and accretion of the discount created by the bifurcation of the embedded conversion features and embedded change in control features from certain of the convertible promissory notes, interest income earned on Ocugen's cash and cash equivalents held with institutional banks, and foreign currency income (losses) due to exchange rate fluctuations on transactions denominated in a currency other than its functional currency.

Critical Accounting Policies and Significant Judgments and Estimates

Ocugen's consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of Ocugen's financial statements requires it to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reported period. Ocugen bases its estimates on historical experience, known trends and events and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Ocugen evaluates its estimates and assumptions on an ongoing basis. Ocugen's actual results may differ from these estimates under different assumptions and conditions.

While Ocugen's significant accounting policies are described in more detail in the notes to its condensed consolidated financial statements appearing elsewhere in this report, Ocugen believes that the following accounting policies and estimates are those most critical to the preparation of its condensed consolidated financial statements:

Stock-based compensation

Ocugen accounts for its stock-based compensation awards in accordance with the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") Topic 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock units and modifications to existing agreements, to be recognized in the statements of operations based on their fair values. Ocugen uses the Black-Scholes option-pricing model to determine the fair value of options granted.

Ocugen's stock-based awards are subject to either service or performance-based vesting conditions. Compensation expense related to awards to employees and directors 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. Compensation expense related to awards to employees with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period to the extent achievement of the performance condition is probable.

Estimating the fair value of options requires the input of subjective assumptions, including expected life of the option,

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

These assumptions used in Ocugen's Black-Scholes option-pricing model are as follows:

Expected Term. Due to the historical lack of a public market for the trading of Ocugen common stock and the lack of sufficient company-specific historical data, the expected term of employee options is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin ("SAB No. 107"), whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term of non-employee options is equal to the contractual term.

Expected Volatility. The expected volatility is based on historical volatilities of similar entities within Ocugen's industry which were commensurate with the expected term assumption as described in SAB No. 107.

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

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

Stock-based compensation expense was \$0.2 million for the three months ended September 30, 2019 and 2018, respectively, and \$0.7 million for the nine months ended September 30, 2019 and 2018, respectively. At September 30, 2019, Ocugen had \$1.0 million of unamortized stock-based compensation expense related to unvested service-based stock options, which is expected to be recognized over a remaining weighted-average vesting period of 1.6 years.

Derivative liabilities

The derivative liabilities include embedded conversion features bifurcated from Ocugen's convertible notes because the number of shares of common stock to be issued upon conversion is variable and embedded change in control features because it represents a redemption feature not clearly and closely related to the debt host. Ocugen estimated the fair value of the embedded conversion, redemption and change in control features at each issuance of convertible promissory notes and at the end of each reporting period using an income approach model. Inputs into this model include the expected time until conversion or change in control and Ocugen's estimate of the probability of conversion or change in control occurring. There are no such derivatives valued as of September 30, 2019, due to either the payment or conversion of the related notes.

Ocugen issued warrants to purchase common stock and accounts for it warrants in accordance with FASB ASC Topic 815-40, *Derivatives and Hedging — Contracts in Entity's Own Equity* ("ASC 815-40"), which is the authoritative guidance on accounting for derivative financial instruments indexed to and potentially settled in a company's own stock. To determine whether a contract is considered indexed to the issuer's own equity, the Company performs the following two-step analysis: (1) evaluate whether the contract contains any exercise contingencies and, if so, whether they disqualify the contract from being classified as equity, and (2) assess whether the settlement terms are consistent with equity classification.

Ocugen entered into a Securities Purchase Agreement with certain accredited investors, pursuant to which Ocugen issued three series of warrants, Series A warrants, Series B warrants and Series C warrants. The Series A warrants and Series C warrants were determined to meet the criteria for equity classification. As of September 30, 2019, the Series B warrants were recognized as a derivative liability as they did not meet the criteria related to equity indexation. The Company classified the Series B warrants on its condensed consolidated balance sheet as a derivative liability which is recognized at fair value at each reporting period subsequent to the initial issuance. Changes in the fair value of derivatives are recognized as other income (expense) in the condensed consolidated statements of operations and comprehensive loss.

Ocugen estimated the fair value of Series B warrants using the Monte Carlo simulation model. Key fair value inputs included the starting stock price, expected stock price volatility during a 45-day reset period, and additional shares issued from escrow. The methodology for measuring fair value is sensitive to the expected stock volatility assumption input mentioned above. Inputs used in the valuation are unobservable and are therefore classified as Level 3 fair value inputs. The use of different valuation techniques or assumptions could result in materially different fair value estimates. See Note 11 in the notes to the condensed consolidated financial statements included in this report for additional information.

Results of Operations

Comparison of the Three Months Ended September 30, 2019 and 2018

The following table summarizes the results of Ocugen's operations for the three months ended September 30, 2019 and 2018 (in thousands):

(in thousands)	Three months ended September 30,		Change
	2019	2018	
Operating expenses:			
Research and development	\$ 1,306	\$ 1,562	\$ (256)
General and administrative	1,408	843	565
Total operating expenses	<u>2,714</u>	<u>2,405</u>	<u>309</u>
Loss from operations	(2,714)	(2,405)	(309)
Other income (expense):			
Change in fair value of derivative liability	(18,512)	1,462	(19,974)
Interest income	—	4	(4)
Interest expense	(796)	(1,002)	206
Other (expense) income	(751)	8	(759)
Total other income (expense)	<u>(20,059)</u>	<u>472</u>	<u>(20,531)</u>
Net loss	<u>\$ (22,773)</u>	<u>\$ (1,933)</u>	<u>\$ (20,840)</u>

Research and development expense

Research and development expense decreased by \$0.3 million or 16.4% for the three months ended September 30, 2019 when compared to the three months ended September 30, 2018 primarily as a result of a decrease in clinical trial activities. Specifically, the patient activity in the year-over-year comparison for OCU300 was lower in 2019, causing a \$0.2 million decrease in clinical activities. Also, the OCU300 trial was well into Phase 3 by the third quarter of 2019 causing a \$0.1 million decrease in preclinical costs.

General and administrative expense

General and administrative expenses increased by \$0.6 million or 67.0% for the three months ended September 30, 2019 when compared to the three months ended September 30, 2018. The increase was primarily related to a \$0.8 million increase in professional fees related to preparing for operating as a public company, partially offset by decreases of \$0.1 million in stock-based compensation and wages and salaries due to reduced headcount.

Change in fair value of derivative liability

The change in fair value of derivative liability was a loss of \$18.5 million for the three months ended September 30, 2019 compared to a gain of \$1.5 million for the three months ended September 30, 2018. The loss relates to the remeasurement of the Series B warrant liability recognized in the third quarter of 2019. The gain relates to the remeasurement of embedded features on the convertible notes which were issued during the second quarter of 2018.

Interest expense

Interest expense was \$0.8 million for the three months ended September 30, 2019 compared to \$1.0 million for the three months ended September 30, 2018. The decreased expense is primarily due to the conversion and repayment of debt during the fiscal year 2019.

Other income (expense)

Other expense was a \$0.8 million the three months ended September 30, 2019 compared to a de minimis amount for the three months ended September 30, 2018. The expense for the three months ended September 30, 2019 primarily relates to equity issuance fees associated with the Series B warrants, which were expensed as incurred.

Comparison of the Nine Months Ended September 30, 2019 and 2018

The following table summarizes the results of Ocugen's operations for the nine months ended September 30, 2019 and 2018 (in thousands):

(in thousands)	Nine months ended September 30,		Change
	2019	2018	
Operating expenses:			
Research and development	\$ 6,339	\$ 7,405	\$ (1,066)
General and administrative	3,544	3,046	498
Total operating expenses	9,883	10,451	(568)
Loss from operations	(9,883)	(10,451)	568
Other income (expense):			
Change in fair value of derivative liabilities	(19,897)	1,209	(21,106)
Loss on debt conversion	(341)	—	(341)
Interest income	1	17	(16)
Interest expense	(1,753)	(3,035)	1,282
Other expense	(752)	(3)	(749)
Total other income (expense)	(22,742)	(1,812)	(20,930)
Net loss	\$ (32,625)	\$ (12,263)	\$ (20,362)

Research and development expense

Research and development expense decreased by \$1.1 million or 14.4% for the nine months ended September 30, 2019 when compared to the nine months ended September 30, 2018 primarily as a result of a net decrease in program development and clinical trial activities of \$0.7 million and a decrease of \$0.4 million in other costs.

Specifically, OCU310 clinical trial activities increased in 2019 by \$2.1 million related to the Phase 3 clinical trial. This increase was offset by (a) \$2.5 million of decreases in preclinical and manufacturing activities within OCU100, OCU200, OCU300, and OCU310, (b) a \$0.2 million decrease in OCU300 clinical activities and (c) a \$0.1 million decrease in OCU400 preclinical activities.

The \$0.4 million decrease in other research and development costs is primarily related to a decrease in employee-related expenses due to a decrease in headcount.

General and administrative expense

General and administrative expenses increased by \$0.5 million, or 16.3%, for the nine months ended September 30, 2019 when compared to the nine months ended September 30, 2018. The increase was primarily due to a \$1.2 million increase in professional fees related to preparing for operating as a public company, partially offset by a \$0.4 million decrease in employee-related expenses resulting from a decrease in headcount, and a decrease of \$0.2 million resulting from severance payments.

Change in fair value of derivative liability

The change in fair value of derivative liability was a loss of \$19.9 million for the nine months ended September 30, 2019 compared to a gain of \$1.2 million related to a change in fair value of the derivatives related to the debt instruments for the nine months ended September 30, 2018. The loss for the nine months ended September 30, 2019 primarily relates to the remeasurement of the Series B Warrant liability.

Loss on debt conversion

The loss on debt conversion of \$0.3 million primarily relates to 2019 conversions of all previously issued convertible debt.

Interest expense

Interest expense was \$1.8 million for the nine months ended September 30, 2019 and \$3.0 million for the nine months ended September 30, 2018. The lower interest expense was primarily due to the 2019 conversions of all previously issued convertible debt.

Other expense

Other expense was \$0.8 million the nine months ended September 30, 2019 compared to a de minimis amount for the nine months ended September 30, 2018. Other expense for the nine months ended September 30, 2019 primarily relates to equity issuance fees associated with the Series B Warrants, which were expensed as incurred.

Liquidity and Capital Resources

Ocugen has not generated any revenue to date and has primarily funded its operations to date through the sale and issuance of common stock and warrants to purchase common stock, proceeds from convertible notes payable, and debt. Specifically, since its inception and through September 30, 2019, Ocugen has raised an aggregate of \$47.7 million to fund its operations, of which \$31.6 million was from the sale of Ocugen common stock and warrants, \$14.9 million was from convertible notes, \$1.0 million was from borrowings under the EB-5 Program, and \$0.2 million was a grant for research from the State of Colorado. As of September 30, 2019, Ocugen had \$15.5 million in cash, cash equivalents and restricted cash.

Since Ocugen's inception, it has devoted substantial resources to research and development and has incurred significant net losses and expects to continue to incur net losses for the foreseeable future. Ocugen incurred net losses of approximately \$32.6 million and \$12.3 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, Ocugen had an accumulated deficit of \$63.9 million.

Although it is difficult to predict future liquidity requirements, Ocugen believes that the net proceeds from the Pre-Merger Financing, together with the existing cash and cash equivalents of the combined company, will be sufficient to fund its operations into mid-2020, during which time, Ocugen expects to continue its development efforts with respect to its product candidates. However, in case of regulatory delays or other unforeseen events, we may require additional funding to accomplish these objectives. Ocugen will need to raise additional capital in the future to further the development and commercialization of its other product candidates. Until such time, if ever, as Ocugen generates product revenue, Ocugen expects to obtain additional financing through the issuance of its common stock, through other equity or debt financings or through collaborations or partnerships with other companies. Ocugen may not be able to raise additional capital on terms acceptable to it, or at all, and any failure to raise capital as and when needed could compromise its ability to execute on its business plan and cause it to delay or curtail its operations until such funding is received.

The following table shows a summary of Ocugen's cash flows for the periods indicated (in thousands):

	Nine months ended September 30,	
	2019	2018
Net cash used in operating activities	\$ (8,150)	\$ (8,844)
Net cash used in investing activities	(2,336)	(77)
Net cash provided by financing activities	24,159	5,254
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 13,673	\$ (3,667)

Operating activities

Cash used in operating activities was \$8.1 million for the nine months ended September 30, 2019 compared with \$8.8 million for the nine months ended September 30, 2018.

Investing activities

Cash used in investing activities was \$2.3 million for the nine months ended September 30, 2019 compared with \$0.1 million for the nine months ended September 30, 2018. The \$2.3 million increase in cash used is primarily related to costs associated with the Merger.

Financing activities

Cash provided by financing activities was \$24.2 million for the nine months ended September 30, 2019 compared to \$5.3 million for the nine months ended September 30, 2018. This \$18.9 million increase is primarily due to the \$22.4 million of proceeds received from the Pre-Merger Financing transaction, \$1.0 million from issuance of the Promissory Note, and \$0.8 million increase from proceeds received relate to the issuance of the convertible debt. These increases were partially offset by payment of \$5.3 million to settle the convertible debt.

Funding requirements

Ocugen expects to continue to incur significant expenses in connection with its ongoing activities, particularly as it continues research and development, including clinical development activities of its product candidates, increases its headcount and adds operational, financial and information systems to execute its business plan, maintains, expands and protects its patent portfolio, contracts to manufacture its product candidates, and operates as a public company.

Ocugen's future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of clinical trials for its product candidates;
- the outcome, timing and cost of the regulatory approval process for its product candidates by the FDA;
- future costs of manufacturing and commercialization;
- the cost of filing, prosecuting, defending and enforcing its patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against it;
- the costs of expanding infrastructure and increasing headcount, as well as the higher corporate infrastructure costs associated with becoming a public company; and
- the extent to which it in-licenses or acquires other products, product candidates or technologies.

Ocugen believes that the net proceeds from the Pre-Merger Financing, together with the existing cash and cash equivalents of the combined company, will be sufficient to fund its operations into mid-2020, during which time

Ocugen expects to continue its development efforts with respect to its product candidates. Ocugen has based this estimate on assumptions that may prove to be wrong, and Ocugen could utilize its available capital resources sooner than it expects. Ocugen expects that it will need to raise additional capital in the future to complete the clinical development of its product candidates. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable Ocugen to continue to implement its long-term business strategy. If Ocugen cannot expand its operations or otherwise capitalize on its business opportunities because it lacks sufficient capital, Ocugen's business, financial condition and results of operations could be materially adversely affected, and it may need to delay or curtail its operations until such funding is received.

Off-Balance Sheet Arrangements

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

Recently Adopted Accounting Pronouncements

For a discussion of recently adopted accounting pronouncements, see Note 3 to our condensed consolidated financial statements included in this report.

Other Company Information

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act ("JOBS Act") was enacted. Section 107 of the JOBS Act permits an "emerging growth company" or a "smaller reporting company" to delay the adoption of new or revised accounting standards until those standards would otherwise apply to private companies. We plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For so long as we are an "emerging growth company" or "smaller reporting company," we intend to rely on exemptions relating to: (1) providing an auditor's attestation report on our system of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis.

We will remain an emerging growth company until December 31, 2019.

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 Securities Exchange Act of 1934, as amended) (the "Exchange Act"), as of September 30, 2019. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that (a) the information required to be disclosed by us in

the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control Over Financial Reporting

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

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we are subject to claims in legal proceedings arising in the normal course of its business. We do not believe that we are currently party to any pending legal actions that could reasonably be expected to have a material adverse effect on our business, financial condition, results of operations or cash flows.

Item 1A. Risk Factors.

Risks Related to Ocugen's Financial Position and Capital Requirements

Ocugen has incurred significant losses from operations and negative cash flows from operations since its inception. Ocugen expects to incur losses over the next several years and may never achieve or maintain profitability.

Since inception, Ocugen has incurred significant net losses and expects to continue to incur net losses for the foreseeable future. Ocugen has not generated any revenue to date and has funded its operations to date through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes, and borrowings under credit facilities. Ocugen incurred net losses of approximately \$32.6 million for the nine months ended September 30, 2019, \$18.2 million for the year ended December 31, 2018, and \$7.8 million for the year ended December 31, 2017. As of September 30, 2019, Ocugen had an accumulated deficit of \$63.9 million and a cash, cash equivalents and restricted cash balance of \$15.5 million.

Ocugen has devoted substantially all of its financial resources and efforts to research and development, including preclinical studies and clinical trials. Ocugen expects that over the next several years it will continue to incur losses from operations as it increases its expenditures in research and development in connection with clinical trials and other development activities. Ocugen's net losses may fluctuate significantly from quarter to quarter and year to year.

Ocugen anticipates that its expenses will increase substantially as compared to prior periods as it completes its Phase 3 trial with respect to OCU300, prepares to commence Phase 1 trials with respect to OCU400 and OCU200, and otherwise develops and prepares for commercialization of its product candidates, as a result of increased headcount, including management personnel to support its clinical, manufacturing and commercialization activities, expanded infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company, and increased insurance premiums, among other factors. Ocugen may seek to obtain additional financing in the future through the issuance of common stock, through other equity or debt financings or through collaborations or partnerships with other companies. Ocugen may not be able to raise additional capital on terms acceptable to it, or at all, and any failure to raise capital as and when needed could compromise its ability to execute on its business plan and cause it to delay or curtail operations until such funding is received.

In addition, Ocugen's license agreements with the University of Colorado, the University of Illinois at Chicago and The Schepens Eye Research Institute impose, among other obligations, royalty, milestone payment, and other financial obligations on it, and Ocugen may enter into additional licensing and funding arrangements with third parties that may impose additional royalty, milestone payment, insurance and other obligations on it.

Due to the inherently unpredictable nature of preclinical and clinical development, Ocugen is unable to estimate with any certainty the costs it will incur and the timelines it will require in its continued development efforts. Additionally, its expenses will also increase if, and, as it:

- pursues the clinical development of OCU300, through Phase 3 clinical development, and otherwise pursues the preclinical and clinical development of its product candidates;
- initiates preclinical studies and clinical trials for any additional product candidates that it may pursue in the future;

- seeks marketing approvals for product candidates that successfully complete clinical development;
- establishes sales, marketing and distribution capabilities for its product candidates for which it obtains marketing approval;
- scales up its manufacturing processes and capabilities to support its clinical trials of its product candidates and commercialization of any of its product candidates for which it obtains marketing approval;
- expands its operational, financial and management systems and increases personnel, including personnel to support its clinical development, manufacturing and commercialization efforts and its operations as a public company;
- hires additional clinical, quality control, scientific and management personnel;
- leverages its proprietary OcuNanoE™ technology to advance high-value therapeutics into preclinical and clinical development;
- in-licenses or acquires the rights to other products, product candidates or technologies;
- develops, maintains, expands and protects its intellectual property portfolio; and
- increases its product liability insurance coverage as it expands its commercialization efforts.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, Ocugen is unable to predict the timing or amount of increased expenses or when, or if, it will be able to achieve profitability. Ocugen's expenses will increase if:

- it is required by the FDA, European Medicines Agency ("EMA") or other foreign regulatory agencies to perform trials or studies in addition to those currently expected;
- there are any delays in enrollment of patients in or completing its clinical trials or the development of its product candidates; or
- there are any third-party challenges to Ocugen's intellectual property portfolio, or the need arises to defend against intellectual property-related claims.

Ocugen's ability to become and remain profitable depends on its ability to generate revenue. Ocugen does not expect to generate revenue that is sufficient to achieve profitability unless and until it obtains marketing approval for and commercializes one of its product candidates. Ocugen does not expect to commercialize any of its product candidates before 2021, if ever. This will require it to be successful in a range of challenging activities, including:

- completing and obtaining favorable results from its ongoing Phase 3 clinical trial of OCU300 for the treatment of ocular redness and discomfort in patients with oGVHD;
- obtaining marketing approval for OCU300 or any other product candidates;
- discovering additional product candidates;
- manufacturing at commercial scale, marketing, selling and distributing those products for which it obtains marketing approval;
- achieving an adequate level of market acceptance of and obtaining and maintaining coverage and adequate reimbursement from third-party payors for its products; and

· obtaining, maintaining and protecting its intellectual property rights.

Ocugen is only in the preliminary stages of many of these activities, and it may never succeed in these activities or generate revenue that is sufficient to achieve profitability. Even if Ocugen does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. If it fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and be forced to reduce or terminate its operations. Ocugen's failure to become profitable or inability to remain profitable would decrease the value of the company and could impair its ability to raise capital, expand its business, maintain its research and development efforts, continue or undertake commercialization efforts, diversify its product offerings or even continue its operations. A decline in the value of the company could also cause you to lose all or part of your investment.

Ocugen's recurring operating losses have raised substantial doubt regarding its ability to continue as a going concern.

Ocugen's recurring operating losses raise substantial doubt about its ability to continue as a going concern. For the year ended December 31, 2018, Ocugen had a net loss of \$18.2 million and net cash used in operating activities of \$11.6 million. Ocugen has no current source of revenue to sustain its present activities, and it does not expect to generate revenue until and unless it receives regulatory approval of and successfully commercialize its product candidates. As a result, Ocugen concluded that there is substantial doubt about its ability to continue as a going concern, and its independent registered public accounting firm included an explanatory paragraph with regard to its ability to continue as a going concern in its report on Ocugen's financial statements as of and for the year ended December 31, 2018, which were included in the Company's Registration Statement on Form S-4/A filed with the SEC on August 2, 2019. The perception of Ocugen's ability to continue as a going concern may make it more difficult for it to obtain financing for the continuation of its operations and could result in the loss of confidence by investors, suppliers and employees.

Ocugen's limited operating history may make it difficult for you to evaluate the success of its business to date and to assess its future viability.

Ocugen has a limited operating history, and its operations to date have been limited to organizing and staffing the company, acquiring rights to intellectual property, business planning, raising capital and developing OCU300 and other product candidates. Consequently, any predictions you make about Ocugen's future success or viability may not be as accurate as they could be if it had a longer operating history.

In addition, as a new business, Ocugen may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Ocugen will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. It may not be successful in such a transition.

Ocugen expects its financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond its control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Ocugen will need substantial additional funding. If Ocugen is unable to raise capital when needed, it could be forced to delay, reduce or eliminate its product development programs or commercialization efforts.

Ocugen expects to devote substantial financial resources to its ongoing and planned activities, particularly as it conducts multiple clinical trials and, assuming positive results from these trials, seeks marketing approval for OCU300 and continues the development of and potentially seeks marketing approval for other clinical and preclinical product candidates, including OCU400, OCU410, OCU200 and OCU100. Ocugen expects its expenses to increase substantially in connection with its ongoing activities, particularly as it advances its preclinical activities and clinical trials. In addition, its expenses will further increase if it suffers any delay in its ongoing Phase 3 clinical program for OCU300, or commencement of its Phase 1/2 clinical programs for OCU400 and OCU200, including delays in enrollment of patients. Ocugen also expects to devote additional financial resources to conducting research and

development, initiating clinical trials of, and potentially seeking regulatory approval for, other potential product candidates, including product candidates that it may develop from its OcuNanoE™ program.

If Ocugen obtains marketing approval for OCU300, or any other product candidate that it develops, it expects to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Furthermore, Ocugen expects to incur additional costs associated with operating as a public company, hiring additional personnel and expanding its facilities. Accordingly, Ocugen may need to obtain substantial additional funding in connection with its continuing operations. If it is unable to raise capital when needed or on attractive terms, it could be forced to delay, reduce or eliminate its research and development programs or any future commercialization efforts.

Ocugen's future capital requirements will depend on many factors, including:

- the progress, costs and results of its Phase 3 clinical trials for OCU300, any clinical trials for its preclinical product candidates, and any clinical activities for regulatory review of OCU300 or its other product candidates outside of the United States;
- the costs and timing of process development and manufacturing scale-up activities associated with OCU300 and its preclinical product candidates;
- the costs, timing and outcome of regulatory review of OCU300 and its preclinical product candidates;
- the costs of commercialization activities for OCU300 or its preclinical product candidates if it receives, or expects to receive, marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;
- subject to receipt of marketing approval, revenue received from commercial sales of OCU300 or its preclinical product candidates;
- its ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the scope, progress, results and costs of any product candidates that it may derive from its OcuNanoE™ program or any other product candidates that it may develop;
- the extent to which it in-licenses or acquires rights to other products, product candidates or technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting its intellectual property rights and defending against any intellectual property-related claims.

As of September 30, 2019, Ocugen had cash, cash equivalents and restricted cash of approximately \$15.5 million. Ocugen believes that its cash and cash equivalents will enable it to fund its operating expenses and capital expenditure requirements through mid-2020. However, Ocugen has based this estimate on assumptions that may prove to be wrong, and its operating plan may change as a result of many factors currently unknown to it. As a result, it could deplete its capital resources sooner than it currently expects and may need additional funding sooner than it estimates.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. Ocugen may never generate the necessary data or results required to obtain regulatory approval of products with the market potential sufficient to enable it to achieve profitability. Ocugen does not expect to generate revenue from sales of any product candidates until at least 2021, if at all. Accordingly, it will need to obtain substantial additional financing to achieve its business objectives. In addition, it may seek additional capital due to favorable market conditions or strategic considerations, even if it believes it has sufficient funds for its current or future operating plans. Adequate additional financing may not be available to it on acceptable terms, or at all. If

adequate funds are not available to it on a timely basis, it may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of its product candidates or delay, limit, reduce or terminate its establishment of sales and marketing capabilities or other activities that may be necessary to commercialize its product candidates.

Raising additional capital may cause dilution to stockholders, restrict Ocugen's operations or require it to relinquish rights to its technologies or product candidates.

Until such time, if ever, as Ocugen can generate substantial product revenues, it expects to finance its cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. To the extent that Ocugen raises additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If Ocugen raises additional funds through collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, it may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to it. If Ocugen is unable to raise additional funds through equity or debt financings when needed, it may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market products or product candidates that it would otherwise prefer to develop and market on its own.

If Ocugen is unable to use carryforward tax losses or benefit from favorable tax legislation to reduce its taxes, its business, results of operations and financial condition may be adversely affected.

Ocugen has incurred significant net operating losses since its inception. As of December 31, 2018, Ocugen had federal net operating loss carryforwards of approximately \$23.7 million. State net operating losses are not materially different from federal net operating losses. If it is unable to use carryforward tax losses to reduce its future taxable income and liabilities in its business, results of operations and financial condition may be adversely affected.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," which will occur if there is a cumulative change in ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre-ownership change net operating losses equal to the value of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate (subject to certain adjustments). The annual limitation for a taxable year generally is increased by the amount of any "recognized built-in gains" for such year and the amount of any unused annual limitation in a prior year. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities.

Recent U.S. tax legislation may materially adversely affect Ocugen's financial condition, results of operations and cash flows.

Recently-enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"), adopting elements of a territorial tax system, imposing a one-time transition tax, or repatriation tax, on all undistributed earnings and profits of certain U.S.-owned foreign corporations, revising the rules governing net operating losses and the rules governing foreign tax credits, and introducing new anti-base erosion provisions. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service (the "IRS"), any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S.

federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

While some of the changes made by the tax legislation may adversely affect Ocugen in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis. Ocugen continues to work with its tax advisors and auditors to determine the full impact that the recent tax legislation as a whole will have on it. Ocugen urges its investors to consult with their legal and tax advisors with respect to such legislation.

Ocugen's existing and future indebtedness may limit cash flow available to invest in the ongoing needs of its business.

As of September 30, 2019, Ocugen had \$1.0 million of outstanding principal borrowings under the EB-5 Loan Agreement, which it is required to repay on the seventh anniversary of the date of the last disbursement under the EB-5 Loan Agreement (unless terminated earlier pursuant to the terms of the EB-5 Loan Agreement). Ocugen is also eligible to borrow an additional \$9.0 million under the EB-5 Loan Agreement, limited by the amount of funds raised by the Lender and subject to availability under the program and certain job creation requirements by it. Ocugen's obligations under this agreement are secured by substantially all of its assets other than its intellectual property. Ocugen could in the future incur additional indebtedness beyond its borrowings under the EB-5 Loan Agreement.

Ocugen's debt combined with its other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring it to dedicate a substantial portion of cash flow from operations or cash on hand to the payment of interest on, and principal of, its debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- increasing its vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting it to restrictive covenants that may reduce its ability to take certain corporate actions or obtain further debt or equity financing;
- limiting its flexibility in planning for, or reacting to, changes in its business and its industry; and
- placing it at a competitive disadvantage compared to its competitors that have less debt or better debt servicing options.

Ocugen intends to satisfy its current and future debt service obligations with its existing cash and funds from external sources. Nonetheless, it may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under its existing debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under the EB-5 Loan Agreement could result in an event of default and acceleration of amounts due. If an event of default occurs and the Lender accelerates the amounts due under the EB-5 Loan Agreement, Ocugen may not be able to make accelerated payments, and the Lender could seek to enforce security interests in the collateral securing such indebtedness.

Risks Related to Ocugen's Business and the Development of its Product Candidates

Ocugen is substantially dependent on the success of its product candidates and cannot guarantee that these product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized.

Ocugen currently has no products approved for commercial distribution. Ocugen has invested a significant portion of its efforts and financial resources in the development of its product candidates. Ocugen's business depends entirely on the successful development and commercialization of its product candidates, which may never occur. Ocugen's ability to generate revenues in the near term is substantially dependent on its ability to develop, obtain regulatory

approval for, and then successfully commercialize its product candidates. Ocugen currently generates no revenues from sales of any products, and it may never be able to develop or commercialize a marketable product.

Ocugen currently has limited experience with its product candidates. For OCU300, it has not conducted any clinical studies specifically with its proprietary nanoemulsion technology in patients with oGVHD. The formulation used in previous clinical studies conducted in patients with oGVHD is different from Ocugen's proposed OCU300 nanoemulsion. The different formulation may impact the final Phase 3 clinical study results for OCU300. Ocugen has evaluated results from an investigator-led retrospective analyses of the use of brimonidine tartrate 0.15% eye drops in patients with oGVHD and an investigator-led prospective Phase 1/2 clinical trial assessing the use of 0.15% and 0.075% brimonidine tartrate eye drops in patients with oGVHD. The formulations used in these studies are different than its proposed OCU300 formulation. These studies and results are not sufficient to establish the safety and efficacy of OCU300 and the results from these studies should be viewed with caution. The results from these studies may not be predictive of adequate and well-controlled prospective studies. Additionally, these clinical studies were not powered for statistical significance due to their small sample size and the Phase 1/2 clinical study was discontinued early due to slow enrollment. These studies may not be predictive of the results of later studies conducted with the OCU300 formulation for which Ocugen intends to seek marketing approval. Moreover, although a dose ranging study was recommended but not required by FDA, Ocugen does not intend to conduct such a study and has proceeded directly into Phase 3 clinical trials. Ocugen's Phase 3 clinical program for OCU300 consists of two clinical trials evaluating OCU300, the first of which is expected to include approximately 60 patients with oGVHD. Ocugen initiated the first Phase 3 trial of OCU300 in June 2018 and the first patient was dosed in December 2018. The timing of the completion of the Phase 3 clinical trials for OCU300 is dependent, in part, on its ability to locate and enroll a sufficient number of eligible patients on a timely basis, as well as a sample size re-estimation based on data from the first 50% of enrolled patients. Ocugen may need to conduct additional studies before it can submit a marketing application for approval of OCU300.

Ocugen's product candidates will require additional clinical and non-clinical development, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before it generates any revenues from product sales. Ocugen cannot assure you that it will meet its timelines for its clinical trials, which may be delayed or not completed for a number of reasons.

Ocugen is not permitted to market or promote any of its product candidates before it receives regulatory approval from the FDA or comparable foreign regulatory authorities, and it may never receive such regulatory approval for any of its product candidates. Even if its product candidates are approved, they may be subject to limitations on the indicated uses and populations for which they may be marketed. They may also be subject to other conditions of approval, may contain significant safety warnings, including boxed warnings, contraindications, and precautions, may not be approved with label statements necessary or desirable for successful commercialization, or may contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a risk evaluation and mitigation strategy ("REMS") to monitor the safety or efficacy of the products. If Ocugen does not receive FDA approval for, and successfully commercialize its product candidates, it will not be able to generate revenue from these product candidates in the United States in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing its product candidates will have a material adverse impact on its business and financial condition.

Ocugen has not previously submitted a marketing application to the FDA, or similar marketing application to comparable foreign authorities, for any product candidate, and it cannot be certain that its product candidates will be successful in clinical trials or receive regulatory approval.

Its product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected or unacceptable adverse events or failure to demonstrate efficacy in clinical trials. Further, its product candidates may not receive regulatory approval even if they are successful in clinical trials.

The success of Ocugen's product candidates and its ability to generate revenues from its product candidates will depend on many factors including its ability to:

- complete and obtain favorable results from its clinical and preclinical trials with respect to its product candidates;

- apply for and receive marketing approval from the applicable regulatory authorities;
- receive approval for its manufacturing processes and third-party manufacturing facilities from the applicable regulatory authorities;
- recruit and enroll qualified patients for clinical trials with respect to its product candidates in a timely manner;
- expand and maintain a workforce of experienced scientists and others with experience in the relevant technology to continue to develop its product candidates;
- launch and create market demand for its product candidates through marketing and sales activities, and any other arrangements to promote these product candidates that it may otherwise establish;
- receive regulatory approval for claims that are necessary or desirable for successful marketing;
- hire, train, and deploy marketing and sales representatives or contract with a third-party for marketing and sales representatives to commercialize product candidates in the United States;
- manufacture product candidates in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- pursue partnerships with, or offer licenses to, qualified third parties to promote and sell product candidates in domestic and key foreign markets where it receives marketing approval;
- maintain patent and trade secret protection and regulatory exclusivity for its product candidates;
- qualify for, identify, register, maintain, enforce and defend intellectual property rights and claims covering its products and intellectual property portfolio;
- not infringe on others' intellectual property rights;
- launch commercial sales of its product candidates, whether alone or in collaboration with others;
- achieve market acceptance of its product candidates by patients, the medical community, and third-party payors;
- achieve appropriate reimbursement, pricing, and payment coverage for its product candidates;
- effectively compete with other therapies and establish a market share; and
- maintain a continued acceptable safety and efficacy profile of its product candidates following launch.

To the extent Ocugen is not able to do any of the foregoing, its business may be materially harmed. Moreover, successful development of its product candidates for additional indications, if any, or for use in broader patient populations and its ability to broaden the label for any approved product candidates will depend on similar factors.

If it is required to conduct additional clinical trials or other testing of its product candidates that it develops beyond those that it currently expects, if it is unable to successfully complete clinical trials of its product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, Ocugen may:

- be delayed in obtaining marketing approval for its product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval without labeled claims necessary for Ocugen to successfully market its products;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings, and contraindications;
- be subject to additional post-marketing testing requirements, surveillance requirements, or REMS; or
- have the product removed from the market after obtaining marketing approval.

To the extent any of the foregoing should occur, its business may be materially harmed.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If Ocugen is not able to obtain, or if there are delays in obtaining, required regulatory approvals, it will not be able to commercialize its product candidates as expected, and its ability to generate revenue will be materially impaired.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. These may require Ocugen to amend its clinical trial protocols, conduct additional studies that require regulatory or Institutional Review Board ("IRB") approval, or otherwise cause delays in the approval or rejection of an application. Ocugen has not obtained regulatory approval for any product candidate and it is possible that none of its existing product candidates or any product candidates it may seek to develop in the future, will ever obtain regulatory approval. Moreover, its product candidates will require additional studies, as well as additional manufacturing development before it will be able to submit marketing applications to the applicable regulatory authorities. Any delay in obtaining or failure to obtain required approvals could materially adversely affect its ability to generate revenue from the particular product candidate, which likely would result in significant harm to its financial position and adversely impact its stock price.

Ocugen's product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, marketing, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA, other regulatory agencies in the United States and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate will prevent Ocugen from commercializing the product candidate. Ocugen has no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties to assist it in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by the regulatory authorities. The FDA or other similar regulatory authorities may determine that its product candidates are not effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude Ocugen from obtaining marketing approval or prevent or limit commercial use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. This is especially true for rare and/or complicated diseases. Failure can occur at any time during the clinical trial process. Ocugen has limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

The results of preclinical studies, preliminary study results, and early clinical trials of Ocugen's product candidates may not be predictive of the results of later-stage clinical trials or the ultimately completed trial. Preliminary and final results from such studies may not be representative of study results that are found in larger, controlled, blinded, and more long-term studies. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Preclinical and early clinical studies may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies have suffered significant setbacks in advanced clinical trials, notwithstanding promising results in earlier trials. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

Ocugen's future clinical trial results may not be successful. Moreover, should there be a flaw in a clinical trial, it may not become apparent until the clinical trial is well advanced.

Ocugen may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent its ability to receive marketing approval or commercialize its product candidates, including:

- regulators, including the FDA and the National Institutes of Health, or IRBs or Institutional Biosafety Committees ("IBCs") may not authorize Ocugen or its investigators to commence or continue a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or regulators, IRBs or IBCs may require that it modify or amend its clinical trial protocols;
- Ocugen may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and its contract research organizations ("CROs");
- regulators may require it to perform additional or unanticipated clinical trials to obtain approval or it may be subject to additional post-marketing testing, surveillance, or REMS requirements to maintain regulatory approval;
- clinical trials of its product candidates may produce negative or inconclusive results, or its studies may fail to reach the necessary level of statistical significance, and it may decide, or regulators may require it, to conduct additional clinical trials or abandon product development programs;
- clinical trials of its product candidates may not produce the necessary result on all study endpoints. Ocugen expects that it will be required to demonstrate effectiveness of both of the co-primary endpoints for marketing approval of OCU300 for the indication of treatment of ocular redness and discomfort in patients with oGVHD. If OCU300 does not achieve statistical significance in both primary endpoints in its Phase 3 clinical trials, the FDA may require it to conduct additional clinical trials to support the approval of its proposed indications;
- the number of patients required for clinical trials of its product candidates may be larger than it anticipates, enrollment in these clinical trials may be slower than it anticipates, or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than it anticipates. By example, the Phase 1/2 clinical study of brimonidine tartrate in patients with oGVHD was discontinued early due to slow enrollment;
- Ocugen's third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to it in a timely manner, or at all, or it may be required to engage in additional clinical trial site monitoring;
- Ocugen, the regulators, IRBs or IBCs may require the suspension or termination of clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected

- characteristics (alone or in combination with other products) of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- changes in marketing approval policies during the development period rendering its data insufficient to obtain marketing approval;
- changes in or the enactment of additional statutes or regulations;
- changes in regulatory review for submitted product applications;
- the cost of clinical trials of its product candidates may be greater than it anticipates or it may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a marketing application;
- the supply or quality of its product candidates or other materials necessary to conduct clinical trials of its product candidates may be insufficient or inadequate;
- Ocugen may decide, or regulators may require it, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical trials, or it may abandon product development programs;
- it may fail to reach an agreement with regulators, IRBs or IBCs regarding the scope, design, or implementation of its clinical trials. For instance, the FDA or comparable foreign regulatory authorities may require changes to its study design that make further study impractical or not financially prudent;
- it may have delays in adding new investigators or clinical trial sites, or it may experience a withdrawal of clinical trial sites;
- patients that enroll in its studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study, increase the needed enrollment size for the study or extend the study's duration;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding its product candidates;
- the FDA or comparable foreign regulatory authorities may disagree with its study design, including endpoints, or its interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA or comparable foreign regulatory authorities may disagree with its intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or its contract manufacturer's manufacturing facility for clinical and future commercial supplies;
- the data collected from clinical trials of its product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a marketing application, or other comparable submissions in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may take longer than it anticipates to make a decision on its product candidates; and

- it may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

Ocugen's product candidate development costs will also increase if it experiences delays in testing or approvals, and it may not have sufficient funding to complete the testing and approval process for any of its product candidates. Ocugen may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of its product candidates. Ocugen does not know whether any preclinical tests or clinical trials above what it currently has planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant delays relating to any preclinical or clinical trials also could shorten any periods during which it may have the exclusive right to commercialize its product candidates or allow its competitors to bring products to market before it does. This may prevent Ocugen from receiving marketing approvals and impair its ability to successfully commercialize its product candidates and may harm its business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of its product candidates. If any of this occurs, its business, financial condition, results of operations, and prospects will be materially harmed.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that Ocugen's data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. The foregoing may cause delays or limitations in the approval or the decision not to approve an application. It is possible that its product candidates will never obtain the appropriate regulatory approvals necessary for Ocugen to commence product sales.

Finally, even if Ocugen was to obtain approval, regulatory authorities may approve any of its product candidates for fewer or more limited indications, populations, or uses than it requests, may contain significant safety warnings, including black box warnings, contraindications, and precautions, may grant approval contingent on the performance of costly post-marketing clinical trials, surveillance, or other requirements, including REMS to monitor the safety or efficacy of the product, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of these scenarios could compromise the commercial prospects for Ocugen's product candidates.

If Ocugen experiences delays in obtaining approval, if it fails to obtain approval of a product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and Ocugen's ability to generate revenues from that product candidate will be materially impaired.

The FDA may determine that Ocugen's product candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by Ocugen's product candidates could cause it, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. For example, if concerns are raised regarding the safety of one of Ocugen's product candidates as a result of undesirable side effects identified during clinical or preclinical testing, the FDA may order it to cease further development, decline to approve such product candidate or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. FDA requests for additional data or information can result in substantial delays in the approval of a new product candidate.

Undesirable side effects caused by or any unexpected characteristics (alone or in combination with other products) for any of Ocugen's product candidates could also result in denial of regulatory approval by the FDA or other comparable foreign authorities for any or all targeted indications or the inclusion of unfavorable information in Ocugen's product labeling, such as limitations on the indicated uses or populations for which the products may be

marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products. These could prevent Ocugen from commercializing and generating revenues from the sale of its product candidates.

While there have been a few adverse events that have occurred in the investigator-led clinical studies of brimonidine tartrate for the treatment of ocular redness and discomfort in patients with oGVHD, overall brimonidine tartrate was well-tolerated. Ocugen does not have any studies exploring long term exposure in these patient populations to brimonidine tartrate or its product candidates. Ocugen's understanding of the relationship between its product candidates and any adverse effects may change as it gathers more information, and unexpected adverse effects may occur.

Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects that prevented further development of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later be found to be caused by the study treatment. Moreover, incorrect or improper use of Ocugen's product candidates (including use more frequently than is prescribed) by patients could cause unexpected side effects or adverse events. There can be no assurance that Ocugen's product candidates will be used correctly, and if used incorrectly, such misuse could prevent its receipt or maintenance of marketing authorization, resulting in label changes or regulatory authority safety communications or warnings, or hamper commercial adoption of its product candidate, if approved, at the rate it currently expects.

For those product candidates that are based on previously approved products, such as OCU300, subjects and patients may also experience adverse events that are included on the label for the FDA approved products.

If any of Ocugen's product candidates is associated with serious adverse events or undesirable side effects or have properties that are unexpected, Ocugen may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm Ocugen's business, financial condition, results of operations, and prospects.

If Ocugen experiences delays or difficulties in the enrollment of patients in clinical trials, its completion of clinical trials and receipt of necessary regulatory approvals could be delayed or prevented.

Ocugen may not be able to initiate or continue conducting clinical trials for its product candidates if it is unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Competitors may also have ongoing clinical trials for product candidates that are intended to treat the same indications as its product candidates, and patients who would otherwise be eligible for Ocugen's clinical trials may instead enroll in clinical trials of its competitors' product candidates. Patient enrollment is affected by other factors including:

- the size and nature of the patient population (for instance, Ocugen is pursuing clinical trials for certain orphan indications, for which the size of the patient population is limited);
- the severity of the disease under investigation;
- the existence of current treatments for the indications for which it is conducting clinical trials;
- the eligibility criteria for and design of the clinical trial in question, including factors such as frequency of required assessments, length of the study and ongoing monitoring requirements;
- the perceived risks and benefits of the product candidate, including the potential advantages or disadvantages of the product candidate being studied in relation to other available therapies;

- competition in recruiting and enrolling patients in clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- effectiveness of publicity created by clinical trial sites regarding the trial;
- patients' ability to comply with the specific instructions related to the trial protocol, proper documentation, and use of the product candidate;
- an inability to obtain or maintain patient informed consents;
- the risk that enrolled patients will drop out before completion or not return for post-treatment follow-up;
- the ability to monitor patients adequately during and after treatment;
- the ability to compensate patients for their time and effort; and
- the proximity and availability of clinical trial sites for prospective patients.

Ocugen's inability to enroll a sufficient number of patients for its clinical trials would result in significant delays and could require it to abandon one or more clinical trials altogether. In particular, there may be low or slow enrollment, and the studies may enroll subjects that do not meet the inclusion criteria, requiring the erroneously enrolled subjects to be excluded and the trial population to be increased. By example, the Phase 1/2 clinical study examining the use of brimonidine tartrate eye drops in patients with oGVHD was discontinued early due to slow enrollment. Moreover, patients in Ocugen's clinical trials, especially patients in its control groups, may be at risk for dropping out of its studies if they are not experiencing relief of their disease. A significant number of withdrawn patients would compromise the quality of its data.

Enrollment delays in Ocugen's clinical trials may result in increased development costs for its product candidates, or the inability to complete development of its product candidates, which would cause the value of its company to decline, limit its ability to obtain additional financing, and materially impair its ability to generate revenues.

Ocugen's development and commercialization strategy for OCU300 depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of approved products. If Ocugen is not able to pursue this strategy, it will need to conduct additional development activities beyond what it currently plans, its development costs will increase, and it may be delayed in receiving regulatory authority approval. The submission of 505(b)(2) New Drug Applications may also subject it to the risk of patent infringement lawsuits or regulatory actions that would delay or prevent its submission of a marketing application to the FDA, or the FDA's review and approval of its marketing applications.

The Hatch-Waxman Act added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act (the "FDCA"). Section 505(b)(2) permits the filing of a New Drug Application ("NDA"), where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) of the FDCA, for purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature and/or the FDA's previous findings of safety and efficacy for an approved product. The FDA also requires companies to perform additional clinical trials or measurements to support any deviation from the previously approved product and to support the reliance on the applicable published literature or referenced product, referred to as bridging. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant, if such approval is supported by study data. The label, however, may require all or some of the limitations, contraindications, warnings or precautions included in the reference product's label, including a black box warning, or may require additional limitations, contraindications, warnings or precautions.

Ocugen currently plans to pursue marketing approval for OCU300 in the United States through 505(b)(2) NDAs and will be completing bridging analyses prior to NDA submission. If the FDA disagrees with its conclusions regarding the appropriateness of its reliance on a reference listed drug or published literature or if it is not otherwise able to bridge to the reference listed drug or published literature to demonstrate that its reliance is scientifically appropriate, it could be required to conduct additional clinical trials or other studies to support its NDA, which could lead to unanticipated costs and delays or to the termination of its development program. If Ocugen is unable to obtain approval for its pharmaceutical formulations through the 505(b)(2) NDA process, it may be required to pursue the more expensive and time consuming 505(b)(1) approval process, which consists of full reports of investigations of safety and effectiveness conducted by or for the applicant.

There may also be circumstances under which the FDA would not allow Ocugen to pursue a 505(b)(2) application. For instance, should the FDA approve a pharmaceutically equivalent product to its product candidates, Ocugen would no longer be able to use the 505(b)(2) regulatory pathway. In that case, it is the FDA's policy that the appropriate submission would be an Abbreviated New Drug Application, or ANDA, for a generic version of the approved product. Ocugen may, however, not be able to immediately submit an ANDA or have an ANDA approval made effective, as it could be blocked by others' periods of patent and regulatory exclusivity protection.

Notwithstanding the approval of a number of products by the FDA under Section 505(b)(2), pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its policies and practices with respect to Section 505(b)(2) regulatory approvals, which could delay or even prevent the FDA from approving any NDA that Ocugen submits pursuant to the 505(b)(2) process. It is also not uncommon for a sponsor of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

If Ocugen cannot seek approval for OCU300 through the 505(b)(2) regulatory pathway, it may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for OCU300, and the complications and risks associated with approval of OCU300, would likely substantially increase. Even if Ocugen is allowed to pursue the 505(b)(2) regulatory pathway to FDA approval, it cannot assure you that OCU300 will receive the requisite approvals for commercialization. Moreover, Ocugen's inability to pursue a 505(b)(2) application could result in new competitive products reaching the market more quickly than its product candidates, which could hurt its competitive position and its business prospects.

Ocugen's use of the 505(b)(2) regulatory pathway may also subject it to the risk of patent infringement lawsuits or other regulatory actions that could prevent its submission of a marketing application for OCU300, or prevent the FDA making the approval of a marketing application effective. Applicants submitting NDAs under Section 505(b)(2) of the FDCA must provide a patent certification for the patents listed in FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, for all reference listed drugs and for all brand name products identified in published literature upon which the 505(b)(2) application relies. The possible certifications are that (1) no patent information has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. If there are any listed patents for the reference listed or brand name products that Ocugen relies upon for its 505(b)(2) applications, the FDA may not approve its 505(b)(2) product candidates until all listed patents have expired, unless Ocugen challenges the listed patents through the last type of certification, also known as a paragraph IV certification, or otherwise indicates that it is not seeking approval of a patented method of use.

If Ocugen does challenge a listed patent through a paragraph IV certification, under the Hatch Waxman Act, the holder of the patents or NDAs that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) application within 45 days of the patent or NDA owner's receipt of notice triggers a one time, automatic, 30-month stay of the FDA's ability to make the 505(b)(2) NDA approval effective. In such a case, the FDA may not make the 505(b)(2) NDA approval effective until the earlier of 30 months from the receipt of the notice of the

paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. Accordingly, Ocugen may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505(b)(2) application approval may, in some cases, not be submitted, or may, in other cases, not be made effective until any existing non-patent regulatory exclusivities have expired or, if possible, are carved out from the label.

Companies that produce branded reference listed drugs routinely bring litigation against applicants that seek regulatory approval to manufacture and market new forms of their branded products. These companies often allege patent infringement or other violations of intellectual property rights as the basis for filing suit. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling such products. Litigation to enforce or defend intellectual property rights is often complex and often involves significant expense and can delay or prevent introduction or sale of Ocugen's product candidates. If patents are held to be valid and infringed by Ocugen's product candidates in a particular jurisdiction, it may be required to cease selling, relinquish or destroy existing stock, or pay monetary damages in that jurisdiction unless it can obtain a license from the patent holder. There may also be situations where Ocugen uses its business judgment and decides to market and sell its approved products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, which is known as an "at risk launch." The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner which may be greater than the profits earned by the infringer. In the case of willful infringement, such damages may be increased up to three times. An adverse decision in patent litigation could have a material adverse effect on Ocugen's business, financial position, and results of operations and could cause the market value of its common stock to decline.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, manufacturing sites, and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause Ocugen's product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification, or FDA approval. For instance, the FDA may require that Ocugen conducts a comparability study that evaluates the potential differences in the product candidate resulting from the change. Delays in designing and completing such a study to the satisfaction of the FDA could delay or preclude its development and commercialization plans, and the regulatory approval of its product candidates. It may also require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of Ocugen's product candidates and jeopardize its ability to commence product sales and generate revenue. Any of the foregoing could limit its future revenues and growth. Any changes would also require that Ocugen devote time and resources to manufacturing development and would also likely require additional testing and regulatory actions on its part, which may delay the development of its product candidates.

Ocugen may not be successful in its efforts to develop product candidates based on its OcuNanoE™ nanoemulsion formulation or expand the use of its OcuNanoE™ nanoemulsion formulation for treating additional diseases and conditions.

Ocugen is currently directing some of its development efforts towards developing its product candidate based on its OcuNanoE™ nanoemulsion formulation and applying its OcuNanoE™ nanoemulsion formulation to support therapeutic interventions of ocular diseases with the potential of improving the tear film stability and targeting of drug molecules to the specialized tissues. Ocugen has product candidates at various stages of development for treatment of eye diseases and is exploring the potential use of its OcuNanoE™ nanoemulsion formulation in other diseases. Ocugen's existing product candidates and any other potential product candidates that it identifies may not be suitable for continued preclinical or clinical development, including as a result of being shown to have harmful side effects, a lack of efficacy or other characteristics that indicate that such product candidates are unlikely to be products that will receive marketing approval and achieve market acceptance. If Ocugen does not successfully develop and

commercialize its product candidates based upon its OcuNanoE™ nanoemulsion formulation, it will not be able to obtain substantial product revenues in future periods.

Ocugen may expend its limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because Ocugen has limited financial and managerial resources, it focuses on research programs and product candidates that it identifies for specific indications. As a result, it may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Ocugen's resource allocation decisions may cause it to fail to capitalize on viable commercial products or profitable market opportunities. Ocugen's spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If it does not accurately evaluate the commercial potential or target market for a particular product candidate, it may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for Ocugen to retain sole development and commercialization rights to such product candidate.

Ocugen may in the future conduct clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

Ocugen may in the future choose to conduct one or more of its clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. If the FDA does not accept the data from any trial that Ocugen conducts outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt Ocugen's development of the applicable product candidates. Moreover, trials conducted outside the United States would be subject to the laws of the applicable foreign jurisdiction. Failure to comply with such laws could result in regulatory enforcement action.

Failure to obtain marketing approval in international jurisdictions would prevent Ocugen's product candidates from being marketed abroad.

In order to market and sell its products in jurisdictions outside the United States, Ocugen must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedures vary among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. Ocugen's clinical trials of its product candidates may not be sufficient to support an application for marketing approval outside the United States.

Ocugen, or any eventual collaborators, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, the failure to obtain approval in one jurisdiction may compromise Ocugen's ability to obtain approval elsewhere. Ocugen may not be able to file for marketing approvals and may not receive necessary approvals to commercialize its products in any market.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the United Kingdom formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the withdrawal could materially impact the regulatory regime with respect to the approval of Ocugen's product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a

result of Brexit or otherwise, would prevent Ocugen from commercializing its product candidates in the United Kingdom and/or the European Union and restrict its ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, Ocugen may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for its product candidates, which could significantly and materially harm its business.

Regulatory approval is limited by the FDA to those specific indications and conditions for which approval has been granted, and Ocugen may be subject to fines, penalties, injunctions, or other enforcement actions if it is determined to be promoting the use of its products for unapproved or “off-label” uses, resulting in damage to Ocugen’s reputation and business.

Ocugen must comply with requirements concerning advertising and promotion for any product candidates for which it obtains marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services’ Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If Ocugen is not able to obtain FDA approval for desired uses or indications for its product candidates, it may not market or promote them for those indications and uses, referred to as off-label uses, and Ocugen’s business may be adversely affected. Ocugen further must be able to sufficiently substantiate any claims that it makes for its products including claims comparing its products to other companies’ products and must abide by the FDA’s strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product’s labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, Ocugen is prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA. These off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by companies concerning off-label use.

If Ocugen is found to have impermissibly promoted any of its product candidates, it may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. Thus, Ocugen will not be able to promote any products it develops for indications or uses for which they are not approved.

In the United States, engaging in the impermissible promotion of Ocugen’s products, following approval, for off-label uses can also subject Ocugen to false claims and other litigation under federal and state statutes, including fraud and abuse and consumer protection laws. Such litigation can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which it promotes or distributes therapeutic products and does business through, for example, corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, suspension and debarment from government contracts, and refusal of orders under existing government contracts. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a company on behalf of the federal government alleging submission of false or fraudulent claims, or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. These False Claims Act lawsuits against sponsors of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, up to \$3.0 billion, pertaining to certain sales practices and promoting off-label uses. In addition, False Claims Act lawsuits may expose sponsors to follow-on claims by private payers based on fraudulent marketing practices. This growth in litigation has increased the risk that companies will have to defend a false claim action, and

pay settlements fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If Ocugen does not lawfully promote its approved products, if any, it may become subject to such litigation and, if it does not successfully defend against such actions, those actions may have a material adverse effect on its business, financial condition, results of operations and prospects.

In the United States, the distribution of product samples to physicians must further comply with the requirements of the U.S. Prescription Drug Marketing Act, and the promotion of biologic and pharmaceutical products are subject to additional FDA requirements and restrictions on promotional statements. If the FDA determines that Ocugen's promotional activities violate its regulations and policies pertaining to product promotion, it could request that Ocugen modify its promotional materials or subject it to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. These regulatory and enforcement actions could significantly harm Ocugen's business, financial condition, results of operations, and prospects.

Even if Ocugen's product candidates receive regulatory approval, it will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, any of Ocugen's product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and Ocugen may be subject to penalties if it fails to comply with regulatory requirements or experiences unanticipated problems with its products.

Any product candidate for which Ocugen obtains marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities, including requirements related to the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with current good manufacturing practices ("cGMPs"), or cGMP-requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and good clinical practices, or GCPs, for any clinical trials that Ocugen conducts post-approval.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses and populations for which the product may be marketed or to the conditions of approval, including significant safety warnings, such as boxed warnings, contraindications, and precautions that are not desirable for successful commercialization. Any approved products may also be subject to a REMS that render the approved product not commercially viable or other post-market requirements, such as Phase 4 studies, or restrictions. Moreover, the FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of Ocugen's product candidates, they may, among other actions, withdraw approval, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

Ocugen and any of its collaborators, including its contract manufacturer, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes.

In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with Ocugen's products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various results, including:

- restrictions on manufacturing, distribution, or marketing of such products;

- restrictions on the labeling, including restrictions on the indication or approved patient population, and required additional warnings, such as black box warnings, contraindications, and precautions;
- modifications to promotional pieces;
- issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or a comparable foreign authority may require that Ocugen establish or modify a similar strategy;
- changes to the way the product is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product;
- refusal to approve pending applications or supplements to approved applications that Ocugen submits;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of Ocugen's products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Non-compliance with any foreign jurisdictions' requirements, including requirements regarding the protection of personal information, can also lead to significant penalties and sanctions.

Any of these events could prevent Ocugen from achieving or maintaining market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of developing and commercializing such product, which in turn could delay or prevent Ocugen from generating significant revenues from its sale. Any of these events could further have other material and adverse effects on its operations and business and could adversely

impact its stock price and could significantly harm its business, financial condition, results of operations, and prospects.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of Ocugen's product candidates, that could limit the marketability of its product candidates, or that could impose additional regulatory obligations on it. Changes in medical practice and standard of care may also impact the marketability of its product candidates.

If Ocugen is slow or unable to adapt to changes in existing requirements, standards of care, or the adoption of new requirements or policies, or if it is not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained and be subject to regulatory enforcement action.

Should any of the above actions take place, they could adversely affect Ocugen's ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on Ocugen's operating results and financial condition.

Ocugen will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely affect its business.

Any name Ocugen intends to use for its product candidates will require approval from the FDA regardless of whether it has secured a formal trademark registration from the U.S. Patent and Trademark Office (the "USPTO"). The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of Ocugen's proposed product names, it may be required to adopt alternative names for its product candidates. If Ocugen adopts alternative names, it would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third-parties, and be acceptable to the FDA. Ocugen may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit its ability to commercialize its product candidates.

In the future Ocugen may seek FDA designations to facilitate product candidate development, such as fast track or breakthrough designation. Ocugen may not receive any such designations or if it receives such designations they may not lead to faster development or regulatory review or approval and it does not increase the likelihood that Ocugen's product candidates will receive marketing approval.

In the future, Ocugen may seek product designations, such as fast track or breakthrough designation, which are intended to facilitate the development or regulatory review or approval process for product candidates. Receipt of such a designation is within the discretion of the FDA. Accordingly, even if Ocugen believes one of its product candidates meets the criteria for a designation, the FDA may disagree. In any event, the receipt of such a designation for a product candidate may not result in a faster development process, review, or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate marketing approval by the FDA. In addition, the FDA may later decide that the product candidates no longer meet the designation conditions, in which case any granted designations may be revoked.

OCU300, OCU400 and OCU100 have received Orphan Drug Designation from the FDA. However, there is no guarantee that Ocugen will be able to maintain this designation, receive this designation for any of its other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity.

Ocugen has obtained from the FDA Office of Orphan Products Orphan Drug Designations ("ODD") for OCU300 for oGVHD, OCU400 for NR2E3 mutation-associated retinal disease and CEP290 mutation-associated retinal disease, and OCU100 for RP. Ocugen was the first company to receive ODD for oGVHD from the FDA. It has obtained orphan medical product designation from the European Commission for OCU100 for RP in the European Union. Ocugen may also seek ODD for its other product candidates, as appropriate. While ODD does provide Ocugen with

certain advantages, it neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process.

Generally, if a product candidate with ODD subsequently receives marketing approval before another product considered by the FDA to be the same, for the same orphan indication, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug or biologic for the same indication for a specified time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for ODD or if the product is sufficiently profitable so that market exclusivity is no longer justified.

Ocugen may not be able to obtain any future ODDs that it applies for, ODDs do not guarantee that Ocugen will be able to successfully develop its product candidates, and there is no guarantee that Ocugen will be able to maintain any ODDs that it receives. For instance, ODDs may be revoked if the FDA finds that the request for designation contained an untrue statement of material fact or omitted material information, or if the FDA finds that the product candidate was not eligible for designation at the time of the submission of the request.

Moreover, even if Ocugen is able to receive and maintain ODDs, it may ultimately not receive any period of regulatory exclusivity if its product candidates are approved. For instance, Ocugen may not receive orphan product regulatory exclusivity if the indication for which it receives FDA approval is broader than the ODD. Orphan exclusivity may also be lost for the same reasons that ODD may be lost. Orphan exclusivity may further be lost if Ocugen is unable to assure a sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if Ocugen obtains orphan exclusivity for any of its current or future product candidates, that exclusivity may not effectively protect the product from competition as different products can be approved for the same condition or products that are the same as Ocugen's can be approved for different conditions. Even after an orphan product is approved, the FDA can also subsequently approve a product containing the same principal molecular features for the same condition if the FDA concludes that the later product is clinically superior. The FDA may further grant ODD to multiple sponsors for the same compound or active molecule and for the same indication. If another sponsor receives FDA approval for such product before Ocugen does, Ocugen would be prevented from launching its product in the United States for the orphan indication for a period of at least seven years unless it can demonstrate clinical superiority. Moreover, third-party payors may reimburse for products off-label even if not indicated for the orphan condition.

Risks Related to the Commercialization of Ocugen's Product Candidates

Ocugen faces significant competition from other biologic, pharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations. Ocugen's operating results will suffer if it fails to compete effectively.

The development and commercialization of new therapeutic products is highly competitive. Ocugen faces competition with respect to its current product candidates and will face competition with respect to any product candidates that Ocugen may seek to develop or commercialize in the future, from major biologic and pharmaceutical companies, specialty biologic and pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Ocugen's product candidates will target markets that are already served by a variety of competing products. Many of these existing products have achieved widespread acceptance among clinicians, patients and payors. In addition, many of these products are available on a generic basis, and Ocugen's product candidates may not demonstrate sufficient additional clinical benefits to clinicians, patients or payors to justify a higher price compared to generic products. In many cases, insurers or other third-party payors, particularly Medicare, seek to encourage the use of generic products.

Ocugen's ability to compete may further be affected in many cases by insurers or other third-party payors, particularly Medicare, seeking to encourage the use of generic or biosimilar products. Generic products are currently being used for certain of the indications that Ocugen is pursuing, and additional products are expected to become available on a generic basis over the coming years.

Ocugen's commercial opportunities could be reduced or eliminated if its competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that Ocugen may develop. Ocugen's competitors also may obtain FDA or other regulatory approval for their products more rapidly than Ocugen may obtain approval for its products, which could result in Ocugen's competitors establishing a strong market position before Ocugen is able to enter the market. In addition, Ocugen's ability to compete may be affected in many cases by insurers or other third-party payors coverage decisions.

Many of the companies against which Ocugen is competing or against which it may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than Ocugen does. Mergers and acquisitions in the biologic, pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of Ocugen's competitors. Early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with Ocugen in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, Ocugen's programs.

If Ocugen is unable to establish effective marketing and sales, capabilities or enter into agreements with third parties to market and sell its product candidates, if they are approved, Ocugen may be unable to generate product revenues.

Ocugen currently does not have a commercial infrastructure for the marketing, sale, and distribution of biologic and pharmaceutical products. If approved, in order to commercialize its products, Ocugen must build its marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. Ocugen may not be successful in doing so. Should Ocugen decide to develop its own marketing capabilities, it may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of FDA requirements non-approval or other reasons, Ocugen would incur these expenses prior to being able to realize any revenue from sales of its product candidates. Even if Ocugen is able to effectively hire a sales force and develop a marketing and sales infrastructure, its sales force and marketing teams may not be successful in commercializing its product candidates.

Subject to successful results of Ocugen's ongoing and anticipated Phase 3 clinical trials and FDA approval of any of its product candidates, Ocugen may build a commercial team of specialty sales and marketing representatives in support of OCU300 and possibly other preclinical product candidates that Ocugen develops in the United States, if and when they are approved, as well as distribution capabilities. As discussed below, Ocugen may also partner with third parties to commercialize and distribute OCU300, or its other product candidates.

There are risks involved with Ocugen establishing its own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive, time-consuming, and could delay any product launch. Further, Ocugen may underestimate the size of the sales force required for a successful product launch and may need to expand its sales force earlier and at a higher cost than it anticipated. If the commercial launch of Ocugen's product candidates for which it recruits a sales force and establish marketing capabilities is delayed or does not occur for any reason, Ocugen would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and Ocugen's investment would be lost if it cannot retain or reposition its sales and marketing personnel.

Ocugen may also seek marketing approval and explore commercialization of OCU300 in certain markets outside the United States. It may also consider seeking marketing approval outside the United States for other preclinical product candidates in future. If Ocugen decides to seek regulatory approval for any of its product candidates outside the

United States (including OCU300), it may need to seek additional patent approvals, licenses to patents held by third parties and/or face claims of infringing third-party patent rights.

Ocugen may also or alternatively decide to collaborate with a third-party or contract sales organization to commercialize any approved product candidates, in which event, its ability to generate product revenues may be limited. By example, Ocugen may retain commercialization rights to OCU300 or OCU310 or utilize a variety of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize OCU300. Ocugen's product revenues and its profitability, if any, under any such third-party collaboration, distribution or other marketing arrangements are likely to be lower than if Ocugen were to market, sell and distribute OCU300 entirely itself.

Ocugen may not be successful in entering into arrangements with third parties to sell, market and distribute its product candidates or may be unable to do so on terms that are favorable to it. In addition, Ocugen would have less control over the sales efforts of any other third parties involved in its commercialization efforts and any of them may fail to devote the necessary resources and attention to sell and market its product candidates effectively. Ocugen could also be held liable if they failed to comply with applicable legal or regulatory requirements.

If Ocugen does not establish sales, marketing and distribution capabilities successfully, either on its own or in collaboration with third parties, it will not be successful in commercializing any product candidates for which it receives marketing approval.

Ocugen has no prior experience in the marketing, sale, and distribution of biologic and pharmaceutical products, and there are significant risks involved in the building and managing of a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products Ocugen may develop will be expensive and time consuming and could delay any product launch, and Ocugen may not be able to successfully develop this capability. Ocugen will have to compete with other biologic, pharmaceutical and biotechnology companies to recruit, hire, train, manage, and retain marketing and sales personnel. In the event Ocugen is unable to develop a team of marketing and sales representatives, it may not be able to commercialize its product candidates, which would limit Ocugen's ability to generate product revenues. Factors that may inhibit Ocugen's efforts to commercialize its product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe its product candidates;
- Ocugen's inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;
- reduced realization on government sales from mandatory discounts, rebates and fees, and from price concessions to private health plans and pharmacy benefit managers necessitated by competition for access to managed formularies;
- the clinical indications for which the products are approved and the claims that Ocugen may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;

- any distribution and use restrictions imposed by the FDA or to which Ocugen agrees as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put Ocugen at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

Should any of the foregoing occur, Ocugen may not be successful in commercializing any product candidates for which it receives marketing approval.

If Ocugen's product candidates do not achieve broad market acceptance, the revenues that it generates from their sales will be limited.

Ocugen has never commercialized a product candidate for any indication. Even if Ocugen's product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which Ocugen obtains regulatory approval do not gain an adequate level of market acceptance, it may not generate significant product revenues or become profitable. Market acceptance of Ocugen's product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond Ocugen's control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

While there are no drugs currently approved in the United States for treatment of oGVHD, there are several product candidates in clinical development for treatment of oGVHD in the United States. It is possible that doctors may rely on these treatments rather than OCU300, if and when it is approved for marketing by the FDA.

If generic or biosimilar versions of any products that compete with any of Ocugen's product candidates are approved for marketing by the FDA, they would likely be offered at a substantially lower price than Ocugen expects to offer for its product candidates, if approved. In the case of OCU300, it is also possible that physicians may prescribe other less expensive brimonidine tartrate products off label rather than prescribe OCU300. As a result, clinicians, patients and third-party payors may choose to rely on products other than Ocugen's product candidates for the treatment of ocular redness and discomfort in patients with oGVHD.

Efforts to educate the medical community and third-party payors on the benefits of Ocugen's product candidates may require significant resources and may not be successful. If any of Ocugen's product candidates is approved but does not achieve an adequate level of market acceptance, Ocugen may not generate significant revenues and it may not become profitable. The degree of market acceptance of any of Ocugen's product candidates will depend on a number of factors, including:

- the efficacy of its product candidates;
- the prevalence and severity of adverse events associated with such product candidates;
- interactions of its products with other medicines patients are taking and any restrictions on the use of its products together with other medications;
- the clinical indications for which the products are approved and the approved claims that Ocugen may make for the products;

- limitations or warnings contained in the product’s FDA-approved labeling, including potential limitations or warnings for such product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for such product candidates, which could reduce the marketing impact of any claims that Ocugen could make following FDA approval, if obtained;
- the relative convenience and ease of administration of such product candidates;
- cost of treatment versus economic and clinical benefit in relation to alternative treatments or therapies;
- the availability of third-party formulary coverage and adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicaid and particularly by Medicare in light of the prevalence of dry eye disease in persons over age 55;
- the price concessions required by third party payors to obtain coverage;
- the extent and strength of Ocugen’s marketing and distribution of such product candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA with respect to such product candidates or to which Ocugen agrees as part of a REMS or voluntary risk management plan;
- the timing of market introduction of such product candidates, as well as competitive products;
- its ability to offer such product candidates for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of its third-party manufacturer and supplier support;
- the approval of other new products;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

The potential market opportunities for Ocugen’s product candidates are difficult to precisely estimate. Ocugen’s estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys, some of which Ocugen may have commissioned. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While Ocugen believes these industry publications and third-party research, surveys and studies are reliable, it has not independently verified such data. In addition, while Ocugen believes that its internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of its management, are inherently uncertain, and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for Ocugen’s product candidates could be smaller than its estimates of the potential market opportunities, and as a result its product revenue may be limited, and it may be more difficult for it to achieve or maintain profitability.

Ocugen's product candidates may face competition sooner than anticipated.

Both Ocugen's drug and biologic product candidates, if approved, may face competition from other products that are the same as or similar to its product candidates. If the FDA or comparable foreign regulatory authorities approve generic or similar versions of any of Ocugen's product candidates that receive marketing approval, or such authorities do not grant its products appropriate periods of regulatory exclusivity before approving generic or similar versions of Ocugen's products, the sales of its products could be adversely affected.

In the case of Ocugen's drug product candidates, once an NDA is approved, the product will become a "reference listed drug" in the FDA's Orange Book. Other applicants may then seek approval of generic versions of Ocugen's products through submission of ANDAs in the United States. In support of an ANDA, a generic applicant would not need to conduct full clinical studies. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration, conditions of use and labeling, among other commonalities, as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is available at the site of action at the same rate and to the same extent as the reference listed drug. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices and are generally preferred by third party payors. As a result, the FDA, the administration and Congress have recently taken steps to encourage increased generic drug competition in the market in an effort to bring down drug costs. Following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product. Moreover, in addition to generic competition, Ocugen could face competition from other companies seeking approval of drug products that are similar to its products using the 505(b)(2) regulatory pathway. Such applicants may be able to rely on Ocugen's product candidates, if approved, or other approved drug products or published literature to develop drug products that are similar to Ocugen's. The introduction of a drug product similar to Ocugen's product candidates could expose it to increased competition.

Any ANDA or 505(b)(2) applicants seeking to rely upon any of Ocugen's product candidates, if such product candidates are approved, would need to submit patent certification statements with their applications for any of Ocugen's patents that are listed in the FDA's Orange Book. There are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Orange Book. Ocugen may be unable to obtain patents covering its product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. If one of Ocugen's product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, an ANDA or 505(b)(2) applicant would not have to submit a patent certification with regard to such patent to the FDA, in which case, Ocugen would not receive the protections provided by the Hatch Waxman Act.

Moreover, if an ANDA or 505(b)(2) applicant files a paragraph IV challenge to any patents that Ocugen may list in the FDA's Orange Book and if Ocugen does not file a patent infringement lawsuit within 45 days of receiving notice of a paragraph IV certification, the ANDA or 505(b)(2) applicant would not be subject to a 30-month stay. If Ocugen did file such an action, the litigation or other proceedings to enforce or defend its intellectual property rights would likely be complex in nature, may be expensive and time consuming, may divert its management's attention from its core business, and may result in unfavorable results that could adversely impact its ability to prevent third parties from competing with its products. Accordingly, upon approval of its product candidates Ocugen may be subject to generic competition or competition from similar products, or may need to commence patent infringement proceedings, which would divert its resources.

Ocugen currently anticipates that it may be eligible for three years of non-patent marketing exclusivity in the United States for OCU300 if it is approved. These three years, however, would only protect Ocugen's modifications in formulation or approved uses in comparison to the reference listed drug, would not prevent other companies from submitting full NDAs, and would not prevent physicians from prescribing other products off-label or third-party payors from reimbursing for them. By example, even if Ocugen receives approval for OCU300, physicians may prescribe other brimonidine tartrate products off-label for the treatment of ocular discomfort and ocular redness in patients with oGVHD. Moreover, applicants may be able to rely on a reference listed drug that is not one of Ocugen's product candidates, or, in the case of 505(b)(2) applicants, published literature, in which case any periods of patent or non-patent protection that it may have may not prevent FDA from making an approval effective.

Similarly, if the FDA licenses OCU400, OCU200 or OCU100, Ocugen may face competition from biosimilar products. The enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Affordable Care Act, or ACA, created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. As in the generic drug product space, the FDA and the administration are taking steps to encourage increased biosimilar competition in the market in an effort to bring down the cost of biologic products. If another company pursues approval of a product that is biosimilar to any biologic product for which Ocugen receives FDA approval, it may need to pursue costly and time-consuming patent infringement actions, which may include certain statutorily specified regulatory steps before an infringement action may be brought. Biosimilar applicants may also be able to bring an action for declaratory judgment concerning Ocugen’s patents, requiring that it spend time and money defending the action.

Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and certain subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period. Moreover, there have been efforts to decrease this period of exclusivity to a shorter timeframe. Future proposed budgets, international trade agreements and other arrangements or proposals may affect periods of exclusivity. Ocugen’s biologic product candidates may qualify for the BPCIA’s 12-year period of exclusivity, however, there is a risk that the FDA will not consider Ocugen’s product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of Ocugen’s reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. It is also possible that payers will give reimbursement preference to biosimilars, even over reference biologics, absent a determination of interchangeability.

For certain of Ocugen’s drug and biologic product candidates, it may seek pediatric exclusivity, which is another type of non-patent marketing exclusivity in the United States. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. Ocugen cannot provide any assurance that pediatric exclusivity will be obtained for any of its product candidates.

To the extent Ocugen does not receive any anticipated periods of regulatory exclusivity or to the extent FDA or foreign regulatory authorities approve any biosimilar, interchangeable, generic, similar, or other competing products, its business would be adversely impacted. Competition that Ocugen’s products may face from generic, biosimilar, interchangeable, similar, or other competing products could materially and adversely impact Ocugen’s future revenue, profitability, and cash flows and substantially limit its ability to obtain a return on the investments it has made in those product candidates.

Ocugen faces potential product liability exposure, and if successful claims are brought against it, Ocugen may incur substantial liability for its product candidates and may have to limit their commercialization.

The use of Ocugen’s product candidates in clinical trials, and the sale of any of its product candidates for which it obtains regulatory approval, exposes Ocugen to the risk of product liability claims. Ocugen faces inherent risk of product liability related to the testing of its product candidates in human clinical trials and will face an even greater risk if Ocugen commercially sells any product candidates that it may develop. For example, Ocugen may be sued if any product candidate it develops allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against Ocugen by consumers, healthcare providers or others using, administering or selling its products. If Ocugen cannot successfully defend itself against these claims, it will incur substantial liabilities or be required to limit development or commercialization of its product candidates. Even successful defense would require

significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for Ocugen’s products and/or product candidates;
- impairment of Ocugen’s business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize Ocugen’s product candidates;
- significant negative media attention;
- decrease in Ocugen’s stock price; or
- initiation of investigations, and enforcement actions by regulators; and product recalls, withdrawals, revocation of approvals, or labeling, marketing or promotional restrictions.

Ocugen currently holds \$5.0 million in product liability insurance coverage in the aggregate, with a per incident limit of \$3.0 million, which may not be adequate to cover all liabilities that it may incur. Ocugen may need to increase its insurance coverage as it expands its clinical trials. Ocugen will need to further increase its insurance coverage if it commences commercialization of any of its product candidates for which it obtains marketing approval. Insurance coverage is increasingly expensive. Ocugen may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. On occasion, large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. A successful product liability claim or series of claims brought against Ocugen could cause its stock price to fall and, if judgments exceed its insurance coverage, could decrease its cash and adversely affect its business and its prospects.

Risks Related to Ocugen’s Dependence on Third Parties

Ocugen relies, and expects to continue to rely, on third parties to conduct, supervise, and monitor its preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements.

Ocugen relies on third parties, study sites, and others to conduct, supervise, and monitor its preclinical and clinical trials for its product candidates and does not currently plan to independently conduct clinical or preclinical trials of any other potential product candidates. Ocugen expects to continue to rely on third parties, such as CROs clinical data management organizations, medical and scientific institutions, and clinical and preclinical investigators, to conduct its preclinical studies and clinical trials. For example, for the clinical studies completed to date concerning the use of brimonidine tartrate for the treatment of ocular discomfort and ocular redness in patients with oGVHD, Ocugen relied on an investigator to sponsor and conduct the studies. For the clinical study concerning the use of brimonidine tartrate for the treatment of the signs and symptoms of dry eye disease, while Ocugen sponsored the study, it relied on third-party vendors and investigators for the conduct of the study.

While Ocugen has agreements governing the activities of such third parties, it has limited influence and control over their actual performance and activities. For instance, Ocugen’s third-party service providers are not its employees, and except for remedies available to it under its agreements with such third parties Ocugen cannot control whether or not they devote sufficient time and resources to its ongoing clinical, non-clinical, and preclinical programs. If these

third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct Ocugen's preclinical studies or clinical trials in accordance with regulatory requirements or its stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to Ocugen's protocols, regulatory requirements or for other reasons, Ocugen's trials may be repeated, extended, delayed, or terminated, it may not be able to obtain, or may be delayed in obtaining, marketing approvals for its product candidates, it may not be able to, or may be delayed in its efforts to, successfully commercialize its product candidates, or it or they may be subject to regulatory enforcement actions. As a result, Ocugen's results of operations and the commercial prospects for its product candidates would be harmed, its costs could increase and its ability to generate revenues could be delayed. To the extent Ocugen is unable to successfully identify and manage the performance of third-party service providers in the future, its business may be materially and adversely affected. Ocugen's third-party service providers may also have relationships with other entities, some of which may be its competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm Ocugen's competitive position.

Ocugen's reliance on these third parties for development activities will reduce its control over these activities. Nevertheless, Ocugen is responsible for ensuring that each of its studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and its reliance on third parties does not relieve it of its regulatory responsibilities. For example, Ocugen will remain responsible for ensuring that each of its trials is conducted in accordance with the general investigational plan and protocols for the trial. Ocugen must also ensure that its preclinical trials are conducted in accordance with good laboratory practices ("GLPs"), as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require Ocugen to comply with GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical and preclinical investigators, and trial sites. If Ocugen or any of its third-party service providers fail to comply with applicable GCPs or other regulatory requirements, it or they may be subject to enforcement or other legal actions, the data generated in its trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require it to perform additional studies.

In addition, Ocugen will be required to report certain financial interests of its third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

Ocugen cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of its trials complies with the applicable regulatory requirements. In addition, Ocugen's clinical trials must be conducted with product candidates that were produced under cGMP conditions. Failure to comply with these regulations may require it to repeat clinical trials, which would delay the regulatory approval process. Ocugen is also required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

Agreements with third parties conducting or otherwise assisting with Ocugen's clinical or preclinical studies might terminate for a variety of reasons, including a failure to perform by the third parties. If any of Ocugen's relationships with these third parties terminate, it may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, if Ocugen needs to enter into alternative arrangements, it could delay its product development activities and adversely affect its business. Though Ocugen carefully manages its relationships with its third parties, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on its business, financial condition and prospects, and results of operations.

Ocugen also relies on other third parties to store and distribute its products for the clinical and preclinical trials that it conducts. Any performance failure on the part of its distributors could delay development, marketing approval, or commercialization of its product candidates, producing additional losses and depriving it of potential product revenue.

If the manufacturers upon whom Ocugen relies fail to produce its product candidates or components in the volumes that it requires on a timely basis, or fail to comply with stringent regulations applicable to biologic and pharmaceutical manufacturers, Ocugen may face delays in the development and commercialization of, or be unable to meet demand for, its product candidates and may lose potential revenues.

Ocugen does not manufacture any of its product candidates or any product components, and it does not currently plan to develop any capacity to do so. Ocugen expects to rely on a qualified supplier to manufacture and supply to it a minimum amount of brimonidine tartrate (the drug substance used in the manufacture of OCU300) for use in process validation campaigns and future commercial needs. Ocugen expects to rely on another third-party manufacturer (U.S. based) to supply commercial drug products of OCU300 if and when approved for marketing by applicable regulatory authorities. Ocugen expects to rely on its qualified supplier and other third parties to manufacture clinical supplies of other product candidates and commercial supplies of all of its products, if and when approved for marketing by applicable regulatory authorities, as well as for packaging, serialization, storage, distribution and other production logistics.

Ocugen's current and anticipated future dependence upon others for the manufacture of its product candidates or any product that it develops may adversely affect its future profit margins and its ability to commercialize any products that receive marketing approval on a timely and competitive basis. In addition, any performance failure on the part of its existing or future manufacturers could delay clinical development or marketing approval.

If these third-party manufacturers do not successfully carry out their contractual duties, meet expected deadlines or manufacture Ocugen's product candidates in accordance with regulatory requirements, if there are disagreements between Ocugen and such parties, or if such parties are unable to expand capacities to support commercialization of any of Ocugen's product candidates for which it obtains marketing approval, Ocugen may not be able to produce, or may be delayed in producing sufficient product candidates to meet its supply requirements. Any delays in obtaining adequate supplies with respect to Ocugen's product candidates and components may delay the development or commercialization of its product candidates.

Ocugen may not succeed in its efforts to establish manufacturing relationships or other alternative arrangements for any of its product candidates, components, and programs. Ocugen's product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for Ocugen and willing to do so. Moreover, because Ocugen's product candidates must be manufactured under sterile conditions, the number of manufacturers who can meet this requirement are even more limited. If Ocugen's existing third-party manufacturers, or the third parties that it engages in the future to manufacture a product or component for commercial sale or for its clinical trials should cease to continue to do so for any reason, Ocugen would likely experience delays in obtaining sufficient quantities of its product candidates for it to meet commercial demand or to advance its clinical trials while it identifies and qualifies replacement suppliers. These third-party facilities may also be affected by natural disasters, such as floods or fire, or such facilities could face manufacturing issues, such as contamination or regulatory findings following a regulatory inspection of such facility. In such instances, Ocugen may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense. The addition of a new or alternative manufacturer may also require FDA approvals and may have a material adverse effect on Ocugen's business.

If for any reason Ocugen is unable to obtain adequate supplies of its product candidates or the components used to manufacture them, it will be more difficult for it to develop its product candidates and compete effectively. Further, even if Ocugen does establish such collaborations or arrangements, its third-party manufacturers may breach, terminate, or not renew these agreements.

Ocugen or its third-party manufacturers may also encounter shortages in the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to produce its product candidates in the quantities needed for its clinical trials or, if its product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand. Such shortages may occur for a variety of reasons, including capacity constraints, delays or disruptions in the market, and shortages caused by the purchase of such materials by Ocugen's competitors or others. Ocugen's or its third-party manufacturers' failure to obtain the raw materials, therapeutic substances, or active pharmaceutical

ingredients necessary to manufacture sufficient quantities of its product candidates may have a material adverse effect on its business.

Any problems or delays Ocugen experiences in preparing for commercial-scale manufacturing of a product candidate or component, including manufacturing validation, may result in a delay in FDA approval or commercial launch of the product candidate or may impair its ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of commercialization of its product candidates and could adversely affect its business. Furthermore, if Ocugen's commercial manufacturers fail to deliver the required commercial quantities of its product candidates on a timely basis and at commercially reasonable prices, it would likely be unable to meet demand for its products and it would lose potential revenues.

While Ocugen has a commercial supply arrangement with a supplier, if its supplier does not perform as it expects or if Ocugen is not able to enter into a final contractual agreement, it may be required to replace its supplier with one or more other suppliers. If this were to occur, Ocugen may incur added costs and delays in identifying and qualifying any such replacements. Additional manufacturers and testing laboratories for its product candidates will be considered for long-term commercial supply if and when such product candidates are approved for marketing by applicable regulatory authorities.

The manufacture of biologic and pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of therapeutics often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state, and foreign regulations. If Ocugen's manufacturers were to encounter any of these difficulties and were unable to perform as agreed, its ability to provide product candidates to patients in its clinical trials and for commercial use, if approved, would be jeopardized. Reliance on third-party manufacturers entails exposure to risks to which it would not be subject if it manufactured the product candidate itself, including:

- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- competition with other product candidates and products for access to a limited number of suitable manufacturing facilities that operate under cGMP regulations;
- reliance on the third party for regulatory compliance and quality assurance;
- reduced day-to-day control over the manufacturing process for Ocugen's product candidates as a result of using third-party manufacturers for all aspects of manufacturing activities;
- reduced control over the protection of its trade secrets and know-how from misappropriation or inadvertent disclosure;
- termination, breach or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to Ocugen or result in delays in the development or commercialization of its product candidates; and
- disruptions to the operations of Ocugen's third-party manufacturers or suppliers caused by conditions unrelated to its business or operations, including the bankruptcy of the manufacturer or supplier.

In addition, all manufacturers of Ocugen's product candidates and therapeutic substances must comply with cGMP requirements enforced by the FDA that are applicable to both finished products and their active components used both for clinical and commercial supply. The FDA enforces these requirements through its facilities inspection program. Ocugen's manufacturers must be approved by the FDA pursuant to inspections that will be conducted after it submits its marketing applications to the agency. Ocugen manufacturers will also be subject to continuing FDA and other regulatory authority inspections should it receive marketing approval. Further, Ocugen, in cooperation with its

contract manufacturers, must supply all necessary chemistry, manufacturing, and control documentation to the FDA in support of a marketing application on a timely basis.

The cGMP requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of Ocugen's product candidates and the therapeutic substances and active pharmaceutical ingredients necessary to produce its product candidates may be unable to comply with its specifications, cGMP requirements and with other FDA, state, and foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If Ocugen's contract manufacturers cannot successfully manufacture material that conforms to its specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. Any such deviations may also require remedial measures that may be costly and/or time-consuming for Ocugen or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon or by Ocugen or third parties with whom Ocugen contracts could materially harm its business. Any delays in obtaining products or product candidates that comply with the applicable regulatory requirements may result in delays to clinical trials, product approvals, and commercialization. It may also require that Ocugen conduct additional studies.

While Ocugen is ultimately responsible for the manufacture of its product candidates, other than through its contractual arrangements, Ocugen has little control over its manufacturers' compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of its product candidates or if it withdraws any such approval in the future, Ocugen may need to find alternative manufacturing facilities, which would significantly impact its ability to develop, obtain and maintain regulatory approval for or market its product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. Ocugen must also receive FDA approval for the use of any new manufacturers for commercial supply.

A failure to comply with the applicable regulatory requirements may result in regulatory enforcement actions against Ocugen's manufacturers or Ocugen, including fines and civil and criminal penalties, including imprisonment, suspension or restrictions of production, injunctions, delay, withdrawal or denial of product approval or supplements to approved products, clinical holds or termination of clinical studies, warning or untitled letters, regulatory authority communications warning the public about safety issues with the product, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, or consent decrees. Depending on the severity of any potential regulatory action, Ocugen's clinical or commercial supply could be interrupted or limited, which could have a material adverse effect on its business.

Ocugen does not currently have arrangements in place for redundant supply for bulk pharmaceutical and biologic substances and finished products. Any change in Ocugen's manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

Ocugen may rely on third parties to perform many essential services for any products that it commercializes, including services related to warehousing and inventory control, distribution, government price reporting, customer service, accounts receivable management, cash collection, and pharmacovigilance and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, Ocugen's ability to commercialize its product candidates will be significantly impacted and it may be subject to regulatory sanctions.

Ocugen may retain third-party service providers to perform a variety of functions related to the sale and distribution of its product candidates, key aspects of which will be out of its direct control. These service providers may provide key services related to warehousing and inventory control, distribution, customer service, accounts receivable management, and cash collection. If Ocugen retains a service provider, it would substantially rely on it as well as other third-party providers that perform services for it, including entrusting its inventories of products to their care

and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to Ocugen, or encounter physical or natural damage at their facilities, Ocugen's ability to deliver product to meet commercial demand would be significantly impaired and it may be subject to regulatory enforcement action.

In addition, Ocugen may engage third parties to perform various other services for it relating to pharmacovigilance and adverse event reporting, safety database management, fulfillment of requests for medical information regarding its product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements, Ocugen could be subject to regulatory sanctions.

Additionally, Ocugen may contract with a third party to calculate and report pricing information mandated by various government programs. If a third party fails to timely report or adjust prices as required, or errors in calculating government pricing information from transactional data in its financial records, it could impact Ocugen's discount and rebate liability, and potentially subject it to regulatory sanctions or False Claims Act lawsuits.

Ocugen may collaborate with third parties for the development or commercialization of its product candidates. Ocugen may not be successful in establishing or maintaining collaborative relationships, which could adversely affect its ability to develop and commercialize its product candidates.

In the future Ocugen may seek collaboration arrangements with biologic, pharmaceutical or biotechnology companies for the development or commercialization of its product candidates. Ocugen may utilize a variety of types of collaboration, distribution and other marketing arrangements with third parties to develop and commercialize its product candidates outside the United States. Ocugen may also enter into arrangements with third parties to perform these services in the United States if it does not establish its own sales, marketing and distribution capabilities in the United States or if it determines that such third-party arrangements are otherwise beneficial. For example, Ocugen may utilize a variety of collaboration, distribution and other marketing arrangements with one or more third parties to facilitate commercialization of OCU300. Ocugen may also consider potential collaborative partnership opportunities for sales, marketing, distribution, development, or licensing or broader collaboration arrangements, including with large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Ocugen is not currently party to any such arrangement.

The success of future collaboration arrangements that Ocugen may enter into will depend heavily on the efforts and activities of its collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to collaboration arrangements. Accordingly, if Ocugen does enter into any such arrangements with any third parties in the future, it will likely have limited control over the amount and timing of resources that its collaborators dedicate to the development or commercialization of its product candidates. Ocugen's ability to generate revenues from these arrangements will depend on its collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Moreover, collaborations with biologic and pharmaceutical companies and other third parties are often terminated or allowed to expire. Any such termination or expiration would adversely affect Ocugen financially and could harm its business reputation.

Ocugen may also license the right to market and sell its product candidates under its collaborators' labeler codes. Alternatively, Ocugen may enter into agreements with collaborators to market and sell its product candidates under its own labeler code, in which case errors and omissions by collaborators in capturing and transmitting transactional data may impact the accuracy of its government price reporting.

Any future collaborations Ocugen might enter into may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development of product candidates and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or Ocugen to regulatory enforcement actions;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Ocugen's product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than Ocugen's;
- product candidates discovered in collaboration with Ocugen may be viewed by its collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of Ocugen's product candidates;
- a collaborator with marketing and distribution rights to one or more of Ocugen's product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for Ocugen with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators may not properly maintain or defend Ocugen's intellectual property rights or may use its proprietary information in such a way as to invite litigation that could jeopardize or invalidate Ocugen's intellectual property or proprietary information or expose it to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose Ocugen to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, Ocugen could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations Ocugen might enter into in the future do not result in the successful development and commercialization of product candidates or if one of Ocugen's collaborators subsequently terminates its agreement with it, Ocugen may not receive any future research funding or milestone or royalty payments under the collaboration. If Ocugen does not receive the funding it expects under the agreements, its development of its product candidates could be delayed, and Ocugen may need additional resources to develop its

product candidates and its product platform. All of the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of Ocugen's collaborators.

Additionally, if any future collaborator of Ocugen's is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate licensed to it by Ocugen. If one of Ocugen's collaborators terminates its agreement with Ocugen, Ocugen may find it more difficult to attract new collaborators and its reputation in the business and financial communities could be adversely affected.

Should Ocugen desire to pursue a collaboration agreement but is not able to establish collaborations, it may have to alter its development and commercialization plans and its business could be adversely affected.

For some of Ocugen's product candidates, Ocugen may decide to collaborate with pharmaceutical or biotechnology companies for the development and potential commercialization of those product candidates. Ocugen faces significant competition in seeking appropriate collaborators and whether it reaches a definitive agreement for a collaboration will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to Ocugen's ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with Ocugen for its product candidate. Ocugen may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

Should Ocugen desire to pursue a collaboration agreement but is unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, it may have to curtail the development of a product candidate, reduce or delay its development program or one or more of its other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase its expenditures and undertake development or commercialization activities at its own expense. If Ocugen elects to fund and undertake development or commercialization activities on its own, it may need to obtain additional expertise and additional capital, which may not be available to it on acceptable terms or at all. If Ocugen fails to enter into collaborations and does not have sufficient funds or expertise to undertake the necessary development and commercialization activities, it may not be able to further develop its product candidates or bring them to market or continue to develop its product platform and its business may be materially and adversely affected.

Risks Related to Legal and Compliance Matters

If Ocugen fails to comply with federal and state healthcare laws, including fraud and abuse and health and other information privacy and security laws, it could face substantial penalties and its business, financial condition, results of operations, and prospects could be adversely affected.

As a biologic and pharmaceutical company, Ocugen is subject to many federal and state healthcare laws, such as the federal Anti-Kickback Statute, the federal civil and criminal False Claims Acts, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992, the federal Health Insurance Portability and Accountability Act of 1996 (as amended by the Health Information Technology for Economics and Clinical Health Act), the Foreign Corrupt Practices Act of 1977, the Patient Protection and Affordable Care Act of 2010, and similar state laws. Ocugen may also be subject to laws regarding transparency and patient privacy. Even though Ocugen does not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws, and regulations pertaining to fraud and abuse, reimbursement programs, government procurement, and patients' rights are and will be applicable to its business. Ocugen would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which it conducts its business.

Efforts to ensure that Ocugen's business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that Ocugen's business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Ocugen or its operations are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that applies to it, Ocugen may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, imprisonment, disgorgement, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of its operations, any of which could materially adversely affect its ability to operate its business and its financial results. If any of the physicians or other healthcare providers or entities with whom Ocugen expects to do business is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect its business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, reimbursement, and fraud laws may prove costly. Any action against Ocugen for violation of these laws, even if Ocugen successfully defends against it, could cause it to incur significant legal expenses and divert its management's attention from the operation of its business.

Ocugen is subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase its costs of compliance, and adversely affect its ability to market its products, obtain collaborators, and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of Ocugen's product candidates, restrict or regulate post-approval activities and affect its ability to profitably sell any products for which it obtains marketing approval. The biopharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Ocugen expects that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that it may receive for any approved products.

In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the ACA, included provisions of importance to Ocugen's business, including, without limitation, its ability to commercialize and the prices it may obtain for any of its product candidates that are approved for sale. These provisions include:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, including products approved through the 505(b)(2) regulatory pathway;
- an increase in the statutory minimum rebates a sponsor must pay under the Medicaid Drug Rebate Program;
- a Medicare Part D coverage gap discount program, in which participating sponsors must agree to offer 50% point-of-sale discounts off negotiated drug prices of drugs and biologics approved under an NDA or BLA (including drugs approved pursuant to the 505(b)(2) regulatory pathway) during the coverage gap period as a condition for the sponsors' outpatient drugs to be covered under Medicare Part D;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, and the addition of new government investigative powers, and enhanced penalties for noncompliance;
- extension of sponsor's Medicaid rebate liability to managed Medicaid plans;
- expansion of eligibility criteria for Medicaid programs;

- expansion of the entities eligible for discounts under the Public Health Service Acts or the PHSA, pharmaceutical pricing program; and
- creation of a special Medicare Part B payment methodology for biosimilars approved under PHSA Section 351(k) in which providers are paid the ASP of the biosimilar plus the margin based on ASP of the reference biologic.

The ACA was recently amended to repeal the individual insurance mandate, and efforts to repeal and replace portions of the law may continue. It remains to be seen, however, whether new legislation will be enacted and, if so, precisely what any new legislation could provide and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. For example, it is possible that any repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that Ocugen may successfully develop and for which it may obtain marketing approval and may affect its overall financial condition and ability to develop or commercialize product candidates. The timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects.

Since the ACA was enacted in 2010, other legislative and regulatory changes have been proposed and adopted. These changes include, among other things, aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went effective on April 1, 2013 and will remain in effect through 2024 unless additional Congressional action is taken. More recently, the Bipartisan Budget Act increased sponsor responsibility for prescription costs in the Medicare Part D coverage gap, and also extended sponsor responsibility for prescription costs in the Medicare Part D coverage gap to biosimilars, which had previously been exempt. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. CMS promulgated regulations governing sponsors' obligations and reimbursement under the Medicaid Drug Rebate Program, and recently promulgated a regulation that limited Medicare Part B payment to certain hospitals for outpatient drugs purchased under the 340B program. To the extent that Ocugen licenses the right to sell a product to another entity under that entity's labeler code, the licensee would further have healthcare reimbursement and pricing regulatory responsibilities.

Ocugen expects that current law and federal and state healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from its biologic and pharmaceutical products, decreased potential returns from its development efforts, new payment methodologies and in additional downward pressure on the price that Ocugen receives for any approved product and/or the level of reimbursement physicians receive for administering any approved product it might bring to market. Reductions in reimbursement levels may negatively impact the prices Ocugen receives or the frequency with which any products it may develop are prescribed or administered. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent it from being able to generate revenue, attain profitability or commercialize its products.

The costs of prescription pharmaceuticals and biologics in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Trump Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals and biologics is also subject to governmental control outside the United States. In certain countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, Ocugen may be required to conduct a clinical trial that compares the cost-effectiveness of its product candidates to other available therapies. If reimbursement of its products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, Ocugen's ability to generate revenues and become profitable could be impaired.

Legislative and regulatory proposals may also be made to expand post-approval requirements and restrict sales and promotional activities. Ocugen cannot be sure whether additional legislative changes will be enacted, or whether the

FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of its product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject Ocugen to more stringent product labeling and post-marketing testing and other requirements.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the biologic and pharmaceutical industry. For instance, the Drug Quality and Security Act (the "DQSA"), imposes obligations on sponsors of biologic and pharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, sponsors are required to provide certain information regarding the product to individuals and entities to which product ownership is transferred, will be required to label products with a product identifier, and are required keep certain records regarding the product. The transfer of information to subsequent product owners by manufacturers is also required to be done electronically. Sponsors are also required to verify that purchasers of the sponsors' products are appropriately licensed. Further, manufacturers have product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Future licensees or affiliates may also have responsibilities under DQSA.

Compliance with the federal track and trace requirements may increase Ocugen's operational expenses and impose significant administrative burdens. As a result of these and other new proposals, Ocugen may determine to change its current manner of operation, provide additional benefits or change its contract arrangements, any of which could have a material adverse effect on its business, financial condition, and results of operations.

Ocugen's employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on its business.

Ocugen is exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, comply with federal procurement rules or contract terms, report financial information or data accurately or disclose unauthorized activities to Ocugen. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to Ocugen's reputation. It is not always possible to identify and deter this type of misconduct, and the precautions Ocugen takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against Ocugen even if the government considers the claim unmeritorious and declines to intervene, which could require Ocugen to incur costs defending against such a claim. Further, due to the risk that a judgment in a False Claims Act case could result in exclusion from federal health programs or debarment from government contracts, whistleblower cases often result in large settlements. If any such actions are instituted against Ocugen, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, financial condition, and results of operations, including the imposition of significant fines or other sanctions.

Ocugen's business and operations would suffer in the event of system failures.

Ocugen's internal computer systems and those of its CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in its operations, it could result in a material disruption of its product candidate development and, if such product candidates are approved, commercialization programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in its regulatory approval efforts and significantly increase its costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to its data or applications, or

inappropriate disclosure of personal, confidential or proprietary information, Ocugen could incur liability and regulatory enforcement actions, and the further development of any of its product candidates could be delayed.

Ocugen is subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing its operations. If it fails to comply with these laws, it could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect its business, results of operations and financial condition.

Ocugen's operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010 (the "Bribery Act"), the U.S. Foreign Corrupt Practices Act (the "FCPA"), and other anti-corruption laws that apply in countries where it does business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit Ocugen, its officers, and its employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Ocugen may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and it may participate in collaborations and relationships with third parties whose actions could potentially subject it to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, Ocugen cannot predict the nature, scope or effect of future regulatory requirements to which its international operations might be subject or the manner in which existing laws might be administered or interpreted. If Ocugen expands its operations outside of the United States, it will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which it plans to operate.

Ocugen is also subject to other laws and regulations governing its international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If Ocugen expands its presence outside of the United States, it will require Ocugen to dedicate additional resources to comply with these laws, and these laws may preclude Ocugen from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit Ocugen's growth potential and increase its development costs.

There is no assurance that Ocugen will be completely effective in ensuring its compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If Ocugen is not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, it may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on its business, financial condition, results of operations and liquidity. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by U.K., U.S. or other authorities could also have an adverse impact on Ocugen's reputation, its business, results of operations and financial condition.

Risks Related to Ocugen's Intellectual Property

Ocugen may be unable to obtain and maintain patent protection for its technology and product candidates, or the scope of the patent protection obtained may not be sufficiently broad or enforceable, such that its competitors

could develop and commercialize technology and products similar or identical to Ocugen's, and Ocugen's ability to successfully commercialize its technology and product candidates may be impaired.

Ocugen's success depends in large part on its ability to obtain and maintain patent protection in the United States and other countries with respect to its proprietary technology and product candidates. Ocugen has sought to protect its proprietary position by filing in the United States and in certain foreign jurisdictions patent applications related to its novel technologies and product candidates.

The patent prosecution process is expensive and time-consuming, and Ocugen may not have filed, maintained or prosecuted and may not be able to file, maintain and prosecute all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner. Ocugen may also fail to identify patentable aspects of its research and development output before it is too late to obtain patent protection.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of its patent rights are highly uncertain. Ocugen's pending and future patent applications may fail to result in issued patents in the United States or in other foreign countries which protect its technology or product candidates, or which effectively prevent others from commercializing competitive technologies and products. In addition, the laws of foreign countries may not protect Ocugen's rights to the same extent as the laws of the United States, and the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, unlike patent law in the United States, European patent law precludes the patentability of methods of treatment of the human body and imposes substantial restrictions on the scope of claims it will grant of broader than specifically disclosed embodiments. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, Ocugen cannot be certain whether it or its licensors were the first to make the inventions claimed in its owned or licensed patents or pending patent applications, or that it or its licensors were the first to file for patent protection of such inventions. Databases for patents and publications, and methods for searching them, are inherently limited so Ocugen may not know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability and commercial value of Ocugen's patent rights are uncertain. Ocugen's pending and future patent applications may not result in patents being issued which protect its technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon Ocugen's ability to generate additional preclinical or clinical data that support the patentability of its proposed claims. Ocugen may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of its patents or narrow the scope of its patent protection.

Even if Ocugen's owned and licensed patent applications issue as patents, they may not issue in a form that will provide Ocugen with any meaningful protection for its proprietary technology and product candidates, prevent competitors from competing with it, or otherwise provide it with any competitive advantage. Ocugen's competitors may be able to circumvent its owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. In particular, a competitor may develop an approach to deliver drugs through the mucus layer to the underlying target tissue that uses a different approach than Ocugen's OcuNanoE™ nanoemulsion formulation, and therefore may not infringe on its patent rights.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability, and Ocugen's owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit its ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of its technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, Ocugen's patent portfolio may not provide it with sufficient rights to exclude others from commercializing products similar or identical to Ocugen's.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of Ocugen's patent applications and the enforcement or defense of its issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of Ocugen's patent applications and the enforcement or defense of its issued patents, which could have a material adverse effect on its business, financial condition, results of operations and prospects. For example, the Leahy-Smith Act created a new administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, that provides a venue for companies to challenge the validity of competitor patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long term impact the PTAB proceedings will have on the operation of Ocugen's business, the outcome of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could therefore increase the likelihood that Ocugen's own patents will be challenged, thereby increasing the uncertainties and costs of maintaining, defending and enforcing them.

If Ocugen is not able to obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of its marketing exclusivity for its product candidates, its business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of its product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product to account for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of Ocugen's product candidates. Nevertheless, Ocugen may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than Ocugen requests.

If Ocugen is unable to obtain patent term extension or restoration, or the term of any such extension is less than it requests, the period during which it will have the right to exclusively market its product may be shortened and its competitors may obtain approval of competing products following its patent expiration sooner, and its revenue could be reduced, possibly materially.

It is possible that Ocugen will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering one of its product candidates even where that patent is eligible for patent term extension, or if Ocugen obtains such an extension, it may be for a shorter period than it had sought. Further, for Ocugen's licensed patents, it does not have the right to control prosecution, including filing with the USPTO, a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of Ocugen's licensed patents is eligible for patent term extension under the Hatch-Waxman Act, it may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

Ocugen may become involved in lawsuits to protect or enforce its patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate its owned and licensed patents, trade secrets, or other intellectual property. As a result, to counter infringement, misappropriation or unauthorized use, Ocugen may be required to file infringement or misappropriation claims or other intellectual property related proceedings, which can be expensive and time-consuming. Any claims Ocugen asserts against perceived infringers could provoke such parties to assert counterclaims against it alleging that it infringes their patents or that its asserted patents are invalid. In addition, in a patent infringement or other intellectual property related proceeding, a court may decide that a patent of Ocugen's is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that Ocugen's patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of Ocugen's patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of its patent applications at risk of not yielding an issued patent. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of Ocugen's confidential information or trade secrets could be compromised by disclosure during this type of litigation.

Ocugen may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in other contested proceedings such as opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings in the United States or elsewhere, challenging its patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, Ocugen's patent rights, allow third parties to commercialize its technology or product candidates and compete directly with it, without payment to it, or result in Ocugen's inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by Ocugen's patents and patent applications is threatened, it could dissuade companies from collaborating with it to license, develop or commercialize current or future product candidates.

In the United States, the FDA does not prohibit clinicians from prescribing an approved product for uses that are not described in the product's labeling. Although use of a product directed by off-label prescriptions may infringe Ocugen's method-of-treatment patents, the practice is common across medical specialties, particularly in the United States, and such infringement is difficult to detect, prevent or prosecute.

Third parties may initiate legal proceedings alleging that Ocugen is infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of Ocugen's business.

Ocugen's commercial success depends upon its ability to develop, manufacture, market and sell OCU300, and other product candidates and use its proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is a considerable amount of intellectual property litigation in the biotechnology and pharmaceutical industries. Ocugen may become party to, or threatened with, infringement litigation claims regarding its products and technology, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom its own patent portfolio may have no deterrent effect. Moreover, Ocugen may become party to future adversarial proceedings or litigation regarding its patent portfolio or the patents of third parties. Such proceedings could also include contested post-grant proceedings such as oppositions, inter partes review, reexamination, interference or derivation proceedings before the USPTO or foreign patent offices.

The legal threshold for initiating litigation or contested proceedings is low, so even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and Ocugen's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than Ocugen does. The risks of being involved in such litigation and proceedings may increase as Ocugen's product candidates near commercialization and as it gains the greater visibility associated with being a public company. Third parties may assert infringement claims against it based on existing patents or patents that may be granted in the future. Ocugen may not be aware of all such intellectual property rights potentially relating to its product candidates and their uses.

Thus, it does not know with certainty that OCU300 or any of its other product candidates, or its development and commercialization thereof, do not and will not infringe or otherwise violate any third party's intellectual property.

If Ocugen is found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, it could be required to obtain a license from such third party to continue developing and marketing its products and technology. However, Ocugen may not be able to obtain any required license on commercially reasonable terms or at all. Even if Ocugen was able to obtain a license, it could be non-exclusive, thereby giving its competitors access to the same technologies licensed to it and could require it to make substantial licensing and royalty payments. Ocugen could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, it could be found liable for monetary damages, including treble damages and attorneys' fees if it is found to have willfully infringed a patent, and could be forced to indemnify its customers or collaborators. A finding of infringement could also result in an injunction that prevents Ocugen from commercializing its product candidates or forces it to cease some of its business operations, which could materially harm its business. In addition, Ocugen may be forced to redesign its product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that Ocugen has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on its business.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and Ocugen's patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance, renewal and annuity fees on any issued patent must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of Ocugen's owned and licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, Ocugen relies on its licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If Ocugen or its licensors fail to maintain the patents and patent applications covering its product candidates, it would have a material adverse effect on its business.

Certain aspects of OCU300 and Ocugen's other product candidates, and certain aspects of its OcuNanoE™ nanoemulsion formulation, are protected by patents exclusively licensed from other companies or institutions. If these third parties terminate their agreements with Ocugen or fail to maintain or enforce the underlying patents, or Ocugen otherwise loses its rights to these patents, its competitive position and its market share in the markets for any of its approved products will be harmed.

A substantial portion of Ocugen's patent portfolio is in-licensed. As such, Ocugen is a party to license agreements and certain aspects of its business depend on patents and/or patent applications owned by other companies or institutions. In particular, Ocugen holds exclusive licenses for patent families relating to OCU300, other of its product candidates, and some aspects of its OcuNanoE™ nanoemulsion formulation.

Pursuant to Ocugen's license arrangement with University of Illinois at Chicago ("UIC"), which relates to OCU300, Ocugen is responsible for and control patent prosecution of licensed patent families developed jointly pursuant to the license arrangement with UIC, while Ocugen and UIC are each responsible for and control patent prosecution of licensed patent families developed or held individually by Ocugen or UIC, respectively.

Pursuant to Ocugen's license arrangement with University of Colorado ("CU"), which relates to OCU200 and OCU100, Ocugen is responsible for and control patent prosecution of all patent families licensed under the CU license arrangement.

Pursuant to Ocugen's license arrangement with The Schepens Eye Research Institute ("SERI"), which relates to nuclear hormone receptor ("NHR") genes *NR1D1*, *NR2E3*, *RORA*, *NUPR1*, and *NR2C1*, from and after December 19,

2017, Ocugen has the right to assume responsibility and control patent prosecution of licensed patent families relating to these NHR genes. Additionally, Ocugen is responsible for and control patent prosecution for any patent applications developed in connection with the SERI licensing arrangement filed after December 19, 2017 that are owned jointly by Ocugen and SERI or solely by Ocugen.

Ocugen's rights with respect to in-licensed patents and patent applications may be lost if the applicable license agreement expires or is terminated. Ocugen is likely to enter into additional license agreements to in-license patents and patent applications as part of the development of its business in the future, under which it may not retain control of the preparation, filing, prosecution, maintenance, enforcement and defense of such patents. If Ocugen is unable to maintain these patent rights for any reason, its ability to develop and commercialize its product candidates could be materially harmed.

Ocugen's licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which Ocugen is licensed and on which its business depends. Even if patents issue from these applications, Ocugen's licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability.

Risks with respect to parties from whom Ocugen has obtained intellectual property rights may also arise out of circumstances beyond Ocugen's control. In spite of Ocugen's best efforts, its licensors might conclude that it has materially breached its intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing its ability to market products covered by these intellectual property agreements. If Ocugen's intellectual property agreements are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to Ocugen's. Moreover, if its intellectual property agreements are terminated, Ocugen's former licensors and/or assignors may be able to prevent it from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on Ocugen's competitive business position and its business prospects.

Some intellectual property which Ocugen owns or has licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit Ocugen's exclusive rights, subject it to expenditure of resources with respect to reporting requirements, and limit its ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights that Ocugen owns or licenses have been generated through the use of United States government funding and may therefore be subject to certain federal regulations under the Bayh-Dole Act. To the best of Ocugen's knowledge, Ocugen's intellectual property for OCU400 for the treatment of *NR2E3* mutation-associated retinal degenerative disease is subject to the Bayh-Dole Act. As a result, the United States government may have certain rights to intellectual property embodied in these patents and patent applications. In general, the Bayh-Dole Act provides the U.S. government certain rights in inventions developed using a government funded program, such as U.S. government's right to a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, under the Bayh-Dole Act the U.S. government has the right to require any invention developed using U.S. government funding to be granted exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). Under the Bayh-Dole Act, the U.S. government also has the right to take title to inventions developed using a U.S. government funded program, if one fails to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements. In addition, the Bayh-Dole Act requires that any products subject to the Bayh-Dole Act be manufactured substantially in the United States. However, under the Bayh-Dole Act, this manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable efforts to manufacture the product substantially in the United States were unsuccessful or that under the circumstances domestic

manufacture is not commercially feasible. Any exercise by the government of any of the foregoing rights under the Bayh-Dole Act may affect Ocugen's competitive position, business, financial condition, results of operations and prospects.

If Ocugen fails to comply with its obligations in its intellectual property licenses and funding arrangements with third parties, it could lose rights that are important to its business.

Ocugen's license agreements with CU, UIC, and SERI under which Ocugen licenses certain of its patent rights and a significant portion of the technology for OCU300, OCU310, and other product candidates, impose royalty and other financial obligations on it and other substantial performance obligations. Ocugen may also enter into additional licensing and funding arrangements with third parties that may impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on it. If Ocugen fails to comply with its obligations under current or future license and collaboration agreements, its counterparties may have the right to terminate these agreements, in which event Ocugen might not be able to develop, manufacture or market any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of Ocugen's products and product candidates. Termination of these agreements or reduction or elimination of Ocugen's rights under these agreements may result in Ocugen having to negotiate new or reinstated agreements with less favorable terms or cause it to lose its rights under these agreements, including its rights to important intellectual property or technology.

In addition, it is possible that CU, UIC or SERI may conclude that Ocugen has materially breached the applicable license agreement and might therefore terminate the agreement, thereby removing its ability to market products covered by its license agreements with CU, UIC, or SERI, respectively. If any license agreement is terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to Ocugen's. Moreover, if any of Ocugen's license agreements is terminated, the counterparty and/or its assignors may be able to prevent it from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on Ocugen's competitive business position and its business prospects.

In addition, the agreements under which Ocugen currently licenses intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what Ocugen believes to be the scope of its rights to the relevant intellectual property or technology or increase what Ocugen believes to be its financial or other obligations under the relevant agreement, either of which could have a material adverse effect on its business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that Ocugen has licensed prevent or impair its ability to maintain its current licensing arrangements on commercially acceptable terms, Ocugen may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on its business, financial conditions, results of operations, and prospects.

Ocugen may not be able to protect its intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect Ocugen's rights to the same extent as the laws of the United States. Consequently, Ocugen may not be able to prevent third parties from practicing its inventions in all countries outside the United States, or from selling or importing products made using its inventions in and into the United States or other jurisdictions. Competitors may use Ocugen's technologies in jurisdictions where it has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where Ocugen has patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with Ocugen's products, and its patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for Ocugen to stop the infringement of its patents or marketing of competing products in violation of Ocugen's intellectual property and proprietary rights generally. Proceedings to

enforce its intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert its efforts and attention from other aspects of its business, could put its patents at risk of being invalidated or interpreted narrowly, could put its patent applications at risk of not issuing, and could provoke third parties to assert claims against it. Ocugen may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, Ocugen's efforts to enforce its intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that it develops or licenses.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If Ocugen or any of its licensors is forced to grant a license to third parties with respect to any patents relevant to its business, its competitive position may be impaired, and its business, financial condition, results of operations, and prospects may be adversely affected.

Ocugen may be subject to claims by third parties asserting that its employees or it has misappropriated their intellectual property or claiming ownership of what Ocugen regards as its own intellectual property.

Many of Ocugen's and its licensors' employees and contractors were previously employed at other biotechnology, medical device or pharmaceutical companies, including its competitors or potential competitors. Although Ocugen tries to ensure that its employees and contractors do not use the proprietary information or know-how of others in their work for it, Ocugen may be subject to claims that these individuals or it has used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is Ocugen's policy to require its employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to it, Ocugen may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that it regards as its own. Furthermore, Ocugen is unable to control whether its licensors have obtained similar assignment agreements from their own employees and contractors. Ocugen's and their assignment agreements may not be self-executing or may be breached, and Ocugen or its licensors may be forced to bring claims against third parties, or defend claims they may bring against Ocugen, to determine the ownership of what Ocugen regards as its intellectual property.

If Ocugen or its licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, Ocugen may lose valuable intellectual property rights or personnel which could have a material adverse effect on its competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and Ocugen could be required to obtain a license from such third party to commercialize its technology or products, which may not be available on commercially reasonable terms or at all. Even if Ocugen is successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause Ocugen to spend substantial resources and distract its personnel from their normal responsibilities.

Even if resolved in Ocugen's favor, litigation or other legal proceedings relating to intellectual property claims may cause it to incur significant expenses and could distract Ocugen's technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of Ocugen common stock. Such litigation or proceedings could substantially increase Ocugen's operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Ocugen may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of Ocugen's competitors may be able to sustain the costs of such litigation or proceedings more effectively than Ocugen can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on Ocugen's ability to compete in the marketplace.

If Ocugen is unable to protect the confidentiality of its trade secrets, its business and competitive position would be harmed.

In addition to seeking patents for Ocugen's technology and product candidates, Ocugen also relies on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain its competitive position. Ocugen seeks to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as its employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. Ocugen also enters into confidentiality and invention or patent assignment agreements with its employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose Ocugen's proprietary information, including its trade secrets, and Ocugen may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of Ocugen's trade secrets were to be lawfully obtained or independently developed by a competitor, Ocugen would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with Ocugen. If any of Ocugen's trade secrets were to be disclosed to or independently developed by a competitor, its competitive position would be harmed.

Risks Related to Employee Matters and Managing Growth

Ocugen's future success depends on its ability to retain key executives and to attract, retain and motivate qualified personnel.

Ocugen is highly dependent on the research and development, clinical and business development expertise of Shankar Musunuri, Ph.D., MBA, its Chief Executive Officer, Chairman of the Board and Co-Founder, Daniel Jorgensen, M.D., M.P.H., MBA, its Chief Medical Officer, and Rasappa Arumugham, Ph.D., its Chief Scientific Officer, as well as the other principal members of its management, scientific and clinical team. Although Ocugen has entered into employment agreements with its executive officers, each of them may terminate their employment with Ocugen at any time. Ocugen does not maintain "key person" insurance for any of its executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, legal and sales and marketing personnel will also be critical to Ocugen's success. The loss of the services of Ocugen's executive officers or other key employees could impede the achievement of its research, development and commercialization objectives and seriously harm its ability to successfully implement its business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in its industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and Ocugen may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Ocugen also experiences competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, Ocugen relies on consultants and advisors, including scientific and clinical advisors, to assist Ocugen in formulating its research and development and commercialization strategy. Ocugen's consultants and advisors may be employed by employers other than it and may have commitments under consulting or advisory contracts with other entities that may limit their availability to Ocugen. If Ocugen unable to continue to attract and retain high quality personnel, its ability to pursue its growth strategy will be limited.

Ocugen expects to expand its development, regulatory and manufacturing capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, Ocugen may encounter difficulties in managing its growth, which could disrupt its operations.

Ocugen expects to experience significant growth in the number of its employees and the scope of its operations, particularly in the areas of drug development, clinical, regulatory affairs, manufacturing, sales, marketing and distribution. To manage its anticipated future growth, Ocugen must continue to implement and improve its managerial, operational and financial systems, expand its facilities and continue to recruit and train additional qualified personnel. Due to Ocugen's limited financial resources and its limited experience in managing such

anticipated growth, it may not be able to effectively manage the expansion of its operations or recruit and train additional qualified personnel. The expansion of Ocugen's operations may lead to significant costs and may divert its management and business development resources. Any inability to manage growth could delay the execution of its business plans or disrupt its operations.

Risks Related to Ocugen Common Stock

The trading price of the shares of the Ocugen's Common Stock could be highly volatile, and purchasers of the Common Stock could incur substantial losses.

Ocugen's stock price has been, and will likely continue to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above their purchase price. The market price for Ocugen's common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- Ocugen's ability to enroll subjects in its ongoing and planned clinical trials;
- results of Ocugen's clinical trials and preclinical studies, and the results of trials of Ocugen's competitors or those of other companies in Ocugen's market sector;
- regulatory approval of Ocugen's product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the U.S. healthcare system;
- the success or failure of Ocugen's efforts to acquire, license or develop additional product candidates;
- innovations or new products developed by Ocugen or its competitors;
- announcements by Ocugen or its competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to Ocugen's relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in Ocugen's financial results or those of companies that are perceived to be similar to Ocugen;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of Ocugen's common stock;
- an inability to obtain additional funding;
- sales of Ocugen's stock by insiders and stockholders;

- general economic, industry and market conditions other events or factors, many of which are beyond Ocugen’s control;
- additions or departures of key personnel; and
- intellectual property, product liability or other litigation against Ocugen.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies’ stock. Such litigation, if instituted against Ocugen, could cause Ocugen to incur substantial costs and divert management’s attention and resources, which could have a material adverse effect on Ocugen’s business, financial condition and results of operations.

Ocugen’s failure to meet the continued listing requirements of the Nasdaq could result in a delisting of the Common Stock.

If Ocugen fails to satisfy the continued listing requirements of the Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist the common stock. Such a delisting would likely have a negative effect on the price of Ocugen’s common stock and would impair your ability to sell or purchase shares of common Stock when you wish to do so. In the event of a delisting, Ocugen can provide no assurance that any action taken by Ocugen to restore compliance with listing requirements would allow the common stock to become listed again, stabilize the market price or improve the liquidity of the common stock, prevent the common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq’s listing requirements.

Ocugen’s executive officers, directors and principal stockholders, if they choose to act together, may control or significantly influence all matters submitted to stockholders for approval.

Ocugen’s executive officers, directors and greater than 5% stockholders own, in the aggregate, approximately 66.0% of Ocugen’s outstanding common stock (assuming no exercise of outstanding options) as of September 30, 2019. As a result, such persons or their appointees to the Company’s Board of Directors, acting together, will have the ability to control or significantly influence all matters submitted to the Board of Directors or stockholders for approval, including the appointment of management, the election and removal of directors and approval of any significant transaction, as well as the Company’s management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving the Company, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of the Company’s business, even if such a transaction would benefit other stockholders.

Ocugen does not currently intend to pay dividends on its common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of Ocugen’s common stock.

Ocugen has never declared or paid any cash dividend on the common stock. Ocugen currently anticipates that it will retain future earnings for the development, operation and expansion of its business and does not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude Ocugen from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that the common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Ocugen has a total of 10,013,605 shares of common stock outstanding as of September 30, 2019. Of these shares, only 3.8 million shares of common stock were freely tradable, without restriction, in the public market as of September 30, 2019, unless they had been purchased by one of Ocugen’s affiliates.

Ocugen’s directors and executive officers and holders of approximately 40.0% of Ocugen’s outstanding shares of common stock have entered into lock up agreements with Ocugen pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of the effective time of the Merger, offer, sell or otherwise transfer

or dispose of any of Ocugen's securities, without prior written consent of Ocugen, subject to certain exceptions. Sale of these shares, or perceptions that they will be sold, could cause the trading price of Ocugen's common stock to decline. After the lock up agreements expire, up to an additional 6.2 million shares of common stock outstanding as of September 30, 2019 will be eligible for sale in the public market.

Additionally, in connection with the Pre-Merger Financing, Ocugen has entered into lock-up agreements with each officer, director or other person that was subject to Section 16 of the Exchange Act immediately following the consummation of the Merger, and each holder of greater than 3% of Ocugen common stock (excluding the shares of Ocugen common stock issuable pursuant to the Financing SPA) immediately prior to the consummation of the Merger (the "Financing Lock-Up Parties"), pursuant to which each of the Financing Lock-Up Parties agreed that until the date that is 30 calendar days after the certain trigger dates specified in the Financing SPA, subject to certain customary exceptions, such Financing Lock-Up Party will not and will cause its affiliates not to (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of or lend, directly or indirectly, any shares of Ocugen common stock or any securities convertible into, exercisable or exchangeable for or that represent the right to receive Ocugen common stock, (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any of the Financing Lock-Up Party's shares of Ocugen common stock or such other securities, in cash or otherwise, (iii) make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of Ocugen common stock or such other securities, in cash or otherwise, (iv) grant any proxies or powers of attorney with respect to any shares of Ocugen common stock or such other securities, deposit any shares of Ocugen common stock or such other securities into a voting trust or enter into a voting agreement or similar arrangement or commitment with respect to any shares of Ocugen common stock or such other securities, or (v) publicly disclose the intention to do any of the foregoing.

The holders of 4,018,786 shares of Ocugen's outstanding common stock, or approximately 40.0% of Ocugen's total outstanding common stock as of September 30, 2019, are entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. Registration of these shares under the Securities Act results in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of Ocugen's common stock.

Sales of a substantial number of common stock by Ocugen's stockholders in the public market could cause Ocugen's stock price to fall.

Sales of a substantial number of shares of Ocugen's common stock in the public market or the perception that these sales might occur could significantly reduce the market price of the common stock and impair Ocugen's ability to raise adequate capital through the sale of additional equity securities.

Ocugen will incur significant increased costs as a result of operating as a public company, and its management will be required to devote substantial time to new compliance initiatives.

Ocugen began operating as a public company as a result of the Merger. As a public company, Ocugen will incur significant legal, accounting and other expenses that Ocugen did not incur as a private company prior to the Merger. Ocugen is subject to the reporting requirements of the Exchange Act, which require, among other things, that Ocugen files with the U.S. Securities and Exchange Commission (the "SEC") annual, quarterly and current reports with respect to Ocugen's business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to Ocugen when it ceases to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which Ocugen operates its business in ways Ocugen cannot currently anticipate.

Ocugen expects the rules and regulations applicable to public companies to substantially increase Ocugen's legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of Ocugen's management and personnel from other business concerns, they could have a material adverse effect on Ocugen's business, financial condition and results of operations. The increased costs will increase Ocugen's net loss, and may require Ocugen to reduce costs in other areas of its business or increase the prices of its products or services. For example, Ocugen expects these rules and regulations to make it more difficult and more expensive for Ocugen to obtain director and officer liability insurance, and Ocugen may be required to incur substantial costs to maintain the same or similar coverage. Ocugen cannot predict or estimate the amount or timing of additional costs Ocugen may incur to respond to these requirements. The impact of these requirements could also make it more difficult for Ocugen to attract and retain qualified persons to serve on its board of directors, its board committees or as executive officers.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about Ocugen's business, Ocugen's stock price and trading volume could decline.

The trading market for Ocugen's common stock depends in part on the research and reports that securities or industry analysts publish about Ocugen, its business, its market or its competitors. Ocugen does not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of Ocugen, the trading price for Ocugen's stock would be negatively impacted. In the event Ocugen obtains securities or industry analyst coverage, if one or more of the analysts who covers Ocugen downgrades its stock, Ocugen's stock price would likely decline. If one or more of these analysts ceases to cover Ocugen or fails to regularly publish reports on Ocugen, interest in Ocugen's stock could decrease, which could cause Ocugen's stock price or trading volume to decline.

If Ocugen fails to maintain proper and effective internal control over financial reporting, Ocugen's ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in Ocugen's financial reporting and the trading price of Ocugen's common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, Ocugen's management will be required to report upon the effectiveness of Ocugen's internal control over financial reporting beginning with the annual report for Ocugen's fiscal year ending December 31, 2019. Additionally, if Ocugen reaches an accelerated filer threshold, Ocugen's independent registered public accounting firm will be required to attest to the effectiveness of Ocugen's internal control over financial reporting. The rules governing the standards that must be met for management to assess Ocugen's internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, Ocugen will need to upgrade its information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If Ocugen or, if required, its auditors are unable to conclude that Ocugen's internal control over financial reporting is effective, investors may lose confidence in Ocugen's financial reporting and the trading price of Ocugen's common stock may decline.

Ocugen cannot assure you that there will not be material weaknesses or significant deficiencies in Ocugen's internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit Ocugen's ability to accurately report its financial condition, results of operations or cash flows. If Ocugen is unable to conclude that its internal control over financial reporting is effective, or if Ocugen's independent registered public accounting firm determines Ocugen has a material weakness or significant deficiency in Ocugen's internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of Ocugen's financial reports, the market price of Ocugen's common stock could decline, and Ocugen could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in Ocugen's internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict Ocugen's future access to the capital markets.

Provisions in Ocugen's charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Ocugen's amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of Ocugen's shares to a potential acquiror or delay or prevent changes in control or changes in Ocugen's management without the consent of Ocugen's board of directors. The provisions in Ocugen's charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of Ocugen's board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of Ocugen's board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on Ocugen's board of directors;
- the prohibition on removal of directors without cause due to the classified board of directors;
- the ability of Ocugen's board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of Ocugen's board of directors to alter Ocugen's amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal Ocugen's amended and restated bylaws or repeal certain provisions of Ocugen's amended and restated certificate of incorporation;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of Ocugen's stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer or the board of directors, which may delay the ability of Ocugen's stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to Ocugen's board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of Ocugen.

Ocugen is also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Ocugen's sixth amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between Ocugen and its stockholders, which could

limit Ocugen's stockholders' ability to obtain a favorable judicial forum for disputes with Ocugen or its directors, officers or employees.

Ocugen's sixth amended and restated certificate of incorporation provides that, unless Ocugen consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on Ocugen's behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against Ocugen arising pursuant to the Delaware General Corporation Law, Ocugen's amended and restated certificate of incorporation or Ocugen's amended and restated bylaws, or any action asserting a claim against Ocugen that is governed by the internal affairs doctrine. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with Ocugen or its directors, officers or other employees, which may discourage such lawsuits against Ocugen and its directors, officers and other employees. By agreeing to this provision, however, stockholders will not be deemed to have waived Ocugen's compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in Ocugen's certificate of incorporation to be inapplicable or unenforceable in an action, Ocugen may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect Ocugen's business and financial condition.

Ocugen could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for Ocugen, because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If Ocugen faces such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm Ocugen's business.

Ocugen may never pay dividends on its common stock so any returns would be limited to the appreciation of Ocugen's stock.

Ocugen currently anticipates that it will retain future earnings for the development, operation and expansion of Ocugen's business and does not anticipate it will declare or pay any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Certain of the Pre-Merger Financing Warrants contain price-based adjustment provisions which, if triggered, may cause substantial additional dilution to the combined organization's stockholders.

Certain of the Pre-Merger Financing Warrants contain price-based adjustment provisions, pursuant to which the number of shares of the combined organization's common stock that are issuable upon exercise of such Pre-Merger Financing Warrants may be adjusted upward based upon the volume weighted average trading price of the combined organization's common stock after closing and in the event of certain dilutive issuances by the Company. Even if Ocugen's stock increases in value, the number of shares of Ocugen's common stock issuable upon exercise of the Pre-Merger Financing Warrants may still increase. The circumstances under which the number of shares of Ocugen's common stock issuable upon exercise of the Pre-Merger Financing Warrants may be adjusted upward are set forth in the Pre-Merger Financing Warrants.

Concurrently with the effectiveness of the Warrant Amendments, the Investors exercised an aggregate of 3,797,329 Series C Warrants, pursuant to Section 1(d) thereof, as amended, each for one share of common stock. If the Pre-Merger Financing Warrants are further exercised, additional shares of the combined organization's common stock will be issued, which will result in dilution to our then-existing stockholders and increase the number of shares eligible for resale in the public market. Ignoring restrictions in the Pre-Merger Financing preventing exercises of Pre-Merger Financing Warrants if the exercising Investor would beneficially own in excess of 4.99% or 9.99% of the outstanding common stock (including the common stock issuable upon such exercise), following the issuance of the maximum number of shares issuable upon exercise of the Pre-Merger Financing Warrants, the Investors would hold

an aggregate of approximately 80.2% of Ocugen's total outstanding common stock following such issuance. Sales of substantial numbers of such shares in the public market could depress the market price of the common stock. If the adjustment provisions in the Pre-Merger Financing Warrants are triggered, a substantial number of additional shares of the common stock may become issuable upon exercise of the Pre-Merger Financing Warrants, potentially increasing the impact of any subsequent exercise of the Pre-Merger Financing Warrants and resale of the shares issuable pursuant thereto.

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

None other than as disclosed in the Form 8-K filed on October 1, 2019.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit	Description
3.1	Amendment to Sixth Amended and Restated Certificate of Incorporation related to the Reverse Stock Split and the Authorized Share Increase (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K as filed October 1, 2019, and incorporated herein by reference).
3.2	Amendment to Sixth Amended and Restated Certificate of Incorporation related to the Name Change (filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K as filed on October 1, 2019, and incorporated herein by reference)
3.3	Amended and Restated Bylaws (filed as Exhibit 3.3 to the Registrant's Current Report on Form 8-K as filed on October 1, 2019, and incorporated herein by reference)
10.1	Amendment No. 1 to Asset Purchase Agreement, dated September 26, 2019, by and between the Registrant and Medavate Corp. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K as filed on October 1, 2019, and incorporated herein by reference).
10.2*#	Co-Development and Commercialization Agreement, dated as of September 27, 2019, by and among the Registrant and CanSino Biologics Inc.
10.3*+	Employment Agreement, dated as of September 10, 2019, by and between the Registrant and Sanjay Subramanian.
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 Financial Officer as required by Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

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

+ Indicates a management contract or compensatory plan or arrangement.

SIGNATURES

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

Ocugen, Inc.

Dated: November 12, 2019

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

Shankar Musunuri, Ph.D., MBA

Chief Executive Officer & Chairman

(Principal Executive Officer)

Dated: November 12, 2019

/s/ Sanjay Subramanian

Sanjay Subramanian

Chief Financial Officer

(Principal Financial Officer and Accounting Officer)

Certain portions of this document have been omitted pursuant to Item 601(b)(10) of Regulation S-K and, where applicable, have been marked with “[***]” to indicate where omissions have been made. The marked information has been omitted because it is (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. The registrant hereby undertakes to provide further information regarding such marked information to the Securities and Exchange Commission upon request.

CO-DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Co-Development and Commercialization Agreement (“**Agreement**”) dated September 27, 2019 (“**Effective Date**”) is made by and between:

- (1) Ocugen, Inc., with an address at 5 Great Valley Parkway, Suite 160, Malvern, PA 19355, USA (“**Ocugen**”); and
- (2) CanSino Biologics Inc., whose registered office address is at 185 South Ave, TEDA West District, Tianjin, 300457, China (“**CanSino**”).

Background

WHEREAS, Ocugen has unique expertise with respect to the development of gene therapy products and has identified and developed prior to the Effective Date the gene therapy product known as OCU400 for use in the Field;

WHEREAS, CanSino wishes to collaborate and cooperate with Ocugen to co-Develop and Commercialize Products in the Field; and

WHEREAS, Ocugen is willing to grant CanSino the exclusive right under the Ocugen Technology and Ocugen Patent Rights to Develop, Manufacture and Commercialize Products in the Field in and for the CanSino Territory.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the Parties, intending to be legally bound, hereby agree as follows:

1. Definitions

In this Agreement, the following words shall have the following meanings:

Adverse Event Any untoward medical occurrence in a patient who is administered a Product, whether or not considered related to such Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or

disease associated with the use of such Product.

Affiliate	With respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with such first Person. For purposes of this definition only, the term “control” (including, with correlative meaning, the terms “controlled by” or “under common control with”) means direct or indirect ownership of fifty percent (50%) or more, including ownership by one or more trusts with substantially the same beneficial interests, of the voting and equity rights of such Person, or the power to direct the management of such Person.
Applicable Laws	Any national, international, federal, state or local laws, treaties, statutes, ordinances, rules and regulations, including any rules, regulations, guidance, guidelines or requirements of any Governmental Authority, Regulatory Authority, national securities exchanges or securities listing organizations, that are in effect from time to time during the Term and apply to a particular activity hereunder.
BLA	A Biologics License Application, as defined in the FDCA and regulations promulgated thereunder, or similar application, or any successor application or procedure required to sell a Product in the Territory.
CanSino Development Activities	All Development activities to be conducted by or on behalf of CanSino with respect to the Development Program as specified in the Development Plan pursuant to this Agreement.
CanSino Territory	Greater China, including mainland China, Hong Kong, Macao and Taiwan.
Claims	All demands, claims and liabilities (whether criminal or civil, in contract, tort, or otherwise) for losses, damages, legal costs, or other expenses of any nature whatsoever, and all costs and expenses (including legal costs) incurred in connection therewith.

Clinical Data	Any and all data (together with all clinical trial reports and the results of analyses thereof) derived or generated from any Clinical Trial involving a Product conducted by or on behalf of a Party or from the testing of subjects or the analysis of samples used in any such Clinical Trial.
Clinical Trial	Collectively, any Phase 1 Clinical Trial, Phase 2 Clinical Trial or Phase 3 Clinical Trial.
CMC Technology	Any Technology that relates to chemistry, manufacture and control for a Product.
Commercialization or Commercialize	Any and all activities directed to the offering for sale and sale of a Product in the Ocugen Territory or the CanSino Territory, as applicable, including: (a) activities directed to marketing, promoting, detailing, warehousing, distributing, importing, exporting, selling and offering to sell such Product; (b) conducting post-registration efficacy and/or safety clinical trials with respect to such Product; (c) interacting with Regulatory Authorities regarding the above; (d) seeking pricing approvals and reimbursement approvals (as applicable) for such Product; and (e) conducting other post-registration studies, including health-economic outcomes research, real-world evidence studies, or investigator-initiated studies/trials. When used as a verb, to “ Commercialize ” and “ Commercializing ” means to engage in Commercialization and “ Commercialized ” has a corresponding meaning.
Commercialization Plan	A written plan for the Commercialization of Products by a Party in the Ocugen Territory or the CanSino Territory, as applicable, during each [three] ([3]) year period beginning in the calendar year in which the First Commercial Sale of the first Product occurs anywhere in such Territory, as such written plan may be amended, modified or updated by the responsible Party from time to time, and which written plan shall contain, among other things: (a) Commercialization

objectives for the Products in such Territory; and (b) a projected timeline and budget for achieving such objectives.

Commercially Reasonable Efforts

With respect to the conduct by a Party of obligations or tasks hereunder, including as it relates to the Development or Commercialization of a Product, the performance of such obligations or tasks by such Party in an active and sustained manner, without undue interruption, pause or delay, using a level of effort consistent with the exercise of good faith and prudent scientific and business judgment commonly used by a biopharmaceutical company of similar size and resources in the development, manufacture or commercialization of biologics and products of comparable market potential as such Product, taking into account all relevant factors, including as applicable, the stage of development, efficacy and safety relative to competitive products in the marketplace, actual or anticipated Regulatory Authority approved labeling, the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), the cost and likelihood of obtaining all Regulatory Approvals, and actual or projected profitability. For clarity, Commercially Reasonable Efforts shall be determined on a market-by-market basis for each Product, and it is anticipated that the level of efforts and resources may be different for different markets and may change over time, reflecting changes in the status of such Product.

Confidential Information

All (a) documents and information provided by or on behalf of one Party to the other Party in connection with or in furtherance of this Agreement, including at any meeting of the JSC, (b) the terms of this Agreement, and (c) all Ocugen Technology, Ocugen Patent Rights, Joint Program Technology, Joint Program Patent Rights and Joint Program Materials that are disclosed or provided by or on behalf of a Party to the other Party, or to any of its employees,

consultants or Affiliates during the Term.

Control or Controlled	With respect to Technology or Patent Rights, the possession by a Party of the right to grant a license or sublicense to such Technology or Patent Rights as provided herein without the payment of consideration to, or violating the terms of any agreement or arrangement with any third party, and without violating any Applicable Laws. For clarity, neither a Party nor any of its Affiliates shall be deemed to Control any Technology or Patent Rights by virtue of the rights granted by the other Party under this Agreement.
Cover or Covered	With respect to a Product, that the Manufacture, use, offer for sale, sale or import of such Product in a particular country by an unlicensed Third Party would infringe a Valid Claim.
CTA	A clinical trial application or any successor application or procedure required to initiate clinical testing of a Product in humans in the Territory, and all supplements and amendments to any of the foregoing.
CTM	Clinical testing materials, including clinical supplies of Products in appropriate containers, for use in Clinical Trials.
Data	Results, data, and analyses thereof, including non-clinical data and Clinical Data.
Development or Develop	With respect to a Product and in accordance with the Development Plan, (a) research, non-clinical and pre-clinical studies, IND-enabling studies and clinical drug development activities that are undertaken with respect to such Product up through and including the date any related Clinical Studies are completed, and (b) the preparation, filing and obtaining of INDs and Marketing Authorizations and all regulatory affairs related to the foregoing. When used as a verb, “ Developing ” means to engage in Development and “ Developed ” has a corresponding meaning. For clarity, “ Development ” shall exclude any Commercialization activities.
Development Plan	The written plan for the Development by the Parties of

Products in the Field in and for their respective Territories for a calendar year or longer period, as such written plan may be amended, modified or updated by the Parties from time to time, and which written plan shall contain, among other things: (a) the Development objectives for the Products and the Development activities to be performed by the Parties in the Field in their respective Territories; (b) the regulatory activities to be conducted by the Parties in their respective Territories; and (c) a projected timeline and budget for all such activities.

Development Program	The development program to be conducted during the Term pursuant to which Ocugen and CanSino shall collaborate with respect to the Development activities set forth in the Development Plan. For clarity, the Development Program shall exclude any Commercialization activities.
Drug Approval Application	In any country in the Territory, an application for Marketing Authorization for a Product in such country, including: (a) an BLA or MAA; (b) a counterpart of an BLA or MAA in such country; and (c) all renewals, supplements and amendments to any of the foregoing.
EMA	The European Medicines Agency or any successor agency or authority thereto.
FDA	The United States Food and Drug Administration, or any successor agency or authority thereto.
FDCA	The United States Federal Food, Drug, and Cosmetic Act, as amended.
Field	The treatment of the following diseases in humans: (1) NR2E3 Mutation-Associated Retinal Degeneration; (2) Leber Congenital Amaurosis (LCA); (3) Bardet-Biedl Syndrome (BBS); (4) Rhodopsin Mutation — Associated Retinal Degeneration
First Commercial Sale	In any country in the Territory, the first sale, transfer or disposition for value to an end user of a Product in such

country after Marketing Authorization for such Product has been received in that country; *provided*, that the following shall not constitute a First Commercial Sale: (a) any sale of such Product by a Party or its Affiliate to another Affiliate of such Party; (b) any use of such Product in Clinical Trials, pre-clinical studies or other research or Development activities; or (c) transfer of such Product for a bona fide charitable purpose, including compassionate use and/or “named patient sales.”

Force Majeure

Any occurrence beyond the reasonable control of a Party that (a) prevents or substantially interferes with the performance by such Party of any of its obligations hereunder, and (b) occurs by reason of any act of God, flood, fire, explosion, earthquake, casualty or accident, or war, revolution, civil commotion, act of terrorism, blockage or embargo, labor dispute, or any injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any Governmental Authority or of any subdivision, authority or representative of any such Governmental Authority.

Governmental Authority

Any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

IND

(a) An Investigational New Drug Application as defined in the FDCA and regulations promulgated thereunder or any successor application or procedure required to initiate clinical testing of a Product in humans in the United States; (b) an equivalent of an Investigational New Drug Application that is required in any other country or region in the Territory before beginning clinical testing of such Product in humans in such country or region; and (c) all supplements and amendments to any of the foregoing.

Joint Program Patent Rights	Any Patent Rights that contain one or more claims to the Joint Program Technology or Joint Program Materials.
Joint Program Materials	Any tangible chemical, biological or physical materials that are controlled by a Party or its Affiliates and that are collected, conceived, generated, developed or reduced to practice in the conduct of the Development Program.
Joint Program Technology	Any (a) Technology that is conceived or first reduced to practice (actually or constructively), whether or not patentable, by or on behalf of Ocugen and/or CanSino and/or their respective Affiliates, whether alone, jointly, or jointly with any third party (including any subcontractors or consultants to Ocugen and/or CanSino and/or their respective Affiliates) in the conduct of or otherwise in connection with the Development Program, and (b) modification of, or an improvement to the Technology set forth in clause (a).
Manufacture	Any activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, release, shipping, holding, conduct of Manufacture Process Development, stability testing, quality assurance and quality control of a Product or any intermediate thereof. When used as a verb, “ Manufacturing ” means to engage in Manufacture and “ Manufactured ” has a corresponding meaning.
Manufacture Process Development	The process development, process qualification, and validation and scale-up of the process to manufacture a Product and analytic development and product characterization with respect thereto.
Marketing Authorization	The Regulatory Approval issued in respect of a Drug Approval Application filed by a Party or any of its Affiliates that allows the marketing and sale of a Product for use in the Field in a country or region in the Territory.
Net Sales	The gross amount billed or invoiced by a Party or any of its Affiliates (each, a “ Seller ”) to third parties throughout the applicable Territory for sales or other dispositions or transfers

for value of a Product less: (a) allowances for normal and customary trade, quantity and cash discounts actually allowed and taken; (b) transportation, insurance, postage charges and customs duties, if included on Seller's bill or invoice or as a separate item; (c) amounts repaid or credited by reason of rejections, defects, recalls or returns or because of retroactive price reductions or wholesaler chargebacks; (d) rebates, chargebacks and discounts to managed care organizations, and other group purchasing organizations, to the extent actually allowed; and (e) sales, use, value added and excise taxes, tariffs and duties and other taxes and government charges directly related to the sale, transportation or delivery of such Product, as applicable (but not including taxes assessed against the income derived from such sale). In addition, Net Sales are subject to the following:

(i) If any Seller effects a sale, disposition or transfer of a Product to a customer in a country other than on customary commercial terms or as part of a package of products and services, the Net Sales of such Product to such customer shall be deemed to be "the fair market value" of such Product. For purposes of this subsection (i), "fair market value" means the value that would have been derived had such Product been sold as a separate product to another customer in the applicable country on customary commercial terms.

(ii) For purposes of this definition, "sale" shall mean any transfer or other distribution or disposition, but shall not include transfers or other distributions or dispositions of such Product at no charge for academic research, preclinical, clinical, or regulatory purposes (including the use of such Product in Clinical Trials) or at no charge in connection with patient assistance programs or other charitable purposes or to physicians or hospitals for promotional purposes (including free samples to a level and in an amount which is customary

in the industry and/or which is reasonably proportional to the market for such Product).

OCU400	The novel gene therapy known as OCU400 (NR2E3-AAV), consisting of a functional copy of the nuclear hormone receptor gene, <i>NR2E3</i> , delivered to target cells in the retina using an adeno-associated viral vector.
Ocugen Development Activities	All Development activities to be conducted by or on behalf of Ocugen with respect to the Development Program as specified in the Development Plan pursuant to this Agreement.
Ocugen Patent Rights	The Patent Rights that contain one or more claims to the Ocugen Technology, which as of the Effective Date are set forth in <u>Schedule 1</u> .
Ocugen Technology	Any Technology that (a) is necessary for the conduct of the Development Program, and (b) (i) is Controlled by Ocugen or its Affiliates as of the Effective Date or (ii) is Controlled by Ocugen or its Affiliates during the Term and conceived or first reduced to practice by Ocugen or its Affiliates or employees or subcontractors of, consultants to, or collaborators with Ocugen or its Affiliates outside of the conduct of the Development Program, or that otherwise relates to a Product (including its composition of matter, formulation, method of delivery or use, and/or its Manufacture). For clarity, Ocugen Technology shall exclude any Joint Program Technology.
Ocugen Territory	The entire world, excluding the CanSino Territory.
Option Period	The period beginning on the date the first IND for the first Product in the Field in the Ocugen Territory is filed with the appropriate Regulatory Authority in the Ocugen Territory and ending ninety (90) days thereafter.
Patent Rights	The rights and interests in and to issued patents and pending patent applications (which, for purposes of this Agreement, include certificates of invention, applications for certificates of invention and priority rights) in any country or region,

including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, all letters patent granted thereon, and all reissues, re-examinations and extensions thereof, and all foreign counterparts of any of the foregoing, and also including any and all utility models and registered designs.

Permits	All necessary consents, approvals and authorizations of all Governmental Authorities, Regulatory Authorities or other Persons in connection with the Development, use, importation, promotion, marketing, sale or supply of Products in each country and region of the applicable Territory.
Person	An individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.
Phase 1 Clinical Trial	A human clinical trial for a Product in any country that would satisfy the requirements of 21 C.F.R. § 312.21(a).
Phase 2 Clinical Trial	A human clinical trial conducted in any country that would satisfy the requirements of 21 C.F.R. § 312.21(b) and is intended to explore one or more doses, dose responses, and duration of effect, and to generate initial evidence of clinical activity and safety, for a Product in the target patient population.
Phase 3 Clinical Trial	A clinical trial in an extended human patient population designed to obtain data determining efficacy and safety of a Product to support Marketing Authorization in the proposed therapeutic indication, as more fully defined in 21 C.F.R. §312.21(c), or its successor regulation, or the equivalent in any foreign country.

Product(s)	In any country of the Territory, any biopharmaceutical preparation, substance, formulation or product comprised, in whole or in part, of OCU400 (or any modification or derivative thereof).
Product Trademark	Any trademark used by a Party in connection with the Commercialization of a Product in the applicable Territory.
Regulatory Approval	With respect to any country or region in the Territory, any approval, registration or authorization of any Regulatory Authority required for the Manufacture, use, storage, transport or Commercialization of a Product for use in the Field in such country or region.
Regulatory Authority	Any national, international, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority over the distribution, importation, exportation, Manufacture, production, use, storage, transport, clinical testing, pricing, sale or reimbursement of a Product in the applicable Territory, including in the case of the Ocugen Territory, the FDA and the EMA.
SERI	The Schepens Eye Research Institute, Inc., a Massachusetts non-profit organization having a principal place of business at 20 Staniford Street, Boston, MA 02114, USA.
SERI Agreement	The Exclusive License Agreement, effective as of December 19, 2017, between SERI and Ocugen, a partially redacted copy of which is attached hereto as <u>Exhibit B</u> .
Serious Adverse Event	Any Adverse Event that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect, as defined more fully in 21 C.F.R. § 312.32.

Significant Development Event

Any of the following material Development events: (a) any material interaction and/or written correspondence between a Party or any of its Affiliates and any Regulatory Authority with respect to a Product; or (b) any material event or result with respect to any Clinical Trial involving a Product.

Technology

Collectively, data, results, technology, inventions, discoveries, improvements, trade secrets and proprietary methods, whether or not patentable and in any tangible or intangible form, including: (a) methods of manufacture or use of, and structural and functional information pertaining to, biologics; (b) compositions of matter, data, formulations, processes, techniques, know-how and results; and (c) unregistered design rights, copyright, database rights, rights in respect of confidential information, rights under data exclusivity laws, rights under orphan drug laws, rights under unfair competition laws, property rights in biological or chemical materials, extension of the terms of any such rights, applications for and the right to apply any of the foregoing registered property and rights, and similar or analogous rights. For clarity, Technology excludes Patent Rights.

Territory

The Ocugen Territory and/or the CanSino Territory, as the context requires.

Valid Claim

Any claim of a pending patent application or an issued (or granted) and unexpired patent that (a) has not been finally cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction, (b) has not been permanently revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, (c) has not been rendered unenforceable through terminal disclaimer or otherwise, (d) is not lost through an interference proceeding, or foreign equivalent, that is

unappealable or unappealed within the time allowed for appeal, and (e) in the case of a claim in a pending patent application, has been pending for not more than seven (7) years after the date of filing of the earliest patent application claiming priority with respect to such claim.

2. Grant of Rights

2.1 License Grants to CanSino; Option. Subject to the provisions of this Agreement, Ocugen hereby grants to CanSino:

(a) an exclusive (even as to Ocugen), non-sublicensable, royalty-bearing license under the Ocugen Technology and the Ocugen Patent Rights, to use, research, Develop, Manufacture and Commercialize Products in the Field in and for the CanSino Territory;

(b) an exclusive (even as to Ocugen), royalty-bearing license, including the right to grant sublicenses solely as provided in Section 2.3, under Ocugen's rights in the Joint Program Technology and Joint Program Patent Rights, to use, research, Develop, Manufacture and Commercialize Products in the Field in and for the CanSino Territory;

(c) an exclusive option (the "**Option**"), exercisable during the Option Period in accordance with Section 2.4, to expand the license under (i) Section 2.1(a) to include a non-exclusive, non-sublicensable, royalty-free license under the Ocugen Technology and the Ocugen Patent Rights, and (ii) Section 2.1(b) to include a non-exclusive, non-sublicensable, royalty-free license under Ocugen's rights in the Joint Program Technology and Joint Program Patent Rights, to Manufacture Products in the Field in the CanSino Territory for commercial sale by Ocugen or its Affiliates in the Ocugen Territory [***] following commercial launch of such Products in the Ocugen Territory [***], pursuant to the terms of a supply agreement to be negotiated by the Parties following CanSino's exercise of the Option (the "**Supply Agreement**").

2.2 License Grant to Ocugen. Subject to the provisions of this Agreement, CanSino hereby grants to Ocugen an exclusive (even as to CanSino), sublicensable, royalty-bearing license under CanSino's rights in the Joint Program Technology and Joint Program Patent Rights, to use, research, Develop, Manufacture and Commercialize Products in the Field in and for the Ocugen Territory; provided, that (a) sublicensing does not relieve Ocugen of any of its obligations under this Agreement and Ocugen shall remain responsible for the acts and omissions of such

Affiliate or third party in relation thereto; (b) Ocugen shall secure all appropriate covenants, obligations and rights from any such Affiliate or sublicensee, including licenses, assignment of intellectual property rights and confidentiality obligations, to ensure that such Affiliate or sublicensee is subject to, and can comply with, all of Ocugen's covenants and obligations under this Agreement; and (c) Ocugen shall provide CanSino with a complete copy of the applicable sublicense agreement executed by Ocugen within fourteen (14) days after its execution.

2.3 CanSino Right to Sublicense. CanSino shall have the right to grant sublicenses, in whole or in part, under the license granted to it under Section 2.1(b) to any of its Affiliates or to any third party with the prior written consent of Ocugen, such consent not to be unreasonably withheld, conditioned or delayed; *provided*, that (a) sublicensing does not relieve CanSino of any of its obligations under this Agreement and CanSino shall remain responsible for the acts and omissions of such Affiliate or third party in relation thereto; (b) CanSino shall secure all appropriate covenants, obligations and rights from any such Affiliate or sublicensee, including licenses, assignment of intellectual property rights and confidentiality obligations, to ensure that such Affiliate or sublicensee is subject to, and can comply with, all of CanSino's covenants and obligations under this Agreement; and (c) CanSino shall provide Ocugen with a complete copy of the applicable sublicense agreement executed by CanSino within fourteen (14) days after its execution.

2.4 Exercise of Option.

(a) CanSino may exercise the Option at any time during the Option Period by giving written notice of exercise to Ocugen (the "**Option Exercise Notice**"); *provided*, that if CanSino determines that it shall not exercise the Option prior to expiration of the Option Period, it shall in good faith provide written notice to Ocugen promptly upon such determination.

(b) During the [***] period following Ocugen's receipt of the Option Exercise Notice, the Parties shall negotiate in good faith the terms of the Supply Agreement, *provided* such period may be extended for [***] as mutually agreed by the Parties. Any Supply Agreement executed by the Parties shall provide, among other things, that the maximum purchase price payable by Ocugen for any Product manufactured and supplied thereunder shall not exceed [***].

2.5 Ocugen Assistance. Ocugen shall provide CanSino with all documents, information and Data in its possession as reasonably requested by CanSino or that are otherwise necessary or useful for CanSino to conduct the CanSino Development Activities under Article 3, including without limitation all Joint Program Materials under the control of Ocugen.

2.6 CanSino Assistance. CanSino shall provide Ocugen with all documents, information and Data in its possession as reasonably requested by Ocugen or that are otherwise necessary or useful for Ocugen to conduct the Ocugen Development Activities under Article 3, including without limitation all Joint Program Materials under the control of CanSino.

2.7 SERI License. CanSino covenants and agrees that it shall comply at all times with Section 2.4 (Reserved Rights), Paragraphs 4.2.1 (Books and Records) and 4.2.2 (Inspections), Sections 5.2-5.6 (U.S. Manufacture, Other Government Laws, Patent Marking, Publicity, and Confidentiality), Article 6 (Patent Preparation, Filing, Prosecution and Maintenance), Article 7 (Patent Infringement and Enforcement), Paragraph 8.4.4 (Termination — Sublicenses), Article 9 (Indemnification, Defense and Insurance), Article 10 (Disclaimer of Warranties) and Article 12 (Dispute Resolution) of the SERI Agreement, which provisions are binding on CanSino in its capacity as Ocugen's sublicensee under the SERI Agreement and are incorporated herein by reference. For the avoidance of doubt, all such provisions shall be binding on CanSino as and to the same extent they are binding on Ocugen or to the extent they are directly applicable to a sublicensee of Ocugen under the SERI Agreement in accordance with their terms. CanSino acknowledges and agrees that, pursuant to Section 2.5.2(d) of the SERI Agreement, CanSino does not have the right to grant further sublicenses of the rights granted by Ocugen to CanSino under Section 2.1(a) and Section 2.1(c) of this Agreement.

2.8 Non-Competition. During the Term, except as set forth in this Agreement, CanSino and its Affiliates shall not, directly or indirectly (with, for the benefit of, using, or with the sponsorship of, any third party) be permitted to research, Develop, Manufacture or Commercialize any preparation, substance, formulation or product that is competitive with or to a Product in the Field anywhere in the world, unless CanSino first obtains Ocugen's written consent, which consent Ocugen may grant or withhold in its sole and absolute discretion.

3. Co-Development of Products

3.1 Objectives and Implementation of Development Program. Consistent with the remaining terms and conditions of this Agreement, the Parties shall collaborate with one another in the Field during the Term as it relates to the Development of Products in and for their respective Territories in accordance with the Development Plan. The initial Development Plan, which describes the Ocugen Development Activities and the CanSino Development Activities to be carried out by the Parties in and for their respective Territories from the Effective Date through the end of calendar year [2020] is attached hereto as Exhibit A. [***] the Parties shall jointly prepare an updated Development Plan and submit it to the JSC for its review and approval pursuant to Section 3.9. The Parties shall use Commercially Reasonable Efforts to collaborate on, prepare and submit each Development Plan to the JSC [***]. Any amendment, modification or update to any Development Plan shall be set forth in a written document prepared by one or both Parties and reviewed by the JSC, shall specifically state that it is an amendment, modification or update to the then-existing Development Plan and shall be sent to the JSC members no later than twenty (20) days prior to the meeting of the JSC at which such amendment, modification or update is to be reviewed and approved. For clarity, all Joint Program Technology and Joint Program Patent Rights shall be jointly owned by the Parties and each Party shall be free to practice such Joint Program Technology and Joint Program Patent Rights in its Territory, subject to any terms or conditions of this Agreement to the contrary.

3.2 Conduct of Development Program; Diligence

(a) Ocugen Diligence. Ocugen shall use Commercially Reasonable Efforts to conduct the Ocugen Development Activities as set forth in the Development Plan and to bring one or more Products in the Field into commercial use in the Ocugen Territory as quickly as possible. Ocugen is solely responsible for the Development of Products in the Field in and for the Ocugen Territory in accordance with the Development Plan.

(b) CanSino Diligence. CanSino shall use Commercially Reasonable Efforts to conduct the CanSino Development Activities as set forth in the Development Plan and to bring one or more Products in the Field into commercial use in the CanSino Territory as quickly as possible. CanSino is solely responsible for the Development of Products in the Field in and for the CanSino Territory in accordance with the Development Plan.

3.3 Costs of Development. Ocugen is solely responsible for all costs and expenses associated with the performance of the Ocugen Development Activities and the Development of Products in the Field in and for the Ocugen Territory as set forth in the Development Plan, and CanSino is solely responsible for all costs and expenses associated with the performance of the CanSino Development Activities and the Development of Products in the Field in and for the CanSino Territory as set forth in the Development Plan.

3.4 Engagement of Third Party Contractors. A Party may engage third party contractors (but CanSino shall not be permitted to grant sublicenses under the Ocugen Technology or the Ocugen Patent Rights) to perform, as applicable, Ocugen Development Activities or CanSino Development Activities hereunder; *provided*, that with respect to any such subcontract, (a) the applicable third party contractor shall execute an agreement containing provisions that (i) are consistent with the cooperation, records and reports, ownership, confidentiality and intellectual property provisions set forth in this Agreement, and (ii) assign any and all intellectual property rights discovered or invented by the third party contractor thereunder to Ocugen or CanSino, as applicable, and (b) such Party shall promptly provide the other Party with a copy of such subcontract upon its execution.

3.5 Compliance. Each Party shall perform all Development activities for which it is responsible under the Development Plan in a good scientific manner and in compliance with all Applicable Laws.

3.6 Records and Reports. Each Party shall maintain complete and accurate records of its activities in respect of the Development Program in accordance with good business practices and in sufficient detail, including in sufficient detail for the purpose of making patent filings and regulatory filings, in good scientific manner, or otherwise in a manner that reflects all work done and results achieved. Each Party may review and copy such records at reasonable times, and upon reasonable notice. Each Party shall provide to the other Party, at least once each calendar quarter for as long as the Development Program is ongoing, a reasonably detailed report that summarizes: (a) all Development activities conducted and results obtained by such Party with respect to each Product during the most recently completed calendar quarter; and (b) any Significant Development Events applicable to such Product.

3.7 Manufacture and Supply of Products Prior to and After Regulatory Approval.

(a) Except as set forth in any supply agreement executed by the Parties, prior to Ocugen's receipt of Regulatory Approval for a Product in the Field in a particular country or regulatory jurisdiction in the Ocugen Territory, CanSino shall be responsible, in

accordance with the Development Plan or as may otherwise be agreed by the JSC, to Manufacture and supply Ocugen with such form and quantity of CTM as Ocugen requires to carry out Clinical Trials and other tests and to otherwise conduct Ocugen Development Activities anywhere in the Ocugen Territory.

(b) Except as set forth in the Development Plan or in any supply agreement executed by the Parties, CanSino shall be responsible, at its sole cost and expense, for the Manufacture and supply of (i) such form and quantity of CTM as CanSino requires to carry out Clinical Trials and other tests and to otherwise conduct CanSino Development Activities anywhere in the CanSino Territory, and (ii) each finished Product in its commercial packaging presentation, for use by CanSino in the Field in each country or regulatory jurisdiction in the CanSino Territory after CanSino's receipt of Regulatory Approval for such Product in such country or regulatory jurisdiction.

(c) Except as set forth in any supply agreement executed by the Parties, including the Supply Agreement, Ocugen shall be responsible, at its sole cost and expense, for the Manufacture and supply of each finished Product in its commercial packaging presentation, for use by Ocugen in the Field in each country or regulatory jurisdiction in the Ocugen Territory after Ocugen's receipt of Regulatory Approval for such Product in such country or regulatory jurisdiction.

3.8 Regulatory Filings/Approvals and Assistance

(a) Each Party shall use Commercially Reasonable Efforts to obtain in its own name Marketing Authorizations for the Products in its Territory, including, where applicable, obtaining accelerated review of each application for Marketing Authorization.

(b) Ocugen shall have the sole right and responsibility for (i) preparing, filing and maintaining all regulatory filings and Regulatory Approvals for the Products in the Field in the name of Ocugen or any of its Affiliates, and (ii) reporting to Regulatory Authorities all Adverse Events and Serious Adverse Events to the extent required by Applicable Laws, in each case for and in respect of the Ocugen Territory. Ocugen shall solely and exclusively own all Regulatory Approvals obtained by Ocugen in and for the Ocugen Territory.

(c) CanSino shall have the sole right and responsibility for (i) preparing, filing and maintaining all regulatory filings and Regulatory Approvals for the Products in the Field in the name of CanSino or any of its Affiliates, and (ii) reporting to Regulatory Authorities all Adverse Events and Serious Adverse Events to the extent required by Applicable Laws, in each case for and in respect of the CanSino Territory. CanSino shall

solely and exclusively own all Regulatory Approvals obtained by CanSino in and for the CanSino Territory.

(d) Upon the reasonable request of Ocugen, CanSino shall reasonably respond to questions or comments from Regulatory Authorities in the Ocugen Territory as it relates to use of Products in the Field. In the event that a Regulatory Authority requests any information that has not been provided to Ocugen by CanSino, to the extent such additional information is under the control of CanSino, CanSino shall provide such information to Ocugen at no additional cost. Upon the reasonable request of CanSino, Ocugen shall reasonably respond to questions or comments from Regulatory Authorities in the CanSino Territory as it relates to use of Products in the Field. In the event that a Regulatory Authority requests any information that has not been provided to CanSino by Ocugen, to the extent such additional information is under the control of Ocugen, Ocugen shall provide such information to CanSino at no additional cost.

(e) CanSino shall reasonably cooperate with any on-site inspection by a Regulatory Authority as regards any Clinical Trial being conducted by Ocugen, as it relates to Ocugen's Manufacture of finished Products in accordance with Section 3.7, or pursuant to this Agreement. Ocugen shall reasonably cooperate with any on-site inspection by a Regulatory Authority as regards any Clinical Trial being conducted by CanSino, as it relates to CanSino's Manufacture and supply of CTM or finished Products to Ocugen in accordance with Section 3.7, or pursuant to this Agreement.

3.9 Further Cooperation. Further to the Parties' respective obligations under Section 2.5 and Section 2.6, each Party shall share with the other Party all information it obtains in its conduct of the Development Program, including but not limited to documents and Data in regard to pre-clinical activities, clinical activities, CMC Technology, Manufacture, and Regulatory Approval in or for its Territory.

3.9 Joint Steering Committee. On the Effective Date, the Parties shall establish a joint steering committee ("JSC"). The JSC shall have and perform the following responsibilities, *provided* the JSC shall have no authority to amend this Agreement: (a) oversight with respect to the conduct of the Development Program and implementation and execution of the Development Plan; (b) reviewing and approving the Development Plan and all amendments thereto; (c) reviewing and discussing the overall performance of Development activities by the Parties and comparing same to the diligence obligations set forth in Section 3.2; (d) reviewing and/or ensuring the exchange of all Technology, proprietary materials, reports or other information submitted to each Party or the JSC

pursuant to this Agreement; (e) attempting to resolve all matters between the Parties that are in dispute; and (f) performing such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as mutually determined by the Parties in writing. The JSC shall be comprised of four (4) members, consisting of two (2) from Ocugen and two (2) from CanSino, which members shall review and discuss at each meeting of the JSC, among other things, the Development Program, including Development activities being undertaken by the Parties and strategies and decisions to carry out co-Development of Products as specified in this Agreement. The JSC shall establish a schedule of times for regular meetings and special meetings may be convened by any member upon not less than thirty (30) days' written notice to the other members. In no event shall the JSC meet less frequently than once every calendar quarter and at least two (2) meetings per calendar year shall be in-person meetings. At each JSC meeting, the presence in person of at least one (1) member designated by each Party shall constitute a quorum and the representatives of a Party shall have one (1) collective vote on all matters before the JSC at such meeting. All decisions of the JSC shall be made by unanimous vote. If unanimous vote is not achieved, the Parties shall resolve the dispute in accordance with the terms of Section 11.6.

4 Commercialization

4.1 Responsibility for Commercialization of Products. Consistent with the remaining terms and conditions of this Agreement, each Party shall be solely responsible for Commercialization of Products in the Field in its Territory. For clarity, Ocugen shall be solely responsible for the Commercialization of Products in the Field in the Ocugen Territory, and CanSino shall be solely responsible for the Commercialization of Products in the Field in the CanSino Territory, in each case including all pre-marketing, marketing, promotion, sales, distribution, import and export activities (including securing reimbursement, sales and marketing and conducting any post-marketing trials or databases and post-marketing safety surveillance), maintaining all issued Marketing Authorizations, maintaining all pharmacovigilance systems and activities as required by Applicable Laws and the timing and launch of all Products. Each Party shall, and shall cause its Affiliates, to market and promote the Products only in the Field in its Territory.

4.2 Commercialization Plan. No later than [six] ([6]) months prior to the expected First Commercial Sale of the first Product anywhere in the Ocugen Territory or the CanSino Territory, as applicable, the responsible Party shall provide to the other Party its initial

Commercialization Plan for its Territory. Each Party shall provide the other Party with an updated Commercialization Plan no later than December 31 of each calendar year beginning with the calendar year in which First Commercial Sale of the first Product in its Territory occurs.

4.3 Responsibility for Commercialization Expenses. Each Party shall be solely responsible for paying all costs and expenses incurred in connection with its Commercialization of Products in the Field in its Territory.

4.4 Commercialization Diligence. In each country or regulatory jurisdiction in the Ocugen Territory in which it receives Marketing Authorization, Ocugen shall use Commercially Reasonable Efforts during the Term to Commercialize the corresponding Product(s) in the Field in such country or regulatory jurisdiction. In each country or regulatory jurisdiction in the CanSino Territory in which it receives Marketing Authorization, CanSino shall use Commercially Reasonable Efforts during the Term to Commercialize the corresponding Product(s) in the Field in such country or regulatory jurisdiction.

4.5 Commercialization Reports. Each Party shall maintain a record of all of its Commercialization activities in accordance with good business practices. No later than December 31 of each calendar year beginning with the calendar year in which First Commercial Sale of the first Product occurs in its Territory, such Party shall provide to the other Party a reasonably detailed report that summarizes the Commercialization activities conducted by such Party during such calendar year.

4.6 Product Trademarks. Ocugen may, in its sole discretion, select, and Ocugen shall own, the Product Trademarks for use on Products in the Field in and for the Ocugen Territory, and Ocugen shall be responsible for the registration, prosecution, maintenance and enforcement thereof. CanSino may, in its sole discretion, select, and CanSino shall own, the Product Trademarks for use on Products in the Field in and for the CanSino Territory, and CanSino shall be responsible for the registration, prosecution, maintenance and enforcement thereof; *provided*, that CanSino shall: (a) notify Ocugen of its choice of any Product Trademark [***] before effecting its first filing of a Marketing Authorization for the related Product(s); and (b) notify Ocugen if it is required by any Regulatory Authority to alter, amend or change such Product Trademark. CanSino warrants that none of the Product Trademarks selected/owned by CanSino pursuant to this Section 4.6 will infringe any third party's rights, and CanSino shall indemnify Ocugen if Ocugen incurs any liability related to CanSino's breach of such warranty.

4.7 Additional Obligations of CanSino. In addition to its other obligations set forth in this Article 4, CanSino shall, during the Term, at its own cost and expense, use Commercially Reasonable Efforts to: (a) initiate, extend, promote and maximize sales of the Products in the Filed in and for the CanSino Territory and not do or take any action which could hinder or interfere with such sales; (b) achieve the sales forecasts contained in the applicable Commercialization Plan; and (c) allocate its promotional and sales resources and such technical support for the promotion, marketing and sales of the Products as may reasonably be required to maximize sales of such Products in the Field in and for the CanSino Territory.

4.8 Compliance with Applicable Laws. CanSino shall undertake to Commercialize Products in the Field in and for the CanSino Territory entirely in accordance with the Marketing Authorization of/for such Products and in accordance with all Applicable Laws.

4.9 Adverse Events. During the Term, each Party shall be responsible for promptly notifying the other Party regarding any Adverse Event, whether actual or suspected, in respect of Products that is suffered anywhere in the world and with respect to which such Party obtains information or knowledge (the “**receiving Party**”) in accordance with the following: (a) the receiving Party shall report to the other Party by telephone (followed by written descriptions) or in writing any information regarding a Serious Adverse Event concerning drug reactions that are life-threatening or cause death within two (2) days after an initial determination by the receiving Party that the Adverse Event is serious; (b) the receiving Party shall report to the other Party in writing any information about any Serious Adverse Event that does not fall within the scope of Section 4.9(a) within seven (7) days after an initial determination by the receiving Party that the Adverse Event is serious; (c) the receiving Party shall report to the other Party by telephone (followed by written descriptions) or in writing any information regarding a non-serious Adverse Event that does not fall within the scope of Section 4.9(a) within ninety (90) days after the date the receiving Party receives the information; and (d) the receiving Party’s reports pursuant to this Section 4.9 shall contain any relevant information reasonably required by the other Party to meet the requirements of any Regulatory Authority in/for its Territory.

5 Payment/Consideration

5.1 Royalties. In consideration for the licenses granted under Sections 2.1 and 2.2 and the rights of each Party to Commercialize Products in its Territory, each Party agrees to pay the other Party royalties under this Agreement as follows:

(a) On a Product-by-Product and country-by-country basis, Ocugen will pay CanSino [***] in such country in the Ocugen Territory in a given calendar year (or partial calendar year), commencing with the First Commercial Sale of such Product in such country and ending upon the last day of the Term for such Product in such country pursuant to Section 9.1; and

(b) On a Product-by-Product and country-by-country basis, CanSino will pay Ocugen [***] in such country in the CanSino Territory in a given calendar year (or partial calendar year), commencing with the First Commercial Sale of such Product in such country and ending upon the last day of the Term for such Product in such country pursuant to Section 9.1.

5.2 Royalty Reports. In accordance with this Agreement, each Party shall prepare and provide to the other Party with its royalty payment, a royalty report showing: (a) the gross sales and Net Sales of each Product by country in its Territory; (b) the total amount of deductions from gross sales taken to determine Net Sales; and (c) a calculation of the amount of the royalty due to the other Party under Section 5.1. The foregoing amounts shall be expressed in both Ren Min Bi (RMB) (i.e., Chinese Yuans) and Dollars and shall be converted using as the applicable foreign exchange the average of the closing rates published in the eastern edition of The Wall Street Journal under the heading "Money Rates" or any other mutually agreed upon source for each applicable calendar quarter for which such report is due.

5.3 Payments. [***] All payments made by a Party under this Section 5.3 shall be made by wire transfer from a banking institution in United States Dollars in accordance with instructions given from time to time by the other Party. CanSino acknowledges and agrees that it shall make the payments required under this Section 5.3 in a timely manner so that Ocugen may comply with its obligations to make payments to SERI in accordance with Articles 3 and 4 of the SERI Agreement.

5.4 Non-Monetary Sales. Neither Party shall enter into any agreement, nor permit any agreement to be made, under which any non-monetary Net Sales are obtained or due to be obtained by a Party, except with the prior written consent of the other Party.

5.5 Prohibited Payments. If, at any time during the continuation of this Agreement, either Party is prohibited from making any of the payments required hereunder by a Governmental Authority in any country (“**the prohibited Party**”), then the prohibited Party shall, within the prescribed period for making said payments, in the appropriate manner, use Commercially Reasonable Efforts to secure from such Governmental Authority in the relevant country permission to make said payments, and shall make such payments within [***] after receiving such permission. If such permission is not granted within [***] after the prohibited Party makes such request for permission, then, at the option of the other Party, the prohibited Party shall make the payments due in the currency of the relevant country, either to a bank account designated by the other Party within such country or to an Affiliate designated by the other Party.

5.6 Books and Records. Each Party shall keep, and shall require its Affiliates to keep, true books of account containing an accurate record (together with all supporting documentation) of all data and information necessary for determining and/or verifying the amounts payable to the other Party hereunder and to SERI pursuant to the SERI Agreement. Each Party shall keep its records at its principal place of business or the principal place of business of the appropriate division of such Party to which this Agreement relates and shall require its Affiliates and permitted sublicensees to keep their books and records related to this Agreement in the same manner.

6 Intellectual Property

6.1 Intellectual Property Rights. As between the Parties, Ocugen shall have sole and exclusive Control of all right, title and interest on a worldwide basis in and to any and all Ocugen Technology and Ocugen Patent Rights, subject to the licenses provided to CanSino pursuant to this Agreement. The Parties shall jointly Control all right, title and interest on a worldwide basis in and to any and all Joint Program Technology, Joint Program Patent Rights and Joint Program Materials. Each Party hereby agrees to promptly notify the other Party of the conception or reduction to practice of any Joint Program Technology or Joint Program Materials and to promptly execute any documents that may be necessary to perfect the other Party’s rights in and to such Joint Program Technology.

6.2 Patent Filing, Prosecution and Maintenance. Ocugen shall, acting through patent counsel of its choice: (a) endeavor to prepare, file, prosecute and maintain the Ocugen Patent Rights and the Joint Program Patent Rights worldwide so as to secure the broadest protection reasonably and lawfully available; (b) consult with CanSino in relation to the

preparation, filing, prosecution and maintenance of the Ocugen Patent Rights and the Joint Program Patent Rights, as well as all changes to patent claims or specifications that would have the effect of reducing or limiting the extent of such patent coverage; and (c) pay all fees and expenses to prepare, file, prosecute and maintain the Ocugen Patent Rights and the Joint Program Patent Rights worldwide as and when due, *provided* CanSino shall reimburse Ocugen for the portion of such fees and expenses that are incurred by Ocugen in, for or with respect to the CanSino Territory. Ocugen shall consult in good faith with CanSino and CanSino shall cooperate with and assist Ocugen in all reasonable respects, in connection with Ocugen's preparation, filing, prosecution and maintenance of such Ocugen Patent Rights and Joint Program Patent Rights. If Ocugen desires to abandon or to not maintain any of the Joint Program Patent Rights in the Field in and for the CanSino Territory (or to cease funding any application or Patent forming a part of such Joint Program Patent Rights), it shall give CanSino [***] prior written notice of same, and CanSino shall have the right but not the obligation, beginning at the end of such [***] period, to pursue preparing, filing, prosecuting and/or maintaining such Joint Program Patent Rights in the Field solely in and for the CanSino Territory, at its sole cost and expense.

6.3 Enforcement and Defense.

(a) Each Party shall inform the other Party promptly if it becomes aware of any infringement, potential infringement or misappropriation of any Ocugen Patent Rights or Joint Program Patent Rights in the Field anywhere in the world, and the Parties shall consult with each other regarding a strategy for enforcement/defense and the best way to respond to such infringement. Notwithstanding the foregoing, as between the Parties, Ocugen shall have the first right, but not the obligation, to address infringement of the Ocugen Patent Rights and the Joint Program Patent Rights anywhere in the world by taking reasonable steps, which may include the institution of legal proceedings or other action, and to compromise or settle such infringement of the Ocugen Patent Rights or the Joint Program Patent Rights, *provided* Ocugen shall keep CanSino informed about such infringement response and CanSino shall provide all reasonable cooperation to Ocugen in connection with such infringement response. In the event that Ocugen initiates any such action, any damages or other payments recovered shall belong solely to Ocugen. Ocugen shall not take any position with respect to, or compromise or settle, any such infringement of the Ocugen Patent Rights or Joint Program Patent Rights in any way that may derogate from CanSino's rights in this Agreement, without the prior written consent of CanSino,

which consent shall not be unreasonably withheld, conditioned or delayed. If Ocugen does not intend to enforce /defend any Ocugen Patent Rights or Joint Program Patent Rights, or ceases to diligently pursue infringement of any Ocugen Patent Rights or Joint Program Patent Rights anywhere in the world, it shall promptly inform CanSino of such fact. All costs relating to Ocugen's infringement responses under this Section 6.3(a) shall be borne solely by Ocugen.

(b) If Ocugen informs CanSino that it does not intend to enforce/defend any Ocugen Patent Rights or Joint Program Patent Rights, or ceases to diligently pursue infringement of any Ocugen Patent Rights or Joint Program Patent Rights anywhere in the world in accordance with Section 6.3(a), then CanSino shall have the right, but not the obligation, at its own expense, upon written notice to Ocugen, to address such infringement of such Ocugen Patent Rights or Joint Program Patent Rights by taking reasonable steps, which may include the institution of legal proceedings or other action, and to compromise or settle such infringement of such Ocugen Patent Rights or Joint Program Patent Rights against the applicable third party, *provided* CanSino shall keep Ocugen informed about such infringement response and Ocugen shall provide all reasonable cooperation to CanSino in connection with such infringement response. CanSino shall not take any position with respect to, or compromise or settle, any such infringement of the Ocugen Patent Rights or Joint Program Patent Rights in any way that may derogate from Ocugen's rights in this Agreement, without the prior written consent of Ocugen, which consent shall not be unreasonably withheld, conditioned or delayed. In the event that CanSino initiates any such action, any damages or other payments recovered shall belong solely to CanSino.

(c) Before starting any legal action under Section 6.3(b), CanSino shall consult with Ocugen as to the advisability of the action or settlement, its effect on the good name of Ocugen, the public interest, and how the action should be conducted.

(d) If the alleged infringement of the Ocugen Patent Rights or the Joint Program Patent Rights is both within and outside the Field, the Parties shall also co-operate with Ocugen's other licensees (if any) in relation to any such action(s).

(e) Each Party agrees to be joined in any suit to enforce the Ocugen Patent Rights or Joint Program Patent Rights in the applicable Territory in accordance with Section 6.3(a) or Section 6.3(b), as applicable, subject to being indemnified and secured in a reasonable manner as to any costs, damages, expenses, or other liabilities such Party may incur in connection therewith or resulting therefrom, and such Party shall have the right to be separately represented in any such suit by its own counsel at its own expense.

6.4 Infringement of Third-Party Rights

(a) If any warning letter or other notice of infringement from a third party is received by a Party, or a legal suit, proceeding or other action is brought against a Party, alleging infringement of the Technology or Patent Rights of such third party by reason of the conduct of the Development Program, the use, Development, Manufacture or Commercialization of any Product in the Field, or the use of any Ocugen Patent Rights or Joint Program Patent Rights hereunder, that Party shall promptly provide full details to the other Party, and the Parties shall discuss as soon as possible the overall strategy for defense of such matter and the best way to respond. Notwithstanding the foregoing, Ocugen shall have the obligation to defend any such suit, proceeding or other action, *provided*, CanSino shall have the right to separate counsel at its own expense in any such suit, proceeding or other action. The Parties shall cooperate with each other in all reasonable respects in any such suit, proceeding or other action, and all expenses with respect to any such suit, proceeding or other action in the Territory shall be borne equally by the Parties. Each Party shall promptly furnish the other Party with a copy of each communication relating to the alleged infringement that is received by such Party, including all documents filed in any litigation.

(b) Ocugen shall have the right to settle the related suit, proceeding or other action with the applicable third party, *provided*, that if the taking of any action or any proposed settlement involves the making of any statement, express or implied, concerning the validity of the Ocugen Patent Rights or the Joint Program Patent Rights, CanSino shall be notified before Ocugen takes such action or makes such settlement.

7 **Representations, Warranties and Covenants**

7.1 Representations and Warranties of the Parties. Each Party represents and warrants to the other Party as of the Effective Date that:

(a) it is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, and has full power and authority to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement;

(b) it has the full right, power, and authority to enter into this Agreement and to grant the rights and licenses granted by it under this Agreement;

(c) there are no existing, or to its knowledge, threatened Claims pending with respect to the subject matter of this Agreement or its right to enter into and perform its obligations under this Agreement;

(d) it has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;

(e) this Agreement has been duly executed and delivered on behalf of it, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with its terms, subject to the general principles of equity and to the laws of bankruptcy, insolvency, moratorium, and other similar laws affecting the enforcement of creditors' rights generally, and to any applicable competition laws;

(f) all Permits required to be obtained by it in accordance with the execution and delivery of this Agreement and the performance of its obligations under this Agreement have been or will be obtained, and in the case of CanSino, all Permits have been or will be obtained in relation to its conduct of any and all activities described hereunder to be performed in or with respect to the CanSino Territory; and

(g) the execution and delivery of this Agreement and the performance of its obligations hereunder do not conflict with or constitute a default under any of its constitutional or formation agreements.

7.2 Ocugen's Additional Warranties. Ocugen further represents and warrants as of the Effective Date, and covenants as and to the extent applicable during the Term, that:

(a) it has full right and authority to grant the licenses and rights granted under this Agreement, and no rights or licenses are required from Ocugen, or to its knowledge, any other Person, in order for CanSino to Develop, Manufacture and Commercialize Products in the Field in and for the CanSino Territory as contemplated under this Agreement other than the rights granted to CanSino under Section 2.1;

(b) to Ocugen's knowledge, there are no Patent Rights Controlled by a third party that would be infringed by CanSino's use of the Ocugen Technology or CanSino's practicing of the Ocugen Patent Rights in the Field in and for the CanSino Territory, and to Ocugen's knowledge, no Claim or litigation has been brought or asserted (and Ocugen has no knowledge of any Claim, whether or not brought or asserted, or of any facts or circumstances that exist that would reasonably be expected to give rise to any such Claim or litigation) by any Person alleging that (i) the Ocugen Patent Rights are invalid or unenforceable or (ii) the conception, development, reduction to practice, disclosing, copying, making, assigning or licensing of the Ocugen Technology or the Ocugen Patent

Rights existing as of the Effective Date as contemplated herein, violates, infringes, constitutes misappropriation of or otherwise conflicts or interferes with or would violate, infringe or otherwise conflict or interfere with, any intellectual property or proprietary right of any other Person; and

(c) to Ocugen's knowledge, no Person is infringing or threatening to infringe, or misappropriating or threatening to misappropriate, the Ocugen Patent Rights existing as of the Effective Date.

(d) it has made and will make commercially reasonable efforts to maintain the validity of the Ocugen Patent Rights and will not surrender its licenses in any way so as to secure the broadest protection reasonably and lawfully available.

8 Confidential Information

8.1 Confidentiality Obligations. Each Party (the "**Receiving Party**") undertakes:

(a) to maintain as secret and confidential all Confidential Information obtained directly or indirectly from the other Party (the "**Disclosing Party**") in the course of, or in anticipation of, this Agreement and to respect the Disclosing Party's rights therein;

(b) not to use such Confidential Information for any purpose other than as contemplated in this Agreement or with the Disclosing Party's prior written consent;

(c) not to disclose such Confidential Information to any Person other than those of its staff or advisers to whom and to the extent that such disclosure is reasonably necessary for the purposes of this Agreement and which are under equally strict confidentiality obligations; and

(d) take all reasonable steps necessary to prevent the unauthorized disclosure or use of any of the Disclosing Party's Confidential Information.

8.2 Exceptions to obligations. The provisions of Section 8.1 shall not apply to Confidential Information which the Receiving Party can demonstrate by reasonable, written evidence:

(a) was, prior to its receipt by the Receiving Party from the Disclosing Party, in the possession of the Receiving Party and at its free disposal; or

(b) is subsequently disclosed to the Receiving Party without any obligations of confidence by a third party who has not derived it directly or indirectly from the Disclosing Party; or

(c) is or becomes generally available to the public through no act or default of the Receiving Party or its agents, employees or Affiliates; or

(d) is independently developed by the Receiving Party by individuals who have not had any direct or indirect access to the Disclosing Party's Confidential Information; or

(e) the Receiving Party is required to disclose to the courts of any competent jurisdiction, or to any Governmental Authority or Regulatory Authority, *provided*, that the Receiving Party shall (i) inform the Disclosing Party as soon as reasonably practicable, and (ii) at the Disclosing Party's request seek to persuade the court, Governmental Authority or Regulatory Authority to have the information treated in a confidential manner, where and to the extent this is possible under such court's or authority's procedures.

8.3 Disclosures to Employees. The Receiving Party shall procure that all of its employees and subcontractors pursuant to this Agreement (if any) who have access to any of the Disclosing Party's information to which Section 8.1 applies shall be made aware of and subject to the obligations of this Article 8 and shall have entered into written undertakings of confidentiality at least as restrictive as those set forth in Section 8.1 which apply to the Disclosing Party's Confidential Information.

8.4 Regulatory Disclosures. Each Party has the right to make announcements or disclosures concerning the transactions contemplated by this Agreement or any ancillary matter, if:

(a) required under Applicable Laws, including the rules of any securities exchange or regulatory or governmental body to which either Party is subject; or

(b) in connection with information supplied to its shareholders from time to time;

provided, that the announcement shall be made after consultation with and the prior agreement of the other Party as to the terms and timetable for publication of the announcement, such consultation and prior agreement to be sought within a reasonable timeframe and not to be unreasonably withheld or delayed by the other Party; *provided, however*, that the Parties acknowledge that each Party may disclose the Confidential Information to any securities exchanges where the securities of a Party or its Affiliates are or intend to be traded, but only to the extent required by such securities exchanges, without further notice to the other Party.

8.5 Return of Confidential Information. Upon the termination of this Agreement for any reason, the Receiving Party shall return to the Disclosing Party any documents or other materials that contain the Disclosing Party's Confidential Information, including all copies made and make no further use or disclosure thereof, *provided*, that the Receiving Party may retain one copy of the Confidential Information of the Disclosing Party in its archives

solely for the purpose of establishing the contents thereof and ensuring compliance with Applicable Laws and its obligations hereunder.

9 Term and Termination

9.1 Commencement and Termination by Expiry. This Agreement, and the licenses granted hereunder, shall come into effect on the Effective Date and, unless terminated earlier in accordance with this Section 9, shall continue in force on a country-by-country and Product-by-Product basis until the later of: (a) the expiration of the last Valid Claim included within the Ocugen Patent Rights claiming or Covering such Product that, but for this Agreement, would be infringed by such Product, as applicable, in such country; and (b) the tenth (10th) anniversary of the First Commercial Sale of such Product in such country (the “**Term**”), and on such date this Agreement and the licenses granted hereunder shall terminate automatically by expiry with respect to such Product in such country. Notwithstanding the foregoing, this Agreement shall terminate contemporaneously upon any termination of the SERI Agreement, *provided*, that if at the time of such termination CanSino is not in breach or default of this Agreement, CanSino shall have the right to request conversion of this Agreement to an agreement/license directly between SERI and CanSino, and SERI shall not unreasonably withhold its acceptance of such conversion if CanSino agrees to be bound by all of the provisions of the SERI Agreement.

9.2 Other Bases of Termination. Either Party may terminate this Agreement at any time by notice in writing to the other Party (the “**Other Party**”), such notice to take effect as specified in the notice:

- (a) in its entirety if the Other Party is in material or persistent breach of this Agreement and, in the case of a breach capable of remedy within [***], the breach is not remedied within [***] of the Other Party receiving written notice specifying the breach and requiring its remedy; or
- (b) in its entirety immediately upon written notice to the Other Party in the event that the Other Party or any of its Affiliates challenges or assists a third party in initiating or pursuing a challenge of any Technology Controlled by such Party; or
- (c) if (i) the Other Party becomes insolvent or unable to pay its debts as and when they become due, or (ii) an order is made or a resolution is passed for the winding up of the Other Party (other than voluntarily for the purpose of solvent amalgamation or reconstruction), or (iii) a liquidator, administrator, administrative receiver, receiver, or trustee is appointed in respect of the whole or any part of the Other Party’s assets or

business, or (iv) the Other Party makes any composition with its creditors, or (v) the Other Party ceases to continue its business, or (vi) as a result of debt and/or maladministration the Other Party takes or suffers any similar or analogous action in any jurisdiction.

9.3 Sale of Remaining Inventory. Upon expiration or termination of this Agreement for any reason, CanSino shall be entitled to sell, use, or otherwise dispose of (subject to payment of royalties under Section 5) any unsold or unused stock of the Products for a period of [***] after the effective date of termination, *provided* that CanSino is then and remains during such [***] period in compliance with all of the other terms and conditions of this Agreement.

9.4 Consequences of Termination by Ocugen Under Sections 9.2(a) and 9.2(b).

If this Agreement is terminated by Ocugen pursuant to Section 9.2(a) or Section 9.2(b), then:

(a) The licenses granted to CanSino under Section 2.1(a) and Section 2.1(b) shall be terminated and of no further force and effect, and to the extent permitted by Applicable Laws, CanSino shall promptly assign to Ocugen all regulatory filings (including any Regulatory Approvals) for the Products in the Field in and for the CanSino Territory.

(b) Within [***] after such termination, CanSino shall provide to Ocugen a fair and accurate summary of the status and results of its Development, Manufacturing and Commercialization activities for Products in the Field in and for the CanSino Territory prior to the effective date of termination.

(c) CanSino shall use Commercially Reasonable Efforts to effect a timely transition to Ocugen of all Development, Manufacturing and Commercialization activities and responsibilities for Products in the Field in and for the CanSino Territory as are in existence as of the date of termination in accordance with a transition plan to be mutually agreed by the Parties. CanSino shall promptly discontinue and wind-down or transfer to Ocugen, at CanSino's cost, any clinical Development activities still ongoing and forward all interim and final reports and underlying data from such activities to Ocugen as part of such transition.

(d) Effective upon such termination and request by Ocugen for such license, CanSino hereby grants to Ocugen a perpetual, irrevocable, exclusive (even as to CanSino, except with respect to Manufacturing if a supply agreement between the Parties is then in effect in accordance with Section 9.4(e)) license, with the right to grant sublicenses, under CanSino's rights in the Joint Program Technology and Joint Program Patent Rights, used in the Development, Manufacture or Commercialization of Products on the date of

termination, solely to continue to Develop, Manufacture (subject to Section 9.4(e)) and/or Commercialize Products in the Field in the CanSino Territory. The foregoing license shall be royalty-bearing as follows: (i) Ocugen shall pay CanSino a royalty of [***] of the Net Sales of Products by Ocugen or its sublicensees (to the extent such Products are thereafter Commercialized by Ocugen or its sublicensees) until such time as the amounts paid under this Section 9.4(d) equals the sum of the actual documented and audited out-of-pocket expenses paid by CanSino to conduct CanSino Development Activities and other Develop Products in the Field in and for the CanSino Territory as part of the Development Program (the "CanSino Development Costs"); and (ii) Sections 5.2, 5.3, 5.4 and 5.5 shall apply *mutatis mutandis* to Ocugen's payment of such royalties. Thereafter, the license granted under this Section 9.4(d) shall be a fully paid-up, non-royalty bearing, perpetual, non-exclusive license in and for the CanSino Territory.

(e) Upon Ocugen's request, CanSino shall, as part of any transition plan mutually agreed by the Parties under Section 9.4(c), at Ocugen's expense, transfer to Ocugen (or its designee) any processes, documents, materials and other Technology, to the extent the foregoing is Controlled by CanSino as of the effective date of termination and used in the Manufacture of Products in the Field in and for the CanSino Territory as of the date of termination; *provided*, that CanSino shall, pursuant to any supply agreement then in place between the Parties, on the terms set forth in such supply agreement, continue to non-exclusively supply Ocugen with clinical and/or commercial quantities of Products under Development or being Commercialized by CanSino in the Field in and for the CanSino Territory, in either case, as of the effective date of termination, until the expiration or termination of such supply agreement in accordance with its terms.

9.5 Consequences of Termination by CanSino Under Sections 9.2(a) and 9.2(b). If this Agreement is terminated by CanSino pursuant to Section 9.2(a) or Section 9.2(b), then:

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

(b) Within [***] after such termination, CanSino shall provide Ocugen with a statement of the CanSino Development Costs and, within [***] after receipt of such report, Ocugen shall reimburse CanSino all such CanSino Development Costs.

(c) Termination of this Agreement shall not result in the termination of the Supply Agreement. That is, CanSino has the right, but not be obligated to, pursuant to any supply agreement then in place between the Parties, on the terms set forth in such supply agreement, continue to supply Ocugen with clinical and/or commercial quantities of Products under Development or being Commercialized by Ocugen in the Field in and for the Ocugen Territory.

9.6 No Further Obligations. Except as provided in this Section 9, and except in respect of any accrued rights, upon the expiration or termination of this Agreement, neither Party shall be under any further obligation to the other.

10 Indemnification; Insurance

10.1 Indemnification of Ocugen Indemnitees by CanSino. CanSino shall indemnify, defend and hold harmless Ocugen, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, the “**Ocugen Indemnitees**”), against all liabilities, damages, losses and expenses (including reasonable attorneys’ fees and expenses of litigation) (collectively, “**Losses**”) incurred by or imposed upon the Ocugen Indemnitees, or any of them, as a direct result of Claims of third parties, including personal injury and product liability claims (collectively, “**Ocugen Indemnity Claims**”), to the extent arising out of: (a) the Development, Manufacture and/or Commercialization of Products by CanSino or any of its agents in the Field in and for the CanSino Territory; (b) any breach of this Agreement by CanSino or any of its Affiliates or agents; or (c) the gross negligence or willful misconduct of any CanSino Indemnitee or agent of CanSino, excluding any CanSino Indemnity Claim or Losses for which Ocugen has an obligation to indemnify CanSino Indemnitees pursuant to Section 10.2, as to which Claims or Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.

10.2 Indemnification of CanSino Indemnitees by Ocugen. Ocugen shall indemnify, defend and hold harmless CanSino, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, the “**CanSino Indemnitees**”), against all Losses incurred by or imposed upon the CanSino

Indemnitees, or any of them, as a direct result of Claims of third parties, including personal injury and product liability claims (collectively, “**CanSino Indemnity Claims**”), to the extent arising out of: (a) the Development, Manufacture and/or Commercialization of Products by Ocugen or any of its agents in the Field in and for the Ocugen Territory; (b) any breach of this Agreement by Ocugen or any of its Affiliates or agents; or (c) the gross negligence or willful misconduct of any Ocugen Indemnitee or agent of Ocugen, excluding any Ocugen Indemnity Claim or Losses for which CanSino has an obligation to indemnify Ocugen Indemnitees pursuant to Section 10.1, as to which Claims or Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.

10.3 Conditions to Indemnification. A Person seeking recovery under this Article 10 (the “**Indemnified Party**”) in respect of an Ocugen Indemnity Claim or a CanSino Indemnity Claim, as applicable (each, an “**Indemnity Claim**”) shall give prompt written notice of such Indemnity Claim to the Party from whom indemnification is sought (the “**Indemnifying Party**”); *provided*, that the Indemnifying Party is not contesting its obligation under this Article 10, and shall permit the Indemnifying Party to control the investigation, defense and settlement of such Indemnity Claim; and *further provided*, that the Indemnifying Party shall (a) act reasonably and in good faith with respect to all matters relating to the settlement or disposition of such Indemnity Claim as the settlement or disposition relates to such Indemnified Party and (b) not settle or otherwise resolve such Indemnity Claim without the prior written consent of such Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). Each Indemnified Party shall cooperate with the Indemnifying Party in its investigation, defense and settlement of any such Indemnity Claim in all reasonable respects and shall have the right to be present in person or through counsel at all legal proceedings with respect to such Indemnity Claim. If the Indemnifying Party does not assume and conduct the defense of the Indemnity Claim as provided above, (i) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Indemnity Claim in any manner the Indemnified Party may deem appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (ii) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 10. The Indemnifying Party shall have no liability for any settlement of Indemnity Claims entered into by the Indemnified Party without the prior written consent of the Indemnifying Party.

10.4 Limited Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS OR LOST REVENUES, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER SECTIONS 10.1 OR 10.2, OR DAMAGES AVAILABLE FOR A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OR A PARTY'S BREACH OF THE INTELLECTUAL PROPERTY OBLIGATIONS IN ARTICLE 6 OR THE CONFIDENTIALITY OBLIGATIONS IN SECTION 8.1.

10.5 Insurance. Each Party shall procure and maintain insurance, including product liability insurance, or shall self-insure, in each case in a manner adequate to cover its obligations under this Agreement and consistent with normal business practices of prudent companies similarly situated at all times during the term of this Agreement and for a period of five (5) years thereafter. Each Party shall procure insurance or self-insure at its own expense. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 10. Each Party shall provide the other Party with written evidence of such insurance or self-insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance.

11 General / Miscellaneous

11.1 Force Majeure. Neither Party shall have any liability or be deemed to be in breach of this Agreement for any delays or failures in performance of this Agreement that result from a Force Majeure. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance and when they cease to do so.

11.2 Amendment. This Agreement may only be amended in a writing signed by duly authorized representatives of both Ocugen and CanSino.

11.3 Waiver. No failure or delay on the part of either Party to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof, nor shall

any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy.

11.4 Invalid Clauses. If any provision or part of this Agreement is held to be invalid, amendments to this Agreement may be made by the addition or deletion of wording as appropriate to remove the invalid part or provision but otherwise retain the provision and the other provisions of this Agreement to the maximum extent permissible under Applicable Laws.

11.5 Notices. Any notice to be given under this Agreement shall be in writing and shall be sent by registered mail or e-mail (confirmed by registered mail) to the address of the relevant Party set out below, or to such other address or email as that Party may from time to time notify to the other Party in accordance with this Section 11.5. The addresses and emails of the Parties are as follows:

in the case of Ocugen, to:

Shankar Musunuri
Chairman, CEO and Co-Founder
Ocugen, Inc.
5 Great Valley Parkway, Suite 160
Malvern, PA 19355, USA
Tel: [***]
Email: [***]

with a copy to:

Deborah Spranger, Esq.
Pepper Hamilton LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312
Tel: [***]
Email: [***]

in the case of CanSino, to:

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

11.6 Dispute Resolution. Before any dispute, difference or disagreement concerning this Agreement (“**Dispute**”) proceeds to arbitration in accordance with this Section 11.6, the Parties shall seek to resolve the matter within the next thirty (30) days by referring it to each Party’s Chief Executive Officer. The Parties’ respective Chief Executive Officers

(or their designees) shall promptly meet in good faith to try to resolve the Dispute. Any unresolved Dispute shall be resolved by binding arbitration conducted at the Hong Kong International Arbitration Centre in accordance with the HKIAC's Procedures for Arbitration in force on the Effective Date. The arbitration shall be conducted in the English language and the award thus rendered shall be final and binding upon both Parties and enforceable in any court having jurisdiction thereof in accordance with its terms. The arbitration tribunal shall consist of three (3) arbitrators. Each Party shall select one (1) arbitrator, and the two (2) arbitrators so selected shall choose a third arbitrator who will act as the chairman of the tribunal, *provided* if the two arbitrators fail to choose a third arbitrator within thirty (30) days after their appointment, then either or both Parties shall immediately request that the HKIAC select the third arbitrator. The place of arbitration shall be Hong Kong (at the HKIAC). Each Party shall bear its own costs and expenses and attorneys' fees in connection with any such arbitration.

11.7 Law and Jurisdiction. The validity, construction and performance of this Agreement shall be governed by the laws of the United Kingdom, without regard to the application of principles of conflicts of law.

11.8 Announcements. Neither Party shall make any press or other public announcement concerning any aspect of this Agreement, or make any use of the name of the other Party in connection with or in consequence of this Agreement, without the prior written consent of the other Party.

11.9 Entire Agreement. This Agreement, including its Exhibits and Schedules, sets out the entire agreement between the Parties relating to its subject matter and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter. The Parties acknowledge that they are not relying on any representation, agreement, term or condition which is not set out in this Agreement.

11.10 Purposes and Scope. The Parties understand and agree that the relationship between the Parties described herein is limited to the activities, rights and obligations as set forth in this Agreement. Nothing in this Agreement shall be construed (a) to create or imply a general partnership between the Parties, (b) to make either Party the agent of the other for any purpose, (c) to alter, amend, supersede or vitiate any other arrangements between the Parties with respect to any subject matter not covered hereunder, (d) to give either Party the right to bind the other, (e) to create any duties or obligations between the Parties except as expressly set forth herein, or (f) to grant any direct or implied licenses or any other rights other than as expressly set forth herein.

11.11 Assignment and Successors. Neither this Agreement nor any obligation of a Party hereunder may be assigned by either Party without the written consent of the other, which consent shall not be unreasonably withheld, conditioned or delayed, except that Ocugen may assign this Agreement and the rights, obligations and interests of Ocugen without such consent (a) in whole or in part, to any of its Affiliates, *provided* that Ocugen shall remain liable and responsible to CanSino for the performance and observance of all such duties and obligations by such Affiliates, or (b) in whole, but not in part, to any purchaser of all or substantially all of its assets or all or substantially all of its assets to which this Agreement relates, or shares representing a majority of its common stock voting rights or to any successor company resulting from any merger, consolidation, share exchange or other similar transaction. Any permitted assignment to a third party shall be for the whole (and not part) of this Agreement.

11.12 Further Assurances and Actions. Each Party, upon the request of the other Party, whether before or after the Effective Date and without further consideration, will do, execute, acknowledge and deliver, or cause to be done, executed, acknowledged or delivered, all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney, instruments and assurances as may be reasonably necessary to effect complete consummation of the transactions contemplated by this Agreement, and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement. The Parties agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by this Agreement.

11.13 Expenses. Each of the Parties will bear its own direct and indirect expenses incurred in connection with the negotiation and preparation of this Agreement and, except as set forth in this Agreement, the performance of the obligations contemplated hereby and thereby.

[remainder of this page intentionally left blank]

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

Ocugen, Inc.

/s/ Shankar Musunuri
Signature

Shankar Musunuri
Print name

Chief Executive Officer
Title

9/27/2019
Date

CanSino Biologics Inc.

/s/ Shou Bai CHAO
Signature

Shou Bai CHAO
Print name

Chief Operating Officer
Title

9/27/2019
Date

EXHIBIT A

INITIAL DEVELOPMENT PLAN

[* * *]

EXHIBIT B
SERI AGREEMENT

[* * *]

EXHIBIT C

Timeline

[* * *]

EXHIBIT D

OCUGEN PATENT RIGHTS

[* * *]

EXECUTIVE EMPLOYMENT AGREEMENT

THIS EXECUTIVE EMPLOYMENT AGREEMENT (this "*Agreement*"), is made as of the September 10, 2019 (the "*Effective Date*") by and between Ocugen, Inc., a Delaware corporation (the "*Company*"), and Sanjay Subramanian, an individual ("*Employee*").

The Company wishes to employ Employee and Employee wishes to be employed by the Company with the employment starting date on October 1, 2019. The parties have now determined it is in its best interest to enter into this Agreement to set forth the terms and conditions of Employee's employment with the Company.

AGREEMENT

NOW, THEREFORE, in consideration of the facts, mutual promises and covenants contained herein and intending to be legally bound hereby, the Company and Employee agree as follows:

1. **Definitions.** As used herein, the following terms shall have the meanings set forth below unless the contexts otherwise requires:

"*Affiliates*" means, with respect to a person, all other persons controlling, controlled by or under common control with the first person; the term "control," and correlative terms, means the power, whether by contract, equity ownership or otherwise, to direct the policies or management of a person; and "person" means an individual, partnership, corporation, limited liability company, trust or unincorporated organization, or a government or agency or political subdivision thereof.

"*Base Compensation*" shall mean the annual rate of compensation set forth in Section 4.1, as such amount may be adjusted from time to time.

"*Board*" shall mean the Company's Board of Directors.

"*Cause*" shall mean the occurrence of any one or more of the events set forth below in clauses (a) through (d), which, in the case of the event or events set forth below in clause (a) is not cured by Employee within the time periods set forth therein:

(a) failure or refusal by Employee to make a reasonable attempt to substantially perform a material portion of the duties of his employment or to comply with the written rules and policies of the Company which failure continues uncured fifteen (15) days after written notice of such failure or refusal (or such longer period as is necessary to cure such event so long as Employee is diligently pursuing such cure and provided such additional period is approved by the CEO) is provided to Employee setting forth in reasonable detail the nature of such failure or refusal;

(b) Employee's repeatedly engaging in willful and serious misconduct in connection with his employment;

(c) engagement by Employee in fraudulent conduct; or

(d) Employee's conviction of, or plea of no contest to, (i) a felony or (ii) other crime the circumstances of which are substantially related to the Employee's position.

"Change of Control" shall mean (i) the closing of the sale, transfer or other disposition of all or substantially all of the Company's assets, (ii) the acquisition by any person or group of persons in any transaction or series of related transactions of direct or indirect beneficial ownership (within the meaning of Section 13(d) of the Securities Exchange Act of 1934), other than the Current Holders of Securities of the Company, of the power, directly or indirectly, to vote or direct the voting of securities having more than 50% of the ordinary voting power for the election of directors of the Company, (iii) the consummation of the merger or consolidation of the Company with or into another entity (except a merger or consolidation in which the holders of capital stock of the Company immediately prior to such merger or consolidation continue to hold not less than fifty percent (50%) of the voting power of the capital stock of the Company or the surviving or acquiring entity immediately following such merger or consolidation), or (iv) a liquidation, dissolution or winding up of the Company; provided, however, that a transaction shall not constitute a Change of Control if the Change of Control is the result of an equity or debt financing, or if its sole purpose is to change the state of the Company's incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately prior to such transaction.

"Current Holders of Securities of the Company" shall mean the current holders of issued and outstanding "Securities" of the Company, their "Affiliates" (as such terms are defined herein), and their respective employees, officers, directors, blood or legal relatives, guardians, legal representatives, and trusts for the primary benefit of any of such persons.

"Disability" shall mean Employee's inability, for a period of six (6) consecutive months, or a cumulative period of one hundred eighty (180) business days out of a period of twelve (12) consecutive months, to perform the essential duties of Employee's position, even after taking into account any reasonable accommodation required by law, due to a mental or physical impairment. The determination of whether Employee is suffering from a Disability shall be made either (a) by an independent physician, mutually chosen by Employee and the Company; or (b) because Employee qualifies as disabled for purposes of the Company's long-term insurance disability plan, if applicable.

"Good Reason" shall mean the occurrence of one or more of the events set forth in clauses (a) through (e) below without the consent of Employee, provided that (i) Employee delivers written notice to the Company of Employee's intention to resign from employment due to one or more of such events, which notice specifies in reasonable detail the circumstances claimed to provide the basis for such resignation, (ii) such event or events are not cured by the Company within thirty (30) days following delivery of such written notice and (iii) if not cured

by the Company, Employee resigns his employment within fifteen (15) days following the Company's cure period:

- (a) a reduction in Employee's annual rate of Base Compensation unless such reduction is made across all executives or employees of the Company;
- (b) a termination or material reduction of a material benefit under any Company benefit plans, programs or arrangements, in which the Employee participates unless such termination or reduction is made across all executives or employees of the Company;
- (c) a material reduction in Employee's job title, powers or authority;
- (d) a change in reporting relationship;
- (e) the Company's material failure to comply with the terms of this Agreement or any stock option or similar agreement with Employee then in effect;
- (f) the requirement by the Company that Employee relocate or transfer Employee's principal office to a location more than 50 miles from Malvern, PA Office (except that the requirement to travel in Section 2.3 shall not trigger this subsection (e)).

"Proceeding" shall have the meaning set forth in Section 8 hereof.

"Severance Period" shall mean a period of twelve months (12) immediately following the effective date of termination of Employee's employment hereunder if such termination is by the Company without Cause or by Employee for Good Reason.

"Securities" means any and all securities as such term is defined in Section 2 of the Securities Act of 1933, as amended, including, without limitation, all common stock, preferred stock, convertible promissory notes, subordinated debt instruments, and other securities issued by the Company.

2. Contingent Employment; Employment and Duties.

2.1. As of the Effective Date, Company hereby employs Employee and Employee hereby accepts appointment as the Chief Financial Officer ("**CFO**") reporting to the Chief Executive Officer ("**CEO**") of the company. Employee shall be member of the Executive Management Team. Employee shall be responsible for all duties and entitled to all authority customarily assigned to the position of CFO, including those duties described on Exhibit A hereto, as well as those other duties and such other authority as specified by the CEO. The Employee should be available to meet periodically with the Chairman of the Audit Committee to discuss financial statement reporting and internal controls.

2.2. Employee shall render such services as are necessary and desirable to protect and advance the best interests of the Company, acting, in all instances, under the supervision of the CEO and in accordance with the policies set by the Company.

2.3. So long as Employee shall remain an employee of the Company, except as provided below, Employee's entire working time, energy, skill and efforts shall be devoted to the performance of Employee's duties hereunder in a manner that will faithfully and diligently further the business and interests of the Company; provided, however, that Employee may (i) serve on corporate, civic or charitable boards or committees; (ii) deliver lectures, fulfill speaking engagements or teach at educational institutions; (iii) manage personal passive investments; (iv) act in a limited role as an advisor; or (v) undertake such other endeavors as may be consented to by the CEO, in each case so long as the foregoing activities, in the aggregate, do not materially interfere with the performance of Employee's duties to the Company in accordance with this Agreement. Employee will be based out of and shall work from Malvern, PA office provided by the Company or other mutually agreeable office. It is anticipated that a substantial amount of travel may be required of the Employee in connection with the performance of his duties.

3. Term. Employee's employment under this Agreement shall commence on the Effective Date and shall continue until Employee's employment is terminated pursuant to Section 6.

4. Compensation and Benefits.

4.1. Employee shall receive Base Compensation at the initial gross annual rate (without regard to authorized tax or other legally required deductions and withholdings) of \$325,000, payable in installments in accordance with the Company's regular payroll practices in effect from time to time.

4.2. In the sole discretion of the CEO within the guidelines set by the Board for the Executive Management Team, the Company may pay to Employee an annual bonus at a target level of 30% of Employee's Base Compensation (the "**Target Bonus**"), based upon performance criteria set for Employee by the Board and certain other factors, including the Company's performance, financial stability, availability of cash, industry benchmarks and standards and market conditions. Any annual bonus so awarded shall be payable by March 15th of each year for the Employee's performance in the previous year (the "**Measuring Year**"). To be eligible for an annual bonus, the Employee must be employed on the date such bonus is paid.

4.3. As soon as practicable but in no event later than the Company's anticipated reverse merger transaction, Employee shall be granted an option to purchase fifty thousand (50,000) shares of the Company's common stock (with such number of shares subject to adjustment in connection with the reverse merger transaction or any similar transaction) pursuant to the terms of the Company's 2014 Equity Stock Option Incentive Plan (the "**Option Award**"). The Option Award shall be subject to an award agreement and shall vest in three equal installments over the 3-year period on the anniversary date of the Effective Date. The Option Award shall have an exercise price equal to the fair market value of the Company's common stock on the date of grant. Employee may be eligible to participate in future stock option awards at the sole discretion of the Board.

5. Fringe Benefits. Employee shall be entitled to the benefits set forth below for so long as Employee's employment with the Company continues:

5.1. The Company will reimburse Employee for all reasonable and necessary expenses incurred by Employee on behalf or for the benefit of the Company upon receipt of documentation therefor in accordance with the Company's regular reimbursement procedures and practices in effect from time to time. The Company from time to time may require prior approval for individual expense items in excess of pre-established aggregate amounts for a fixed period or in excess of pre-established amounts for any type of expenditure during any fixed period.

5.2. Upon Employee's achieving the eligibility requirements therefor, if any, Employee will be eligible to participate in all applicable and established Company benefit plans, programs and arrangements that may exist from time to time (including, without limitation, pension, profit sharing, 401(k) plans, and medical and life insurance programs) on the same terms as apply generally to other similarly situated employees of the Company from time to time.

5.3. Employee shall be entitled to the vacation, sick and other personal time off (PTO), in accordance with the Company's employee handbook or policy for the same. Employee shall be entitled to take four (4) weeks of paid vacation each calendar year, which vacation shall be prorated for any partial calendar year and shall accrue in equal installments throughout the calendar year. Any unused vacation at the end of each calendar year may be carried over to the extent provided under the Company's PTO policies.

6. Termination; Payments to Employee.

6.1. If Employee dies or suffers a Disability, the Employee's employment with the Company shall terminate as of the date of death or Disability.

6.2. Subject to Section 6.4 and Section 6.5 below, either Employee or the Company may terminate this Agreement and Employee's employment hereunder immediately upon written notice to the other party.

6.3. If Employee's employment terminates for any reason, Employee (or his estate in the event of Employee's death) shall be entitled to receive a lump sum cash payment equal to the sum of the following: (i) payment of accrued but unpaid Base Compensation up to the date of termination, and any earned but unused paid vacation through the date of termination, if any and (ii) unreimbursed business expenses covered by Section 5.1 hereof.

6.4. In addition to the amounts to be paid to Employee in accordance with the provisions of Section 6.3 above, and except as otherwise provided in Section 6.5, if Employee's employment is terminated (i) by the Company without Cause or (ii) by Employee for Good Reason, Employee shall be entitled to receive the following (collectively, (A), (B) and (C) the "**Severance Payment**"): (A) for the duration of the Severance Period, Employee's then current Base Compensation minus any applicable taxes, and other withholdings, payable in accordance with the Company's standard payroll practices; (B) from the commencement of the Severance Period until the earlier of the expiration of the Severance Period or such date as Employee, may be eligible for health insurance coverage under another employer's or a spouse's employer's

health plan, the Company will pay the Employee's COBRA premium for any applicable health or dental insurance, if he is eligible to elect COBRA continuation coverage; and (C) any annual bonus, earned but unpaid for the previous calendar year, if applicable.

6.5. If Employee's employment is terminated (i) by the Company without Cause or (ii) by Employee for Good Reason, in either case within three (3) prior to or within twelve (12) months after a Change of Control, Employee shall be entitled to receive the following (collectively, (A), (B), (C), (D) and (E) the "**Change of Control Severance Payment**"), in lieu of the Severance Payment described in Section 6.4 and in addition to the amounts to be paid to Employee in accordance with the provisions of Section 6.3 above: (A) for the duration of the Severance Period, Employee's then current Base Compensation minus any applicable taxes, and other withholdings, payable in accordance with the Company's standard payroll practices; (B) from the commencement of the Severance Period until the earlier of the expiration of the Severance Period or such date as Employee, may be eligible for health insurance coverage under another employer's or a spouse's employer's health plan, the Company will pay the Employee's COBRA premium for any applicable health or dental insurance, if he is eligible to elect COBRA continuation coverage; (C) any annual bonus, earned but unpaid for the previous calendar year, if applicable; (D) one (1) times his then-current Target Bonus payable in a lump sum; and (E) all unvested restricted stock, stock options and other equity incentives awarded to the Employee by the Company will become immediately and automatically fully vested and exercisable (as applicable).

6.6. Employee shall not be entitled to receive the Severance Payment or Change of Control Severance Payment unless and until Employee executes within sixty (60) days following termination of his employment, and does not revoke as permitted by law, a release in a form reasonably acceptable to the Company (the "**Release**") that unconditionally releases, waives, and fully and forever discharges the Company and its past and current shareholders, directors, officers, employees, and agents from and against any and all claims, liabilities, obligations, covenants, rights, demands and damages of any nature whatsoever, whether known or unknown, anticipated or unanticipated, including without limitation, any claims relating to or arising out of Employee's employment with the Company, claims arising under the Age Discrimination and Employment Act of 1967, as amended, Title VII of the Civil Rights Act of 1964, as amended, or the Civil Rights Act of 1991, or claims arising under the applicable state fair employment laws, but excluding Employee's right to indemnification from the Company in respect of his services as a director, officer or employee of the Company or any of its Affiliates. The release shall also contain customary non-disparagement covenants by Employee. Employee's right to receive the Severance Payment or Change of Control Severance Payment is conditioned upon Employee's performance of the obligations and covenants contained in this Employment Agreement and the Exhibits to this Agreement. In the event of any material breach of any such obligations during or after payment of the Severance Payment or Change of Control Severance Payment, the Company may cease to make any remaining payments.

The Severance Payment or Change of Control Severance Payment will begin to be paid as soon as practicable following the date the Release becomes irrevocable, provided that (i) the initial payment shall include a catch-up payment to cover amounts retroactive to the day

immediately following the effective date of the Employee's termination of employment and (ii) any bonus amounts owed under Section 6.4(C) or 6.5(C) shall be paid at the same time bonuses are paid to active employees. If the Severance Payment or Change of Control Severance Payment are deferred compensation subject to the requirements of Section 409A of the Code, if the 60-day period described in the previous paragraph begins in one taxable year and ends in a second taxable year, such payments shall not commence until the second taxable year.

6.7. Notwithstanding anything in this Agreement to the contrary, all payments to be made upon a termination of employment under this Agreement will only be made upon a "separation from service" within the meaning of Section 409A of the Internal Revenue Code of 1986 (the "**Code**"). To the maximum extent permitted under Section 409A of the Code and its corresponding regulations, the cash severance benefits payable under this Agreement are intended to meet the requirements of the short-term deferral exemption under Section 409A of the Code and the "separation pay exception" under Treas. Reg. §1.409A-1(b)(9)(iii). For purposes of the application of Treas. Reg. § 1.409A-1(b)(4) (or any successor provision), each payment in a series of payments to Employee will be deemed a separate payment. In addition, to the extent compliance with the requirements of Treas. Reg. § 1.409A-3(i)(2) (or any successor provision) is necessary to avoid the application of an additional tax under Section 409A of the Code to payments due to Employee upon or following his "separation from service", then notwithstanding any other provision of this Agreement (or any otherwise applicable plan, policy, agreement or arrangement), any such payments that are otherwise due within six months following the Employee's "separation from service" will be deferred without interest and paid to Employee in a lump sum immediately following such six month period. This paragraph should not be construed to prevent the application of Treas. Reg. § 1.409A-1(b)(9)(iii) (or any successor provision) to amounts payable hereunder. For purposes of the application of Section 409A of the Code, each payment in a series of payments will be deemed a separate payment.

7. Noncompetition; Nonsolicitation; Confidential Information, etc. As a condition to Employee's employment and in consideration of the compensation and benefits described herein, Employee agrees to execute the non-competition agreement attached hereto as Exhibit B and Employee Non-Disclosure and Business Ideas Agreement attached hereto as Exhibit C, effective as of the Effective Date.

8. Indemnification. Subject to the Company's Articles of Incorporation and By-laws, the Company shall indemnify Employee to the fullest extent permitted by law against all costs, expenses, liabilities and losses (including, without limitation, attorneys' fees, judgments, fines, penalties, and amounts paid in settlement) reasonably incurred by Employee in connection with any "Proceeding" (as defined herein). For the purposes of this Section 8, a "**Proceeding**" shall mean any action, suit or proceeding, whether civil, criminal, administrative or investigative, and derivative or direct, in which Employee is made, or is threatened to be made, a party to, or a witness in, such action, suit or proceeding by reason of the fact that he is or was an officer, director or employee of the Company or is or was serving as an officer, director, member, employee, trustee or agent of any other entity at the request of the Company.

9. Golden Parachute Tax Provisions.

9.1. In the event that the Company or any of their Affiliates undergoes a Change of Control prior to the time that it (or any Affiliate that would be treated, together with the Company, as a single corporation under Section 280G of the Code and the regulations thereunder) has stock that is readily tradeable on an established securities market (within the meaning of the Section 280G of the Code and the regulations thereunder), if the payments or benefits provided under this Agreement, either alone or together with other payments or benefits which Employee receives or is entitled to receive from the Company or any of its Affiliates, would constitute an “excess parachute payment” within the meaning of Section 280G of the Code, the following provisions shall apply:

9.1.1. The Company or any of applicable Affiliates will cooperate in good faith with Employee such that any such payments or benefits will not be deemed an “excess parachute payment” within the meaning of Section 280G of the Code.

9.1.2. In the event that any payments or benefits (whether payable pursuant to this Agreement or otherwise) to Employee could be exempt from Section 280G of the Code if the shareholder approval requirements under Section 280G(b)(5) of the Code and the regulations thereunder were met, such payments will be conditioned on shareholder approval in accordance with Section 280G(b)(5)(B) of the Code and regulations thereunder and the Company or any of its applicable Affiliates agrees to use best efforts to seek to obtain such shareholder approval. The actions of the Company or any of its applicable Affiliates pursuant to this provision are not intended to bind, nor shall be construed as binding, the shareholders of the Company or any of its applicable Affiliates.

9.2. In the event that the Company or any of its applicable Affiliates undergoes a Change of Control at such time that it (or any Affiliate that would be treated, together with the Company, as a single corporation under Section 280G of the Code and the regulations thereunder) has stock that is readily tradeable on an established securities market (within the meaning of the Section 280G of the Code and the regulations thereunder), if the payments or benefits provided under this Agreement, either alone or together with other payments or benefits which Employee receives or is entitled to receive from the Company or any of its applicable Affiliates, would constitute an “excess parachute payment” within the meaning of Section 280G of the Code, Employee shall be entitled to receive (i) an amount limited so that no portion thereof shall fail to be tax deductible under Section 280G of the Code or subject to an excise tax under Section 4999 of the Code (the “*Limited Amount*”), or (ii) if the amount otherwise payable hereunder together with other payments or benefits which Employee receives or is entitled to receive from the Company or any of its applicable Affiliates (without regard to clause (i)) reduced by all taxes applicable thereto (including, for the avoidance of doubt, the excise tax imposed by Section 4999 of the Code) would be greater than the Limited Amount reduced by all taxes applicable thereto, the amount otherwise payable hereunder together with other payments or benefits which Employee receives or is entitled to receive from the Company or any of its applicable Affiliates.

9.3. In the event that any payments under this Agreement or otherwise are required to be reduced as described in this Section 9, the adjustment will be made, first, by reducing the cash severance, if any, due to Employee pursuant to Section 6; second, if additional reductions are necessary, by reducing the payments due to Employee under Section 6.5(D) (Target Bonus) and third, if additional reductions are still necessary, by eliminating the accelerated vesting of equity-based awards, starting with those awards for which the amount required to be taken into account under the Section 280G of the Code rules is the greatest; provided, that in all events, such reductions shall be done in a manner consistent with the requirements of Section 409A of the Code, to the extent applicable.

10. Miscellaneous.

10.1. Binding Nature of Agreement. This Agreement shall be binding upon the Company and shall inure to the benefit of the Company, its Affiliates, successors and assigns, including any transferee of the business operation, as a going concern, in which Employee is employed and shall be binding upon Employee, Employee's heirs and personal representatives. None of the rights or obligations of Employee hereunder may be assigned or delegated, except that in the event of Employee's death or Disability, any rights of Employee hereunder shall be transferred to Employee's estate or personal representative, as the case may be. The Company may assign its rights and obligations under this Agreement in whole or in part to any one or more Affiliates or successors. Any entity into which the Company is merged or with which the Company is consolidated or which acquires the business of the Company or the business unit in which Employee is to be principally employed shall be deemed to be a successor of the Company for purposes hereof.

10.2. Entire Agreement. This Agreement, including its Exhibits, contains the entire understanding among the parties hereto with respect to the subject matter hereof, and supersedes all prior and contemporaneous agreements and understandings, inducements or conditions, express or implied, oral or written. The express terms hereof control and supersede any course of performance and/or usage of the trade inconsistent with any of the terms hereof. Notwithstanding the foregoing, nothing herein shall limit the application of any generally applicable Company policy, practice, plan or the terms of any manual or handbook applicable to the Company's employees generally.

10.3. Notices. All notices, requests, consents, and other communications required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been duly given if delivered personally, or mailed first-class, postage prepaid, by registered or certified mail (notices sent by mail shall be deemed to have been given on the third day after the date sent), or by nationally recognized overnight carrier (notices sent by overnight shall be deemed to have been given on the day after the date sent) or by confirmed facsimile or electronic mail transmission with a hard copy deposited in first class mail the same day or the following day, as follows (or to such other address as either party shall designate by notice in writing to the other):

If to Company:

Ocugen Inc.
5 Great Valley Parkway, Suite #160
Malvern, PA 19355
Attention: Shankar Musunuri

If to Employee, to the address on file with the Company.

10.4. Governing Law; Forum. This Agreement shall be governed by the laws of Delaware.

10.5. Headings. The article and section headings contained in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

10.6. Amendment. This Agreement may be amended, modified, superseded, canceled, renewed, or extended and the terms or covenants of this Agreement may be waived, only by a written instrument executed by both of the parties, or in the case of a waiver, by the party waiving compliance.

10.7. Waiver. The failure of either party at any time or times to require performance of any provision of this Agreement shall in no manner affect the right at a later time to enforce the same. No waiver by either party of the breach of any term or covenant contained in this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such breach, or a waiver of the breach of any other term or covenant contained in this Agreement.

10.8. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall constitute an original and all of which taken together shall constitute one and the same instrument.

[signature page follows]

IN WITNESS WHEREOF, the parties have executed this Agreement on the date first above written.

COMPANY:

OCUGEN, INC.

By: /s/ Shankar Musunuri
Shankar Musunuri

Its: Chairman and CEO

EMPLOYEE:

/s/ Sanjay Subramanian
Name: Sanjay Subramanian

[Signature Page to Employment Agreement]

EXHIBIT A
Duties

Employee shall be the Company's Chief Financial Officer reporting to the CEO responsible for:

- Managing company's day-day financial operations and additional activities assigned by the CEO
 - Setting and execution of annual goals in line with company goals
 - Supporting CEO for the meetings with potential investors for all fund-raising activities
 - Establishing and supporting the management of the Company's annual budget
 - Building and maintaining strong collaborations with financial partners (including investors, banks, auditors, etc.)
 - Leading activities related to selection of ERP
 - Presenting at investor conferences and supporting analyst calls as needed
 - Supporting Executive Management Team as needed
-

EXHIBIT B
EMPLOYMENT NON-COMPETITION AGREEMENT

THIS EMPLOYMENT NON-COMPETITION AGREEMENT by and between the undersigned employee (the “Employee”) and Ocugen, Inc., a Delaware corporation (“Company”) is effective as of the commencement of the Employee’s employment pursuant to the Executive Employment Agreement dated as of September 10, 2019.

RECITALS

- A. Employee’s position in the Company is such that Employee will, at times, either personally generate, or be entrusted with, information, ideas and materials which are the Company’s property, involve trade secrets, involve customer information and customer lists, or relate to confidential matters of the Company; and
- B. The Company will expend and continue to expend substantial time, effort and money to develop its technology and products, to service its customers and future customers and to provide the Employee the opportunity and the resources to extend the goodwill of the Company.

AGREEMENT

In consideration of Employee’s commencement of employment, and as a condition thereto, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Employee and the Company hereby agree as follows:

1. Non-Competition.

1.1. Following Employment. Without the Company’s prior written consent, while the Employee is employed and for twelve (12) months following the end, for whatever reason, of the Employee’s employment with the Company (the “Non-Competition Period”), the Employee agrees that in the Restricted Area, Employee will not perform substantially the same or similar functions or duties which Employee provided to the Company in the Restricted Field for any person (including Employee), entity, division, business unit, or association (“Person”) that is engaged or is contemplating engaging in the Restricted Field; or (b) advise or consult with any Person primarily engaged or is contemplating engaging in the Restricted Field regarding the same or similar functions or duties for which Employee was responsible for at the Company.

1.2. Restricted Field. For purposes hereof, “Restricted Field” means the business of (i) developing, designing, manufacturing, marketing and selling biopharmaceutical products that are intended for treatment of age related macular degeneration, geographic atrophy, diabetic retinopathy, or retinitis pigmentosa or (ii) the sale or development of any other products sold or developed by the Company in the twelve months prior to the end of Employee’s employment.

1.3. Restricted Area. For purposes hereof, “Restricted Area” means the United States. Employee understands that the market for the Company’s products is worldwide

and that the Company is marketing, promotion, and attempting to sell, and selling its products worldwide.

2. No Interference. Employee further agrees that while Employee is employed and for a period twelve (12) months thereafter, Employee shall not take any directed action to cause any customer, supplier, or vendor of the Company to terminate or materially diminish its relationship with the Company.

3. Employee Disclosures and Acknowledgments.

3.1. Scope of Restrictions. Employee acknowledges and represents that the scope of the restrictions contained in this Employment Non-Competition Agreement are appropriate, necessary and reasonable for the protection of the Company's legitimate business interests and customer goodwill. Employee acknowledges that the restrictions imposed herein will not prevent Employee from earning a living at the end of Employee's employment with the Company.

3.2. Prospective Employers. Employee agrees, during the term of any restriction contained in this Employment Non-Competition Agreement, to disclose this Employment Non-Competition Agreement to any entity which offers employment to Employee. Employee further agrees that the Company may send a copy of this Employment Non-Competition Agreement to, or otherwise make the provisions hereof known to, any of Employee's potential or future employers.

4. Miscellaneous.

4.1. Binding Effect. This Employment Non-Competition Agreement binds Employee's heirs, executors, administrators, legal representatives and assigns and inures to the benefit of the Company and its successors and assigns. The Company may assign this Employment Non-Competition Agreement.

4.2. Amendment or Waiver. No provision of this Employment Non-Competition Agreement may be amended or waived other than in writing by the party against whom enforcement of such amendment or waiver is sought.

4.3. Injunctive Relief. The parties agree that damages will be an inadequate remedy for breaches of this Agreement and in addition to damages and any other available relief, a court shall be empowered to grant injunctive relief without the Company's posting of any bond or other security. The Company shall be entitled to recover from Employee all litigation costs and attorneys' fees incurred by the Company in any action or proceeding relating to this Agreement in which the Company prevails. The Employee shall be entitled to recover from Company all litigation costs and attorneys' fees incurred by the Employee in any action or proceeding relating to this Agreement in which the Employee prevails.

4.4. Enforceability. Employee agrees that if, at any time, despite the express agreement of the parties hereto, a court of competent jurisdiction holds that any portion of this Employment Non-Competition Agreement is unenforceable for any reason, the

maximum restrictions that are reasonable under the circumstances, as determined by such court, will be substituted for any such restrictions held unenforceable.

4.5. No Strict Construction. The language used in this Employment NonCompetition Agreement shall be deemed to be the language chosen by the parties hereto to express their mutual intent, and no rule of strict construction shall be applied against any person or entity.

4.6. Governing Law. This Employment Non-Competition Agreement shall be governed by and construed in accordance with the substantive and procedural laws of Delaware.

4.7. Entire Agreement. This Agreement represents the parties' entire understanding with respect to the subject matter contained herein and supersedes any previous agreements, oral or otherwise, between the parties.

[remainder of this page is intentionally left blank]

This Employment Non-Competition Agreement is dated as of the date first written above.

Employee

/s/ Sanjay Subramanian

Name: Sanjay Subramanian

Ocugen, Inc. (“Company”)

By: /s/ Shankar Musunuri

Shankar Musunuri

Chairman and CEO

[Signature Page to Non-Competition Agreement]

EXHIBIT C

OCUGEN, INC. EMPLOYEE NONDISCLOSURE AND BUSINESS IDEAS AGREEMENT

THIS EMPLOYEE NONDISCLOSURE AND BUSINESS IDEAS AGREEMENT (“Agreement”) by and between the undersigned employee (“Employee”) and Ocugen, Inc., a Delaware corporation (“Company”) is made effective as of the commencement date of Employee’s employment with or provision of services to the Company, as applicable.

RECITALS

A. During such time that Employee is engaged by the Company in any capacity, whether as an advisor, consultant or employee, and whether Employee is engaged by the Company in only one or in more than one such capacity(ies) (the “Period of Engagement”), Employee will personally generate, or be entrusted with, information, ideas and materials which are the Company’s confidential and proprietary property, including, without limitation, trade secrets, confidential customer information and information related to other confidential and proprietary matters of the Company.

B. The Company has expended, and will continue to expend, substantial time, effort and money to protect such confidential and proprietary Company property and supplier and customer relationships, to service its suppliers and customers and to provide Employee the opportunity and the resources to extend the goodwill of the Company.

AGREEMENT

In consideration of and as a condition to the commencement of Employee’s employment with or provision of services to the Company, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Employee and the Company hereby agree as follows:

1. Confidentiality Obligations.

1.1. During Engagement. During the Period of Engagement, Employee will not directly or indirectly use or disclose any Confidential Information (as defined in Section 1.6, below) or Trade Secret (as defined in Section 1.7, below) of the Company, except as authorized by and in the interest and for the benefit of the Company.

1.2. Trade Secrets Post-Engagement. After the end, for whatever reason, of the Period of Engagement, Employee will not directly or indirectly use or disclose any Trade Secret of the Company.

1.3. Confidential Information Post-Engagement. After the end, for whatever reason, of the Period of Engagement, Employee will not directly or indirectly use or disclose any Confidential Information of the Company.

1.4. General Skills and Knowledge. Nothing in this Agreement shall prevent Employee, after the end of the Period of Engagement, from using general skills and knowledge gained while employed by or providing services to the Company.

1.5. Trade Secret Law. Nothing in this Agreement shall limit or supersede any common law, statutory or other protections of trade secrets where such protections provide the Company with greater rights or protections than provided for in this Agreement.

1.6. Confidential Information. The term “Confidential Information” means all confidential and proprietary information of, about or related to the Company, or provided to the Company by its customers, suppliers or affiliates, that is not known generally to the public or the Company’s competitors. Confidential Information may include, but is not limited to: (i) all know-how and other technical information relating to the products and services of the Company, specifications, designs, processes, methods, know-how, plans, policies, procedures, employees, legal and regulatory affairs, assets, discoveries, inventions, trademarks, patents, patents pending, patent applications, copyrights, copyright applications, scientific or technical data, research or development, distribution, sales, marketing, expenses, business plans, financial statements and data, customer and supplier lists, costs of goods, source code and relationships with third parties; (ii) information which is marked or otherwise designated or treated as confidential or proprietary by the Company; and (iii) information received by the Company from others which the Company has an obligation to treat as confidential.

1.7. **Trade Secret.** The term “Trade Secret” has that meaning set forth under applicable law.

1.8. **Exclusions.** Notwithstanding Sections 1.6 or 1.7, above, as applicable, the terms “Confidential Information” and “Trade Secret” do not include, and the obligations set forth in this Agreement do not apply to, any information which: (i) can be demonstrated by written evidence by Employee to have been known by Employee prior to the Period of Engagement; or (ii) is or becomes generally available to the public through no act or omission of Employee.

2. **Non-Solicitation.** During the Period of Engagement and for a period of twelve (12) consecutive months immediately thereafter, Employee shall not directly or indirectly encourage any other provider of services to the Company to terminate his/her employment with or provision of services to the Company or solicit such an individual for employment or services in a manner which would end or diminish that other Employee’s services to the Company. Nothing herein shall be interpreted to limit the ability of Employee to act as a reference for another provider of services to the Company.

Also during the Period of Engagement and for a period of twelve (12) consecutive months immediately thereafter Employee will not, directly or indirectly, solicit or otherwise attempt to sell to any Restricted Customer (as defined below) any goods or services that are substantially similar to those sold by the Company in the 12 months prior to the termination of the Employee’s employment. Restricted Customer means any individual or entity (i) to whom or to which (A) the Company sold its respective products or services in the twelve months prior to the termination of Employee’s employment, or (B) the Company has sent a product quotation to such potential customer for the Company’s products or services in the six months prior to the termination of Employee’s employment and the Company has continued to solicit such potential customer to close the sale related to or in connection with such product quotation; or (ii) with whom/which Employee had direct contact on behalf of the Company related to a sale or potential sale during the 12 months preceding the termination of Employee’s employment.

3. **Business Idea Rights.**

3.1. **Assignment.** The Company will own, and Employee hereby assigns and agrees to assign to the Company, all rights in all Business Ideas (as defined in Section 3.4, below) which Employee originates or develops either alone or working with others during the Period of Engagement. All Business Ideas which are or form the basis for copyrightable works are hereby assigned to the Company and/or shall be assigned to the Company or shall be considered “works for hire” as that term is defined by United States copyright law.

3.2. **Disclosure.** During the Period of Engagement, Employee will promptly disclose all Business Ideas to the Company.

3.3. **Execution of Documentation.** Employee, at any time during or after the Period of Engagement, will promptly execute all documents which the Company may reasonably require to perfect its patent, copyright and other rights to such Business Ideas throughout the world.

3.4. **Business Ideas.** The term “Business Ideas” means all ideas, designs, modifications, formulations, specifications, concepts, know-how, trade secrets, discoveries, inventions, data, software, developments and copyrightable works, whether or not patentable or registrable, that are (i) related to any business engaged in or contemplated by the Company; (ii) originated or developed during Employee’s working hours for the Company, or (iii) originated or developed in whole or in part using materials, labor, facilities, or equipment furnished by the Company.

4. **Return of Property.** Upon the end, for whatever reason, of the Period of Engagement or upon request by the Company at any time, Employee shall immediately return to the Company all property, documents, records, and materials belonging and/or relating to the Company and all copies of all such materials. Upon the end, for whatever reason, of the Period of Engagement or upon request by the Company at any time, Employee further agrees to destroy such records maintained by Employee on Employee’s own computer equipment and to certify in writing, at the Company’s request, that such destruction has occurred.

5. **Employee Disclosures and Acknowledgments.**

5.1. **Confidential Information of Others.** Employee certifies that Employee has not, and will not, disclose or use during the Period of Engagement any confidential information which Employee acquired as a result of any previous employment or

provision of services, or under a contractual obligation of confidentiality or secrecy, before Employee became an employee of or provider of services to the Company. Employee has no prior obligations (written and oral), such as confidentiality agreements or covenants restricting future employment or consulting, that Employee has entered into which restrict Employee's ability to perform any services as an employee of or provider of services to the Company.

5.2. **Scope of Restrictions.** By entering into this Agreement, Employee acknowledges and agrees that the scope of the restrictions contained in this Agreement are appropriate, necessary and reasonable for the protection of the Company's business, goodwill and property rights, including the protection of the Company's Confidential Information and Trade Secrets. Employee further acknowledges and agrees that the restrictions imposed by this Agreement will not prevent him/her from earning a living in the event of, and after, the end, for whatever reason, of the Period of Engagement.

5.3. **Prospective Employers.** Employee agrees, during the term of any restriction contained in this Agreement, to disclose this Agreement to any entity which offers to Employee employment or the opportunity to provide services. Employee further agrees that the Company may send a copy of this Agreement to, or otherwise make the provisions hereof known to, any of Employee's potential or future employers or business engagements.

6. Miscellaneous.

6.1. **Entire Agreement; Amendment or Waiver.** This Agreement contains the entire understanding between the parties with respect to the subject matter hereof, and all prior discussions, negotiations, agreements, correspondence, and understandings, whether oral or written, between Employee and the Company with respect to the subject matter hereof, including, without limitation, any Nondisclosure Agreement dated prior to this agreement, are hereby superseded. No provision of this agreement may be amended or waived other than in writing by the party against whom enforcement of such amendment or waiver is sought.

6.2. **Injunctive Relief.** The parties agree that damages will be an inadequate remedy for breaches of this Agreement and in addition to damages and any available relief, a court shall be empowered to grant injunctive relief without the necessity of posting bond or other security.

6.3. **Governing Law.** This Agreement and all questions arising in connection herewith shall be governed by and construed in accordance with the laws of Delaware.

6.4. **Consideration.** Execution of this Agreement is a condition of Employee's commencement of employment with the Company.

6.5. **Severability.** The obligations imposed by, and the provisions of, this Agreement are severable and should be construed independently of each other. The invalidity of one provision shall not affect the validity of any other provision.

6.6. **Terminable-At-Will.** Nothing in this Agreement shall be construed to limit the right of either party to terminate the employment at any time for any or no reason with or without notice.

6.7. Notwithstanding anything in this Agreement to the contrary, nothing herein prohibits the Employee from initiating communications directly with, responding to any inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including the U.S. Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General (collectively, the "Regulators"), or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. In connection with any such activity, the Employee must identify any information that is confidential and ask the Regulator for confidential treatment of such information. Despite the foregoing, the Employee is not permitted to reveal to any third party, including any governmental, law enforcement, or regulatory authority, information that is protected from disclosure by any applicable privilege, including but not limited to the attorney-client privilege, attorney work product doctrine and/or other applicable legal privileges. The Company does not waive any applicable privileges or the right to continue to protect its privileged attorney-client information, attorney work product, and other privileged information. Notwithstanding any other provisions of this Agreement, pursuant to 18 USC Section 1833(b), the Employee shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a Company trade secret that is made: (a) confidentially to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (b) in a

complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. If the Employee files a lawsuit for retaliation by the Company for reporting a suspected violation of law, the Employee may disclose a Company trade secret to the Employee's attorney and use the trade secret information in related court proceedings, provided that Employee files any document containing the trade secret information under seal and does not disclose the trade secret, except pursuant to court order.

IN WITNESS WHEREOF, Employee and the Company have executed this Nondisclosure and Business Ideas Agreement to be effective as of the date first above written.

EMPLOYEE:

/s/ Sanjay Subramanian

Date: September 10, 2019

COMPANY:

OCUGEN, INC.

By: /s/ Shankar Musunuri

Shankar Musunuri
Chairman & CEO

Date: September 10, 2019

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 12, 2019

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

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

CERTIFICATION

I, Sanjay Subramanian, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ocugen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ Sanjay Subramanian

Sanjay Subramanian

Chief Financial Officer

(Principal Financial Officer and Accounting Officer)

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, 2019 (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 12, 2019

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

Shankar Musunuri, Ph.D., MBA

Chief Executive Officer & Chairman

(Principal Executive Officer)

Date: November 12, 2019

/s/ Sanjay Subramanian

Sanjay Subramanian

Chief Financial Officer

(Principal Financial Officer and 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.