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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

Commission File Number 001-36751

OCUGEN, INC.
(Exact Name of Registrant as Specified in its Charter)

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

263 Great Valley Parkway
Malvern, Pennsylvania 19355
(Address of principal executive offices, including zip code)

(484) 328-4701
(Registrant's telephone number, including area code)

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock	**OCGN**	**The Nasdaq Stock Market LLC (The Nasdaq Capital Market)**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act

Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act

Yes ☐ No ☒

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

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

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

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

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

Indicate by check mark whether the registrant whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

As of June 30, 2020, the last day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $28.6 million, based upon the closing price of the registrant's common stock on June 30, 2020.

As of March 1, 2021, there were 188,088,860 outstanding shares of the registrant's common stock, $0.01 par value per share.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates certain information by reference from the registrant's proxy statement for the 2021 annual meeting of stockholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2020.

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

FORWARD-LOOKING STATEMENTS

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

The forward-looking statements in this Annual Report on Form 10-K and the documents incorporated herein by reference include, among other things, statements about:

- our estimates regarding expenses, future revenue, capital requirements, and timing and availability of and the need for additional financing;
- our ability to obtain sufficient additional capital to continue to advance our product candidates and our preclinical programs;
- our activities with respect to COVAXIN, our vaccine candidate for the prevention of COVID-19, in collaboration with Bharat Biotech International Limited (“Bharat Biotech”), including our plans and expectations regarding clinical development, manufacturing, pricing, regulatory review and compliance, reliance on third parties, and commercialization, if authorized or approved;
- the extent to which health epidemics and other outbreaks of communicable diseases, including the COVID-19 pandemic, could disrupt our business and operations;
- the uncertainties associated with the clinical development and regulatory authorization or approval of product candidates, including potential delays in the commencement, enrollment, and completion of clinical trials;
- our ability to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market and the risk that products will not achieve broad market acceptance;
- uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom;
- our ability to maintain our collaboration with Bharat Biotech and to establish additional collaborations and/or partnerships;
- our ability to comply with regulatory schemes applicable to our business and other regulatory developments in the United States and foreign countries;
- the performance of third-parties upon which we depend, including third-party contract research organizations (“CROs”), and third-party suppliers, manufacturers, group purchasing organizations, distributors, and logistics providers;
- the pricing and reimbursement of our product candidates, if authorized or approved;
- our ability to obtain and maintain patent protection, or obtain licenses to intellectual property and defend our intellectual property rights against third-parties;
- our ability to maintain our relationships, profitability, and contracts with our key commercial partners;
- our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers; and
- our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including Good Manufacturing Practice (“GMP”) compliance and other relevant regulatory authorities.

We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans,

intentions, and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly under “Risk Factors,” that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations, or investments we may make.

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

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Solely for convenience, tradenames and trademarks referred to in this Annual Report on Form 10-K appear without the ® or TM symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these tradenames or trademarks, as applicable. All tradenames, trademarks, and service marks included or incorporated by reference in this Annual Report on Form 10-K are the property of their respective owners.

PART I

Item 1. Business

OVERVIEW

We are a biopharmaceutical company focused on developing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19.

Our cutting-edge technology pipeline includes:

- **COVID-19 Vaccine** — COVAXIN is a whole-virion inactivated COVID-19 vaccine candidate being developed to prevent COVID-19 infection in humans. We are co-developing COVAXIN with Bharat Biotech for the U.S. market.
- **Modifier Gene Therapy Platform** — Based on nuclear hormone receptors ("NHRs"), we believe our gene therapy platform has the potential to address many retinal diseases, including retinitis pigmentosa ("RP"), leber congenital amaurosis ("LCA"), and dry age-related macular degeneration (“AMD”).
- **Novel Biologic Therapies for Retinal Diseases** — We are developing OCU200, a novel biologic product candidate, to treat diabetic macular edema (“DME”), diabetic retinopathy (“DR”), and wet AMD.

COVID-19 Vaccine

In February 2021, we entered into a Co-Development, Supply and Commercialization Agreement (the “Covaxin Agreement”) with Bharat Biotech, pursuant to which we obtained an exclusive right and license under certain of Bharat Biotech’s intellectual property rights, with the right to grant sublicenses, to develop, manufacture, and commercialize COVAXIN for the prevention of COVID-19 in humans in the United States, its territories and possessions (the “Ocugen Covaxin Territory”). Under the Covaxin Agreement, we will be solely responsible for such activities for the Ocugen Covaxin Territory.

COVAXIN is a whole-virion inactivated COVID-19 vaccine candidate being developed by Bharat Biotech, a global leader in vaccine innovation, and has been granted approval for emergency use in India. COVAXIN is formulated with the inactivated SARS-CoV-2 virus, an antigen, and an adjuvant therefore utilizing a historically proven approach to vaccine design. COVAXIN requires a two-dose vaccination regimen given 28 days apart and is stored in standard vaccine storage conditions (2-8°C). The Phase 1 and Phase 2 clinical trials conducted in India reported strong Immunoglobulin G ("IgG") responses against the spike protein, receptor-binding domain ("RBD"), and the nucleocapsid protein of the SARS-CoV-2 virus, along with strong cellular responses. Strong cellular responses are necessary for memory and long-term durability of vaccines. In an analysis from the National Institute of Virology, serum samples collected from individuals vaccinated with COVAXIN showed similar neutralization titer to the U.K. strain as to the original strain. No statistical difference was observed in neutralizing antibodies titer between the U.K. strain and the original strain. These results support COVAXIN's potential to generate immune responses to multiple protein antigens of the virus and thereby potentially reducing or eliminating potential viral escape.

Bharat Biotech is conducting a Phase 3 clinical trial in India. Enrollment in the Phase 3 clinical trial is complete. COVAXIN demonstrated a vaccine efficacy of 81% in the first interim analysis of the Phase 3 clinical trial, and an analysis from the National Institute of Virology indicated potential significant immunogenicity against the U.K. variant and other heterologous strains. We are currently evaluating the clinical and regulatory path for COVAXIN in the United States including obtaining Emergency Use Authorization ("EUA") from the U.S. Food and Drug Administration (the "FDA") and, eventually, biologic license application (“BLA”) approval in the U.S. market, as well as our commercialization strategy, if authorized or approved. We have initiated discussions with the FDA regarding the development of COVAXIN, but an EUA application has not been submitted at this time. We are also in active discussions with manufacturers in the United States to produce a significant number of doses of COVAXIN to support commercialization of the vaccine in the United States, if authorized or approved.

Modifier Gene Therapy Platform

We are developing a breakthrough modifier gene therapy platform to generate therapies designed to fulfill unmet medical needs in the area of retinal diseases, including inherited retinal diseases ("IRDs") and dry AMD. Our modifier gene therapy platform is based on NHRs, which have the potential to restore homeostasis, the basic biological processes in the retina. Unlike single-gene replacement therapies, which only target one genetic mutation, we believe that our gene therapy platform, through its use of NHRs, represents a novel approach in that it may address multiple retinal diseases with one product. IRDs such as RP, a group of rare genetic disorders that involve a breakdown and loss of cells in the retina and can lead to visual impairment and blindness, affect over 2.0 million people worldwide. Over 150 gene mutations have been associated with RP and this number

represents only 60% of the RP population. The remaining 40% of RP patients cannot be genetically diagnosed, making it difficult to develop individual treatments. We believe our first gene therapy candidate, OCU400, has the potential to be broadly effective in restoring retinal integrity and function across a range of IRDs. For example, we believe OCU400 has the potential to eliminate the need for developing more than 150 individual products and provide one treatment option for all RP patients.

OCU400 has received four Orphan Drug Designations ("ODDs") from the FDA for the treatment of certain disease genotypes: nuclear receptor subfamily 2 group E member 3 ("*NR2E3*"), centrosomal protein 290 ("*CEP290*"), rhodopsin ("*RHO*"), and phosphodiesterase 6B ("*PDE6ß*") mutation-associated inherited retinal degenerations. We are planning to initiate two Phase 1/2a clinical trials for OCU400 in the United States in the second half of 2021. OCU400 additionally received Orphan Medicinal Product Designation ("OMPD") from the European Commission, based on the recommendation of the European Medicines Agency ("EMA"), for RP and LCA in February 2021, which we believe further supports the potential broad spectrum application of OCU400 to treat many IRDs. We are currently evaluating options to commence OCU400 clinical trials in Europe in 2022. Our second gene therapy candidate, OCU410, is being developed to utilize the nuclear receptor genes RAR-related orphan receptor A ("*RORA*") for the treatment of dry AMD. This candidate is currently in preclinical development. We are planning to initiate a Phase 1/2a clinical trial for OCU410 in 2022.

Novel Biologic Therapies for Retinal Diseases

We are also conducting preclinical development for our biologic product candidate, OCU200. OCU200 is a novel fusion protein designed to treat DME, DR, and wet AMD. We had a pre-Investigational New Drug ("IND") meeting with the FDA in November 2020 and received guidance on IND-enabling preclinical studies to support the Phase 1/2a study. We expect to initiate IND-enabling preclinical studies for OCU200 in 2021 and initiate a Phase 1/2a clinical trial for OCU200 in 2022.

OUR STRATEGY

Our product candidates have the potential to save lives from COVID-19 and cure blindness diseases. We are committed to developing these product candidates and bringing them to market to serve patients in multiple disease areas. Key elements of the strategy we employ to accomplish this objective include:

- ***Advancing our COVID-19 vaccine product candidate towards EUA and commercialization in the United States.*** We have initiated discussions with the FDA regarding the development of COVAXIN. COVAXIN has been granted approval for emergency use in India. A Phase 3 clinical trial is ongoing in India. COVAXIN demonstrated a vaccine efficacy of 81% in the first interim analysis of the Phase 3 clinical trial. We intend to advance the development of COVAXIN towards EUA and ultimately BLA approval in the United States.
- ***Establishing our modifier gene therapy platform and advancing OCU400 and OCU410 into clinical development.*** We intend to advance OCU400 and OCU410 into and through clinical development for the treatment of multiple IRDs and for the treatment of dry AMD, respectively. In addition to OCU400 and OCU410, we will also explore additional NHR-based product candidates for multiple eye disease indications. We expect to file the INDs to start Phase 1/2a clinical trials in the United States for OCU400 and OCU410 in the second half of 2021 and in 2022, respectively.
- ***Advancing preclinical biological programs into clinical development.*** We intend to advance OCU200 into and through clinical development for the treatment of DME, DR, and wet AMD. This candidate is currently in preclinical development. We expect to file the IND to start the Phase 1/2a clinical trial in 2022.
- ***Exploring potential partnerships with leading pharmaceutical and biotechnology companies to maximize patient access, global reach, and the value of our product candidates.*** We plan to explore licensing, intellectual property acquisitions, and collaboration opportunities with qualified potential partners in key global markets as needed to maximize the positive impact of our product candidates on patients globally.

COMPETITIVE STRENGTHS

Our key competitive strengths include:

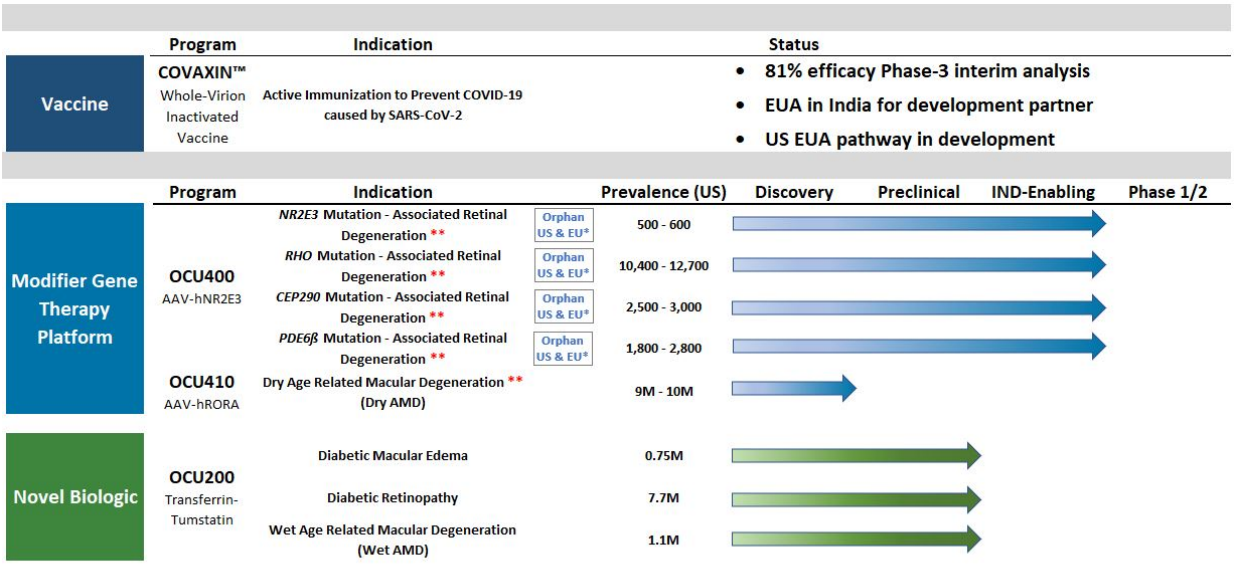
- ***Vaccine Expertise.*** Key members of our management team and key advisors possess proven expertise and a track record of success in vaccine development and commercialization. We have established a vaccine scientific advisory board composed of leading academic and industry experts with extensive experience in the vaccine field. We intend to utilize this collective experience to evaluate the clinical and regulatory path to EUA and commercialization of COVAXIN in the United States.
- ***Orphan Drug Designations.*** OCU400 has received four ODDs from the FDA for the treatment of certain disease genotypes: *NR2E3*, *CEP290*, *RHO*, and *PDE6ß* mutation-associated inherited retinal degenerations. OCU400 has

additionally received OMPD from the European Commission, based on the recommendation of the EMA, for RP and LCA, which we believe further supports the potential broad spectrum application of OCU400 to treat many IRDs.

- ***Gene Therapy Manufacturing.*** We have established a strategic partnership with CanSino Biologics Inc. ("CanSinoBIO") for chemistry, manufacturing, and controls ("CMC") development and manufacturing of clinical supplies for our first gene therapy candidate, OCU400. The partnership secures hard-to-find manufacturing capacity and expertise for gene therapy product development. We believe this partnership will accelerate the development timeline, increase reliability of our product candidate manufacturing, and provide a significant reduction in associated costs.
- ***Intellectual Property Portfolio.*** Our intellectual property portfolio contains patents and pending patent applications related to composition of matter, pharmaceutical compositions, and methods of use for our product candidates. As of March 1, 2021, our patent portfolio included a total of 45 issued or registered patents and 12 pending patent applications, including those licensed from leading institutions. Our patents and pending patent applications are for a diverse range of geographical locations representing major markets including both in the United States as well as in foreign countries.
- ***Licensing and Development Arrangements with Leading Institutions and Global Biotechnology Companies.*** We have licensing agreements with leading companies, academic institutions, and medical institutions that cover four of our product candidates. In February 2021, we entered into the Covaxin Agreement with Bharat Biotech with respect to the development and commercialization of COVAXIN in the United States. In December 2017, we entered into an exclusive worldwide license agreement with The Schepens Eye Research Institute ("SERI"), an affiliate of Harvard Medical School, pursuant to which we acquired patent rights for NHRs, including those used in our OCU400 and OCU410 programs. In March 2014, we entered into an exclusive worldwide license agreement with the University of Colorado ("CU") pursuant to which we acquired rights to the transferrin-tumstatin fusion protein technology used in OCU200 as well as other technology.
- ***Experienced Management Team and Highly Esteemed Scientific Advisory Boards.*** Our management team has extensive experience with a proven track record of success in developing, launching, and managing the life cycle of many biopharmaceuticals at leading pharmaceutical and biotechnology companies. We believe that the experience of our management team, our scientific advisory board members, and our broad network of relationships with leaders within the industry and the medical community provides us with insight into the identification of product opportunities, product development, and product commercialization.

OUR PRODUCT CANDIDATE PIPELINE

Our current product pipeline candidates are summarized in the following chart:



COVID-19 VACCINE PRODUCT CANDIDATE

We have entered into the Covaxin Agreement with Bharat Biotech, pursuant to which we have obtained an exclusive right and license under certain of Bharat Biotech's intellectual property rights, with the right to grant sublicenses, to develop, manufacture, and commercialize COVAXIN in the United States. COVAXIN is a whole-virion inactivated COVID-19 vaccine being developed to prevent COVID-19 infection in humans. We have initiated discussions with the FDA regarding the development of COVAXIN, including discussions about EUA.

Overview of COVID-19 and Available Prevention Options

In December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was first reported to have surfaced in Wuhan, China. COVID-19 has since spread worldwide and has been declared a pandemic by the World Health Organization as well as declared a national emergency by the United States. SARS-CoV-2 is a newly discovered strand of coronavirus which can be contracted through contact with an infected person, through the air by coughing or sneezing, or through touching an object or surface contaminated with SARS-CoV-2. COVID-19 is predominantly a respiratory illness that can also affect other organs and can be fatal. Those infected with COVID-19 may experience a wide range of mild to severe symptoms including fever or chills, cough, shortness of breath or difficulty breathing, fatigue, and loss of taste or smell, among other symptoms. Symptoms typically appear two to 14 days after exposure to a person infected with COVID-19. Asymptomatic cases can occur among those infected with COVID-19, further contributing to the rapid spread of COVID-19 both in the United States and worldwide.

Since COVID-19 was first discovered in December 2019, new variants of SARS-CoV-2 have emerged. New variants of a virus emerge when a mutation to the virus' genes occurs. The emergence of new variants of viruses is not uncommon. Current research suggests that some of the new variants of SARS-CoV-2 identified thus far are more contagious and spread more rapidly than the originally identified virus and may cause more severe illness and be associated with higher rates of fatality.

Within the United States, the FDA utilizes EUA as a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, which includes the current COVID-19 pandemic. Through the granting of an EUA, the FDA allows the use of unapproved medical products to prevent serious and life-threatening conditions when there are no adequate, approved, and available alternatives and that medical product meets certain regulatory criteria. For a COVID-19 vaccine for which there is adequate manufacturing information to ensure its quality and consistency, issuance of an EUA requires a determination by the FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner. It is the FDA's expectation that, following the submission of an EUA application and the issuance of an EUA, a sponsor will continue to collect placebo-controlled data in any ongoing trials for as long as feasible and would also work towards a submission of a BLA as soon as possible.

Three COVID-19 vaccine candidates have been issued EUAs by the FDA for the prevention of COVID-19 in the United States: the vaccine developed in a collaboration between Pfizer Inc. and BioNTech SE ("Pfizer/BioNTech SE"), the vaccine developed by Moderna Inc., and the vaccine developed by Johnson & Johnson/Janssen Biotech. Each of these COVID-19 vaccines is authorized for the use of the prevention of COVID-19. Pfizer/BioNTech SE's COVID-19 vaccine has been authorized for use for the prevention of COVID-19 in individuals 16 years of age and older. Moderna Inc.'s and Johnson & Johnson/Janssen Biotech's COVID-19 vaccines have been authorized for use for the prevention of COVID-19 in individuals 18 years of age and older. No COVID-19 vaccines have been approved under a BLA by the FDA.

Both Pfizer/BioNTech SE and Moderna Inc.'s COVID-19 vaccines are messenger RNA ("mRNA") vaccines. mRNA vaccines are a relatively new type of vaccine. They protect against infectious disease by providing instructions for cells to generate a spike protein, which triggers an immune response producing antibodies thereby protecting against future infection. mRNA vaccines do not contain an inactivated virus, which is the more historically common approach to vaccine development. Research is ongoing regarding the effectiveness of the mRNA vaccines on the emerging COVID-19 variants. Johnson & Johnson/Janssen Biotech's COVID-19 vaccine is a viral vector vaccine. It uses an adenovirus as a vector of an antigen's genetic code to mimic components of a pathogen (the SARS-CoV-2 virus). Antigens are produced to mimic the pathogen without causing severe disease. When the body encounters antigens, the body will induce a humoral and cellular immune response against the antigen by producing immune cells and antibodies thereby protecting against future infection if the body encounters the actual pathogen in the future.

COVAXIN for the Prevention of COVID-19

COVAXIN is a whole-virion inactivated COVID-19 vaccine being developed to prevent COVID-19 infection. We are co-developing COVAXIN with Bharat Biotech, a global leader in vaccine innovation, for the prevention of COVID-19 in humans within the U.S. market. Pursuant to the Covaxin Agreement we entered into with Bharat Biotech, we obtained an exclusive right and license under certain of Bharat Biotech's intellectual property rights, with the right to grant sublicenses, to develop, manufacture, and commercialize COVAXIN for the Ocugen Covaxin Territory. Under the Covaxin Agreement, we will be solely responsible for such activities for the Ocugen Covaxin Territory.

COVAXIN is formulated with the inactivated SARS-CoV-2 virus, an antigen, and an adjuvant therefore utilizing a historically proven approach to vaccine design. COVAXIN utilizes the whole-virion inactivated SARS-CoV-2 virus to trigger the immune system to create antibodies against multiple antigens. COVAXIN has an antigen concentration of six micrograms and utilizes a toll-like receptor 7/8 agonist molecule (IMG) adsorbed to alum (Algel) as an adjuvant to increase and boost COVAXIN's immunogenicity. COVAXIN has certain characteristics that may be beneficial as compared to the currently authorized vaccines. As the FDA has recognized in its recently updated EUA guidance, the rise of COVID-19 genetic variants has raised concerns that these variants may be able to escape neutralization by vaccines. COVAXIN is designed to fulfill a significant unmet need in the U.S. national arsenal of vaccines against COVID-19. COVAXIN elicits a broad-spectrum immune response (including spike and nucleocapsid proteins) and induces both humoral and cellular responses. Therefore, we believe COVAXIN may be effective against the recently emerging new variants such as the U.K. (B.1.1.7), Brazilian (P.2), and South African (B.1.351) variants, thereby potentially minimizing or eliminating potential viral escape. In an analysis from the National Institute of Virology, serum samples collected from individuals vaccinated with COVAXIN showed similar neutralization titer to the U.K. strain as to the original strain. No statistical difference was observed in neutralizing antibodies titer between the U.K. strain and the original strain. Additionally, the inactivated virus platform is based on safe and proven technology. The inactivated viral vaccine approach is known to be safe in all age groups including infants (e.g., polio vaccine) and is easy to stockpile, store, and distribute as it requires only standard vaccine storage conditions (2-8°C).

The inactivated SARS-CoV-2 virus within COVAXIN is manufactured in a Biosafety Level 3 facility and inactivated using β-propiolactone treatment at a low temperature. As an inactivated virus vaccine, COVAXIN has the advantage of using all the proteins in the virus to elicit the immune response, rather than just spike proteins as in the mRNA and adenovirus vaccines. Compared to those vaccines, an inactivated whole-virion vaccine is expected to produce a more robust response that can elicit memory and cross-react with mutated strains. Once vaccinated with COVAXIN, the immune system can respond to a live infection of SARS-CoV-2. COVAXIN is administered in two doses occurring 28 days apart. COVAXIN is administered into the deltoid muscle of the upper arm.

Approximately 375 healthy adults aged 18 to 55 years were evaluated in the Phase 1 trial in India. Approximately 380 healthy adults and adolescents aged 12 to 65 years were evaluated in the Phase 2 trial in India. The Phase 1 and 2 trials conducted in India reported strong IgG responses against the spike protein, RBD, and the nucleocapsid protein of SARS-CoV-2 along with strong cellular responses. Strong cellular responses are necessary for memory and long-term durability of vaccines. A Phase 3 clinical trial in India began in November 2020 and is ongoing involving approximately 25,800 volunteers aged 18 to 98 years, including 2,433 over the age of 60 and 4,500 with comorbidities. Enrollment in the Phase 3 clinical trial is complete. COVAXIN demonstrated a vaccine efficacy of 81% in the first interim analysis of the Phase 3 clinical trial, and an analysis from the National Institute of Virology indicated potential significant immunogenicity against the U.K. variant and other heterologous strains.

In January 2021, COVAXIN was granted approval for emergency use in India. We are currently evaluating the clinical and regulatory path for COVAXIN in the United States including obtaining EUA from the FDA and, eventually, BLA approval in the U.S. market, as well as our commercialization strategy, if authorized or approved. We have initiated discussions with the FDA regarding the development of COVAXIN. We and Bharat Biotech agreed to share any profits generated from the commercialization of COVAXIN in the United States, with us retaining 45% of such profits, and Bharat Biotech receiving the balance of such profits.

OUR MODIFIER GENE THERAPY PLATFORM AND GENE THERAPY PRODUCT CANDIDATES

We are developing OCU400 using our breakthrough modifier gene therapy platform. OCU400 has received ODD from the FDA for the treatment of certain disease genotypes: *NR2E3*, *CEP290*, *RHO*, and *PDE6ß* mutation-associated inherited retinal degenerations. OCU400 additionally received OMPD from the European Commission, based on the recommendation of the EMA, for RP and LCA in February 2021, which we believe further supports the potential broad spectrum application of OCU400 to treat many IRDs. We plan to initiate two Phase 1/2a clinical trials for OCU400 in the United States in the second half of 2021, one Phase 1/2a clinical trial for the treatment of the *NR2E3* disease genotype and one Phase 1/2a clinical trial for

the treatment of the *RHO* disease genotype. We are currently evaluating options to commence OCU400 clinical trials in Europe in 2022. OCU400 is the first product candidate being developed by us with our modifier gene therapy platform utilizing NHRs. We are also utilizing our modifier gene therapy platform for the development of OCU410, a product candidate designed to treat dry AMD through the utilization of nuclear receptor genes *RORA*. We plan to initiate a Phase 1/2a clinical trial for OCU410 in 2022.

Breakthrough Platform Therapy Based on Nuclear Hormone Receptors

NHRs have long been known to play a critical role in modulating cellular homeostasis by regulating basic biological processes including development, metabolism, circadian cycle, and energy homeostasis. Our modifier gene therapy platform is being designed to target NHRs, which have the potential to restore homeostasis to the retina and to provide therapeutic benefit to patients suffering from IRDs. Moreover, unlike single-gene replacement therapies, which only target one genetic mutation, we believe that our NHR-based approach represents a breakthrough modifier gene therapy platform that has the potential to restore retinal integrity and function across a range of genetically diverse IRDs and other degenerative retinal diseases, leading to multiple potential product opportunities. This approach has shown potential to rescue many genetic defects and may lead to vision-sparing therapies for rare IRDs including a broad spectrum of RP as well as potentially LCA and other forms of retinal and macular degeneration, providing us with significant potential long-term value.

The NHR-based gene therapy platform encompasses the targeted delivery and expression of certain NHRs that are expressed naturally in retinal tissue. Preclinical studies conducted by Dr. Neena Haider and others have shown that *NR2E3*, a member of the NHR family, is a dual activator and repressor that, with other transcription factors, modulates cell fate and differentiation of rod and cone photoreceptor cells in the eye (**Figure 1**). The delivery of *Nr2e3* in a mouse, lacking a functional *Nr2e3* gene, restored the retina structure and function. We believe that *NR2E3* may partially or fully rescue photoreceptors, which are responsible for light detection in the retina, from degeneration in patients with IRDs and improve patients' vision.

Figure 1 Schematic representation of the potential mechanism impacting *NR2E3* retinal degeneration.

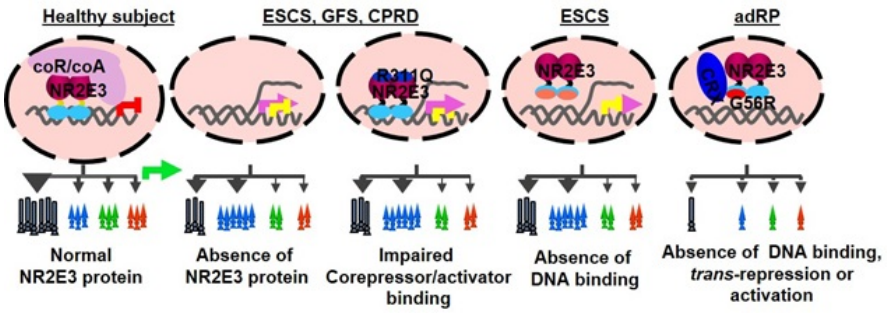
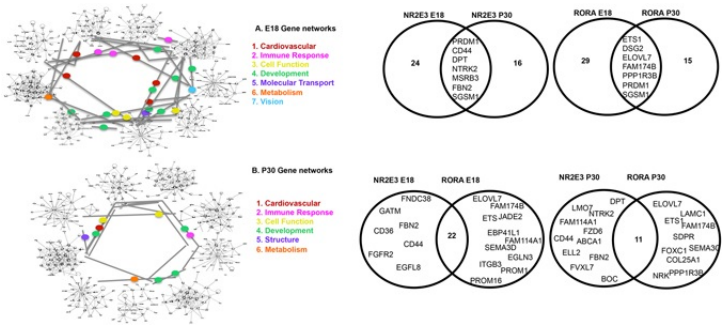


Figure 1 *above includes the following definitions: corepressor ("coR"), coactivator ("coA"), enhanced S-cone syndrome ("ESCS"), Goldman Favre syndrome ("GFS"), clumped pigmentary retinal degeneration ("CPRD"), and autosomal dominant retinitis pigmentosa ("adRP"). Rod photoreceptors are displayed in grey and cone photoreceptors are displayed in blue, green, and red.*

Dr. Haider's lab at SERI, an affiliate of Harvard Medical School, and others have shown the preclinical phenotypic outcome results from a mutational load on a biological system that includes the primary mutation and other factors such as modifier alleles impacting the normal homeostatic state. The use of genetic modifiers represents a broadened means of potentially treating a variety of retinal degenerative diseases, as compared to single-gene replacement therapy. While single-gene replacement therapies have shown tremendous promise in rare retinal diseases, they are highly specific and cannot improve a multitude of disease-causing genetic defects. On the other hand, NHRs play a vital role in regulating retinal cell development, maturation, metabolism, visual cycle function, and survival (**Figure 2**).

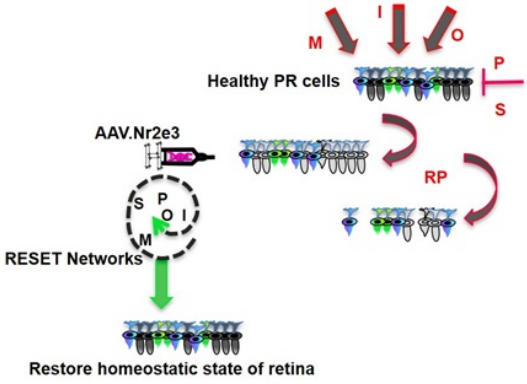
Figure 2 Interacting *NR2E3* and *RORA* Associated Gene Networks.



*As displayed in **Figure 2** above, Ingenuity Pathway Analyses ("IPA Analyses") were conducted to evaluate embryonic day 18 targets and post-natal day 30 targets. An IPA Analysis of embryonic day 18 targets (analysis A above) identified nine gene networks with seven biological classifications. An IPA Analysis of post-natal day 30 targets (analysis B above) identified nine gene networks with six biological classifications. The venn diagrams show the unique and overlapping gene targets of both NR2E3 and RORA at embryonic day 18 and post-natal day 30. The comparison of RORA embryonic day 18 and post-natal day 30 or NR2E3 embryonic day 18 and post-natal day 30 show less overlap than RORA and NR2E3 at embryonic day 18 or RORA and NR2E3 at post-natal day 30.*

Disease outcome is a result of a primary mutation as well as modifier alleles. *NR2E3* is a master regulator of several key pathways in retinal development and function. *NR2E3* potentially prevents and reduces disease by resetting the homeostatic state of key gene networks in the presence of a primary mutation (**Figure 3**).

Figure 3 Schematic representation of potential *NR2E3* mediated therapy.



*As displayed in **Figure 3** above, NR2E3 potentially resets key gene networks that contribute to retinal degeneration in RP. **Figure 3** above includes the following definitions: photoreceptor cells ("PR") as well as the following gene networks: metabolism ("M"), inflammation, ("I"), oxidative stress ("O"), photoreceptor genes ("P"), and cell survival ("S").*

In summary, *NR2E3* regulates multiple transcriptional networks, such as cell survival, metabolism, inflammation, and phototransduction, that impact retinal diseases, such as RP. It was also demonstrated preclinically that *RORA* offers a protective allele in AMD where the loss of photoreceptor cells leads to blindness. *NR2E3* regulates the expression of both Nuclear Receptor Subfamily 1 Group D Member 1 ("*NR1D1*") and *RORA*. Thus, the nuclear receptors work in overlapping networks to modulate normal retinal development and function. These receptors impact gene expression of hundreds of genes and numerous networks and, as such, may be potent modifiers of retinal disease and degeneration.

***NR2E3* Modifier Gene Therapy Demonstrated Efficacy in many IRD models**

Efficacy of *Nr2e3* was evaluated in five RP models: FVB-*Pde6ß* ^{rd1}/NJ ("*rd1*"), Rhodopsin null allele ("*Rho*$^{-/-}$"), B6.129S6(Cg)-*Rho*$^{tm1.1Kpal}$/J ("*Rho*^{P23H}"), BXD24/TyJ-*Cep290*^{rd16}/J ("*rd16*"), and *Nr2e3*^{rd7}/J ("*rd7*") following subretinal

delivery. These models represent a heterogeneous group of RP diseases in humans and are relevant in establishing the modifier role of *NR2E3*. The effect of *Nr2e3* gene therapy was evaluated at both early and late disease states in these animal models using a minimal number of seven animals per experimental group. C57BL6/J ("B6") in these models represents the control.

These animals were dosed with adeno-associated viral ("AAV"): AAV8-*Nr2e3* in the subretinal space at post-natal day zero and evaluated at post-natal day 30 (B6 and *rd1*) or post-natal day 90 to 120 ($Rho^{-/-}$, Rho^{P23H}, *rd16*, and *rd7*) using fundus imaging, electroretinogram ("ERG"), histology, and immunostaining of retinal layers. Considerable improvement was observed in the clinical phenotype for Rho^{P23H}, *rd16*, and *rd7* mice in fundus imaging, though not all models have a contrasting clinical phenotype (**Figure 4**). Further histological analyses of retinal sections demonstrated improvement in the integrity of the retinal layers, and overall anatomy and morphology of the retina in all of these models (**Figure 5**). Immunohistochemistry analyses of retina showed that *Nr2e3* delivery enhanced the expression of opsin proteins (blue and green) in treated mice in all the models except *rd7*. In the *rd7* model, the disease phenotype starts with a higher number of S-cone and a higher expression of opsin proteins. In this model, *Nr2e3* treatments restored the physiological level of opsin proteins in photoreceptors (**Figure 6**) needed for normal vision. Similarly, treated animals showed improvement in retinal ERG signal, both in photopic (light-adapted) and scotopic (dark-adapted) conditions (**Figure 7**).

Figure 4: AAV8-*Nr2e3* rescues clinical phenotype in multiple mouse models of RP.

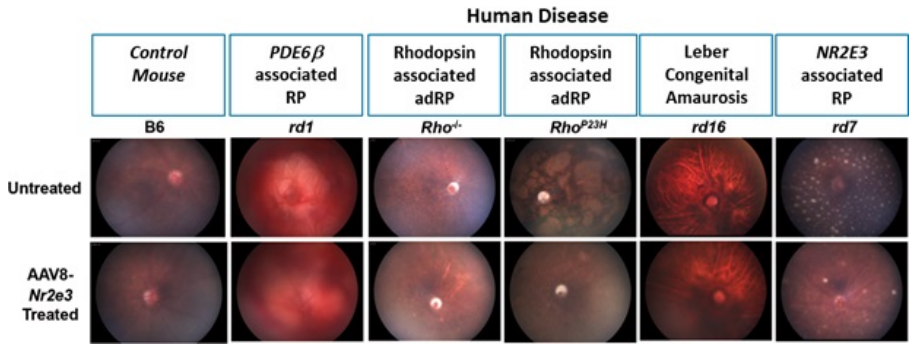
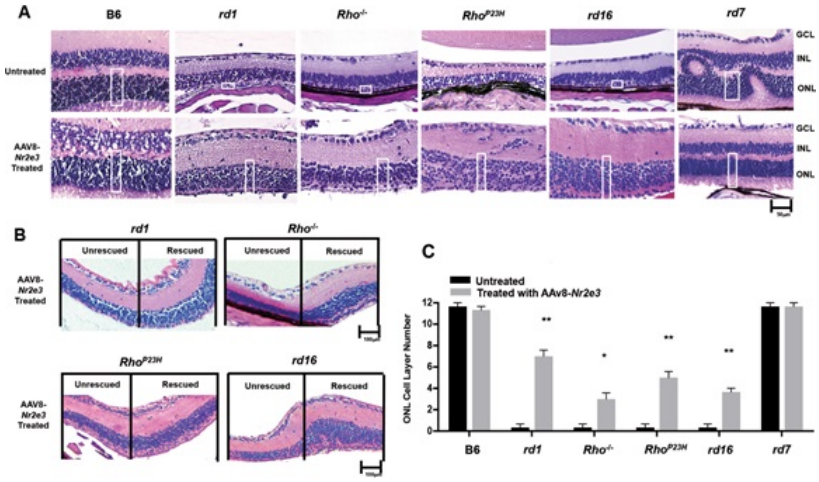


Figure 4 *above displays the fundus of post-natal day zero injected AAV8-Nr2e3 treated and untreated animals evaluated at post-natal day 30 (B6 and rd1) or post-natal day 90 to 120 ($Rho^{-/-}$, Rho^{P23H}, rd16, and rd7).*

Figure 5: AAV8-*Nr2e3* treatment preserves retinal morphology and retinal integrity in RP models.



Analysis A within ***Figure 5*** *above displays the hematoxylin and eosin staining of AAV8-Nr2e3 treated and untreated retinas. The white boxes in analysis A indicate the location of the cell count. Analysis B above displays the rescued and un-rescued regions in retinas treated with AAV8-Nr2e3. Analysis C above displays the cell layer numbers of the outer nuclear layer ("ONL") from AAV8-Nr2e3 treated and untreated animals in different RP models.*

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Figure 6: AAV8-*Nr2e3* preserves cone and rod opsin expression in multiple mouse models of RP.

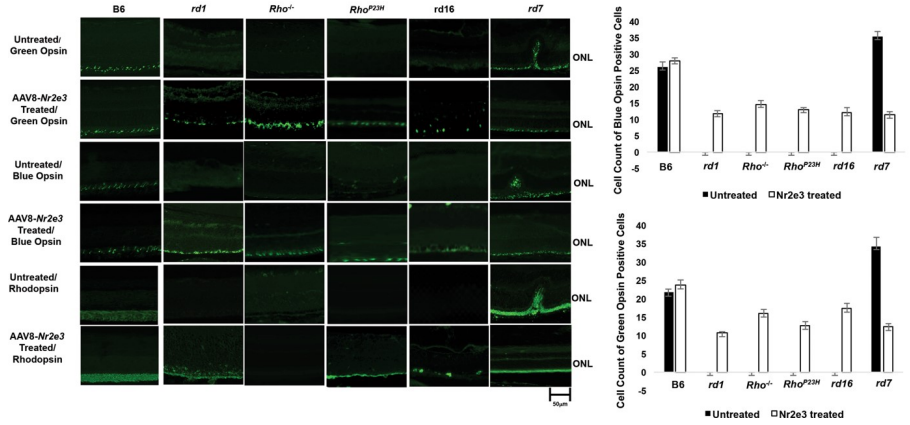
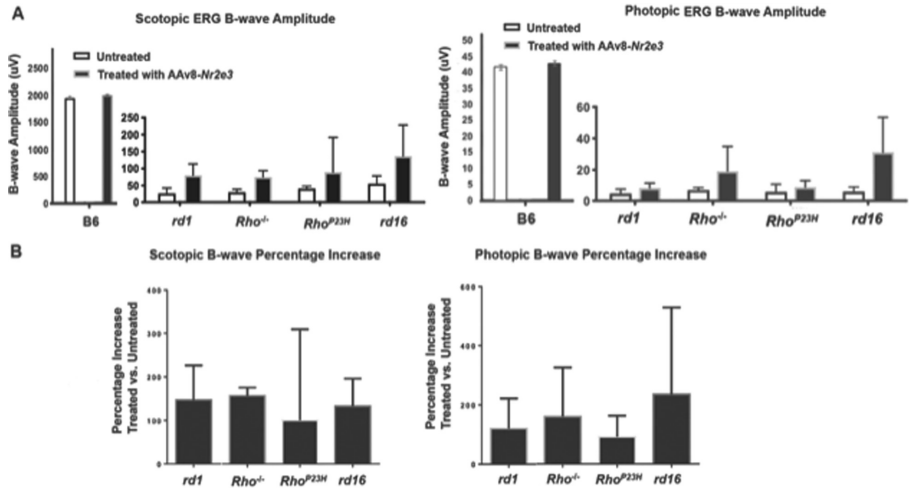


Figure 6 *above displays the immunohistochemistry of post-natal day zero injected AAV8-Nr2e3 to treated and untreated retinas labeled with green opsin, blue opsin, and rhodopsin. These treated and untreated retinas were evaluated at post-natal day 30 (B6 and rd1) or post-natal day 90 to 120 (Rho$^{-/-}$, Rho^{P23H}, rd16, and rd7). The right panel displays the semiquantitative analysis of cell counts of blue and green opsin-positive photoreceptor cells per 100 micrometers.*

Figure 7: Improved ERG responses in AAV8-*Nr2e3* treated RP retinas.



*Analysis A within **Figure 7** above displays the evaluation of photopic (light-adapted) and scotopic (dark-adapted) ERG B-wave amplitudes, which were evaluated at post-natal day 30 (B6 and rd1) or post-natal day 90 to 120 (Rho$^{-/-}$, Rho^{P23H}, and rd16) in AAV8-Nr2e3 treated and untreated animals. Analysis B above displays the percent increase in ERG B-wave responses in the treated RP models.*

The efficacy of *Nr2e3* was also evaluated in these animal models at a late disease stage. AAV8-*Nr2e3* was injected subretinally at post-natal day 21 and evaluated two to three months post injection in *Rho*$^{-/-}$, *Rho*^{P23H}, *rd16*, and *rd7* mice. Fundus imaging and histological analyses indicated a reduction in retinal degeneration in these models (**Figure 8**). The improvement in the rescue of retinal layers was between approximately 30% to 80% of the retina, depending on the delivery location and distribution of *Nr2e3* following dosing. Approximately three to five layers of ONL cells were preserved in *Nr2e3* treated animals compared with zero to one layer for untreated animals. These ONL photoreceptors induce phototransduction in the retina and thereby initiate the vision process. Immunohistochemistry labeling showed enhanced expression of blue and green cone opsins and rhodopsin in photoreceptors of treated groups compared to untreated groups (**Figure 9**) suggesting preservation of photoreceptors with light absorbing opsins.

Figure 8: AAV8-*Nr2e3* rescues RP degeneration after disease onset.

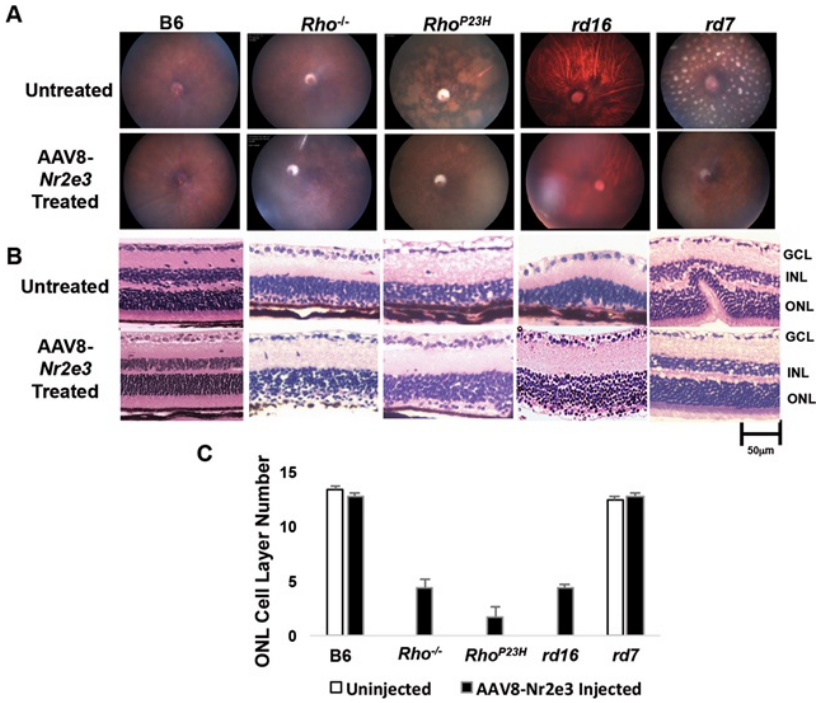


Figure 8 *above displays analysis of animals injected with AAV8-Nr2e3 at post-natal day 21 and evaluated at two to three months post injection. Analysis A above displays the fundus of* $Rho^{-/-}$, Rho^{P23H}, *rd16, and rd7. Analysis B above displays the hematoxylin and eosin staining showing partial preservation of photoreceptor cells in treated mutant animals. Analysis C above shows the comparison of cell layer numbers of ONL between AAV8-Nr2e3 treated and untreated animals in the four RP models.*

Figure 9: AAV8-*Nr2e3* rescues rod and cone opsin expression after disease onset.

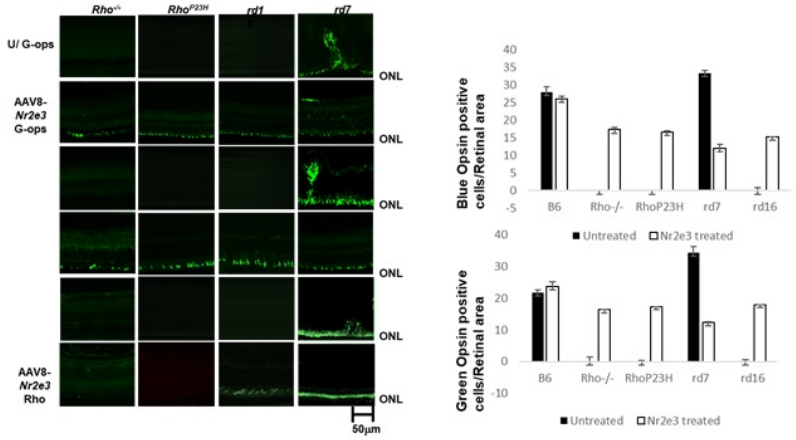
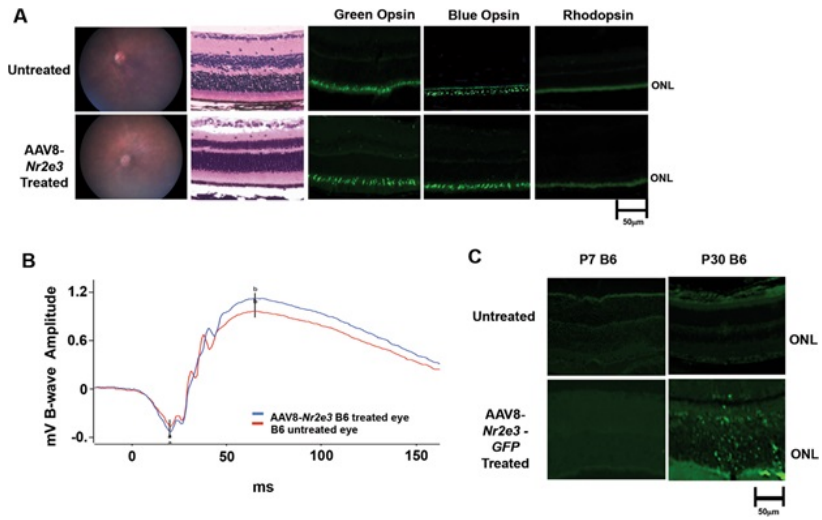


Figure 9 *above displays the analysis of animals that were injected with AAV8-Nr2e3 at post-natal day 21 and evaluated two to three months after injection. The immunohistochemistry of green opsin, blue opsin, and rhodopsin of treated and untreated animals in* $Rho^{-/-}$, Rho^{P23H}, *rd16, and rd7 is shown within the left panel. The semiquantitative analysis of the cell counts of blue and green opsin-positive photoreceptor cells per 50 micrometers of the retina is shown within the right panels.*

Safety of *NR2E3* in a Rodent Model

The safety of *Nr2e3* was evaluated in healthy mice following subretinal administration. B6 mice were treated with AAV8-*Nr2e3*-green fluorescent protein ("GFP") fusion construct at post-natal day zero and evaluated after both seven days and one month for any toxic effect as well as expression of Nr2e3-GFP fusion protein in the retina. The expression of the Nr2e3 protein in a mouse retina did not show any detrimental effect on retinal cells, including photoreceptors (**Figure 10**). Also, there was no difference in retinal anatomy (as indicated by fundus), histology (the cell layers), expression of opsin and rhodopsin proteins (immunohistochemistry), and retinal function (as indicated by ERG recording) between treated and untreated mice (**Figure 10**). Expression of enhanced GFP-Nr2e3 fusion protein was observed at post-natal day 30 in treated animals. These results confirm that overexpression of the Nr2e3 protein following subretinal injection of AAV8-*Nr2e3* was well-tolerated and safe to the retina.

Figure 10: Overexpression of AAV8-*Nr2e3* has no detrimental effects on the retina.



*The analysis in **Figure 10** above utilized a population size of five animals and displays the B6 control AAV8-Nr2e3 treated animals showing no abnormalities. Analysis A above displays the following: fundus, hematoxylin and eosin histology staining, blue opsin, green opsin, and rhodopsin labeling of photoreceptor cells. Analysis B above displays the ERG response of the B6 control in both treated and untreated animals. The animals were injected at post-natal day zero and tissue was collected at post-natal day 30. Analysis C above displays the GFP label of AAV8-Nr2e3-GFP injected at post-natal zero with GFP expression assessed at both post-natal day seven and post-natal day 30.*

Overview of Inherited Retinal Diseases and Current Treatment Options

IRDs are caused by genetic mutations that are passed down within families and lead to progressive disease, severe visual impairment, and blindness. Treating these conditions has been a significant challenge due to the sheer volume of potential therapeutic gene targets. Gene replacement therapy is a promising approach to provide a sustained restoration effect of normal retinal function for a mutated gene, but such therapies can only address one gene at a time, limiting their effectiveness. Developing a custom gene therapy for genetic defects in each of the more than 150 known gene defects linked to RP would not only be expensive but also may not be possible due to size, class, or localization that will impact delivery of the gene. Not all genes and disease expressions are amenable to gene therapy, and for the approximately 40% of patients whose genetic mutations remain unknown, there are few or no therapeutic options. Modifier gene therapy to ameliorate multiple forms of RP without requiring knowledge of the mutated gene, may provide a robust and feasible treatment for RP.

RP is a group of heterogeneous, pleiotropic IRDs that affect approximately one in every 4,000 individuals. RP is associated with over 150 gene mutations that affect over 2.0 million individuals worldwide. Currently, there is no cure for RP and over 40% of RP cannot be genetically diagnosed. RP is heterogeneous and varies greatly in age of onset, rate of progression, and even genetic etiology, yet a common pathology of photoreceptor cell degeneration develops.

There is currently no approved treatment which slows or stops the progression of multiple forms of RP. Proposed treatments for RP include gene-replacement therapy, retinal implant devices, retinal transplantation, stem cells, vitamin therapy, and other

pharmacological treatments. Gene-replacement therapies are promising but are limited to treating just a single mutation and therefore cannot address the multiple mutations implicated by RP. In addition, while gene therapies may provide a new functional gene, they do not necessarily eliminate the underlying genetic defect which may still cause stress and toxic effects. Therefore, the development of gene specific replacement therapy is highly challenging, especially when multiple and unknown genes are involved.

Similar to RP, no or minimal treatment options are available for a large number of other retinal degenerative diseases including dry AMD and LCA. AMD is a degeneration of the macula of the retina that leads to impairment and loss of central vision. AMD is characterized by thickening and loss of normal architecture within the Bruch's membrane, lipofuscin accumulation in the retinal pigment epithelium ("RPE"), and drusen formation beneath the RPE in the Bruch's membrane. These deposits consist of complement components, other inflammatory molecules, lipids, lipoproteins B and E, and glycoproteins. Dry AMD involves the slow deterioration of the retina with submacular drusen, atrophy, loss of macular function, and central vision impairment. LCA is a group of IRDs characterized by severe impairment of vision or blindness at birth. LCA is caused by a degeneration and/or dysfunction of photoreceptors in the eye. Luxturna has been approved to treat LCA caused by retinoid isomerohydrolase ("*RPE65*") gene mutations. No treatment options have been approved by the FDA for LCA caused by mutation in other LCA causing genes.

As a result, there remains a significant unmet medical need for a treatment with application across multiple genetic forms of RP as well as other ocular degenerative diseases, such as dry AMD and LCA.

OCU400 for Inherited Retinal Disorders

OCU400 is our first product candidate being developed with our modifier gene therapy platform. OCU400 is a novel gene therapy product candidate with the potential to be broadly effective in restoring retinal integrity and function across a range of genetically diverse IRDs. OCU400 comprises a functional copy of a NHR gene, *NR2E3*, delivered to target cells in the retina using an AAV vector that has the potential to be used as a gene therapeutic not only for the treatment of retinal diseases associated with mutations in genes such as *NR2E3*, *RHO*, *CEP290*, and *PDE6ß*, but also other gene mutations associated with IRDs, including RP and LCA. As a potent modifier gene, expression of *NR2E3* within the retina may help reset retinal homeostasis, potentially stabilizing cells and rescuing photoreceptor degeneration. OCU400 has received four ODDs from the FDA for the treatment of the following disease genotypes: *NR2E3*, *RHO*, *CEP290*, and *PDE6ß* mutation-associated inherited retinal degenerations. OCU400 additionally received OMPD from the European Commission, based on the recommendation of the EMA, for RP and LCA in February 2021, which we believe further supports the potential broad spectrum application of OCU400 to treat many IRDs.

We completed the preclinical studies in multiple animal models of RP using the mouse NHR gene, *Nr2e3*. In five unique mouse models of RP, treatment with the AAV-*NR2E3* gene by subretinal injection effectively prevented the further development of multiple genetically diverse IRDs by protecting photoreceptors from further damage after disease onset. We have completed pilot toxicology studies in the large animal model and have started Good Laboratory Practice ("GLP") toxicology studies and non-GLP biodistribution studies. We have also successfully completed current Good Clinical Practice ("GCP") manufacturing at commercial scale (200 liters) for Phase 1/2a clinical supplies. After the completion of GLP toxicology studies, we are planning to file the IND application to initiate Phase 1/2a clinical trials.

OCU410 for the Treatment of Dry AMD

OCU410 is being developed for the treatment of dry AMD and is our second product candidate using a second candidate gene from our modifier gene therapy platform. OCU410 utilizes an AAV vector for the retinal delivery of the *RORA* gene. Various genes with AMD are regulated by *RORA*, which plays a role in numerous indications including the pathology of dry AMD. The RORA protein plays an important role in lipid metabolism and demonstrated an anti-inflammatory role, which we believe could be a potential therapeutic candidate for dry AMD. OCU410 is currently in preclinical development.

NOVEL BIOLOGIC PRODUCT CANDIDATE FOR RETINAL DISEASES

OCU200 is our novel biologic product candidate in preclinical development. OCU200 is a novel fusion protein designed to treat DR, DME, and wet AMD. We had a pre-IND meeting with the FDA in November 2020 and received guidance on IND-enabling preclinical studies to support the anticipated Phase 1/2a clinical trial. We expect to initiate IND-enabling preclinical studies for OCU200 in 2021. We plan to initiate a Phase 1/2a clinical trial for OCU200 in 2022.

Overview of DR and DME

DR is a complication from diabetes arising from the over-accumulation of glucose, which can block blood vessels in the retina and cut off the blood supply, leading to damage to the blood vessels in the retina. DR is classified as two subtypes: non-proliferative DR and proliferative DR. Non-proliferative DR is the early stage in which blood vessels are not able to grow, blood vessel walls weaken, and nerve fibers in the retina may swell. Proliferative DR is the advanced stage in which damaged blood vessels are closed off, leading to growth of new abnormal blood vessels in the retina. This growth of new abnormal blood vessels in the retina can lead to scar tissue, which can result in the detachment of the retina from the back of the eye.

Complications from DR could lead to DME. In DME, bulges can protrude from the vessel walls, leading to the leakage of fluid and blood into the retina. This leakage results in swelling, or “edema,” in the central part of the retina, the macula, which is the region primarily responsible for central and color vision. DME may occur at any stage of DR, but is more likely to occur later in the disease progression. DME is the most common reason for vision loss for patients with DR.

DR and DME are the most common vision-threatening diseases occurring in diabetic patients. Approximately 7.7 million people are affected with DR and approximately 0.7 million with DME in the United States. The number of people affected by DR and DME is expected to increase as the number of diabetic patients increases, due to poor disease management and lifestyle-related changes.

Currently there are limited treatment options available for DR and DME patients and a significant unmet need for the development of safe and effective therapies. Current first-line treatments for DR and DME include laser photocoagulation, use of anti-vascular endothelial growth factor ("VEGF") therapy, and corticosteroids which are sub-optimally active in these patients. Anti-VEGF therapy and corticosteroids do not work effectively in approximately 50% of patients.

Additionally, current therapies target only one pathway associated with DR and DME, either angiogenesis (development of new blood vessels) with anti-VEGF therapy or inflammation in case of corticosteroid therapy. The development of a therapeutic which targets multiple causative pathways of DR and DME, such as angiogenesis, oxidation, and inflammation, would offer the best treatment option for all of these patients. We believe that OCU200 possesses unique characteristics to target these pathways and has the potential to offer better treatment options for all patients.

Overview of Wet AMD

OCU200 also has the potential to represent a superior treatment option for patients suffering from wet AMD. Most AMD cases begin as dry AMD and may progress towards the advanced “wet” form, which is characterized by penetration of abnormal blood vessels in the retina that leak blood and proteins. The result can be irreversible damage to photoreceptor cells and rapid, severe vision loss, particularly in the center of the field of vision, causing significant function impairment. If left untreated, neovascularization in wet AMD patients typically results in significant vision loss and the formation of a scar under the macular region of the retina. Wet AMD accounts for 90% of all AMD-related blindness.

Wet AMD is a leading cause of blindness in people over the age of 55 in the United States and the European Union. The incidence of wet AMD increases substantially with age, and we expect that the number of cases of wet AMD will increase with the growth of the elderly population in the United States. It has been estimated that approximately 11.0 million patients in the United States have some form of AMD of which, approximately 1.1 million, or 10%, suffer from wet AMD. Approximately 200,000 new cases of wet AMD are diagnosed each year in the United States.

Current therapies for wet AMD focus on reducing neovascularization through the inhibition of a single key regulator, VEGF. Current FDA approved therapeutics for wet AMD include intravitreal injection of either Lucentis or Eylea, which target VEGF. Bevacizumab (Avastin), the parent antibody from which ranibizumab was derived, is also used as an off-label treatment. Though these products have been effective in mitigating the disease symptoms, they have substantial limitations as demonstrated in clinical studies. For example, a significant percentage of patients do not respond to therapy and experience continuous deterioration of their vision. Additionally, the long-term, repeated dosing of anti-VEGF therapy results in reduced effectiveness and approximately 30-50% patients continue to show fluid persistence in the subretinal space, even after one to two years of treatment.

Given the above limitations of these existing treatments, we believe that a substantial unmet medical need still exists for the treatment of DR, DME, and wet AMD.

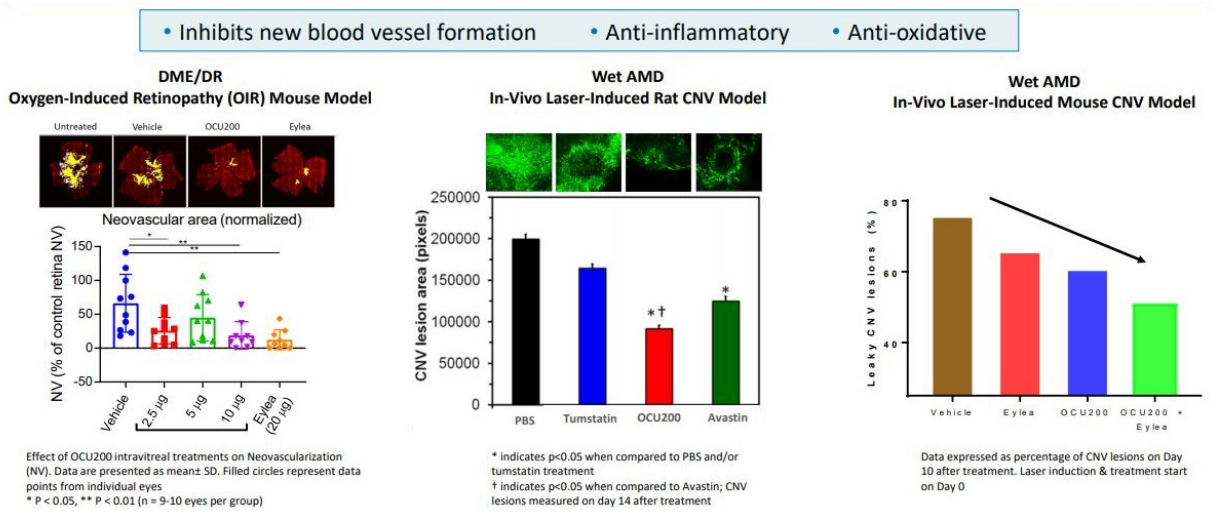
OCU200 for the Treatment of DR, DME, and Wet AMD

OCU200 is being developed to treat severely sight-threatening diseases like DR, DME, and wet AMD. Patients affected by these diseases share common symptoms, such as blurriness in vision and progressive vision loss through disease progression. The formation of fragile and leaky new abnormal blood vessels leads to fluid accumulation in and around the retina, causing vision damage.

OCU200 is a novel fusion protein consisting of two human proteins, tumstatin and transferrin, that are already present normally in retinal tissues. OCU200 possesses unique features which enable it to efficiently target leaky blood vessels, regress the existing abnormal blood vessels, and inhibit the growth of new blood vessels in the retina and choroid. Tumstatin, which acts as an anti-VEGF, anti-inflammatory, and anti-oxidative agent, is the active component of OCU200. It binds to integrin receptors, which play a crucial role in disease pathogenesis. Transferrin facilitates the targeted delivery of tumstatin into the retina and choroid and potentially helps increase the interaction between tumstatin and integrin receptors. OCU200 is designed to address the limitations of current therapies by targeting multiple mechanisms associated with ocular neovascularization and inflammation specifically focusing on non-responders to currently available treatment options.

OCU200 demonstrated efficacy in an in-vitro cell culture model where it inhibited new vessel formation. In an animal model for DME and DR (oxygen-induced retinopathy in mice), OCU200 demonstrated comparable efficacy at a significantly lower dose (10 micrograms per eye) compared to existing approved therapy (Eylea, 20 micrograms per eye) in preventing disease manifestation and progression (**Figure 11**). In animal models for wet AMD (laser induced choroidal neovascularization in mice and rats), OCU200 demonstrated comparable or slightly better activity compared to anti-VEGF control groups in preventing the formation and growth of new leaky blood vessels and subsequent disease symptoms (**Figure 11**).

Figure 11 OCU200 Demonstrated Efficacy in Animal Models for DR, DME, and Wet AMD.



COMPETITION

The biopharmaceutical industry is characterized by rapidly advancing technologies as well as a strong emphasis on intellectual property leading to a highly competitive environment for the development and commercialization of new vaccines and therapeutic products. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future. We face competition from many different sources, including from major pharmaceutical companies, specialty 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.

We face, and will continue to face, intense competition from companies as well as institutions pursing research and development of vaccines, technologies, drugs, or other therapies that would compete with COVAXIN, if authorized and approved in the United States. Our competitors may develop vaccines or effective therapies or other treatment for COVID-19

more rapidly or more effectively than us. The competitive landscape of potential COVID-19 vaccines and therapies has been rapidly developing since the beginning of the COVID-19 pandemic, with several hundreds of companies claiming to be investigating possible candidates and more than 5,000 studies registered worldwide as investigating COVID-19. We are aware of several competitors developing late-stage COVID-19 vaccines, including Pfizer Inc./BioNTech SE, Moderna, Inc., AstraZeneca PLC, Johnson & Johnson/Janssen Biotech, Inc., and Novavax, Inc. Vaccines developed by Pfizer Inc./BioNTech SE, Moderna, Inc., and Johnson & Johnson/Janssen Biotech have already been granted EUAs by the FDA. We are also aware of others pharmaceutical companies that are working on inactivated virus-based COVID-19 vaccines. Furthermore, the FDA has authorized and many companies are developing therapeutics to treat COVID-19.

The development and commercialization of new therapeutic products is also highly competitive. We are aware of several companies focusing on gene therapies for various ophthalmic indications, including Adverum Biotechnologies, Inc., Applied Genetic Technologies Corporation, MeiraGTx Holdings plc, IVERIC bio, Inc., REGENXBIO Inc., ProQR Therapeutics N.V., Generation Bio Co, Greybug Vision, Inc., and Spark Therapeutics, Inc. (acquired by the Roche Group in 2019). Spark Therapeutics' product Luxturna, which is currently the only gene therapy approved for an IRD in the United States, addresses only one out of at least 150 known mutations of the *RPE65* gene. Companies that may compete with our OCU200 product candidate include the Roche Group, Regeneron Pharmaceuticals, Inc., Novartis AG, and Kodiak Sciences Inc. The Roche Group, Regeneron Pharmaceuticals, Inc., and Novartis AG have marketed anti-VEGF products.

Many of our competitors, either alone or with strategic partners, may have significantly greater financial resources to support research and development, manufacturing, preclinical testing, and clinical trials, as well as regulatory and marketing efforts. These organizations also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, patient registration for clinical trials, and in acquiring technologies necessary for our programs. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

MANUFACTURING

We utilize our in-house expertise and know-how to develop and scale up the manufacturing processes before these processes are transferred to third-party contract manufacturers and testing labs to understand and establish controls of critical process parameters and critical quality attributes. We also have personnel with deep product development experience who actively manage the third-party contract manufacturers producing products that are in our development and commercialization pipeline. In addition, our strategic partners CanSinoBIO and Bharat Biotech have state-of-the-art facilities with significant expertise in manufacturing.

Clinical and Commercial Supply of COVAXIN

In February 2021, we entered into the Covaxin Agreement with Bharat Biotech, pursuant to which we will be responsible for the manufacture of COVAXIN for the Ocugen Covaxin Territory. Bharat Biotech has agreed to provide to us all pre-clinical and clinical data, and to transfer to us certain proprietary technology owned or controlled by Bharat Biotech, that is necessary for the successful commercial manufacture and supply of COVAXIN to support commercial sale in the Ocugen Covaxin Territory, including pursuant to any EUA for the Ocugen Covaxin Territory approved by the FDA. In certain circumstances set forth in the Covaxin Agreement, and until we are capable and primarily responsible for the manufacture and supply of COVAXIN for the Ocugen Covaxin Territory, Bharat Biotech has the exclusive right to manufacture COVAXIN for the Ocugen Covaxin Territory and is responsible for manufacturing and supplying clinical testing materials required for our development activities, and all of our requirements of commercial quantities of COVAXIN.

Bharat Biotech has agreed to provide a specified minimum number of doses in calendar year 2021. We and Bharat Biotech will enter into supply agreements setting forth the terms of such supply. We are currently evaluating manufacturing opportunities for COVAXIN in anticipation of the technology transfer from Bharat Biotech. We are in active discussions with manufacturers in the United States to produce a significant number of doses of COVAXIN to support commercialization of the vaccine in the United States, if authorized or approved. For more information, see “—License and Development Agreements—Covaxin Agreement” and see Note 16 in the notes to the consolidated financial statements included in this report.

Clinical Supply of OCU400

In September 2019, we entered into a co-development and commercialization agreement (the “CanSinoBIO Agreement”) with CanSinoBIO with respect to the development and commercialization of the gene therapy product candidate, OCU400, with respect to certain disease indications (the “OCU400 Field”). The CanSinoBIO Agreement also grants CanSinoBIO an exclusive

option (the “Option”) to obtain a non-exclusive license from us to manufacture Products (defined below) in the OCU400 Field in the CanSinoBIO Territory (defined below) for commercial sale by us or our affiliates in the Ocugen OCU400 Territory (defined below) but not including the United States, subject to the terms of a supply agreement to be negotiated by us and CanSinoBIO upon CanSinoBIO’s exercise of the Option. CanSinoBIO will have an exclusive license under our intellectual property and intellectual property jointly developed by CanSinoBIO and us (the “Joint IP”) to develop, manufacture, and commercialize products containing OCU400 (“Products”) in the OCU400 Field in and for China, Hong Kong, Macau, and Taiwan (the “CanSinoBIO Territory”) and we will maintain exclusive development, manufacturing, and commercialization rights under our intellectual property and have an exclusive license under the Joint IP with respect to Products in the OCU400 Field in and for any global location outside the CanSinoBIO Territory (the “Ocugen OCU400 Territory”). CanSinoBIO will be responsible for all costs for CMC development and manufacture of clinical supplies of OCU400 for all territories. CanSinoBIO will be solely responsible for all costs and expenses of its development activities in the CanSinoBIO Territory and we will be responsible for all costs and expenses of our development activities in the Ocugen OCU400 Territory. CanSinoBIO will pay us an annual royalty between mid-to-high single digits based on net sales of Products in the CanSinoBIO Territory, and we will pay to CanSinoBIO an annual royalty between low-to-mid single digits based on net sales of Products in the Ocugen OCU400 Territory. See Note 4 in the notes to the consolidated financial statements included in this report for additional information.

Clinical Supply of OCU200

In October 2020, we entered into a manufacturing agreement with a contract manufacturing organization for the manufacture of OCU200, our novel biologics product candidate for the treatment of DME, DR, and wet AMD. Under the manufacturing agreement, our manufacturer will manage all CMC and clinical manufacturing activities as well as provide supplies for IND-enabling preclinical studies and our planned Phase 1/2a clinical trials.

LICENSE AND DEVELOPMENT AGREEMENTS

We are party to license agreements under which we license or co-own patents, patent applications, technical information, and other intellectual property for our product candidates: COVAXIN, OCU400, OCU410, and OCU200. Certain diligence and financial obligations are tied to these agreements. We consider the following agreements to be material to our business.

Covaxin Agreement

In February 2021, we entered into the Covaxin Agreement with Bharat Biotech to co-develop COVAXIN, a whole-virion inactivated COVID-19 vaccine being developed to prevent COVID-19 infection, for the U.S. market.

Pursuant to the Covaxin Agreement, we obtained an exclusive right and license under certain of Bharat Biotech’s intellectual property rights, with the right to grant sublicenses, to develop, manufacture, and commercialize COVAXIN, a whole-virion inactivated vaccine candidate, for the prevention of COVID-19 in humans in the Ocugen Covaxin Territory. In consideration of the license and other rights granted by Bharat Biotech to us, we and Bharat Biotech agreed to share any profits generated from the commercialization of COVAXIN in the Ocugen Covaxin Territory, with us retaining 45% of such profits, and Bharat Biotech receiving the balance of such profits.

Under the Covaxin Agreement, we and Bharat Biotech will collaborate to develop COVAXIN for our respective territories. Except with respect to U.S. manufacturing under certain circumstances as described below, we have the exclusive right and are solely responsible for researching, developing, manufacturing, and commercializing COVAXIN for the Ocugen Covaxin Territory. Bharat Biotech has the exclusive right and is solely responsible for researching, developing, manufacturing, and commercializing COVAXIN outside of the Ocugen Covaxin Territory.

Bharat Biotech has agreed to provide to us all pre-clinical and clinical data, and to transfer to us certain proprietary technology owned or controlled by Bharat Biotech, that is necessary for the successful commercial manufacture and supply of COVAXIN to support commercial sale in the Ocugen Covaxin Territory, including pursuant to any EUA for the Ocugen Covaxin Territory approved by the FDA. Bharat Biotech has agreed to manufacture our supply of COVAXIN pending completion of a technology transfer described in the Covaxin Agreement and has agreed to provide a specified minimum number of doses in calendar year 2021. For more information, see “—Manufacturing—Clinical and Commercial Supply of COVAXIN” and see Note 16 in the notes to the consolidated financial statements included in this report.

License Agreement with The Schepens Eye Research Institute, Inc.

In December 2017, we entered into an exclusive license agreement with SERI, which was amended in January 2021 (as so amended the "SERI Agreement"). The SERI Agreement gives us an exclusive, worldwide, sublicensable license to patent

rights, biological materials and technical information for NHR genes *NR1D1*, *NR2E3* (OCU400), *RORA* (OCU410), Nuclear Protein 1, Transcriptional Regulator ("*NUPR1*"), and Nuclear Receptor Subfamily 2 Group C Member 1 ("*NR2C1")*. The January 2021 amendment to the SERI Agreement additionally grants us rights in co-owned intellectual property pursuant certain patent applications and provisional patent applications. Under the SERI Agreement, we may make, have made, use, offer to sell, sell, and import licensed products. Under this agreement, we must use commercially reasonable efforts to bring one or more licensed products to market as soon as reasonably practicable.

We have made payments of $0.2 million to SERI pursuant to the terms of the SERI Agreement since the SERI Agreement inception. The SERI Agreement requires us to pay licensing fees for patent rights granted, an annual license maintenance fee, payment of certain regulatory and commercial milestones in the aggregate amount of $16.1 million, and low single-digit percentage royalties on annual net sales of products that fall under the licensed patent rights.

SERI maintains control of patent preparation, filing, prosecution, and maintenance. We are responsible for SERI's out-of-pocket expenses related to the filing, prosecution, and maintenance of the licensed patent rights. In the event that SERI decides to discontinue the prosecution or maintenance of the licensed patent rights, we have the right, but not the obligation, to file for, or continue to prosecute, maintain, or enforce such licensed patent rights. See Note 4 in the notes to the consolidated financial statements included in this report for additional information.

License Agreement with University of Colorado

In March 2014, we entered into an exclusive license agreement with CU, which was amended in January 2017 and clarified by a letter of understanding in November 2017 (as so amended and clarified, the "CU Agreement"). The CU Agreement gives us an exclusive, worldwide, sublicensable license to patents for OCU200 to make, have made, use, import, offer to sell, sell, have sold, and practice the licensed products in all therapeutic applications. Under the CU Agreement, we must use commercially reasonable efforts to develop, manufacture, sublicense, market, and sell the licensed products. Under the agreement, we have assumed primary responsibility for preparing, filing, and prosecuting broad patent claims for OCU200 for CU's benefit. Further, we have assumed primary responsibility for all patent activities, including all costs associated with the perfection and maintenance of the patents for OCU200.

We have made payments of $0.1 million to CU and issued 0.1 million shares of common stock to CU since the CU Agreement's inception pursuant to the terms of the CU Agreement. The CU Agreement requires the payment for certain regulatory milestones aggregating to $1.5 million, an annual minimum payment beginning the third year after the effective date, low single-digit percentage earned royalties on net sales, and royalties in the mid-teens on sublicense income of OCU200. See Note 4 in the notes to the consolidated financial statements included in this report for additional information.

INTELLECTUAL PROPERTY

We have applied, obtained, and licensed patent protection for our product candidates. We intend to maintain and defend our intellectual property rights to protect our technology, inventions, processes, and improvements that are commercially important to the development of our business. There is no guarantee that any of our current or future intellectual property will advance the commercial success of our product candidates. There is also no guarantee patents will be issued or registered for any pending patent applications or patent applications that we may file in the future. Our commercial success also depends in part on our non-infringement of the patents and proprietary rights of third parties.

As of March 1, 2021, our patent portfolio included a total of eight issued patents in the United States, 37 issued or registered patents in foreign countries, three pending patent applications in the United States, and nine pending patent applications in foreign countries. Our issued or registered patents and pending patent applications include those licensed from SERI and CU. Certain pending patent applications cover multiple of our product candidates. Our intellectual property includes compositions of matter, methods of use, product candidates, and other proprietary technology. As of March 1, 2021, we had exclusive rights or owned rights to: (i) one issued U.S. patent, two pending U.S. patent applications, and four pending foreign patent applications related to OCU400; (ii) two pending U.S patent applications and four pending foreign patent applications related to OCU410; and (iii) one issued U.S. patent, 24 issued or registered foreign patents, one pending U.S. patent application, and six pending foreign patent applications related to OCU200. In February 2021, we entered into the Covaxin Agreement with Bharat Biotech, pursuant to which we obtained an exclusive right and license under certain of Bharat Biotech's intellectual property rights, with the right to grant sublicenses, to develop, manufacture, and commercialize COVAXIN, a whole-virion inactivated vaccine candidate, for the prevention of COVID-19 in the Ocugen Covaxin Territory. In some instances, we may need to license additional patents and trade secrets to commercialize our product candidates in certain territories.

In addition to patents, we may rely, in some circumstances, on trade secrets to protect our technology. We seek to protect our proprietary technology and processes, and obtain and maintain ownership of certain technologies, in part, by confidentiality and invention assignment agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

GOVERNMENT REGULATION AND PRODUCT APPROVAL

Government authorities in the United States, at the federal, state, and local level, and in other countries, extensively regulate, among other things, the research, development, testing, approval, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, sales, import, and export of biopharmaceutical and drug products such as those we are developing. In addition, labelers of biopharmaceutical and drug products (the entity owning the National Drug Code listed for a product) participating in Medicaid and Medicare are required to comply with mandatory price reporting, discount, rebate, and other requirements. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA Regulation

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations. In addition to the FDCA and its implementing regulations, biologic products are regulated under the Public Health Service Act (“PHSA”) and its implementing regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in compliance with the FDA’s GLP regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin at U.S. clinical trial sites;
- approval by an Institutional Review Board (“IRB”) for each clinical site, or centrally, before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy, in the case of a drug product candidate, or safety, purity, and potency, in the case of a biologic product candidate for its intended use, performed in accordance with GCPs;
- development of manufacturing processes to ensure the product candidate’s identity, strength, quality, purity, and potency;
- submission to the FDA of a New Drug Application ("NDA"), in the case of a drug product candidate, or BLA, in the case of a biologic product candidate;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the products are produced to assess compliance with current GMPs, and to assure that the facilities, methods, and controls are adequate to preserve the therapeutics’ identity, strength, quality, purity, and potency as well as satisfactory completion of an FDA inspection of selected clinical sites, selected clinical investigators to determine GCP compliance; and payment of user fees; and
- FDA review and approval of the NDA or BLA to permit commercial marketing for particular indications for use.

Preclinical Studies and IND Submission

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with the FDA’s GLPs. Prior to commencing the first clinical trial at a U.S. investigational site with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols among other things, to the FDA as part of an IND.

An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical Trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval of the study by an IRB. Investigators must also provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety, the effectiveness criteria to be evaluated, and a statistical analysis plan. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND. If a product candidate is being investigated for multiple intended indications, separate INDs may also be required. In addition, an IRB at each study site participating in the clinical trial and/or a central IRB must review and approve the plan for any clinical trial, informed consent forms, and communications to study subjects before a study commences at that site. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits, and whether the planned human subject protections are adequate. The IRB must continue to oversee the clinical trial while it is being conducted. Progress reports detailing the results of the clinical trials must also be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events or other significant safety information is found.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements or if the trial poses an unexpected serious harm to subjects. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to subjects, a lack of favorable results, or changing business priorities.

Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health ("NIH") for public dissemination on their *clinicaltrials.gov* website. Sponsors or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

The manufacture of investigational drugs and biologics for the conduct of human clinical trials is subject to current GMP requirements. Investigational drugs and biologics and active ingredients and therapeutic substances imported into the United States are also subject to regulation by the FDA. Further, the export of investigational products outside of the United States is subject to regulatory requirements of the receiving country, as well as U.S. export requirements under the FDCA.

In general, for purposes of NDA and BLA approval, human clinical trials are typically conducted in three sequential phases, which may overlap or be combined.

- *Phase 1*—Studies are initially conducted in healthy human volunteers or subjects with the target disease or condition to test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution, and excretion. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.
- *Phase 2*—Controlled studies are conducted in limited subject populations with a specified disease or condition to evaluate preliminary efficacy, identify optimal dosages, dosage tolerance and schedule, possible adverse effects and safety risks, and expanded evidence of safety.
- *Phase 3*—These adequate and well-controlled clinical trials are undertaken in expanded subject populations, generally at geographically dispersed clinical trial sites, to generate enough data to provide statistically significant evidence of clinical efficacy and safety of the product candidate for approval, to establish the overall risk-benefit profile of the product candidate, and to provide adequate information for the labeling of the product candidate. Typically, two Phase 3 trials are required by the FDA for product approval. Under some limited circumstances, however, the FDA may approve an NDA or BLA based upon a single Phase 3 clinical study.

The FDA may also require, or companies may conduct, additional clinical trials for the same indication after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm or refute the effectiveness of a product candidate, and can provide important safety information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with current GMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, manufacturers must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

There are also various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

Marketing Application Submission, Review by the FDA, and Marketing Approval

Assuming successful completion of the required clinical and preclinical testing, the results of product development, including CMC, non-clinical studies, and clinical trial results, including negative or ambiguous results, as well as positive findings, are all submitted to the FDA, along with the proposed labeling, as part of an NDA, in the case of a drug, or BLA, in the case of a biologic, requesting approval to market the product for one or more indications. In most cases, the submission of a marketing application is subject to a substantial application user fee. These user fees must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in certain circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application. Product candidates that are designated as orphan products, which are further described below, are also not subject to application user fees unless the application includes an indication other than the orphan indication.

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or NDA or supplement to a BLA or NDA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration, must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Orphan products are also exempt from the PREA requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy (“REMS”) to ensure that the benefits of the product candidate outweigh the risks. The REMS plan could include medication guides, physician communication plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. An assessment of the REMS must also be conducted at set intervals. Following product approval, a REMS may also be required by the FDA if new safety information is discovered and the FDA determines that a REMS is necessary to ensure that the benefits of the product continue to outweigh the risks.

Once the FDA receives an application, it has 60 days to review the NDA or BLA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. The FDA may request additional information. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (“PDUFA”), the FDA has set the review goal of completing its review of 90% of all applications for new molecular entities within 10 months of the 60-day filing date. The FDA also has the review goal of completing its review of 90% of non-new molecular entity marketing applications within 10 months of the agency’s receipt of the application. These review goals are referred to as the PDUFA date. The PDUFA date is only a goal, thus, the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the sponsor otherwise provides substantial additional information or clarification regarding the submission.

The FDA may also refer certain applications to an advisory committee. Before approving a product candidate for which no active ingredient (including any ester or salt of an active ingredients) has previously been approved by the FDA, the FDA must either refer that product candidate to an external advisory committee or provide in an action letter, a summary of the reasons why the FDA did not refer the product candidate to an advisory committee. The FDA may also refer other product candidates to an advisory committee if FDA believes that the advisory committee's expertise would be beneficial. An advisory committee is typically a panel that includes clinicians and other experts, which review, evaluate, and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product candidate meets the agency's approval standards and whether the manufacturing methods and controls are adequate to assure and preserve the product's identity, strength, quality, potency, and purity. Before approving a marketing application, the FDA typically will inspect the facility or facilities where the product is manufactured, referred to as a Pre-Approval Inspection. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontractors, are in compliance with current GMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving a marketing application the FDA will inspect one or more clinical trial sites to assure compliance with GCPs.

After evaluating the marketing application and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter ("CRL"). A CRL indicates that the review cycle for the application is complete and the application is not ready for approval. It also describes all of the specific deficiencies that the FDA identified. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the marketing application, and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes; or major, for example, requiring additional clinical trials. If a CRL is issued, the applicant may either: resubmit the marketing application, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. The FDA has the goal of reviewing 90% of application resubmissions following a CRL in either two or six months of the resubmission date, depending on the kind of resubmission. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications or populations for use of the product, require that contraindications, warnings, or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product's safety and efficacy after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may also not approve label statements that are necessary for successful commercialization and marketing.

After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval. The FDA may also withdraw the product approval if compliance with the pre- and post-marketing regulatory standards are not maintained or if problems occur after the product reaches the marketplace. Further, should new safety information arise, additional testing, product labeling changes, or FDA notification may be required.

Emergency Use Authorization

The speed at which all parties are moving to create, test, and obtain authorization or approval of a vaccine for COVID-19 in the United States is highly unusual, and evolving or changing plans or priorities at the FDA, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory pathway and timeline for COVAXIN authorization or approval in the United States. COVAXIN was granted approval for emergency use in India. A Phase 3 clinical trial is ongoing in India. The FDA may not accept data from the studies conducted with COVAXIN at clinical trial sites in India and may require us to conduct clinical studies in the United States before considering an application for an EUA. Results from clinical testing may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. In addition, the FDA's analysis of any clinical data may differ from our interpretation and the FDA may require that we conduct additional analysis or trials.

The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. If we are granted an EUA for COVAXIN in the United States, we would be able to commercialize COVAXIN without FDA approval. The EUA is only effective for the duration of the COVID-19 public health emergency. The FDA may revoke or terminate the EUA sooner if, for example, we fail to comply with the conditions of authorization or other terms of the EUA or our vaccine is determined to be less effective or safe than it was initially believed to be. We cannot predict how long, if ever, an EUA would remain in place.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity for both drugs and biologics, and also Orange Book listed patents in the case of drugs. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform and reporting on the requested studies within the statutory timeframe.

Orphan Products

The Orphan Drug Act provides incentives for the development of products for rare diseases or conditions. Specifically, sponsors may apply for and receive ODD if a product candidate is intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the United States, or affecting more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States will be recovered from U.S. sales. ODD must be requested before submitting an NDA or BLA. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain ODD if there is a product already approved by the FDA that is considered by the FDA to be the same as the already approved product and is intended for the same indication. This hypothesis must be demonstrated to obtain orphan exclusivity. If granted, prior to product approval, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and certain user-fee waivers. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act. In addition, if a product candidate receives FDA approval for the indication for which it has ODD, the product is generally entitled to orphan exclusivity, which means the FDA may not approve any other application to market the same product for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. After the FDA grants ODD, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. ODD does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive FDA approval for a particular active moiety to treat a particular disease with FDA ODD is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with Orphan Drug exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of ODD are tax credits for certain research activities and a waiver of the NDA or BLA application user fee.

Patent Term Restoration

If approved, drug and biologic products may also be eligible for periods of U.S. patent term restoration. If granted, patent term restoration extends the patent life of a single unexpired patent, that has not previously been extended, for a maximum of five years. The total patent life of the product with the extension also cannot exceed fourteen years from the product’ approval date. Subject to the prior limitations, the period of the extension is calculated by adding half of the time from the effective date of an IND to the initial submission of a marketing application, and all of the time between the submission of the marketing application and its approval. This period may also be reduced by any time that the applicant did not act with due diligence.

Special FDA Expedited Review and Approval Programs

The FDA has various programs that are intended to expedite or simplify the process for the development and FDA review of certain products that are intended for the treatment of serious or life threatening diseases or conditions, and demonstrate the potential to address unmet medical needs or present a significant improvement over existing therapy. The purpose of these programs is to provide important new therapeutics to patients earlier than under standard FDA review procedures.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product candidate is intended to treat a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need. If Fast Track designation is obtained, sponsors may be eligible for more frequent development meetings and correspondence with the FDA. In addition, the FDA may initiate review of sections of an application before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information. Whether the FDA is able to commence its review of portions of an application, however, before receipt of the complete submission, depends on a number of factors. In some cases, a Fast Track product may be eligible for accelerated approval or priority review.

The FDA may give a priority review designation to product candidates that are intended to treat serious conditions and, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of the serious condition. A priority review means that the goal for the FDA is to review an application within six months, rather than the standard review of 10 months under current PDUFA guidelines.

Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means the FDA may approve the product based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. A drug or biologic candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect of the product. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug or biologic from the market on an expedited basis. All promotional materials for drug or biologic candidates approved under accelerated regulations are subject to prior review by the FDA.

Under the provisions of the Food and Drug Administration Safety and Innovation Act, enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies are eligible for intensive guidance on an efficient development program beginning as early as Phase 1 trials, a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative and cross-disciplinary review, rolling review, and the facilitation of cross-disciplinary review.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements related to manufacturing, recordkeeping, and reporting, including adverse experience reporting, deviation reporting, shortage reporting, and periodic reporting, product sampling and distribution, advertising, marketing, promotion, certain electronic records and signatures, and post-approval obligations imposed as a condition of approval, such as Phase 4 clinical trials, REMS, and surveillance to assess safety and effectiveness after commercialization.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing annual program user fee requirements for approved products, excluding orphan products. In addition, manufacturers and other entities involved in the manufacture and distribution of approved therapeutics are required to register their establishments with the FDA and certain state agencies, list their products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with current GMP and other requirements. Manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with current GMPs. Regulatory authorities may undertake regulatory enforcement action, withdraw product approvals, require label modifications, or request product recalls, among other actions, if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval or notification before being implemented. FDA regulations also require investigation and correction of any deviations from current GMP and specifications,

and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain current GMP compliance.

The FDA also strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. A company can make only those claims relating to a product that are approved by the FDA. Physicians, in their independent professional medical judgment, may prescribe legally available products for unapproved indications that are not described in the product's labeling and that differ from those tested and approved by the FDA. Biopharmaceutical companies, however, are required to promote their products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including, but not limited to, criminal and civil penalties under the FDCA and False Claims Act ("FCA"), exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts.

In addition, the distribution of prescription biopharmaceutical samples is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of samples at the federal level. Both the PDMA and state laws limit the distribution of prescription biopharmaceutical product samples and impose requirements to ensure accountability in distribution. Free trial or starter prescriptions provided through pharmacies are also subject to regulations under the Medicaid Drug Rebate Program and potential liability under anti-kickback and false claims laws.

Moreover, the enacted Drug Quality and Security Act imposes obligations on sponsors of biopharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, sponsors are required to provide certain information regarding the products to individuals and entities to which product ownership is transferred, are required to label products with a product identifier, and are required to keep certain records regarding the product. The transfer of information to subsequent product owners by sponsors is also required to be done electronically. Sponsors must also verify that purchasers of the sponsors' products are appropriately licensed. Further, under this legislation, manufactures have product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences or 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. Similar requirements additionally are and will be imposed through this legislation on other companies within the biopharmaceutical product supply chain, such as distributors and dispensers, as well as certain sponsor licensees and affiliates.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in significant regulatory actions. Such actions may include refusal to approve pending applications, license or approval suspension or revocation, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, suspension and debarment from government contracts, refusal of orders under existing government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, civil or criminal penalties including fines and imprisonment, and adverse publicity, among other adverse consequences.

Additional controls for biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of the product to the FDA together with a release protocol showing the results of all of the manufacturer's tests performed on the lot. The FDA

may also perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer.

In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Gene therapy products are also subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, which require, among other things, that trials involving recombinant or synthetic nucleic acid molecules be reviewed by an Institutional Biosafety Committee ("IBC"). The IBC reviews, approves, and supervises research involving recombinant or synthetic nucleic acid molecules.

In addition to the regulations discussed above, there are a number of additional standards that apply to clinical trials involving the use of gene therapy. The FDA has issued various guidance documents regarding gene therapies, which outline additional factors that the FDA will consider during product development. By example, the FDA recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a prolonged period of time.

Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations

Our business activities, including but not limited to, research, marketing, sales, promotion, distribution, medical education, and other activities following product approval will be subject to regulation by numerous federal and state regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services and its various divisions, including the Centers for Medicare and Medicaid Services ("CMS") and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense, and state and local governments. Our business activities must comply with numerous healthcare laws, including but not limited to, anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations, which are described below, as well as state and federal consumer protection and unfair competition laws. Moreover, to the extent that we license the right to sell our product candidates, if approved, to another entity under that entity's labeler code, the licensee would have regulatory responsibilities, including healthcare, reimbursement, pricing, and reporting regulatory responsibilities.

The federal Anti-Kickback Statute, which regulates, among other things, marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order, or the referral to another for the furnishing or arranging for the furnishing of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs, in whole or in part. The term "remuneration" has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical industry members on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. There are certain statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of a federal healthcare covered business, including purchases of products paid by federal healthcare programs, the statute has been violated. The Patient Protection and Affordable Care Act of 2010, as amended (the "ACA"), modified the intent requirement under the Anti-Kickback Statute to a stricter standard, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil FCA.

The federal civil FCA prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The civil FCA has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average

Manufacturer Price, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses not expressly approved by the FDA in a product's label, and allegations as to misrepresentations with respect to products, contract requirements, and services rendered. In addition, private payors have been filing follow-on lawsuits alleging fraudulent misrepresentation, although establishing liability and damages in these cases is more difficult than under the FCA. Intent to deceive is not required to establish liability under the civil FCA. Civil FCA actions may be brought by the government or may be brought by private individuals on behalf of the government, called "qui tam" actions. If the government decides to intervene in a qui tam action 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. The civil FCA provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into millions of dollars. For these reasons, since 2004, FCA lawsuits against biopharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, as much as $3.0 billion, regarding certain sales practices and promoting off label uses. Civil FCA liability may further be imposed for known Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts, that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act. In addition, conviction or civil judgment for violating the FCA may result in exclusion from federal health care programs, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

The government may further prosecute conduct constituting a false claim under the criminal FCA. The criminal FCA prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil FCA, requires proof of intent to submit a false claim.

The civil monetary penalties statute is another potential statute under which biopharmaceutical companies may be subject to enforcement. Among other things, the civil monetary penalties statue imposes fines against any person who is determined to have knowingly presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

Payment or reimbursement of prescription therapeutics by Medicaid or Medicare requires the product's labeler to submit certified pricing information to CMS. The Medicaid Drug Rebate statute requires labelers, as a condition of payment by Medicaid, to calculate and report price points, which are used to determine Medicaid rebate payments shared between the states and the federal government and Medicaid payment rates for certain therapeutics, to pay quarterly rebates on prescriptions paid by Medicaid, and to provide a discount based on the Medicaid rebate percentage to certain hospitals and clinics under the 340B program. For most therapeutics paid under Medicare Part B, labelers must also calculate and report their Average Sales Price ("ASP"), which is used to determine the Medicare Part B payment rate. In addition, therapeutics covered by Medicaid are subject to an additional inflation penalty which can substantially increase rebate payments. For products approved under a BLA (including biosimilars) or an NDA, the Veterans Health Care Act ("VHCA") requires labelers, as a condition of payment by Medicaid, to calculate and report to the Veterans Administration ("VA") a different price called the Non-Federal Average Manufacturing Price, which is used to determine the maximum price that can be charged to certain federal agencies, referred to as the Federal Ceiling Price ("FCP"). Like the Medicaid rebate amount, the FCP includes an inflation penalty. A Department of Defense statute and regulation requires labelers to provide this discount on therapeutics dispensed by retail pharmacies when paid by the TRICARE Program, the health care program for military personnel, retirees, and related beneficiaries. All of these price reporting requirements create risk of submitting false information to the government, and potential FCA liability.

The VHCA also requires labelers of covered therapeutics participating in the Medicaid program to enter into Federal Supply Schedule contracts with the VA through which their covered therapeutics must be sold to certain federal agencies at FCP. This necessitates compliance with applicable federal procurement laws and regulations, including submission of commercial sales and pricing information, and subjects us to contractual remedies as well as administrative, civil, and criminal sanctions. In addition, the VHCA requires labelers participating in Medicaid to agree to provide different mandatory discounts to certain Public Health Service grantees and other safety net hospitals and clinics under the 340B program based on the labelers's reported Medicaid pricing information. The 340B program has its own regulatory authority to impose sanctions for non-compliance and adjudicate overcharge claims against labelers by the purchasing entities.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") also created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, in connection with the delivery or payment for health care benefits, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Additionally, the ACA

amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

The ACA further created new federal requirements for reporting, by applicable drug manufacturers of covered therapeutics, payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members, including the Physician Payments Sunshine Act.

Further, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its respective implementing regulations imposes certain requirements on covered entities relating to the privacy, security, and transmission of certain individually identifiable health information, known as protected health information. Among other things, HITECH, through its implementing regulations, makes HIPAA's security standards and certain privacy standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Certain state laws also regulate sponsors' use of prescriber-identifiable data. Certain states also require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; impose restrictions on marketing practices; or require drug companies to track and report information related to payments, gifts, and other items of value to physicians and other healthcare providers.

Recently, states have enacted or are considering legislation intended to make drug prices more transparent and deter significant price increases, typically as consumer protection laws. These laws may affect our future sales, marketing, and other promotional activities by imposing administrative and compliance burdens.

If our operations are found to be in violation of any of the laws or regulations described above or any other applicable laws, we may be subject to penalties or other enforcement actions, including criminal and significant civil monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Enforcement actions can be brought by federal or state governments, or as "qui tam" actions brought by individual whistleblowers in the name of the government under the civil FCA if the violations are alleged to have caused the government to pay a false or fraudulent claim.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Coverage and Reimbursement

The commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, and other third-party payors provide coverage for and establish adequate reimbursement levels for our product candidates. Government authorities, private health insurers, and other organizations generally decide which therapeutics they will pay for and establish reimbursement levels for healthcare. Medicare is a federally funded program managed by CMS through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each

state creates specific regulations that govern its individual program, including supplemental rebate programs that restrict coverage to therapeutics on the state Preferred Drug List. Similarly, government laws and regulations establish the parameters for coverage of prescription therapeutics by health plans participating in state exchanges and TRICARE. Some states have also created pharmacy assistance programs for individuals who do not qualify for federal programs. In the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such products and services.

In the United States, the European Union, and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be and sometimes at or below the provider's acquisition cost. In the United States, it is also common for government and private health plans to use coverage determinations to leverage rebates from labelers in order to reduce the plans' net costs. These restrictions and limitations influence the purchase of healthcare services and products and lower the realization on labelers' sales of prescription therapeutics. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Third-party payors may limit coverage to specific therapeutic products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication or might impose high copayment amounts to influence patient choice. Third-party payors also control costs by requiring prior authorization or imposing other dispensing restrictions before covering certain products and by broadening therapeutic classes to increase competition. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Absent clinical differentiators, third-party payors may treat products as therapeutically equivalent and base formulary decisions on net cost. To lower the prescription cost, labelers frequently rebate a portion of the prescription price to the third-party payors. Recently, purchasers and third-party payors have begun to focus on value of new therapeutics and sought agreements in which price is based on achievement of performance metrics.

Federal programs also impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics and mandatory rebates on retail pharmacy prescriptions paid by Medicaid and TRICARE. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government programs may result in lower reimbursement for our product candidates or exclusion of our product candidates from coverage. In addition, government programs like Medicaid include substantial penalties for increasing commercial prices over the rate of inflation which can affect realization and return on investment.

Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. In addition, many government programs as a condition of participation mandate fixed discounts or rebates from labelers regardless of formulary position or utilization, and then rely on competition in the market to attain further price reductions, which can greatly reduce realization on the sale.

Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement, and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, competition within therapeutic classes, judicial decisions and governmental laws and regulations related to Medicare, Medicaid, and healthcare reform, biopharmaceutical coverage and reimbursement policies, and pricing in general. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of our product candidates will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government health administration authorities, such as Medicare and Medicaid, private health insurers, and other third-party payors.

As a result of the above, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective, or the rebate percentages required to secure coverage may not yield an adequate margin over cost. Additionally, companies are increasingly finding it necessary to establish bridge programs to assist patients access new therapies during protracted initial coverage determination periods.

Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved or that significant price concessions will not be required to avoid restrictive conditions. High health plan co-payment requirements may result in patients refusing prescriptions or seeking alternative therapies. Additionally, where a new indication

has been approved for a drug previously approved under a different NDA or BLA, health plans may cover off-label use of the original drug, even if it cannot be marketed for the new indication. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in therapeutic development. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidates or exclusion of our products and product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

Healthcare Reform Measures

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, and expanding access. In the United States, the biopharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the ACA created hybrid payment methodology for biosimilars under Medicare Part B, which covers products administered by physicians in an outpatient setting, intended to neutralize the incentive to purchase higher priced biologics reimbursed at ASP plus 6% of ASP by paying providers ASP of a biosimilar but adding the margin based on ASP of the reference biologic. More recently, the Bipartisan Budget Act extended labeler responsibility for prescription costs in the Medicare Part D coverage gap to biosimilars, which had previously been exempt.

Similarly, the American Recovery and Reinvestment Act of 2009 established funding for the federal government to compare the effectiveness of different treatments for the same illness. The Agency for Healthcare Research and Quality among other things, conducts patient-centered outcome research, develops evidence-based tools and resources on medication therapies, maintains databases of health care related data and standards, and issues periodic reports on specific studies. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the organization’s research has had or will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor’s product could adversely affect the sales of our product candidates. If third-party payors do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates or may severely restrict access, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Moreover, the ACA broadened access to health insurance, attempts to reduce or constrain the growth of healthcare spending, enhanced remedies against fraud and abuse, added new transparency requirements for healthcare and health insurance industries, imposed new taxes and fees on the health care industry, and imposed additional health policy reforms. The law expanded the eligibility criteria and mandatory eligibility categories for Medicaid programs, thereby potentially increasing both the volume of sales and labelers’ Medicaid rebate liability. The law also expanded the 340B discount program that mandates discounts to certain hospitals, community centers, and other qualifying providers, by expanding the categories of entities eligible to purchase under the program, although, with the exception of children’s hospitals, these newly eligible entities are ineligible to receive discounted 340B pricing on orphan therapeutics used to treat an orphan disease or condition. The ACA revised the definition of “average manufacturer price ("AMP")” for reporting purposes, which generally increased the amount of Medicaid rebates to states and created a separate AMP for certain categories of therapeutics provided in non-retail outpatient settings. The law additionally extended labeler’s Medicaid rebate liability to covered therapeutics dispensed to patients enrolled in Medicaid managed care organizations and increased the statutory minimum rebates a labeler must pay under the Medicaid Drug Rebate program. The revisions to the AMP definition and Medicaid rebate formula can have the further effect of increasing the required 340B discounts. Further, the ACA requires labelers of therapeutics, to pay 50% of the pharmacy charge to Medicare Part D patients while they are in the coverage gap, and this percentage was increased to 70% by the Bipartisan Budget Act of 2018. Finally, the ACA imposes a significant annual fee on companies that manufacture or import branded prescription therapeutic products. Substantial new provisions affecting compliance have also been enacted through the ACA and otherwise, including the reporting of therapeutic sample distribution, which may require us to modify our business practices with healthcare practitioners. Although the ACA was amended to repeal the individual insurance mandate, and efforts to repeal and replace portions of the law continue, it is likely that pressure on biopharmaceutical pricing, especially under the Medicare program, will continue, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our product candidates.

The cost of biopharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the biopharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

In addition, other legislative and regulatory changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011, as amended, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. The Bipartisan Budget Act of 2018 retained the federal budget "sequestration" Medicare payment reductions of 2%, and extended it through 2027 unless congressional action is taken, and also increased labeler responsibility for prescription costs in the Medicare Part D coverage gap. The American Taxpayer Relief Act of 2012, further reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our financial operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could further limit the prices we are able to charge, or the amounts of reimbursement available, for our product candidates once they are approved.

In 2016, CMS issued a final rule regarding the Medicaid drug rebate program. The final rule, effective April 2016, among other things, extended labeler rebate obligations to U.S. territories, revised the manner in which the AMP is calculated by labelers participating in the program, and implements certain amendments to the Medicaid rebate statute created under the ACA. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The full impact of these laws, as well as other new laws and reform measures that may be proposed and adopted in the future remains uncertain, but may result in additional reductions in Medicare and other health care funding, or higher production costs which could have a material adverse effect on our customers and, accordingly, our financial operations.

There have been several U.S. Congressional inquiries and proposed and adopted federal and state legislation designed to, among other things, bring more transparency to drug pricing and deter price increases, review the relationship between pricing and sponsor patient programs, and reform government program reimbursement methodologies for drugs. While any proposed measures will require authorization through additional legislation to become effective, Congress and the current U.S. Presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

EMPLOYEES

Investing in, developing, and maintaining human capital is critical to our success. We have 15 full-time employees as of March 1, 2021. We emphasize a number of measures and objectives in managing our human capital assets, including, among

others, employee safety and wellness, talent acquisition and retention, employee engagement, development and training, diversity and inclusion, and compensation and pay equity. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

CORPORATE INFORMATION

We were originally incorporated as a Massachusetts corporation in 2000 under the name Histogenics Corporation. In 2006, we underwent a corporate reorganization pursuant to which we were reincorporated as a Delaware corporation. On September 27, 2019, we completed a reverse merger (the "Merger") with Ocugen OpCo, Inc. ("OpCo") in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of April 5, 2019, by and among OpCo, Restore Merger Sub, Inc., our wholly owned subsidiary ("Merger Sub"), and us, as amended, pursuant to which Merger Sub merged with and into OpCo, with OpCo surviving as our wholly owned subsidiary. Immediately after completion of the Merger, we changed our name to Ocugen, Inc and the business previously conducted by OpCo became the business conducted by us. Our common stock trades on The Nasdaq Capital Market (“Nasdaq”) under the symbol “OCGN.”

Our principal offices are located at 263 Great Valley Parkway, Malvern, Pennsylvania 19355, and our telephone number is (484) 328-4701. Our website address is www.ocugen.com. Our website and the information contained on, or that can be accessed through, our website shall not be deemed to be incorporated by reference in, and is not considered part of, this Annual Report. You should not rely on any such information in making your decision whether to purchase our common stock.

AVAILABLE INFORMATION

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission ("SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The SEC maintains an internet website, www.sec.gov, that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC.

Copies of each of our filings with the SEC on Form 10-K, Form 10-Q, and Form 8-K and all amendments to those reports, can be viewed and downloaded free of charge at our website, www.ocugen.com, as soon as reasonably practicable after the reports and amendments are electronically filed with or furnished to the SEC.

Our code of ethics, other corporate policies and procedures, and the charters of our Audit Committee, Compensation Committee, and Nominating/Corporate Governance Committee are available through our website at www.ocugen.com.

Item 1A. Risk Factors.

Risk Factors Summary

- Investing in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks and uncertainties described in "Part I, Item 1A. Risk Factors" of this Annual Report on Form 10-K. These risks and uncertainties include, but are not limited to, the following:
- We have incurred significant losses from operations and negative cash flows from operations since our inception and may continue to incur net losses over the next several years.
- We may need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- We are substantially dependent on the success of our product candidates and we cannot guarantee that our product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized.
- The ongoing COVID-19 pandemic and actions taken in response to it may result in disruptions to our business operations.
- Our product candidates generated from our modifier gene therapy platform are based on a novel technology and face an uncertain regulatory environment, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval.
- COVAXIN, the COVID-19 vaccine candidate that is the subject of our Covaxin Agreement with Bharat Biotech, is being evaluated by Bharat Biotech in a Phase 3 clinical trial in India and the regulatory path in the United States is currently being evaluated. We may be unable to successfully produce and commercialize a vaccine that effectively and safely treats the virus in a timely manner, if at all, and ultimately may be unable to obtain EUA or BLA approval in the United States.
- The regulatory pathway for COVAXIN is continually evolving, and may result in unexpected or unforeseen challenges.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our completion of clinical trials and receipt of necessary regulatory approvals could be delayed or prevented.
- We may expend our limited resources to pursue a particular 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.
- We have no prior experience in the marketing, sale, and distribution of pharmaceutical products and there can be no assurance that our products, if approved, will be successfully commercialized.
- We face significant competition from other pharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations.
- We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and any future clinical trials we may initiate, 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.
- If the manufacturers upon whom we rely fail to produce our product candidates or components pursuant to the terms of contractual arrangements with us or fail to comply with stringent regulations applicable to biologic and pharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.
- We may seek to collaborate with third parties for the development or commercialization of our product candidates and we may not be successful in establishing or maintaining collaborative relationships, any of which could adversely affect our ability to develop and commercialize our product candidates.
- We may be unable to obtain and maintain patent protection for our technology and product candidates, or the scope of the patent protection obtained may not be sufficiently broad or enforceable, such that our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.
- Certain aspects of our product candidates are protected by patents exclusively licensed from other companies or institutions and if these third parties terminate their agreements with us or fail to maintain or enforce the underlying patents or licenses thereto, or we otherwise lose our rights to these patents, our competitive position and our market share in the markets for any of our approved products will be harmed.

- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming, and unsuccessful.
- We have used almost all of our unreserved, authorized shares.
- Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.
- Raising additional funding may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.
- The trading price of the shares of our common stock could be highly volatile, and purchasers of the common stock could incur substantial losses.
- If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting, and the trading price of our common stock may decline.

Risks Related to Our Financial Position and Capital Requirements

We have incurred significant losses from operations and negative cash flows from operations since our inception. We may incur losses over the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant net losses and may continue to incur net losses in the future. We have not generated significant revenue to date and have funded our operations to date through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes, debt, and grant proceeds. We incurred net losses of approximately $21.8 million for the year ended December 31, 2020, and $20.2 million for the year ended December 31, 2019. As of December 31, 2020, we had an accumulated deficit of $73.3 million and a cash, cash equivalents, and restricted cash balance of $24.2 million.

To date, we have not commercialized any products or generated any revenues from the sale of products, and absent the realization of sufficient revenues from product sales, if any, of our current or future product candidates, if authorized or approved, we may never attain profitability in the future. To date, we have devoted substantially all of our financial resources and efforts to research and development, including preclinical and clinical studies. We may continue to incur losses from operations in the next several years as we increase our expenditures in research and development in connection with clinical trials and other development and commercialization activities. Even if we obtain an EUA or regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received such authorization or approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share for our products in those markets.

We anticipate that our expenses will increase substantially in 2021 as compared to 2020 as we develop, seek an EUA for and potentially commercialize COVAXIN in the United States and prepare to commence human clinical trials with respect to OCU400, OCU410, and OCU200. Our expenses will increase as a result of increased headcount, including management personnel to support our research and development and clinical activities, expanded infrastructure, and increased insurance premiums, among other factors.

Due to the inherently unpredictable nature of preclinical and clinical development and the numerous risks and uncertainties associated with such activities, we are unable to predict with any certainty the nature or amounts of the costs we will incur, the timelines we will require in our continued development efforts or the timing, or if, we will be able to achieve profitability.

Additionally, our expenses will also increase if, and, as we:

- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future, particularly if there are any delays in enrollment of patients in or completing our clinical trials or the development of our product candidates;
- seek marketing approvals for product candidates that successfully complete clinical development;
- establish sales, marketing, and distribution capabilities for our product candidates for which we obtain an EUA or marketing approval;
- scale up our manufacturing processes and capabilities to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain an EUA or marketing approval;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing, and commercialization efforts, and our operations as a public company;
- hire additional clinical, quality control, and scientific personnel;
- acquire other companies, products, product candidates, or technologies, or in-license the rights to other products, product candidates, or technologies; and
- develop, maintain, expand, and protect our intellectual property portfolio.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate revenue that is sufficient to achieve profitability unless and until we obtain an EUA or marketing approval for and commercialize one of our product candidates. Our product candidates are in various stages of preclinical and clinical development and it may be several years before we obtain regulatory approval for any candidate, if ever. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become profitable or inability to remain profitable would decrease the value of the company and could impair our ability to raise capital, expand our business, maintain

our research and development efforts, continue or undertake commercialization efforts, diversify our product offerings or even continue our operations. A decline in the value of the company could also cause you to lose all or part of your investment.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is a highly speculative endeavor. Biopharmaceutical product development entails substantial upfront capital expenditures and there is significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, to gain any required regulatory approvals or to become commercially viable. To date, our operations have been limited to organizing and staffing the company, acquiring rights to intellectual property, business planning, raising capital, and developing our product candidates. We have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We have encountered, and will continue to encounter, risks and difficulties frequently experienced by growing companies in a rapidly developing and changing industry, such as the biopharmaceutical industry, including challenges in forecasting accuracy, determining appropriate investments of our limited resources, gaining market acceptance of our products, if authorized or approved, managing a complex regulatory landscape, and developing new product candidates. Our current operating model may require changes in order for us to scale our operations efficiently. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. You should consider our business and prospects in light of the risks and difficulties we face as a company focused on developing products in the fields of biopharmaceuticals and biotechnology.

We expect our 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 our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We may need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

We expect to devote substantial financial resources to our ongoing and planned product development activities, particularly as we commence development and commercialization activities with respect to COVAXIN in the United States and continue the development of and potentially seek marketing approval for other product candidates, including OCU400, OCU410, OCU200, and any potential future product candidates. As of December 31, 2020, we had cash, cash equivalents, and restricted cash of approximately $24.2 million, and since that date we have received net proceeds of $4.8 million from the sale of our common stock in an at-the-market offering and $21.2 million from the sale of our common stock in a registered direct offering. We believe that our cash, cash equivalents, and restricted cash will enable us to fund our operating expenses and capital expenditure requirements through at least one year from the date the consolidated financial statements included in this report are issued. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us.

Conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete. We cannot predict when we will be able to generate the necessary data or results required to obtain regulatory approval of products with the market potential sufficient to enable us to achieve profitability, if ever. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. Our future capital requirements will depend on many factors, including:

- the progress, costs, and results of any clinical trials for our product candidates, and any clinical activities for regulatory review of our product candidates outside of the United States;
- the costs, timing, and outcome of regulatory review of our preclinical product candidates;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates, if we receive, or expect to receive, and EUA or marketing approval;
- the costs of commercialization activities for our product candidates if we receive, or expect to receive, an EUA or marketing approval, including the costs and timing of establishing product sales, marketing, distribution, and outsourced manufacturing capabilities;

- subject to receipt of an EUA or marketing approval, revenue received from commercial sales of our product candidates;
- our 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 additional product candidates that we may derive from our modifier gene therapy platform or any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates, or technologies; and
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and protecting our intellectual property rights, and defending against any intellectual property-related claims.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Moreover, adequate additional financing may not be available to us on acceptable terms, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce, or terminate preclinical studies, clinical trials, or other development activities for one or more of our product candidates or delay, limit, reduce, or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

We may need additional funding in order to enable us to successfully develop COVAXIN, and such funding may not be available on acceptable terms, or at all. The commitment of substantial resources to this program entails additional risks.

We may need additional funding in order to enable us to successfully develop and obtain FDA authorization or approval and have sufficient capacity to manufacture, commercialize, and distribute COVAXIN, if authorized or approved by the FDA. Such funding may not be available on acceptable terms, or at all. Moreover, our commitment of substantial financial resources and personnel to the joint development of a vaccine candidate entails additional risks. In particular, this commitment may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of COVID-19 as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate.

Raising additional capital may cause dilution to stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect to raise additional capital through public and private placements of equity and/or debt, payments from potential strategic research and development, sale of assets, government grants, licensing and/or collaboration arrangements with pharmaceutical companies or other institutions, and other funding from the government. To the extent that we raise 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 the rights of our stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

If we raise additional funds through collaborations, strategic alliances, licensing arrangements, or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. Such arrangements may require us to grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market on our own.

Our existing and future indebtedness may limit cash flow available to invest in the ongoing needs of our business.

As of December 31, 2020, we had incurred indebtedness consisting of (i) $0.4 million of outstanding principal borrowings from Silicon Valley Bank ("SVB") under the Paycheck Protection Program (the "PPP") of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), which matures on April 30, 2022 and bears interest at a rate of 1% per annum, payable monthly commencing on either the date the Small Business Administration (the "SBA") compensates SVB for any forgiven amounts or 10 months after the end of our covered period under the PPP, which ended in October 2020 and (ii) $1.5 million of outstanding principal borrowings under a Loan Agreement (the "EB-5 Loan Agreement") with EB5 Life Sciences, L.P. ("EB-5 Life Sciences"), which we are 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). Our obligations under the EB-5 Loan Agreement are secured by substantially all of our assets other than our intellectual property. We could in the future incur additional indebtedness beyond our borrowings under the PPP of the CARES Act and our borrowings under the EB-5 Loan Agreement.

Our existing or future debt could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of cash flow from operations or cash on hand to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts, and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry, and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing (for instance, the EB-5 Loan Agreement includes restrictive covenants related to, among other things, the disposition of our property, the incurrence by us of any additional indebtedness, and the creation by us of any liens or other encumbrances);
- limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

A failure to comply with the covenants under the EB-5 Loan Agreement, including covenants to take or avoid specific actions as set forth above, could result in an event of default and acceleration of amounts due. If an event of default occurs and EB-5 Life Sciences accelerates the amounts due under the EB-5 Loan Agreement, we may not be able to make accelerated payments, and EB-5 Life Sciences could seek to enforce security interests in the collateral securing such indebtedness.

All or a portion of our borrowings under the PPP of the CARES Act may be forgiven by the SBA. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest and we cannot provide any assurance that any amount of our borrowings under the PPP of the CARES Act will ultimately be forgiven by the SBA. If we are unable to obtain forgiveness of all or any portion of our borrowings under the PPP of the CARES Act, our liquidity could be reduced and our business, financial condition, and results of operations may be adversely affected.

In order to satisfy our current and future debt service obligations, we will be required to raise funds from external sources. We may be unable to arrange for additional financing to pay the amounts due under our existing debt. Funds from external sources may not be available on acceptable terms, if at all. Our failure to satisfy our current and future debt obligations could adversely affect our financial condition and results of operations.

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

We have incurred significant net operating losses since our inception. As of December 31, 2020, we had U.S. federal and state net operating loss carryforwards of approximately $128.0 million and $126.7 million, respectively. If we are unable to use carryforward tax losses to reduce our future taxable income and liabilities in our 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 and any potential future U.S. tax legislation may materially adversely affect our 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, 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.

Furthermore, it is also possible that there will be technical corrections or other legislation proposed with respect to the tax reform legislation, the effect of which cannot be predicted and may be adverse to us or our stockholders. Further, the new presidential administration in 2021 may result in additional amendments to the Code or reversal of the 2017 changes.

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

Risks Related to Our Business and the Development of Our Product Candidates

We are substantially dependent on the success of our product candidates. We cannot guarantee that our product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized.

We have invested a significant portion of our efforts and financial resources in the development of our product candidates. Notwithstanding such investment, we currently have no products approved for commercial distribution and we generate no revenues from sales of any products. Our business and our ability to generate revenues in the near term depends entirely on the successful development and commercialization of our product candidates, which may never occur. Our 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, our product candidates may not receive regulatory approval even if they are successful in clinical trials, and our product candidates may not be successfully commercialized even if they receive regulatory approval.

Our product candidates are various stages of development ranging from preclinical development to late-stage clinical development.

The success of our product candidates and our ability to generate revenues from our product candidates will depend on many factors including our ability to:

- complete and obtain favorable results from our clinical and preclinical trials with respect to our product candidates;
- apply for and receive marketing approval from the applicable regulatory authorities;
- receive regulatory approval for claims that are necessary or desirable for successful marketing;
- receive approval for our manufacturing processes and third-party manufacturing facilities from the applicable regulatory authorities;
- recruit and enroll qualified patients for clinical trials with respect to our 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 our product candidates;
- 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;
- launch and create market demand for our product candidates through marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;
- achieve market acceptance of our product candidates by patients, the medical community and third-party payors;
- effectively compete with other therapies and establish a market share;
- maintain a continued acceptable safety and efficacy profile of our product candidates following commercial launch;
- achieve appropriate reimbursement, pricing, and payment coverage for our product candidates;

- 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 we receive marketing approval;
- develop our product candidates for additional indications or for use in broader patient populations;
- maintain patent and trade secret protection and regulatory exclusivity for our product candidates;
- qualify for, identify, register, maintain, enforce and defend intellectual property rights and claims covering our products and intellectual property portfolio; and
- not infringe on others' intellectual property rights.

To the extent we are not able to do any of the foregoing, our business may be materially harmed. If we do not receive FDA approval for, and successfully commercialize our product candidates, we will not be able to generate revenue from these product candidates in the United States in the foreseeable future or at all.

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

The research, testing, manufacturing, labeling, approval, selling, marketing, and distribution of pharmaceutical products are subject to extensive regulation by the FDA and other regulatory authorities, which regulations differ from country to country. 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. The outcome of the approval process is inherently uncertain and depends upon numerous factors, including the substantial discretion of the regulatory authorities. This is especially true for rare and/or complicated diseases. Failure can occur at any time during the clinical trial process. We cannot predict if or when we might receive regulatory approvals for any of our product candidates currently under development. Any delay in our obtaining or our failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

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. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. 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. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. 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. The FDA or other similar regulatory authorities may determine that our product candidates are not effective or only moderately effective (e.g., studies may not produce the necessary result on all study endpoints), that our studies failed to reach the necessary level of statistical significance, or that our product candidates have undesirable or unintended side effects, toxicities, or other characteristics that preclude us from obtaining marketing approval or prevent or limit commercial use.

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

- regulators, including the FDA and the NIH, or IRBs or IBCs may not authorize us or our 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 we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our CROs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- us, 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 or regulations, or changes in or the enactment of additional statutes or regulations, during the development period rendering our data insufficient to obtain marketing approval and requiring us to conduct additional studies;
- the cost of clinical trials of our product candidates may be greater than we anticipate or we 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 our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- patients that enroll in our 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;
- the FDA or comparable foreign regulatory authorities may disagree with our study design, including endpoints, or our 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 our intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our contract manufacturer's manufacturing facility for clinical and future commercial supplies;
- the data collected from clinical trials of our 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 we anticipate to make a decision on its product candidates; and
- we 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.

Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do. This may prevent us from receiving marketing approvals and impair our ability to successfully commercialize our product candidates and may harm our 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 our product candidates. If any of this occurs, our business, financial condition, results of operations, and prospects will be materially harmed.

The failure to comply with FDA and comparable foreign regulatory requirements may, either before or after product approval, if any, subject us to administrative or judicially imposed sanctions, including:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on our products, manufacturers, or manufacturing process;

- warning letters, Form 483s, or untitled letters alleging violations;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions, or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending marketing applications or supplements to approved marketing applications.

Even if we were to obtain regulatory approval of a product candidate, the FDA or comparable foreign regulatory authorities may grant approval for fewer or more limited indications, populations, or uses than we request, may require significant safety warnings, including black box warnings, contraindications, and precautions, may grant approval contingent on the performance of costly post-marketing clinical trials, surveillance, restrictions on use or other requirements, including a 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 our product candidates.

The ongoing COVID-19 pandemic and actions taken in response to it may result in disruptions to our business operations, which would have a material adverse effect on our business, financial position, operating results and cash flows.

In December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States and several European countries. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. Further, the President of the United States declared the COVID-19 pandemic a national emergency. The Governor of Pennsylvania declared a state of emergency and has issued orders impacting our business operations.

We currently expect to commence two Phase 1/2a clinical trials for OCU400, our product candidate for the treatment of multiple IRDs, in the United States in the second half of 2021. If COVID-19 continues to spread in the United States and elsewhere, it may delay enrollment in these planned clinical trials, and in any clinical trials that we may commence for our other product candidates in 2022. Some patients may not be able to comply with clinical trial protocols if any future quarantines impede patient movement or interrupt healthcare services. Moreover, limitations on global international travel may delay key trial activities, including necessary interactions with regulators, ethics committees, and other important agencies and contractors. We may be faced with limitations in employee resources that would otherwise be focused on the conduct of clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people. Any of the above could delay our planned clinical trials for OCU400 or prevent us from completing these clinical trials at all, and harm our ability to obtain approval for OCU400 or our other product candidates.

Moreover, we may experience additional disruptions that could severely impact our business and development activities, including, but not limited to, strain on our suppliers and other third parties, possibly resulting in supply disruptions of our product candidates for preclinical development and potential future clinical trials we expect to initiate, decrease in clinical enrollment in any clinical trials we initiate, and the ability to raise capital when needed on acceptable terms, if at all. Disruptions in our operations or supply chain, whether as a result of restricted travel, quarantine requirements, or otherwise, could negatively impact our ability to proceed with our clinical trials, preclinical development, and other activities and delay our ability to receive product approval and generate revenue.

In addition, the continued spread of COVID-19 may lead to severe disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets. It is possible that the continued spread of COVID-19 could cause an economic slowdown or recession or cause other unpredictable events, each of which could adversely affect our business, results of operations, or financial condition.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. The extent to which COVID-19 impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19, the emergence of any new mutations or variants of the virus, the duration of the outbreak, travel restrictions imposed by the United States and other countries, business closures or

business disruption in the United States and other countries, and the actions taken throughout the world, including in our markets, to contain COVID-19 or treat its impact. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our preclinical development efforts, healthcare systems, or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

COVAXIN, the COVID-19 vaccine candidate that is the subject of the Covaxin Agreement with Bharat Biotech, is being evaluated by Bharat Biotech in a Phase 3 clinical trial in India and the regulatory path in the United States is currently being evaluated. We may be unable to successfully produce and commercialize a vaccine that effectively and safely treats the virus in a timely manner, if at all, and ultimately may be unable to obtain emergency use authorization or regulatory approval in the United States.

In February 2021, we entered into the Covaxin Agreement, with Bharat Biotech, pursuant to which we obtained an exclusive right and license under certain of Bharat Biotech's intellectual property rights, with the right to grant sublicenses, to develop, manufacture, and commercialize COVAXIN, a whole-virion inactivated COVID-19 vaccine candidate, in the United States of America, its territories and possessions. COVAXIN has been granted approval for emergency use in India. A Phase 3 clinical trial is ongoing in India and enrollment is complete. COVAXIN demonstrated a vaccine efficacy of 81% in the first interim analysis of the Phase 3 clinical trial. Notwithstanding receipt of the approval for emergency use in India, Bharat Biotech's development efforts in India remain subject to ongoing clinical trials. Bharat Biotech may be unable to develop or produce a vaccine that successfully vaccinates against the SARS-CoV-2 virus or emerging variants of the virus. Moreover, subjects receiving COVAXIN in Bharat Biotech's clinical trials, as well as patients receiving the vaccine under the emergency use approval in India, may experience allergic reactions or other adverse events, which could adversely impact the U.S. market's perception of the vaccine. Any of these events could materially impair our ability to develop COVAXIN in the United States.

Our development efforts with respect to the U.S. market are in their initial stages, and we may be unable to obtain authorization or approval of COVAXIN in the United States, in a timely manner, if at all. We have initiated discussions with the FDA but no EUA application has been submitted at this time. The FDA may determine that the studies conducted in India were not done in compliance with FDA regulations, including GCP regulations. For this and other reasons, the FDA may not accept data from the studies conducted with COVAXIN at clinical trial sites in India and may require us to conduct clinical studies in the United States before considering an application for an EUA in the United States. Even if we conduct clinical trials in the United States, we may not be successful in obtaining an EUA from the FDA if our development efforts were to result in findings relating to a lack of efficacy, safety concerns, or other issues. Our inability to obtain an EUA from the FDA could materially and adversely affect our business, financial condition, and results of operations.

As an organization, we have no experience in the development, manufacturing, distribution or commercialization of a vaccine candidate.

We have never undertaken the development, manufacturing, distribution, or commercialization of a vaccine candidate, and we may be unable to obtain regulatory authorization or approval in the United States. Additionally, development of an effective vaccine candidate depends on the success of our and our partner's manufacturing capabilities. We have not previously ramped our organization for a commercial launch of any product, and doing so in a pandemic environment with an urgent, critical global need creates additional challenges such as clinical trials, licensing, distribution channels, intellectual property disputes or challenges, and the need to establish teams of people with the relevant skills. We may also face challenges with sourcing a sufficient amount of raw materials to support the demand for a vaccine, including any potential import issues. We may be unable to effectively create a supply chain for COVAXIN that will adequately support demand. Furthermore, there are no assurances that any vaccine candidate would be approved or authorized by the FDA at all or for inclusion in government stockpile programs, which may be material to the commercial success of a vaccine product candidate, in the United States.

The regulatory pathway for COVID-19 vaccine candidates, including COVAXIN, is continually evolving, and may result in unexpected or unforeseen challenges.

COVAXIN has moved rapidly through the regulatory review process for emergency use in India. We cannot predict the speed at which we will be able to obtain authorization or approval of COVAXIN in the United States, if at all. Evolving or changing plans or priorities at the FDA, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory pathway and timeline for COVAXIN authorization or approval in the United States. The FDA may not accept data from the studies conducted with COVAXIN at clinical trial sites in India and may require additional clinical trials. Any results from further clinical testing may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. In addition, the FDA's analysis of any clinical data may differ from our interpretation and the FDA may require that we conduct additional

analysis or trials. Further, the ongoing Phase 3 trial in India may demonstrate that the vaccine candidate is ineffective or has an unacceptable safety profile.

The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. If we are granted an EUA by the FDA for COVAXIN, we would be able to commercialize it without FDA approval. However, the FDA may revoke the EUA where it is determined that the COVID-19 public health emergency no longer exists or warrants such authorization, and we cannot predict how long, if ever, an EUA would remain in place. Such revocation could adversely impact our business in a variety of ways, including if COVAXIN is not yet approved by the FDA and if we, Bharat Biotech and our manufacturing partners have invested in the supply chain to provide COVAXIN under an EUA in the United States. In addition, the FDA may revoke or terminate the EUA sooner if, for example, we fail to comply with the conditions of authorization or other terms of the EUA or if COVAXIN is determined to be less effective or safe than it was initially believed to be. We cannot predict how long, if ever, an EUA would remain in place.

Our ability to produce a successful vaccine may be curtailed by one or more government actions or interventions, which may be more likely during a global health crisis such as COVID-19.

Given the significant global impact of the COVID-19 pandemic, it is possible that the U.S. government may take actions that directly or indirectly have the effect of diminishing some of our rights or opportunities with respect to COVAXIN and the economic value of a COVID-19 vaccine to us could be limited. In the United States, the Defense Production Act of 1950, as amended, or the Defense Production Act, gives the U.S. government rights and authorities that may directly or indirectly diminish our own rights or opportunities with respect to COVAXIN and the economic value of a COVID-19 vaccine to us could be limited. Our potential third-party service providers may be impacted by government entities regarding potentially invoking the Defense Production Act or other potential restrictions to all or a portion of services they might otherwise offer. Government entities imposing restrictions or limitations on our third-party service providers may require us to obtain alternative service sources for our vaccine candidate, including COVAXIN. If we are unable to timely enter into alternative arrangements, or if such alternative arrangements are not available on satisfactory terms, we will experience delays in the development or production of our vaccine candidate, increased expenses, and delays in potential distribution or commercialization of our vaccine candidate, when and if approved.

Our product candidates generated from our modifier gene therapy platform are based on a novel technology and face an uncertain regulatory environment, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval.

A substantial portion of our product research and development efforts is centered around our modifier gene therapy platform. The regulatory approval and successful commercialization of product candidates such as OCU400, a gene therapy designed to treat RP and other IRDs, and OCU410, a gene therapy designed to treat dry AMD, depend on the successful development of this platform. There can be no assurance that any development problems we experience in the future related to our modifier gene therapy platform will not cause significant delays or unanticipated costs, or that such development problems can be solved. The clinical trial requirements of the FDA, the EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as OCU400 and OCU410 can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. For example, the FDA established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research (“CBER”) to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the U.S. NIH, are also subject to review by the NIH Novel and Exceptional Technology and Research Advisory Committee (“NExTRAC”), formerly the Recombinant DNA Advisory Committee, which now focuses on emerging areas of research including, but not restricted to, technologies surrounding advances in recombinant or synthetic nucleic acid research. Although the FDA decides whether individual gene therapy protocols may proceed, it is possible the NExTRAC review process, which is still being implemented, could delay the initiation of a clinical trial, even if the FDA has reviewed the trial design and details and approved its initiation. Before a clinical trial can begin at a study site, the institution’s IRB, and its IBC, have to review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates, or lead to significant post-approval limitations or restrictions. As we advance our gene therapy product candidates, we will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our gene therapy product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected for orphan ophthalmology product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

Existing data on the safety and efficacy of gene therapy is very limited and sometimes include historically poor clinical efficacy of previous non-replicating gene therapy products. In addition, there have been publicized safety issues associated with previous gene therapy products in third-party clinical trials, including patient deaths. The results of preclinical and clinical trials performed for our product candidates will not definitively predict safety or efficacy in humans. OCU400 and OCU410 use an AAV vector. Possible serious side effects of other viral vector-based gene therapies in general include uncontrolled viral infections and the development of cancer, particularly lymphoma or leukemia. The risk of insertional mutagenesis or oncogenesis remains a significant concern for gene therapy, and we cannot provide any assurance that it will not occur in any of our planned or future clinical trials with respect to our product candidates based on our modifier gene therapy platform. There is also the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. Potential procedure-related adverse reactions, including inflammation, can also occur. If any such adverse events occur during clinical trials, further advancement of such clinical trials could be halted or delayed, which would have a material adverse effect on our business and operations.

Finally, public attitudes may be influenced by claims that gene therapy technology is unsafe, unethical, or immoral. If we are unable to convincingly demonstrate the safety and efficacy of our product candidates arising from our gene modifier platform, our product candidates, even if approved by the FDA or foreign regulatory authorities, may not gain the acceptance of the public or the medical community.

The development and manufacture of biologics is a complex process and entails particular risks.

OCU200, our product candidate currently in preclinical development, is a novel biologic designed to treat retinal diseases. The process of developing and manufacturing biologics is complex, highly regulated, and subject to multiple risks, and we have no experience in successfully developing, manufacturing, or commercializing a biologics product. The manufacturing of biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions, and higher costs.

The raw materials required in our third-party vendors' manufacturing processes are derived from biological sources. We cannot assure you that our third-party vendors have, or will be able to obtain on commercially reasonable terms, or at all, sufficient rights to these materials derived from biological sources. Such raw materials are difficult to procure and may also be subject to contamination or recall. If microbial, viral, or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product, and adversely harm our business. A material shortage, recall, or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the clinical and commercial manufacturing of our product candidates, which could materially and adversely affect our operating results and development timelines.

In addition, our biologics product candidates may expose us to additional potential product liability claims. The development of biologics products entails a risk of additional product liability claims because of the risk of transmitting disease to human recipients, and substantial product liability claims may be asserted against us as a result.

OCU400 has received four ODDs from the FDA and two OMPDs from the European Commission. However, there is no guarantee that we will be able to maintain these designations, receive this designation for any of our other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity.

We have obtained from the FDA Office of Orphan Products ODDs for OCU400 for *NR2E3*, *CEP290*, *RHO*, and *PDE6ß* mutation-associated inherited retinal degenerations. OCU400 additionally received OMPD from the European Commission,

based on the recommendation of the EMA, for RP and LCA in February 2021. We may also seek ODD or OMPD for our other product candidates, as appropriate. While these ODDs and OMPDs provide us with certain advantages, they neither shorten the development time or regulatory review time of a product candidate nor give 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 or EMA to be the same, for the same orphan indication, the product is entitled to a period of marketing exclusivity, which precludes the FDA or EMA 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 10 years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for OMPD or if the product is sufficiently profitable so that market exclusivity is no longer justified.

We may not be able to obtain any future ODDs or OMPDs that we apply for, ODDs or OMPDs do not guarantee that we will be able to successfully develop our product candidates, and there is no guarantee that we will be able to maintain any ODDs or OMPDs that we receive. 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 we are able to receive and maintain ODDs or OMPDs, we may ultimately not receive any period of regulatory exclusivity if our product candidates are approved. For instance, we may not receive orphan product regulatory exclusivity if the indication for which we receive FDA or EMA regulatory approval is different than the ODD or OMPD. Orphan exclusivity may also be lost for the same reasons that ODD or OMPD may be lost. Orphan exclusivity may further be lost if we are unable to assure a sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan exclusivity for any of our 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 ours can be approved for different conditions. Even after an orphan product is approved, the FDA or EMA can also subsequently approve a product containing the same principal molecular features for the same condition if the regulatory authority concludes that the later product is clinically superior by means of greater effectiveness, greater safety, or providing a major contribution to patient care.

If another sponsor receives approval for such product before we do, we would be prevented from launching our product for the orphan indication during the period of marketing exclusivity unless we can demonstrate clinical superiority.

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

In the future, we 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 we believe one of our 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.

The FDA may determine that our product candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization. If such side effects are identified during the development of our product candidates, we may need to abandon our development of such product candidates.

Undesirable side effects caused by our product candidates could cause us, 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 our product candidates as a result of undesirable side effects identified during clinical or preclinical testing, the FDA may order us to cease further development 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 our 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 our 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 us from commercializing and generating revenues from the sale of our product candidates.

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 our 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 our product candidates will be used correctly, and if used incorrectly, such misuse could prevent our receipt or maintenance of marketing authorization, resulting in label changes or regulatory authority safety communications or warnings, or hamper commercial adoption of our product candidate, if approved, at the rate we currently expect.

If any of our product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we 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. We may also be held liable for harm caused to patients and our reputation may suffer. Any of these occurrences may significantly harm our business, financial condition, results of operations, and prospects.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our completion of clinical trials and receipt of necessary regulatory approvals could be delayed or prevented.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. Our two planned Phase 1/2a clinical studies for OCU400 could be discontinued early if they experience slow enrollment, and we may also experience similar difficulties in future clinical trials for our other product candidates currently in preclinical development. If patients are unwilling to participate in our clinical trials because of negative publicity from adverse events related to gene therapy or in the industry more broadly, in the clinical trials for related third party product candidates, or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our product candidates, or termination of the clinical trials altogether.

We or our clinical trial sites may not be able to identify, recruit, and enroll a sufficient number of patients, or those with the required or desired characteristics in a clinical trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by other factors including:

- the size and nature of the patient population (for instance, we are 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 we are 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.

We may not be able to initiate or continue conducting clinical trials for our product candidates if we are 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. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us 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. Moreover, patients in our clinical trials, especially patients in our control groups, may be at risk for dropping out of our studies if they are not experiencing relief of their disease. A significant number of withdrawn patients would compromise the quality of a study's data.

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

Data from preclinical studies and early-stage clinical trials may not be predictive of success in later clinical trials.

The results of preclinical studies, preliminary study results, and early clinical trials of our 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. 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.

In addition, from time to time, we may publish interim, "top-line," initial, or preliminary data from our clinical studies. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Preliminary, initial, or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a result, interim, "top-line", initial, and preliminary data should be viewed with caution until the final data are available. Adverse changes between preliminary, initial, "top-line" or interim data and final data could significantly harm our business prospects.

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

We 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.

We may in the future choose to conduct one or more of our 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, such as IRB or ethics committee approval and informed consent. 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. In addition, while these clinical trials are subject to the applicable local laws (and therefore failure to comply with such laws could result in regulatory enforcement action), acceptance of the data by the FDA will be dependent upon its determination that the trials were conducted consistent with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct 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 our development of the applicable product candidates. For example, the Phase 1 and Phase 2 clinical trials of COVAXIN were conducted in India and a Phase 3 clinical trial is currently ongoing there. The FDA may not accept data from the studies conducted with COVAXIN at clinical trial sites in India, and instead require clinical trials be conducted in the United States.

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

In order to market and sell our products in jurisdictions outside the United States, we must obtain separate marketing approvals in international jurisdictions and comply with numerous and varying regulatory requirements. The approval procedures vary among countries and 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. Our clinical trials of our product candidates may not be sufficient to support an application for marketing approval outside the United States. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming.

We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. We, 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 our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Additionally, in June 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. In March 2017, the United Kingdom formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. In October 2019, the United Kingdom and European Union agreed upon the terms of the U.K.'s withdrawal from the E.U. in the form of a Withdrawal Agreement. The Withdrawal Agreement was ratified by the U.K Parliament, and the European Parliament in Brussels, in late January 2020, with the consequence that Brexit formally occurred on January 31, 2020. The 11-month transition period ended on December 31, 2020. Following the transition period, the United Kingdom is no longer a part of the single market and customs union of the E.U. In December 2020, the United Kingdom and E.U. announced they had entered into a post-Brexit deal on certain aspects of trade and other strategic and political issues. However, this deal may not avoid all disruption resulting from Brexit. 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 our 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 us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

We may be subject to fines, penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain 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. We may not market or promote them for other indications and uses, referred to as off-label uses. We further must be able to sufficiently substantiate any claims that we make for our products including claims comparing our 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, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA.

If we are found to have impermissibly promoted any of our product candidates, we 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.

In the United States, engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us 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 we promote or distribute therapeutic products and do 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 FCA, which allows any individual to bring a lawsuit against a company on behalf of the federal government ("qui tam" action) 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 FCA 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, FCA lawsuits may expose sponsors to follow-on claims by private payors 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 we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our 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. PDMA, and the promotion of biologic and pharmaceutical products are subject to additional FDA requirements and restrictions on promotional statements. If the FDA determines that our promotional activities violate our regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us 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 our business, financial condition, results of operations, and prospects.

Even if our product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense.

Any product candidate for which we obtain 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 GMPs or current GMP-requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and GCPs, for any clinical trials that we conduct 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. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our 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.

We and any of our collaborators, including our contract manufacturer, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with current GMPs 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 our 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 we establish or modify a similar strategy;
- liability for harm caused to patients or subjects;
- reputational harm;
- warning, untitled, Form 483s, or cyber letters;
- suspension of marketing, withdrawal or recall 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 we submit;
- fines, restitution, or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our 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.

Any of these events could prevent us 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 us from generating significant revenues from its sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our stock price and could significantly harm our 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 our product candidates, that could limit the marketability of our product candidates, or that could impose

additional regulatory obligations on us. Changes in medical practice and standard of care may also impact the marketability of our product candidates.

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

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have 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 our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we 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. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Related to the Commercialization of Our Product Candidates

We have no prior experience in the marketing, sale, and distribution of pharmaceutical products and there can be no assurance that our products, if approved, will be successfully commercialized.

We have no prior experience in the marketing, sale, and distribution of 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 we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, manage, and retain marketing and sales personnel. Factors that may inhibit our efforts to commercialize our 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 our product candidates;
- our 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 we 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 we agree 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 us 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, we may not be successful in commercializing any product candidates for which we receive marketing approval.

We face significant competition from other pharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations. Our operating results will suffer if we fail to compete effectively.

The development and commercialization of new vaccines and therapeutic products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty 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.

The competitive landscape of potential COVID-19 vaccines and treatment therapies has been rapidly developing since the beginning of the COVID-19 pandemic, with several hundreds of companies claiming to be investigating possible candidates and more than 5,000 studies registered worldwide as investigating COVID-19. We are aware of several competitors developing late-stage COVID-19 vaccines, including Pfizer Inc./BioNTech SE, Moderna, Inc., AstraZeneca PLC, Johnson & Johnson/Janssen Biotech, Inc., and Novavax, Inc. Vaccines developed by Pfizer Inc./BioNTech SE, Moderna, Inc., and Johnson & Johnson/Janssen Biotech have already been granted EUAs by the FDA. We are also aware of others pharmaceutical companies that are working on inactivated virus-based COVID-19 vaccines. Furthermore, the FDA has authorized and many companies are developing therapeutics to treat COVID-19. If the FDA requires us to conduct clinical trials, enrollment in such trials may be impacted given the commercial availability of other EUA authorized vaccines. Furthermore, the FDA has authorized and many companies are developing therapeutics to treat COVID-19. The success or failure of other vaccines, or perceived success or failure, may adversely impact our ability to obtain any future funding for our joint COVID-19 vaccine development efforts or for us to ultimately commercialize any vaccine candidate, if authorized or approved by the FDA. In addition, we may not be able to compete effectively if our product candidate does not satisfy government procurement requirements with respect to biodefense products. If existing vaccines in the market or if competitors develop and commercialize additional COVID-19 vaccines before we can complete regulatory review and obtain an EUA or regulatory approval for COVAXIN, or if they develop and commercialize one or more COVID-19 vaccines that are safer, more effective, have fewer or less severe side effects, have broader market acceptance, are more convenient, or are less expensive than COVAXIN, our business, financial condition, and results of operations would be materially adversely affected.

We are aware of several companies focusing on gene therapies for various ophthalmic indications, including Adverum Biotechnologies, Inc., Applied Genetic Technologies Corporation, MeiraGTx Holdings plc, IVERIC bio, Inc., REGENXBIO Inc., ProQR Therapeutics N.V., Generation Bio Co, Greybug Vision, Inc., and Spark Therapeutics, Inc. (acquired by the Roche Group in 2019). Spark Therapeutics, Inc.'s product Luxturna (Spark Therapeutics), which is currently the only gene therapy approved for an IRD in the United States, addresses only one out of at least 150 known mutations of the *RPE65* gene. Companies that may compete with our OCU200 product candidate include the Roche Group, Regeneron Pharmaceuticals, Inc., Novartis AG, and Kodiak Sciences Inc. The Roche Group, Regeneron Pharmaceuticals, Inc., and Novartis AG have marketed anti-VEGF products.

Our product candidates will target markets that are already served by competing products. Many of these existing products have achieved widespread acceptance among clinicians, patients, and payors.

Our commercial opportunities could be reduced or eliminated if our 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 we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. They may obtain patent protection or other intellectual property rights that allow them to develop and commercialize their products before us and could limit our ability to develop or commercialize our product candidates.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payors coverage decisions. Our ability to compete may be affected in many cases by insurers or other third-party payors, particularly Medicare, seeking to encourage the use of generic or biosimilar products. Many of the products that will compete with our product candidates, if approved, are available on a generic basis, and our product candidates may not demonstrate sufficient additional clinical benefits to clinicians, patients, or payors to justify a higher price compared to generic products. Additional competing products are expected to become available on a generic basis over the coming years. In many cases, insurers or other third-party payors, particularly Medicare, seek to encourage the use of generic products.

Many of the companies against which we are competing or against which we 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 we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our 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 us 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, our programs.

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

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of biologic and pharmaceutical products. If approved, in order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. If we do not establish sales, marketing, and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates for which we receive marketing approval.

Subject to FDA approval of any of our product candidates, we may build a commercial team of specialty sales and marketing representatives in support of our product candidates that we develop in the United States, if and when they are approved, as well as distribution capabilities. There are risks involved with us establishing our own sales, marketing, and distribution capabilities. Recruiting and training a sales force is expensive and time-consuming, particularly to the extent that we seek to commercialize any product for an indication, such as wet AMD, that has a large patient population. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations to recruit, hire, train, and retain marketing and sales personnel. Further, we may underestimate the size of the sales force required for a successful product launch and may need to expand our sales force earlier and at a higher cost than we anticipate. If the commercial launch of our product candidates for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with a third-party or contract sales organization to commercialize any approved product candidates, in which event, our ability to generate product revenues may be limited. Our product revenues and our profitability, if any, under any third-party collaboration, distribution or other marketing arrangements are likely to be lower than if we were to market, sell, and distribute the applicable product candidate entirely ourselves. We may not be successful in entering into arrangements with third parties to sell, market, and distribute our product candidates or may be unable to do so on terms that are favorable to us. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. We could also be held liable if such third parties failed to comply with applicable legal or regulatory requirements.

In the event we are unable to develop a team of marketing and sales representatives or to establish an effective third-party contractual relationship for such services, we may not be able to commercialize our product candidates, which would limit our ability to generate product revenues. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our product candidates.

If our product candidates do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

Even if our 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. 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. We have never commercialized a product candidate for any indication, and efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. With respect to our product candidates being developed based on our modifier gene therapy platform, market acceptance may also be constrained by ethical, social, and legal concerns about gene therapy and genetic research, which could result in additional regulations restricting or prohibiting the products and processes we may use. The novelty of the technology and any negative publicity surrounding adverse events associated with gene therapy may also prevent the medical community, patients, and third-party payors from accepting gene therapy products in general, and our product candidates in particular, as medically useful, cost-effective, and safe.

Market acceptance of our product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control. If any product candidates for which we obtain regulatory approval does not gain an adequate level of market acceptance, it may not generate significant product revenues or become profitable.

The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- the efficacy of our product candidates;
- the prevalence and severity of adverse events associated with such product candidates;
- the clinical indications for which the products are approved and the approved claims that we 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 we 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 retinal diseases in persons over age 55;
- the price concessions required by third party payors to obtain coverage;
- the extent and strength of our manufacturing, marketing, and distribution of such product candidates;
- distribution and use restrictions imposed by the FDA with respect to such product candidates or to which we agree as part of a REMS or voluntary risk management plan;
- the extent of availability of generic or biosimilar versions of any products that compete with any of our product candidates and the extent to which they are offered at a substantially lower price than we expect to offer for our product candidates, if approved;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

If the market opportunities for our product candidates are smaller than we believe, our revenue may be adversely affected, and our business may suffer.

The potential market opportunities for our product candidates are difficult to precisely estimate. Our 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 we 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 we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. In addition, while we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our 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 our product candidates could be smaller than our estimates of the potential market opportunities, and as a result our product revenue may be limited, and it may be more difficult for us to achieve or maintain profitability.

If third-party payors do not reimburse patients for our products candidates, if approved, or if reimbursement levels are set too low for us to sell our product candidates at a profit, our ability to successfully commercialize our product candidates, if approved, and our results of operations will be harmed.

Our ability to successfully commercialize our product candidates, if approved, will depend in part on the extent to which coverage and adequate reimbursement for our product candidates will be available in a timely manner from third-party payors, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers, and managed care organizations. This is particularly true with respect to OCU200, our novel biologic product candidate, in the case of wet AMD, which is most prevalent in persons over age 55. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Reimbursement decisions by particular third-party payors depend upon a number of factors, including each third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific condition or disease;
- cost effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for our product candidates from government authorities or other third-party payors may be a time consuming and costly process that could require us to provide supporting scientific, clinical, and cost-effectiveness data, including expensive pharmacoeconomic studies beyond the data required to obtain marketing approval, for the use of each product candidate to each government authority or other third-party payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement.

Third-party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with cost-effective diagnosis methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors also may refuse to reimburse for procedures and devices deemed to be experimental. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

Increasingly, third-party payors are also requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. These third-party payors could also impose price controls and other conditions that must be met by patients prior to providing coverage for use of our product candidates, if approved. For example, insurers may establish a “step-edit” system that requires a patient to first use a lower price alternative product prior to becoming eligible for reimbursement of a higher price product.

Third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Levels of reimbursement may also decrease in the future, and future legislation, regulation, or reimbursement policies of third-party payors may adversely affect the demand for and reimbursement available for our product candidates, which in turn, could negatively impact pricing. If patients are not adequately reimbursed for our product candidates, if approved, they may reduce or discontinue purchases of it, which would result in a significant shortfall in achieving revenue expectations and negatively impact our business, prospects and financial condition.

If we obtain approval to commercialize our product candidates outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to conducting marketing and sales activities in international jurisdictions and entering into international business relationships, including:

- different regulatory requirements for approval of drugs and biologics in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- the need to seek additional patent approvals, licenses to patents held by third parties, and/or face claims of infringing third-party patent rights;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;

- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA, the U.K. Bribery Act 2010 (the "Bribery Act") or other comparable foreign regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including pandemics or other outbreaks of infectious disease, earthquakes, typhoons, floods, and fires.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials we may initiate, 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.

We rely on third parties, study sites, and others to conduct, supervise, and monitor our preclinical trials for our product candidates. We expect 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 our ongoing preclinical studies and planned clinical trials.

While we have, or expect to have, agreements governing the activities of such third parties, we will have limited influence and control over their actual performance and activities. Third-party service providers are not our employees, and except for remedies available to us under agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies or planned clinical trials. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and planned clinical trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical trials are conducted in accordance with GLP and under current GMP conditions, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us 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. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites, and IRBs.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or any planned clinical trials in accordance with regulatory requirements or our 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 our protocols, regulatory requirements or for other reasons:

- we or our CROs or other third-party collaborators may be subject to regulatory enforcement or other legal actions;
- the data generated in our preclinical studies or planned clinical trials may be deemed unreliable and our such studies and trials may need to be repeated, extended, delayed, or terminated;
- we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates; or
- we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies or planned clinical trials will comply with the applicable regulatory requirements. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Our anticipated reliance on third parties in connection with our planned clinical trials will entail additional risks. Our third-party service providers may have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, we will be required to report certain financial interests of our 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. Lastly, we are 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 our clinical or preclinical studies might terminate for a variety of reasons, including a failure to perform by the third parties. If any of our relationships with these third parties terminate, we 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 we need to enter into alternative arrangements, it could delay our product development activities and adversely affect our business. Though we intend to carefully manage our relationships with third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects, and results of operations.

We will also rely on other third parties to store and distribute our product candidates for the preclinical trials that we conduct or for clinical trials we plan to conduct in the future. Any performance failure on the part of our distributors could delay development, marketing approval, or commercialization of our product candidates, producing additional losses and depriving us of potential product revenue.

If we encounter difficulties in negotiating commercial manufacturing and supply agreements with third-party manufacturers and suppliers of our product candidates or any product components, our ability to commercialize our product candidates, if approved, would be impaired.

We do not manufacture any of our product candidates or any product components, and we do not currently plan to develop any capacity to do so. Accordingly, we are, and expect to continue to be, dependent upon third parties for the manufacture of our product candidates and any approved products. For example, we do not currently have the capacity to manufacture COVAXIN, and we do not currently plan to develop any capacity to do so. Bharat Biotech has agreed to provide to Ocugen all preclinical and clinical data, and to transfer to us certain proprietary technology owned or controlled by Bharat Biotech, that is necessary for the successful commercial manufacture and supply of COVAXIN to support commercial sale in the United States, if authorized or approved, including pursuant to an EUA. Until the completion of that technology transfer and until we are capable and primarily responsible for the manufacture and supply of COVAXIN in the United States through third parties, Bharat Biotech has the exclusive right to manufacture COVAXIN and we will be wholly dependent on Bharat Biotech for the manufacture and supply of clinical testing materials required for our development activities and all of our requirements of commercial quantities of COVAXIN, if authorized or approved. We and Bharat Biotech intend to enter into supply agreements setting forth the terms of such supply arrangement, but can be no assurance that we will be able to successfully enter into such agreements. Bharat Biotech has agreed to provide a specified minimum number of doses in calendar year 2021, but there can be no assurance that they will in fact provide such number of doses, whether due to shortages in supply, diversion of vaccine resources to other uses deemed more immediate, or other factors. There can be no assurance that we will be successful in transitioning the manufacture of COVAXIN for the U.S. market from Bharat Biotech to a third-party manufacturer. If we are unable to obtain adequate supply of COVAXIN, our U.S. development and commercialization efforts would be impaired.

Additionally, we have entered into a strategic partnership with CanSinoBIO to manufacture our gene therapy pipeline product candidates for inherited retinal diseases. Under this agreement, CanSinoBIO will provide all CMC development and clinical supplies for the development of OCU400. The agreement also provides CanSinoBIO an option to support commercial manufacturing for OCU400 and commercialization rights to CanSinoBIO in Greater China. We expect to rely on our qualified suppliers and other third parties to manufacture clinical supplies of other product candidates and commercial supplies of all of our products, if and when approved for marketing by applicable regulatory authorities, as well as for packaging, serialization, storage, distribution, and other production logistics. We, however, may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our product candidates, components, and programs, or may be unable to do so on commercially favorable terms. If we are unable to enter into such agreements on commercially favorable terms, our future profit margins would be adversely affected and our ability to commercialize any products that receive marketing approval on a timely and competitive basis would be impaired. As a result, our business, financial condition, and results of operations would be materially adversely affected.

If the manufacturers upon whom we rely fail to produce our product candidates or components pursuant to the terms of contractual arrangements with us or fail to comply with stringent regulations applicable to biologic and pharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.

As with the third parties on which we rely or expect to rely for our preclinical activities and planned clinical trials, we have agreements governing the activities of our manufacturers but have limited influence and control over their actual performance and activities. Our third-party manufacturers are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our manufacturing requirements. If these third-party manufacturers do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements, and if there are disagreements between us and such parties, clinical development or marketing approval of our product candidates could be delayed.

The manufacture of 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 our manufacturers were to encounter any of these difficulties and were unable to perform as agreed, our ability to provide product candidates to patients in our planned clinical trials and for commercial use, if approved, would be jeopardized.

In addition, all manufacturers of our product candidates and therapeutic substances must comply with current GMP 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. Our manufacturers must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the agency. Our manufacturers will also be subject to continuing FDA and other regulatory authority inspections should we receive marketing approval. Further, we, in cooperation with our contract manufacturers, must supply all necessary CMC documentation to the FDA in support of a marketing application on a timely basis.

The current GMP requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our product candidates and the therapeutic substances and active pharmaceutical ingredients necessary to produce our product candidates may be unable to comply with our specifications, current GMP 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 our contract manufacturers cannot successfully manufacture material that conforms to our 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 us 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 resulting 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 we conduct additional studies.

While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with the applicable regulatory requirements may result in regulatory enforcement actions against our manufacturers or us, 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 FCA, corporate integrity agreements, or consent decrees. Depending on the severity of any potential regulatory action, our clinical or commercial supply could be interrupted or limited, which could have a material adverse effect on our business.

Any problems or delays we experience 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 our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of commercialization of our product candidates and could adversely affect our business.

We or our third-party manufacturers may also encounter shortages in the materials necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization.

We or our third-party manufacturers may also encounter shortages in the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to produce our product candidates in the quantities needed for our clinical trials or, if our 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 our competitors or others. We or our third-party manufacturers' failure to obtain the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to manufacture sufficient quantities of our product candidates may cause the manufacturers to fail to deliver the required commercial quantities of our product candidates on a timely basis and at commercially reasonable prices. If such failure occurs, we would likely be unable to meet the demand for our products and we would lose potential revenues.

The number of available, qualified third-party manufactures is limited, and if we are compelled to locate an alternative manufacturing partner our product development activities and commercialization could be delayed and additional expense would be incurred.

There are a limited number of manufacturers that operate under current GMP regulations and that are both capable of manufacturing for us and willing to do so, and therefore our product candidates may compete with other products and product candidates for access to manufacturing facilities. Moreover, because our product candidates must be manufactured under sterile conditions, the number of manufacturers who can meet this requirement are even more limited. If our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product or component for commercial sale or for any clinical trials we expect to initiate in the future should cease to continue to do so for any reason (including the termination of our agreements with such manufacturers, which can occur for a variety of reasons, or the bankruptcy of such manufacturers), it would be difficult to obtain a suitable alternative manufacturer. We would likely experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. Any change in our 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.

If the FDA or a comparable foreign regulatory authority does not approve the facilities for the manufacture of our product candidates or if the FDA withdraws any such approval in the future, we may need to find alternative manufacturing facilities. 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. We must also receive FDA approval for the use of any new manufacturers for commercial supply. Any such developments would significantly impact our ability to develop, obtain, and maintain regulatory approval for or market our product candidates, if approved.

The number of available third-party facilities may also be further limited by natural disasters, such as pandemics, including the ongoing COVID-19 pandemic, 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, an appropriate replacement third-party relationship may not be readily available to us or on acceptable terms, which would cause additional delay and increased expense and may have a material adverse effect on our business.

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

We are currently party to the Covaxin Agreement with Bharat Biotech for the development and commercialization of COVAXIN in the United States and the CanSinoBIO Agreement with CanSinoBIO for the development and commercialization of our initial gene therapy product candidate, OCU400. Our joint development efforts are in the early stages and in the future we may seek to enter into additional collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of other product candidates. We may utilize a variety of types of collaboration, distribution, and other marketing arrangements with third parties to develop and commercialize our product candidates, both inside and outside the United States. In particular, we may enter into arrangements with third parties to perform certain services in the United States if we do not establish our own sales, marketing, and distribution capabilities in the United States or if we determine that such third-party arrangements are otherwise beneficial. We 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.

The success of our current and future collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to collaboration arrangements. Accordingly, with respect to any such arrangements with any third parties, we will likely have

limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend in part on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. For example, if Bharat Biotech were to fail to successfully complete the ongoing Phase 3 clinical trial of COVAXIN, or were to fail to report safety data in accordance with regulatory requirements, our ability to develop COVAXIN in the United States would be impaired.

Moreover, 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 pharmaceutical companies and other third parties are often terminated or allowed to expire. Any such termination or expiration would adversely affect us financially and could harm our business reputation. In particular, any termination of the Covaxin Agreement would prevent us from developing COVAXIN for the U.S. market.

Our current and future collaborations may pose a number of additional risks, including the following:

- 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 us to regulatory enforcement actions;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our 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 ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our 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 us 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 our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties or fail to maintain intellectual property rights which they license to us, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we 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 do not result in the successful development and commercialization of product candidates or if one of our collaborators subsequently terminates our agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration, as applicable. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed, and we may need additional resources to develop our

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

Additionally, if any collaborator of ours is involved in a business combination, the collaborator might de-emphasize or terminate development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

Should we desire to pursue a collaboration agreement but are not able to establish collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected.

For some of our product candidates, we may decide to collaborate with pharmaceutical or biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborators and whether we reach a definitive agreement for a collaboration will depend, among other things, upon our 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 our 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. We 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. Should we desire to pursue a collaboration agreement but are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

Risks Related to Legal and Compliance Matters

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

As a biologic and pharmaceutical company, we are subject to many federal and state healthcare laws, such as the federal Anti-Kickback Statute, the federal civil and criminal FCA, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the VHCA, the HIPAA, the FCPA, the ACA, and similar state laws. We may also be subject to laws regarding transparency and patient privacy. Even though we do 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 our business.

It is possible that governmental authorities will conclude that our 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 we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that applies to us, we 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 our operations, any of which could materially adversely affect our ability to operate our business and our financial results. 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 us for violation of these laws, even if we successfully defends against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

We are subject to new legislation, regulatory proposals, and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our 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 our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any products for which we obtain marketing approval. The biopharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. We expect 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 we may receive for any approved products.

In 2010, the ACA, included provisions of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our 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 FCA 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 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 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 we may successfully develop and for which we may obtain marketing approval and may affect our 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 in April 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 we license 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.

We expect 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 our biologic and pharmaceutical products, decreased potential returns from our development efforts, new payment methodologies, and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which any

products we 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 us from being able to generate revenue, attain profitability, or commercialize our products.

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, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

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 our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, and results of operations.

Our 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 our business.

We are 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 (i) comply with FDA regulations, or other similar regulatory requirements, (ii) comply with manufacturing standards, including current GMP requirements, (iii) comply with applicable fraud and abuse laws, (iv) comply with federal and state data privacy, security, fraud and abuse, and other healthcare laws and regulations in the United States and abroad, (v) provide accurate information to the FDA, (vi) properly calculate pricing information required by federal programs, (vii) comply with federal procurement rules or contract terms, (viii) report financial information or data accurately or (ix) disclose unauthorized activities to us. 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 our reputation.

It is not always possible to identify and deter this type of misconduct, and the precautions we take 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.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws, and other laws governing our operations. If we fail to comply with these laws, we 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, which could adversely affect our business, results of operations, and financial condition.

If we expand our operations outside of the United States, we must dedicate additional resources to compliance with anti-corruption laws, including the Bribery Act, the FCPA, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit us, our officers, and our 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. 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. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA, or local anti-corruption laws. We are also subject to other laws and regulations governing our 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 we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we 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 our business, financial condition, results of operations, and liquidity. The SEC 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., United States, or other authorities could also have an adverse impact on our reputation, our business, results of operations, and financial condition.

Risks Related to Our Intellectual Property

We may be unable to obtain and maintain patent protection for our technology and product candidates, or the scope of the patent protection obtained may not be sufficiently broad or enforceable, such that our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

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

The patent prosecution process is expensive and time-consuming, and we 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. We may also fail to identify patentable aspects of our 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 our patent rights are highly uncertain. Our pending and future patent applications may

fail to result in issued patents in the United States or in other foreign countries which protect our 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 our 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, we cannot be certain whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our 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 we 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 our patent rights are uncertain. Our pending and future patent applications may not result in patents being issued which protect our 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 our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We 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 our patents or narrow the scope of our patent protection.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection for our proprietary technology and product candidates, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. In some instances, we may need to license additional patents and trade secrets to commercialize our product candidates in certain territories.

The issuance of a patent is not conclusive as to our inventorship, ownership, scope, validity, or enforceability, and our 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 our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our 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, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

In 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. 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 in 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 our patent applications and the enforcement or defense of our issued patents, which could have a material adverse effect on our 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 ("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 our 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 our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining, defending, and enforcing them.

If we are 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 our marketing exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our 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 our product candidates. Nevertheless, we 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 we request.

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

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering one of our product candidates even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we do 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 our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

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

Competitors and other third parties may infringe, misappropriate, or otherwise violate our owned and licensed patents, trade secrets, or other intellectual property. As a result, to counter infringement, misappropriation, or unauthorized use, we may be required to file infringement or misappropriation claims or other intellectual property related proceedings, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringed their patents or that our asserted patents are invalid. In addition, in a patent infringement or other intellectual property related proceeding, a court may decide that a patent of ours 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 our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, and could put any of our 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 our confidential information or trade secrets could be compromised by disclosure during this type of litigation.

We 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 our 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, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us 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 our 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 we are 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 our business.

Our commercial success depends upon our ability to develop, manufacture, market, and sell our product candidates and use our 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. We may become party to, or threatened with, infringement litigation claims regarding our products and technology, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Moreover, we may become party to future adversarial proceedings or litigation regarding our 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 our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we do. The risks of being involved in such litigation and proceedings may increase as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses.

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

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

Certain aspects of our product candidates are protected by patents exclusively licensed from other companies or institutions. If these third parties terminate their agreements with us or fail to maintain or enforce the underlying patents or licenses thereto, or we otherwise lose our rights to these patents, our competitive position and our market share in the markets for any of our approved products will be harmed.

A substantial portion of our patent portfolio is in-licensed. As such, we are party to license agreements and certain aspects of our business depend on patents and/or patent applications owned by other companies or institutions. In particular, we hold

exclusive licenses for patent families relating to OCU400, OCU410, and OCU200 and an exclusive license in the United States with respect to patents relating to COVAXIN.

Pursuant to the CU Agreement, which primarily relates to OCU200, we are responsible for and control patent prosecution of all patent families licensed under the CU Agreement.

Pursuant to the SERI Agreement, which relates to NHR genes *NR1D1*, *NR2E3*, *RORA*, *NUPR1*, and *NR2C1*, from and after December 19, 2017, we have the right to assume responsibility and control patent prosecution of licensed patent families relating to these NHR genes. Additionally, we are responsible for and control patent prosecution for any patent applications developed in connection with the SERI Agreement filed after December 19, 2017 that are owned jointly by us and SERI or solely by us.

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

Our licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are licensed and on which our business depends. Even if patents issue from these applications, our 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. In some cases, our licensors may in-license certain patents licensed to us. If our licensors were to fail to maintain such licenses, we may need to obtain additional licenses with respect to the applicable product candidates.

Risks with respect to parties from whom we have obtained intellectual property rights may also arise out of circumstances beyond our control. In spite of our best efforts, our licensors might conclude that we have materially breached our intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing our ability to market products covered by these intellectual property agreements. If our 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 ours. Moreover, if our intellectual property agreements are terminated, our former licensors and/or assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on our competitive business position and our business prospects.

Some intellectual property which we own or have 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 our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights that we own or licenses have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations under the Bayh-Dole Act. To the best of our knowledge, our intellectual property for OCU400 for the treatment of *NR2E3* mutation-associated retinal degenerative disease and other retinal degenerative diseases is subject to the Bayh-Dole Act. As a result, the U.S. 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 our competitive position, business, financial condition, results of operations, and prospects.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

Our agreements under which we license certain of our patent rights and a significant portion of the technology for our product candidates, impose royalty and other financial obligations on us and other substantial performance obligations. We 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 us. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we 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 our products and product candidates. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

In addition, it is possible that our licensors may conclude that we have materially breached the applicable license agreement and might therefore terminate the agreement, thereby removing our ability to market products covered by such agreements. If any license 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 ours. Moreover, if any of our license agreements are terminated, the counterparty and/or its assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on our competitive business position and our business prospects.

In addition, the agreements under which we currently license 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 we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We may not be able to protect our 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 our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with our products, and our 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 us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our and our licensors' employees and contractors were previously employed at other biotechnology, medical device, or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have 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 our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Furthermore, we are unable to control whether our licensors have obtained similar assignment agreements from their own employees and contractors. Our and their assignment agreements may not be self-executing or may be breached, and we or our licensors may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which may not be available on commercially reasonable terms or at all. Even if we are 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 us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our 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 our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we 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 our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we 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 our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it,

from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Our Common Stock

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us 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.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of common stock in the public market, the market price of our common stock could decline. We had 184.0 million shares of common stock outstanding as of December 31, 2020, which were all freely tradable, without restriction, in the public market as of December 31, 2020.

If a substantial number of shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline, we are unable to predict the effect that sales may have on the prevailing market price of our common stock.

We have used almost all of our unreserved, authorized shares.

We have used almost all of our unreserved authorized shares and will need stockholder approval to implement an increase in our authorized shares of common stock or a reverse stock split. Our sixth amended and restated certificate of incorporation and the Delaware General Corporation Law (the "DGCL"), currently require the approval of stockholders holding not less than a majority of all outstanding shares of capital stock entitled to vote in order to approve an increase in our authorized shares of common stock or a reverse stock split. There are no assurances that stockholder approval will be obtained, in which event we will be unable to raise additional capital through the issuance of shares of common stock to fund our future operations.

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

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our Board of Directors. The provisions in our 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 our 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 our 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 our Board of Directors;
- the prohibition on removal of directors without cause due to the classified Board of Directors;
- the ability of our 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 our Board of Directors to alter our 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 our amended and restated bylaws or repeal certain provisions of our 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 our 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 our 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 our 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 us.

We are also subject to the anti-takeover provisions contained in Section 203 of the DGCL. 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.

Our 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 us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our sixth amended and restated certificate of incorporation provides that, unless we consent 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 our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us 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 of 1933, as amended, 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 us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. By agreeing to this provision, however, stockholders will not be deemed to have waived our 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 our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risk Factors

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

Our stock price has been, and will likely continue to be volatile. During the 60 trading days immediately prior to the date of this report, the closing price of our common stock has ranged from a low of $0.29 to a high of $15.81. 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 our common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- our ability to enroll subjects in our ongoing and planned clinical trials;
- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for our use, or changes or delays in the regulatory review process;
- the level of expenses related to any of our product candidates or clinical development programs;
- regulatory developments in the United States and foreign countries;
- reports of adverse events in other of our products, competing biologics, or gene therapy products;

- 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 our efforts to acquire, license, or develop additional product candidates;
- innovations or new products developed by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- manufacturing, supply, or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators, or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to ours;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by insiders and stockholders or the perception that such sales could occur;
- our ability to effectively manage our growth;
- ineffectiveness of our internal control over financial reporting;
- additions or departures of key personnel, including major changes in our board or management;
- intellectual property, product liability, or other litigation against us; and
- general economic, industry, market conditions, and other events or factors, many of which are beyond our control.

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 us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical, and business development expertise of Shankar Musunuri, Ph.D., MBA, our Chief Executive Officer, Chairman of the Board, and Co-Founder, as well as the other principal members of our management, scientific, and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, legal, and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our 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 our 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 we 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. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy, including with respect to our development of COVAXIN for the U.S. market. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development, regulatory, and manufacturing capabilities and potentially implement sales, marketing, and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical, regulatory affairs, manufacturing, sales, marketing, and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of our attention to managing these growth activities. Due to our limited financial resources and our limited experience in managing such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company we have incurred, and will continue to incur, significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley"), the Dodd-Frank Wall Street Reform, and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We have had to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being a public company and our management and other personnel devote a substantial amount of time towards maintaining compliance with these requirements. These requirements increase our legal and financial compliance costs and make some activities more time-consuming and costly. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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 are applicable to us. 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 we operate our business in ways we cannot currently anticipate.

If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs could impact our results of operations, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our board committees, or as executive officers.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.
Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological agents coverage, and our commercial general liability policy specifically excludes coverage for damages and fines arising from biological agents. Accordingly, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws, regulations, and permitting requirements. These current or future laws, regulations, and permitting requirements may impair our research, development, or production efforts. Failure to comply with these laws, regulations, and permitting requirements also may result in substantial fines, penalties, or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Any third-party contract manufacturers and suppliers we engage will also be subject to these and other environmental, health, and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Pursuant to Section 404 of Sarbanes-Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting. Additionally, if we reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our 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, we will need to upgrade our information technology systems; implement additional financial and management controls, reporting systems, and procedures; and hire additional accounting and finance personnel. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

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

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for our product candidates and may have to limit our commercialization.

The use of our product candidates in clinical trials, and the sale of any of our product candidates for which we obtain regulatory approval, exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies, or others selling or otherwise coming into contact with our products. For example, we may be sued if any product candidate we develop 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. If we cannot successfully defend ourself against these claims, we will incur substantial liabilities or be required to limit development or commercialization of our 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 our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- exhaustion of any available insurance and our capital resources;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;
- decrease in our stock price;
- initiation of investigations, and enforcement actions by regulators; or
- product recalls, withdrawals, revocation of approvals, or labeling, marketing, or promotional restrictions.

While we currently hold product liability insurance coverage in an amount that we believe is customary for similarly situated companies, the amount of that coverage may not be adequate. We may need to increase our insurance coverage as we begin our clinical trials. We will need to further increase our insurance coverage if we commence commercialization of any of our product candidates for which we obtain marketing approval. Insurance coverage is increasingly expensive. We 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. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and our prospects.

Our business and operations would suffer in the event of system failures, and we face risks related to our collection and use of data, which could result in investigations, inquiries, litigation, fines, legislative and regulatory action, and negative press about our privacy and data protection practices.

Our internal computer systems and those of our 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 our operations, it could result in a material disruption of our product candidate development and, if such product candidates are approved, commercialization programs.

Additionally, our business processes personal data, including some data related to health. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations. We also face risks inherent in handling large volumes of data and in protecting the security of such data. We could be subject to attacks on our systems by outside parties or fraudulent or inappropriate behavior by our service providers or employees. Third parties may also gain access to our systems using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks, or other means, and may use such access to obtain personal data. Data breaches could subject us to individual or consumer class action litigation and governmental investigations and proceedings by federal, state, and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and/or

criminal liability. As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities, including various domestic and international privacy and security regulations. The legislative and regulatory landscape for privacy and data protection continues to evolve. In the United States, certain states may adopt privacy and security laws and regulations that may be more stringent than applicable federal law. For example, California enacted the California Consumer Privacy Act ("CCPA"), which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. We may also in the future be subject to data protection laws and regulations of other jurisdictions, such as the European Union's General Data Protection Regulation ("GDPR"), which provides data subjects with certain rights and requires organizations to adopt technical and organizational safeguards to protect personal data. In the event that we are subject to or affected by privacy and data protection laws, including the CCPA or GDPR and other domestic or international privacy and data protection laws, we may expend significant resources to comply with such laws, and any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties

Our headquarters are located in Malvern, Pennsylvania, and consist of an aggregate of approximately 16,401 square feet of leased office, laboratory, and storage space.

Item 3. Legal Proceedings.

From time to time, we are subject to claims in legal proceedings arising in the normal course of our 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 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on the Nasdaq under the symbol “OCGN."

Stockholders

As of March 1, 2021, we had 188.1 million shares of common stock outstanding held by approximately 21 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in “street” name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have not declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain future earnings, if any, to finance our operations and do not anticipate declaring or paying any cash dividends in the foreseeable future. As a result, we anticipate that only appreciation of the price of our common stock, if any, will provide a return to investors for at least the foreseeable future.

Unregistered Sales of Equity Securities and Use of Proceeds

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

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report on Form 10-K.

Share Repurchase

On October 9, 2019, we announced that our 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, we plan 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.

Item 6. Selected Financial Data

Not applicable.

Item 7. 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 Annual Report on Form 10-K. 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 "Special Note Regarding Forward-Looking Statements" sections of this Annual Report on Form 10-K 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.

On September 27, 2019, we completed a reverse merger (the "Merger") with Ocugen OpCo, Inc. ("OpCo") in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of April 5, 2019, by and among OpCo, Restore Merger Sub, Inc., our wholly owned subsidiary ("Merger Sub"), and us, as amended, pursuant to which Merger Sub merged with and into OpCo, with OpCo surviving as our wholly owned subsidiary. Immediately after completion of the Merger, we changed our name to Ocugen, Inc. For accounting purposes, the Merger is treated as a "reverse asset acquisition" under generally acceptable accounting principles in the United States ("GAAP") and OpCo is considered the accounting acquirer. Accordingly, OpCo's historical results of operations replaced the our 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 our financial statements.

Overview

We are a biopharmaceutical company focused on developing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19.

Our cutting-edge technology pipeline includes:

- **COVID-19 Vaccine** — COVAXIN is a whole-virion inactivated COVID-19 vaccine candidate being developed to prevent COVID-19 infection in humans. We are co-developing COVAXIN with Bharat Biotech International Limited ("Bharat Biotech") for the U.S. market.
- **Modifier Gene Therapy Platform** — Based on nuclear hormone receptors ("NHRs"), we believe our gene therapy platform has the potential to address many retinal diseases, including retinitis pigmentosa ("RP"), leber congenital amaurosis ("LCA"), and dry age-related macular degeneration ("AMD").
- **Novel Biologic Therapies for Retinal Diseases** — We are developing OCU200, a novel biologic product candidate, to treat diabetic macular edema ("DME"), diabetic retinopathy ("DR"), and wet AMD.

COVID-19 Vaccine

In February 2021, we entered into a Co-Development, Supply and Commercialization Agreement (the "Covaxin Agreement") with Bharat Biotech, pursuant to which we obtained an exclusive right and license under certain of Bharat Biotech's intellectual property rights, with the right to grant sublicenses, to develop, manufacture and commercialize COVAXIN for the prevention of COVID-19 in humans in the United States, its territories and possessions (the "Ocugen Covaxin Territory"). Under the Covaxin Agreement, we will be solely responsible for such activities for the Ocugen Covaxin Territory.

COVAXIN is a whole-virion inactivated COVID-19 vaccine candidate being developed by Bharat Biotech, a global leader in vaccine innovation, and has been granted approval for emergency use in India. COVAXIN is formulated with the inactivated SARS-CoV-2 virus, an antigen, and an adjuvant therefore utilizing a historically proven approach to vaccine design. COVAXIN requires a two-dose vaccination regimen given 28 days apart and is stored in standard vaccine storage conditions (2-8°C). The Phase 1 and Phase 2 clinical trials conducted in India reported strong Immunoglobulin G responses against the spike protein, receptor-binding domain, and the nucleocapsid protein of the SARS-CoV-2 virus, along with strong cellular responses. Strong cellular responses are necessary for memory and long-term durability of vaccines. In an analysis from the National Institute of Virology, serum samples collected from individuals vaccinated with COVAXIN showed similar neutralization titer to the U.K. strain as to the original strain. No statistical difference was observed in neutralizing antibodies titer between the U.K. strain and the original strain. These results support COVAXIN's potential to generate immune responses to multiple protein antigens of the virus and thereby potentially reducing or eliminating potential viral escape.

Bharat Biotech is conducting a Phase 3 clinical trial in India. Enrollment in the Phase 3 clinical trial is complete. COVAXIN demonstrated a vaccine efficacy of 81% in the first interim analysis of the Phase 3 clinical trial, and an analysis from the National Institute of Virology indicated potential significant immunogenicity against the U.K. variant and other heterologous strains. We are currently evaluating the clinical and regulatory path for COVAXIN in the United States including obtaining Emergency Use Authorization ("EUA") from the U.S. Food and Drug Administration (the "FDA") and, eventually, biologic license application approval in the U.S. market, as well as our commercialization strategy, if authorized or approved. We have initiated discussions with the FDA regarding the development of COVAXIN, but an EUA application has not been submitted at this time. We are also in active discussions with manufacturers in the United States to produce a significant number of doses of COVAXIN to support commercialization of the vaccine in the United States, if authorized or approved.

Modifier Gene Therapy Platform

We are developing a breakthrough modifier gene therapy platform to generate therapies designed to fulfill unmet medical needs in the area of retinal diseases, including inherited retinal diseases ("IRDs") and dry AMD. Our modifier gene therapy platform is based on NHRs, which have the potential to restore homeostasis, the basic biological processes in the retina. Unlike single-gene replacement therapies, which only target one genetic mutation, we believe that our gene therapy platform, through its use of NHRs, represents a novel approach in that it may address multiple retinal diseases with one product. IRDs such as RP, a group of rare genetic disorders that involve a breakdown and loss of cells in the retina and can lead to visual impairment and blindness, affect over 2.0 million people worldwide. Over 150 gene mutations have been associated with RP and this number represents only 60% of the RP population. The remaining 40% of RP patients cannot be genetically diagnosed, making it difficult to develop individual treatments. We believe our first gene therapy candidate, OCU400, has the potential to be broadly effective in restoring retinal integrity and function across a range of IRDs. For example, we believe OCU400 has the potential to eliminate the need for developing more than 150 individual products and provide one treatment option for all RP patients.

OCU400 has received four Orphan Drug Designations from the FDA for the treatment of certain disease genotypes: nuclear receptor subfamily 2 group E member 3 ("*NR2E3*"), centrosomal protein 290 ("*CEP290*"), rhodopsin ("*RHO*"), and phosphodiesterase 6B ("*PDE6ß*") mutation-associated inherited retinal degenerations. We are planning to initiate two Phase 1/2a clinical trials for OCU400 in the United States in the second half of 2021. OCU400 additionally received Orphan Medicinal Product Designation from the European Commission, based on the recommendation of the European Medicines Agency, for RP and LCA in February 2021, which we believe further supports the potential broad spectrum application of OCU400 to treat many IRDs. We are currently evaluating options to commence OCU400 clinical trials in Europe in 2022. Our second gene therapy candidate, OCU410, is being developed to utilize the nuclear receptor genes RAR-related orphan receptor A for the treatment of dry AMD. This candidate is currently in preclinical development. We are planning to initiate a Phase 1/2a clinical trial for OCU410 in 2022.

Novel Biologic Therapies for Retinal Diseases

We are also conducting preclinical development for our biologic product candidate, OCU200. OCU200 is a novel fusion protein designed to treat DME, DR and wet AMD. We had a pre-Investigational New Drug ("IND") meeting with the FDA in November 2020 and received guidance on IND-enabling preclinical studies to support the Phase 1/2a study. We expect to initiate IND-enabling preclinical studies for OCU200 in 2021 and initiate a Phase 1/2a clinical trial for OCU200 in 2022.

Product Candidates for the Treatment of Ocular Surface Diseases

We were developing OCU300, a small molecule therapeutic for the treatment of symptoms associated with ocular graft-versus-host disease, and OCU310, a treatment for patients with dry eye disease. The Phase 3 clinical trial for OCU300 was discontinued in 2020 based on results of a pre-planned interim sample size analysis conducted by an independent Data Monitoring Committee, which indicated the trial was unlikely to meet its co-primary endpoints upon completion. A Phase 3 clinical trial for OCU310 was completed in 2019 but results of the trial showed OCU310 did not meet its co-primary endpoints. We are no longer pursuing the development of either of these ocular surface diseases product candidates.

Impact of COVID-19 on our Business

The COVID-19 pandemic continues to evolve and we are closely monitoring the situation. If the number of active cases of COVID-19 continues to be high in the United States and elsewhere, the pandemic may delay enrollment in our planned clinical trials. Among other things, continued spread of COVID-19 may result in limitations on global international travel, which may delay key trial activities including necessary interactions with regulators. We may be faced with limitations in employee resources that would otherwise be focused on the conduct of clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people. Moreover, we may experience additional

disruptions that could severely impact our business and development activities, including, but not limited to, strain on our suppliers and other third parties and the disruption of our ability to raise capital when needed on acceptable terms, if at all. Disruptions in our operations or supply chain, whether as a result of restricted travel, quarantine requirements or otherwise, could negatively impact our ability to proceed with our clinical trials, preclinical development, and other activities and delay our ability to receive product approval and generate revenue. Impacts that may result from the COVID-19 pandemic remain highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our preclinical development efforts, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Financial Operations Overview

We have no products approved for commercial sale and have not generated significant revenue to date. We have never been profitable and have incurred operating losses in each year since inception. We incurred net losses of approximately $21.8 million and $20.2 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $73.3 million and a cash, cash equivalents, and restricted cash balance of $24.2 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

As of December 31, 2020, we viewed our operations and managed our business as one operating segment consistent with how our chief operating decision-maker, our Chief Executive Officer, makes decisions regarding resource allocation and assessing performance. As of December 31, 2020, substantially all of our assets were located in the United States. Our headquarters and operations are located in Malvern, Pennsylvania.

Collaboration revenue

Collaboration revenue consists of royalty payments received in connection with agreements accounted for as collaborative arrangements under Financial Accounting Standards Board ("FASB") Accounting Standards Codification (“ASC”) Topic 808, *Collaborative Arrangements*. We assess whether royalty payments from collaboration partners represent consideration from a customer. If the collaboration partner is considered a customer, we account for those payments within the scope of FASB ASC Topic 606, *Revenue from Contracts with Customers*. However, if we conclude that our collaboration partner is not a customer, we will record royalty payments received as collaboration revenue in the period in which the underlying sale occurs and record expenses and expense reimbursements as either research and development expense or general and administrative expense, or a reduction thereof, based on the underlying nature of the expense or expense reimbursement. See Note 4 in the notes to the consolidated financial statements included in this report for additional information.

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, severance, and other related costs, including stock-based compensation, for personnel serving in our research and development functions, as well as allocated rent and utilities expenses. External expenses include development, clinical trials, patent costs, and regulatory compliance costs incurred with research organizations, contract manufacturers, and other third-party vendors. License fees paid to acquire access to proprietary technology are expensed to research and development unless it is determined that the technology is expected to have an alternative future use. All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred to research and development expense due to the uncertainty about the recovery of the expenditure. We record costs for certain development activities, such as clinical trials, based on our evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to us by our 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.

Research and development expenses account for a significant portion of our operating expenses. We plan to incur research and development expenses for the foreseeable future as we expect to continue the development of our product candidate. We anticipate that our research and development expenses, excluding charges to in-process research and development expense, will increase in 2021 as compared to 2020 as we evaluate the clinical, regulatory, and commercialization path for COVAXIN in the United States as well as conduct preclinical and clinical activities with respect to our other product candidates. We are planning to initiate two Phase 1/2a clinical trials for OCU400 in the United States in the second half of 2021 and Phase 1/2a clinical trials for OCU410 and OCU200 in 2022. We are also currently evaluating options to commence OCU400 clinical trials in Europe in 2022.

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

At this time, due to the inherently unpredictable nature of preclinical and clinical development as well as regulatory approval and commercialization, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in our continued development and commercialization efforts. As a result of these uncertainties, successful development and completion of clinical trials as well a regulatory approval and commercialization are 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. We will continue to make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to our ability to enter into collaborations with respect to each product candidate, the scientific and clinical success of each product candidate as well as ongoing assessments as to the commercial potential of each product candidates.

General and administrative expense

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

We anticipate that our general and administrative expenses will increase in 2021 as compared to 2020 as a result of higher corporate infrastructure costs including, but not limited to accounting, legal, human resources, consulting, and investor relations fees. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Severance-related expense

In June 2020, we communicated notice to five employees of termination of their employment. This reduction represented one-third of our workforce at the time of communication. All terminations were “without cause” and each employee received termination benefits upon departure. The termination dates varied for each employee and ranged from June 30, 2020 to December 31, 2020.

As a result of the workforce reduction, we recognized severance-related charges of $1.1 million during the year ended December 31, 2020. For the year ended December 31, 2020, we recognized $0.2 million of severance-related charges within general and administrative expense and $0.9 million of severance-related charges within research and development expense. We expect to pay severance benefits of $0.7 million in 2021.

Change in fair value of derivative liabilities

Change in fair value of derivative liabilities includes the change in fair value each reporting period of (a) the conversion and change in control features embedded in certain convertible notes, which were required to be bifurcated and recognized at fair value, and (b) the change in the fair value of the Series B Warrants that were issued in connection with a Securities Purchase Agreement entered into with certain accredited investors in June 2019. The change in fair value of derivative liabilities was $3.2 million during the year ended December 31, 2019. There were no derivative instruments fair valued on a recurring basis during the year ended December 31, 2020.

Interest expense

Interest expense primarily includes debt coupon interest, the amortization of debt issuance costs, and the accretion of debt discounts.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with GAAP. The preparation of our financial statements requires us 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. We base our estimates on historical experience, known trends and events and various other factors that we believe 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

While our significant accounting policies are described in more detail in the notes to the consolidated financial statements appearing elsewhere in this report, we believe that the following accounting policies and estimates are those most critical to the preparation of our consolidated financial statements:

Stock-based compensation

We account for our stock-based compensation awards in accordance with the FASB ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options and modifications to existing agreements, to be recognized in the consolidated statements of operations and comprehensive loss based on their fair values. We use the Black-Scholes option-pricing model to determine the fair value of options granted. We recognize forfeitures as they occur.

Our stock-based awards are subject to service-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. Stock-based awards generally vest over a one to three year requisite service period and have a contractual term of 10 years.

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 our Black-Scholes option-pricing model represent our best estimates and involve a number of variables, uncertainties, assumptions, and the application of our judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These assumptions used in our Black-Scholes option-pricing model are as follows:

Expected Term. Due to the historical lack of a public market for the trading of our 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 No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.

Expected Volatility. The expected volatility is based on historical volatilities of us and similar entities within our industry for periods commensurate with the expected term assumption.

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 we have not historically paid, and do not expect for the foreseeable future to pay, a dividend on our common stock.

Stock-based compensation expense was $0.7 million and $0.9 million for the years ended December 31, 2020 and 2019, respectively. At December 31, 2020, we had $1.1 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 two years.

Change in Fair Value of Derivative Liabilities

We issued convertible notes in 2018 and 2019 that contained embedded conversion and change in control features. The fair values of the embedded conversion and change in control features at the issuance of each convertible note and at the end of each reporting period were estimated using an income approach model. Inputs into this model included the expected time until conversion or change in control and our estimates of probability of conversion or change in control occurring, which were classified as Level 3 fair value inputs. There were no such derivatives valued as of December 31, 2020 and 2019, due to either the payment or conversion of the related convertible note. The change in fair value of the embedded conversion and change in control features was recognized within other income (expense) in the consolidated statements of operations and comprehensive loss until the payment or conversion of each convertible note. The change in fair value of derivative liabilities for the convertible notes was $1.3 million during the year ended December 31, 2019. Due to the conversions and payments of the

convertible notes during 2019, no change in fair value of derivative liabilities was recorded during the year ended December 31, 2020 for the convertible notes.

In 2019, we also issued warrants to purchase our common stock: the Series A Warrants, Series B Warrants, and Series C Warrants (collectively the "Pre-Merger Financing Warrants") and we accounted for these warrants in accordance with FASB ASC Topic 815-40, *Derivatives and Hedging — Contracts in Entity's Own Equity*. The Series A Warrants and Series C Warrants were determined to meet the criteria for equity classification. The Series B Warrants were recognized as a derivative liability at fair value as the Series B Warrants did not meet the criteria related to equity indexation. The fair value of Series B Warrants was estimated using the Monte Carlo simulation model. Key fair value inputs included the starting stock price, expected stock price volatility during the Reset Period (as defined in the Series B Warrants), and additional shares issued from escrow. The methodology for measuring fair value was sensitive to the expected stock volatility assumption input. Upon conclusion of the Reset Period, we estimated the fair value of the Series B Warrants using a Black-Scholes valuation model. Inputs used in the valuation were unobservable and were therefore classified as Level 3 fair value inputs.

The Series B Warrants change in fair value each reporting period for the derivative liability was recognized within the consolidated statements of operations and comprehensive loss until the Series B Warrants were reclassified as equity in November 2019 following a final mark to market upon the completion of a Reset Period (as defined in the Series B Warrants) pursuant to which the number of shares of common stock underlying the Series B Warrants was increased based on the trading price for the common stock. The change in fair value of derivative liability for the Series B Warrants was $1.9 million during the year ended December 31, 2019. Due to the Series B Warrants reclassification as equity during 2019, no change in fair value of derivative liabilities was recorded during the year ended December 31, 2020 for the Series B Warrants.

Accounting for the Warrant Exchange

On April 22, 2020, we and OpCo entered into Amendment and Exchange Agreements (each an "Exchange Agreement" and collectively, the "Exchange Agreements") with the Series A Warrants holders. Pursuant to the Exchange Agreements, among other things, the number of common stock issuable upon the exercise of the Series A Warrants was adjusted. Concurrently with the Exchange Agreements, the Series A Warrants holders exchanged the Series A Warrants for shares of common stock and promissory notes (the "Warrant Exchange Promissory Notes") (collectively, the "Warrant Exchange").

We accounted for the Warrant Exchange by recognizing the fair value of the consideration transferred in excess of the carrying value of the Series A Warrants as a reduction of additional paid-in capital. The fair value of the consideration transferred was comprised of (i) the fair value of the common stock issued based on the number of shares issued and our stock price on the date of issuance and (ii) the fair value of the Warrant Exchange Promissory Notes at the date of issuance based on Level 2 fair value inputs. The fair value of the consideration transferred was in excess of the fair value of the Series A Warrants immediately prior to the consideration transfer. The excess consideration was accounted for as a deemed dividend to the Series A Warrant holders and is reflected as an additional net loss attributed to common stockholders in the calculation of basic and diluted net loss per common share for the year ended December 31, 2020. The fair value of the Series A Warrants immediately prior to the consideration transfer was estimated using a Black-Scholes valuation model. Inputs used in the valuation were unobservable and were therefore classified as Level 3 fair value inputs. See Note 11 in the notes to the consolidated financial statements included in this report for additional information.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following table summarizes the results of our operations for the years ended December 31, 2020 and 2019:

(in thousands)	Year ended December 31, 2020	2019	Change
Revenues			
Collaboration revenue	$ 43	$ —	$ 43
Total revenues	43	—	43
Operating expenses			
Research and development	$ 6,353	$ 8,086	$ (1,733)
In-process research and development	7,000	—	7,000
General and administrative	7,974	6,077	1,897
Total operating expenses	21,327	14,163	7,164
Loss from operations	(21,284)	(14,163)	(7,121)
Other income (expense)			
Change in fair value of derivative liabilities	—	(3,187)	3,187
Loss on debt conversion	—	(341)	341
Interest income	1	1	—
Interest expense	(721)	(1,768)	1,047
Other income (expense)	183	(785)	968
Total other income (expense)	(537)	(6,080)	5,543
Net loss	$ (21,821)	$ (20,243)	$ (1,578)

Collaboration revenue

Collaboration revenue increased by $42,620 for the year ended December 31, 2020 compared to the year ended December 31, 2019 as a result of a collaboration agreement with Advaite, Inc. for the development of Advaite's RapCov COVID-19 Testing Kit, which commenced in April 2020. We did not have any collaboration revenue during the year ended December 31, 2019.

Research and development expense

Research and development expense decreased by $1.7 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. The decrease was primarily due to a decrease of $2.5 million related to the discontinuation of OCU310 clinical trial activities in 2019 and a decrease of $0.3 million in employee-related expenses, partially offset by an increase of $0.9 million in severance-related charges related to the employee terminations announced in June 2020 and $0.2 million related to consulting fees.

In-process research and development expense

In-process research and development expense increased by $7.0 million for the year ended December 31, 2020 compared to the year ended December 31, 2019 as a result of the NeoCart asset, which ceased to meet the criteria to be classified as held for sale during the year ended December 31, 2020. See Note 3 in the notes to the consolidated financial statements included in this report for additional information.

General and administrative expense

General and administrative expenses increased by $1.9 million, for the year ended December 31, 2020 compared to the year ended December 31, 2019. The increase was primarily due to an increase of $0.9 million in insurance premiums, $0.5 million in employee-related expenses, $0.3 million in Board of Director fees, and $0.2 million in severance-related charges related to the employee terminations announced in June 2020, partially offset by a decrease of $0.2 million in consulting fees.

Change in fair value of derivative liability

The change in fair value of derivative liability was a loss of $3.2 million for the year ended December 31, 2019 due to the remeasurements of derivative liabilities related to the Series B Warrants and certain convertible notes. We did not have recurring fair value measurements of derivative liabilities for the year ended December 31, 2020 due to the reclassification of the Series B Warrants to equity and the conversions of convertible notes.

Loss on debt conversion

The loss on debt conversion was $0.3 million for the year ended December 31, 2019 relating to conversions in 2019 of certain convertible notes. We did not have a loss on debt conversion during the year ended December 31, 2020.

Interest expense

Interest expense was $0.7 million for the year ended December 31, 2020 and $1.8 million for the year ended December 31, 2019. The decrease in interest expense was primarily due to the conversions and/or payments of all convertible notes during 2019. Interest expense for the year ended December 31, 2020 primarily relates to the Warrant Exchange Promissory Notes.

Other income (expense)

Other income was $0.2 million for the year ended December 31, 2020. Other expense was $0.8 million for the year ended December 31, 2019. Other income for the year ended December 31, 2020 primarily relates to the recognition of deferred grant proceeds. Other expense for the year ended December 31, 2019 primarily relates to equity issuance costs related to the Series B Warrants which were expensed during the year ended December 31, 2019 since the Series B Warrants were liability classified.

Liquidity and Capital Resources

As of December 31, 2020, we had $24.2 million in cash, cash equivalents, and restricted cash. We have not generated significant revenue to date and have primarily funded our operations to date through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes, debt, and grant proceeds. Specifically, since our inception and through December 31, 2020, we have raised an aggregate of $90.3 million to fund our operations, of which $77.7 million was from the sale of our common stock and warrants, $10.3 million was from the issuance of convertible notes, $2.1 million was from debt, and $0.2 million from grant proceeds.

During the year ended December 31, 2020, we sold an aggregate of 108.1 million shares of our common stock in separate at-the-market offerings ("ATMs") commenced in May 2020, June 2020, and August 2020. We sold 34.3 million shares under the May 2020 ATM, 24.8 million shares under the June ATM, and 49.0 million shares under the August 2020 ATM. During the year ended December 31, 2020, we received net proceeds of $36.3 million from the ATMs. The offerings were made pursuant to our effective "shelf" registration statement on Form S-3 filed with the SEC on March 27, 2020, the base prospectus contained therein dated May 5, 2020, and the prospectus supplements related to the offerings dated May 8, 2020, June 12, 2020, and August 17, 2020. As of December 31, 2020, we had sold all of the shares of common stock available for issuance under the prospectus supplements filed on May 8, 2020 and June 12, 2020 in connection with the May 2020 and June 2020 ATMs. See Note 9 in the notes to the consolidated financial statements included in this report for additional information.

In February 2021, we entered into a Securities Purchase Agreement pursuant to which we sold in a registered direct offering (the "Registered Direct Offering") 3.0 million shares and received net proceeds of $21.2 million, after deducting placement agent fees and related offering expenses of $1.7 million.

Since our inception, we have devoted substantial resources to research and development and have incurred significant net losses and may continue to incur net losses in the future. We incurred net losses of approximately $21.8 million and $20.2 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $73.3 million. In addition, as of December 31, 2020, we had accounts payable and accrued expenses of $3.3 million and indebtedness of $2.1 million.

The following table shows a summary of our cash flows for the periods indicated:

(in thousands)	Year ended December 31, 2020	2019
Net cash used in operating activities	$ (14,709)	$ (16,893)
Net cash used in investing activities	(307)	(2,357)
Net cash provided by financing activities	31,611	25,066
Net increase in cash, cash equivalents and restricted cash	$ 16,595	$ 5,816

Operating activities

Cash used in operating activities was $14.7 million for the year ended December 31, 2020 compared with $16.9 million for the year ended December 31, 2019. The decrease in cash used in operating activities was primarily driven by a decrease in payments for accounts payable offset by an increase in prepayments, current and other assets during the year ended December 31, 2020 as compared to the year ended December 31, 2019.

Investing activities

Cash used in investing activities was $0.3 million for the year ended December 31, 2020 compared with $2.4 million for the year ended December 31, 2019. The decrease in cash used by investing activities was primarily driven by the payment of acquisition costs related to the Merger during the year ended December 31, 2019 with no comparable payments made during the year ended December 31, 2020, partially offset by an increase in the purchases of property and equipment made during the year ended December 31, 2020 as compared to the year ended December 31, 2019.

Financing activities

Cash provided by financing activities was $31.6 million for the year ended December 31, 2020 compared to $25.1 million for the year ended December 31, 2019. During the year ended December 31, 2020, cash provided by financing activities was primarily driven by gross proceeds of $37.8 million received under May 2020, June 2020, and August 2020 ATMs and $0.9 million in proceeds from the issuance of debt, partially offset by payments of equity issuance costs of $1.5 million and repayments of debt of $5.6 million. During the year ended December 31, 2019, cash provided by financing activities included proceeds from the issuance of common stock and the Pre-Merger Financing Warrants in connection with the Merger of $22.6 million, proceeds from the issuance of convertible debt of $6.8 million, and proceeds from an April 2019 stock subscription agreement of $1.0 million, partially offset by repayments of debt of $5.3 million.

Indebtedness

On April 30, 2020, we were granted a loan from Silicon Valley Bank ("SVB") in the aggregate amount of $0.4 million, pursuant to the Paycheck Protection Program (the “PPP”) of the Coronavirus Aid, Relief and Economic Security Act of 2020, which was enacted on March 27, 2020. The loan was in the form of a promissory note dated April 30, 2020 in favor of SVB (the "PPP Note"). The PPP Note matures on April 30, 2022 and bears interest at a rate of 1.0% per annum. Principal and interest payments are payable monthly commencing on either (i) the date the Small Business Administration compensates SVB for any forgiven amounts or (ii) 10 months after the end of our loan forgiveness covered period, which ended in October 2020. Certain amounts of the loan may be forgiven if they are used for qualifying expenses as described by the PPP. At December 31, 2020, there was $0.4 million of principal outstanding under the PPP Note.

On April 22, 2020, we issued the Warrant Exchange Promissory Notes with an aggregate principal amount of $5.6 million to existing investors in connection with the Warrant Exchange. The Warrant Exchange Promissory Notes had a maturity date of April 21, 2021 and did not bear interest. The Warrant Exchange Promissory Notes permitted prepayment in whole or in part at any time without penalty or premium. In the event that we consummated a financing transaction that generated cash to us, we were required to use 20% of the net proceeds of such transaction to prepay a portion of the outstanding amount under each Warrant Exchange Promissory Note if the transaction occurred on or prior to August 22, 2020, and 30% of the net proceeds to prepay a portion of the outstanding amount under each Warrant Exchange Promissory Note if the transaction occurred after August 22, 2020. During the year ended December 31, 2020, we made payments to the Warrant Exchange Promissory Note holders of $5.6 million, causing the Warrant Exchange Promissory Notes to be repaid in full and no longer outstanding at December 31, 2020.

In September 2016, pursuant to U.S. government's Immigrant Investor Program, commonly known as the EB-5 program (the "EB-5 Program"), we entered into entered into an arrangement (the "EB-5 Loan Agreement") to borrow up to $10.0 million from EB5 Life Sciences, L.P. in $0.5 million increments. Borrowings are at a fixed interest rate of 4.0% and are to be utilized in the clinical development, manufacturing, and commercialization of our products and for our general working capital needs. Outstanding borrowings pursuant to the EB-5 Program become due upon the seventh anniversary of the final disbursement. Amounts repaid cannot be re-borrowed. Under the terms and conditions of the EB-5 Loan Agreement, we borrowed $0.5 million on March 26, 2020. At December 31, 2020, there was $1.5 million of principal outstanding under the EB-5 Loan Agreement.

Funding requirements

We expect to continue to incur significant expenses in connection with our ongoing activities, particularly as we continue research and development, including preclinical and clinical development of our product candidates, contract to manufacture our product candidates, add operational, financial and information systems to execute our business plan, maintain, expand and protect our patent portfolio, and operate as a public company.

Our 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 our product candidates;
- the outcome, timing, and cost of the regulatory approval process for our product candidates by the FDA including EUA for COVAXIN;
- future costs of manufacturing and commercialization, including COVAXIN if authorized or approved;
- the cost of filing, prosecuting, defending, and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the costs of expanding infrastructure, as well as the higher corporate infrastructure costs associated with operating as a public company;
- the expenses needed to attract and retain skilled personnel;
- the extent to which we in-license or acquire other products, product candidates, or technologies; and
- the impact of the COVID-19 pandemic.

Our management plans to continue to raise additional capital to support the development and commercialization of our product candidates through public and private placements of equity and/or debt, payments from potential strategic research and development, sale of assets, government grants, licensing and/or collaboration arrangements with pharmaceutical companies or other institutions, and other funding from the government. There can be no assurance that these future funding efforts will be successful. If we cannot obtain the necessary funding, we will need to delay, scale back or eliminate some or all of our research and development programs; consider other various strategic alternatives, including a merger or sale; or cease operations. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition, and results of operations could be materially adversely affected.

As of December 31, 2020, we had cash, cash equivalents, and restricted cash of approximately $24.2 million, and since that date we have received net proceeds of $4.8 million from the sale of our common stock under the August 2020 ATM and net proceeds of $21.2 million from the sale of our common stock under the Registered Direct Offering. As a result of our cash, cash equivalents, and restricted cash balance as of December 31, 2020 and the net proceeds received subsequent to December 31, 2020 from the August 2020 ATM and the Registered Direct Offering, we believe that our cash, cash equivalents, and restricted cash will enable us to fund our operating expenses and capital expenditure requirements through at least one year from the date the consolidated financial statements included in this report are issued.

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements, see Note 2 to our consolidated financial statements included in this report.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data

The financial statements required by this item are set forth beginning at page F-1 of this report and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. 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 December 31, 2020. 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.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive officer and principal financial officer and effected by our Board of Directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in conformity with GAAP and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision of and with the participation of our Chief Executive Officer and Chief Financial Officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the

criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework of 2013. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2020.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Series B Convertible Preferred Stock Certificate of Designation

On March 18, 2021, we filed the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (the "Series B Certificate of Designation") in connection with the issuance of 54,745 shares of Series B Convertible Preferred Stock ("Series B Preferred Stock") to Bharat Biotech pursuant to a Preferred Stock Purchase Agreement.

Each share of Series B Preferred Stock is convertible, at the option of Bharat Biotech, into 10 shares of our common stock only after (i) our receipt of stockholder approval to increase the number of authorized shares of common stock under our Sixth Amended and Restated Certificate of Incorporation and (ii) our receipt of shipments by Bharat Biotech of the first 10.0 million doses of COVAXIN manufactured by Bharat Biotech pursuant to a supply agreement expected to be entered into with respect to the parties' Covaxin Agreement, and further on the terms and subject to the conditions set forth in the Series B Certificate of Designation. The conversion rate of the Series B Preferred Stock is subject to adjustment in the event of a stock dividend, stock split, reclassification, or similar event with respect to our common stock.

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

2021 Annual Stockholder Meeting

Our Board of Directors has established Friday, June 11, 2021 as the date of our 2021 Annual Meeting of Stockholders (the "2021 Annual Meeting").

In light of the ongoing COVID-19 pandemic, for the safety of our stockholders and in accordance with federal, state, and local guidance that has been issued regarding group gatherings, we have decided that the 2021 Annual Meeting will be held in a virtual format only, via the Internet, with no physical in-person meeting. Stockholders of record at the close of business on Monday, April 19, 2021 will be entitled to vote at the 2021 Annual Meeting.

Because the date of the 2021 Annual Meeting has been advanced by more than 30 calendar days from the date of the preceding year's annual meeting, in accordance with Rule 14a-5(f) under the Exchange Act, we are informing stockholders of certain dates related to the 2021 Annual Meeting.

Pursuant to Rule 14a-8 under the Exchange Act, a stockholder intending to present a proposal to be included in the proxy materials for the 2021 Annual Meeting must deliver a proposal in writing to our principal executive offices no later than a reasonable time before we begin printing and mailing the proxy materials for the 2021 Annual Meeting. According to our bylaws, a stockholder must provide notice to the our corporate secretary of proposals intended to be presented at, but not included in the proxy materials for, the 2021 Annual Meeting, including director nominations for election to our Board of Directors, in a timely manner. Under our bylaws, in order to be timely, in the event that the date of the annual meeting is advanced more than 30 days prior to or delayed more than 30 days after the anniversary of the preceding year's annual meeting, notice by the stockholder must be delivered to us by the close of business on the later of (x) the 90th day prior to such annual meeting or (y) the 10th day following the day on which public announcement of the date of such meeting is first made.

As such, the new deadline for submission of proposals to be included in the proxy materials or otherwise to be considered at the 2021 Annual Meeting is the close of business on Monday, March 29, 2021, which we consider a reasonable time before we will begin printing and mailing proxy materials and is the 10th day following the date of filing of this Annual Report. Proposals

should be addressed to: Corporate Secretary, Ocugen, Inc., 263 Great Valley Parkway, Malvern, PA 19355. Any such proposal must (i) meet the requirements set forth in the rules and regulations of the SEC in order to be eligible for inclusion in the proxy materials for the 2021 Annual Meeting and (ii) contain the information specified in, and otherwise comply with, our bylaws. We may omit any proposal from the proxy materials that does not comply with the SEC's rules.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

The information required by this Item is incorporated by reference from the discussion responsive thereto contained in the Proxy Statement for our 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference from the discussion responsive thereto contained in the Proxy Statement for our 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item is incorporated by reference from the discussion responsive thereto contained in the Proxy Statement for our 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated by reference from the discussion responsive thereto contained in the Proxy Statement for our 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 14. Principle Accountant Fees and Services.

The information required by this Item is incorporated by reference from the discussion responsive thereto contained in the Proxy Statement for our 2021 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

PART IV

Item 15. Exhibits, Financial Statements

The financial statement schedules and exhibits filed as part of this Annual Report on Form 10-K are as follows:

(a)(1) Financial Statements

See “Index to Consolidated Financial Statements” beginning on page F-1 of this report.

(a)(2) Financial Statement Schedules

Financial statement schedules have been omitted because the required information is not present, not present in amounts sufficient to require submission of the schedules, or because the required information is provided in the financial statements or notes thereto.

(a)(3) Exhibits

The exhibits required to be filed as part of this report are listed in the Exhibit Index attached hereto and are incorporated herein by reference.

EXHIBIT INDEX

Exhibit	Description
2.1	Agreement and Plan of Merger and Reorganization, dated April 5, 2019, by and among the Registrant, Ocugen, Inc. and Restore Merger Sub, Inc. (filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K as filed on April 8, 2019, and incorporated herein by reference)
2.2	Consent and Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated June 13, 2019, by and among the Registrant, Ocugen, Inc. and Restore Merger Sub, Inc. (filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)
3.1	Sixth Amended and Restated Certificate of Incorporation (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K as filed on December 8, 2014, and incorporated herein by reference)
3.2	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)
3.3	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)
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Histogenics Corporation (filed as Exhibit 3.3 to the Registrant's Current Report on Form 8-K as filed on September 16, 2016, and incorporated herein by reference)
3.5*	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock of Ocugen, Inc.
3.6	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)
4.1*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
4.2	Amended and Restated Royalty Agreement dated as of October 14, 2014 (filed as Exhibit 4.5 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-199202), as filed on November 7, 2014, and incorporated herein by reference)
4.3	Form of Series A Investor Warrant (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K as filed on October 7, 2019, and incorporated herein by reference)
4.4	Form of Series B Investor Warrant (filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K as filed on October 7, 2019, and incorporated herein by reference)
4.5	Form of Series C Investor Warrant (filed as Exhibit 4.3 to the Registrant's Current Report on Form 8-K as filed on October 7, 2019, and incorporated herein by reference)
4.6	Form of Amendment to Warrants to Purchase Common Stock (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K as filed on November 6, 2019, and incorporated herein by reference)
4.7	Registration Rights Agreement, dated June 13, 2019, by and among the Registrant and certain investors named therein (filed as Exhibit 4.3 to the Registrant's Current Report on Form 8-K as filed on June 14, 2019, and incorporated herein by reference)
4.8*	Form of Common Stock Purchase Warrant
10.1+	Ocugen, Inc. 2014 Stock Option Plan (filed as Exhibit 10.30 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)
10.2+	Form of Incentive Stock Option Agreement under Ocugen, Inc. 2014 Stock Option Plan (filed as Exhibit 10.31 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)
10.3+	Form of Nonstatutory Stock Option Agreement under Ocugen, Inc. 2014 Stock Option Plan (filed as Exhibit 10.32 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)

Exhibit	Description
10.4+	Ocugen, Inc. 2019 Equity Incentive Plan (filed as Appendix A to the Registrant's Proxy Statement on Schedule 14A as filed on November 8, 2019, and incorporated herein by reference)
10.5+	Form of Incentive Stock Option Agreement under Ocugen, Inc. 2019 Equity Incentive Plan (filed as exhibit 10.29 to the Registrant's Form 10-K as filed on March 27, 2020, and incorporated herein by reference)
10.6+	Form of Nonstatutory Stock Option Agreement under Ocugen, Inc. 2019 Equity Incentive Plan (filed as exhibit 10.30 to the Registrant's Form 10-K as filed on March 27, 2020, and incorporated herein by reference)
10.7+*	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement
10.8#	Exclusive License Agreement, effective as of March 3, 2014, between The Regents of the University of Colorado and Ocugen Opco, Inc. (filed as Exhibit 10.33 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)
10.9#	First Amendment to the Exclusive License Agreement, dated as of January 23, 2017, by and between The Regents of the University of Colorado and Ocugen Opco, Inc. (filed as Exhibit 10.34 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)
10.10	Letter of Understanding, dated November 8, 2017, between The Regents of the University of Colorado and Ocugen Opco, Inc. (filed as Exhibit 10.35 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)
10.11#	Exclusive License Agreement, effective as of December 19, 2017, between The Schepens Eye Research Institute, Inc and Ocugen Opco, Inc. (filed as Exhibit 10.37 to the Registrant's Registration Statement on Form S-4 (SEC File No. 333-232147), as filed on June 14, 2019, and incorporated herein by reference)
10.12*#	Lease Agreement, dated October 9, 2020, by and between the Registrant and WPT Land 2 LP
10.13	Loan and Security Agreement, effective as of September 12, 2016, by and between EB5 Life Sciences, LP and Ocugen Opco, Inc. (filed as Exhibit 10.42 to the Registrant's Registration Statement on Form S-4/A (SEC File No. 333-232147), as filed on July 23, 2019, and incorporated herein by reference)
10.14	Asset Purchase Agreement dated May 8, 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 May 13, 2019, and incorporated herein by reference)
10.15	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)
10.16	Amendment No. 2 to Asset Purchase Agreement, dated October 4, 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 7, 2019, and incorporated herein by reference)
10.17#	Co-Development and Commercialization Agreement, dated as of September 27, 2019, by and among the Registrant and CanSino Biologics Inc. (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q as filed on November 12, 2019, and incorporated herein by reference)
10.18+	Employment Agreement, dated as of September 10, 2019, by and between the Registrant and Sanjay Subramanian (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q as filed on November 12, 2019, and incorporated herein by reference)
10.19+	Amendment to Executive Employment Agreement, dated as of January 1, 2020, by and between the Registrant and Sanjay Subramanian (filed as Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q as filed on May 8, 2020, and incorporated herein by reference)
10.20+	Amended and Restated Employment Agreement, dated as of January 1, 2020, by and between the Registrant and Shankar Musunuri (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K as filed on January 3, 2020, and incorporated herein by reference)

Exhibit	Description
10.21+	Amended and Restated Employment Agreement, dated as of January 1, 2020, by and between the Registrant and Daniel Jorgensen (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K as filed on January 3, 2020, and incorporated herein by reference)
10.22+	Amended and Restated Employment Agreement, dated as of January 1, 2020, by and between the Registrant and Rasappa Arumugham (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K as filed on January 3, 2020, and incorporated herein by reference)
10.23+	Amended and Restated Employment Agreement, dated as of January 1, 2020, by and between the Registrant and Vijay Tammara (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q as filed on May 8, 2020, and incorporated herein by reference)
10.24	At Market Issuance Sales Agreement, dated August 14, 2020, by and among the Registrant, Cantor Fitzgerald & Co. and Oppenheimer & Co. Inc. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K as filed August 17, 2020, and incorporated herein by reference)
21.1*	List of Subsidiaries
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm to the Registrant
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.

Item 16. 10-K Summary

Not applicable.

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: March 19, 2021

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

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

Dated: March 19, 2021

/s/ Sanjay Subramanian

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

Pursuant to the requirement of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
/s/		
/s/ Shankar Musunuri Shankar Musunuri	Chairman, Chief Executive Officer and Director (Principal Executive Officer)	March 19, 2021
/s/ Sanjay Subramanian Sanjay Subramanian	Chief Financial Officer (Principal Financial and Accounting Officer)	March 19, 2021
/s/ Ramesh Kumar Ramesh Kumar	Director	March 19, 2021
/s/ Junge Zhang Junge Zhang	Director	March 19, 2021
/s/ Uday B. Kompella Uday B. Kompella	Director	March 19, 2021
/s/ Manish Potti Manish Potti	Director	March 19, 2021
/s/ Suha Taspolatoglu Suha Taspolatoglu	Director	March 19, 2021
/s/ Kirsten Castillo Kirsten Castillo	Director	March 19, 2021
/s/ Prabhavathi Fernandes Prabhavathi Fernandes	Director	March 19, 2021

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

OCUGEN, INC.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Ocugen, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Ocugen, Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for Warrant Amendment and Exchange

Description of the Matter	As discussed in Note 11 to the consolidated financial statements, the Company entered into a subscription agreement in April 2020 that resulted in adjustments to the number of Series A warrants and the exercise price of those warrants. Concurrently, the Company amended the Series A warrants to adjust the number of shares of common stock issuable upon exercise and exchanged the amended Series A warrants for shares for common stock and promissory notes. This series of transactions constituted the Warrant Amendment and Exchange and resulted in a net reduction of additional paid-in capital of $5.2 million which included, among other components, the fair value of common stock issued of $8.6 million and a deemed dividend of $12.5 million to the Series A warrant holders. Auditing the accounting conclusions for the Warrant Amendment and Exchange was complex due to the unusual and non-recurring nature of the transaction, which required extensive audit effort. In particular, the accounting for the Warrant Amendment and Exchange involved an assessment of whether these transactions should be analyzed as one or separate transactions, whether there were any additional rights or privileges that should be given separate accounting recognition and how the transaction should affect the calculation of net loss per share.
How We Addressed the Matter in Our Audit	To test the accounting for the Warrant Amendment and Exchange, our audit procedures included, among others, inspecting the agreements and evaluating the completeness and accuracy of the Company's technical accounting analyses of the transactions and application of the relevant accounting guidance. This also included the involvement of subject matter resources to assist in evaluating management's conclusion on the interpretation and application of the relevant accounting literature.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.

Philadelphia, Pennsylvania
March 19, 2021

OCUGEN, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 24,039,325	$ 7,444,052
Prepaid expenses and other current assets	1,838,357	1,322,167
Asset held for sale	—	7,000,000
Total current assets	25,877,682	15,766,219
Property and equipment, net	632,967	222,464
Restricted cash	151,226	151,016
Other assets	714,477	667,747
Total assets	$ 27,376,352	$ 16,807,446
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 395,034	$ 1,895,613
Accrued expenses	2,930,395	2,270,045
Short-term debt, net	234,119	—
Operating lease obligation	44,248	172,310
Other current liabilities	9,755	205,991
Total current liabilities	3,613,551	4,543,959
Non-current liabilities		
Operating lease obligation, less current portion	389,317	163,198
Long term debt, net	1,823,043	1,072,123
Other non-current liabilities	—	9,755
Total non-current liabilities	2,212,360	1,245,076
Total liabilities	5,825,911	5,789,035
Commitments and contingencies (Note 15)		
Stockholders' equity		
Convertible preferred stock; $0.01 par value; 10,000,000 shares authorized; seven issued and outstanding shares at December 31, 2020 and 2019	—	—
Common stock; $0.01 par value; 200,000,000 authorized; 184,133,384 and 52,746,728 shares issued at December 31, 2020 and 2019, respectively; 184,011,884 and 52,625,228 shares outstanding at December 31, 2020 and 2019, respectively	1,841,334	527,467
Treasury Stock, at cost, 121,500 shares at December 31, 2020 and 2019	(47,864)	(47,864)
Additional paid-in capital	93,058,748	62,018,632
Accumulated deficit	(73,301,777)	(51,479,824)
Total stockholders' equity	21,550,441	11,018,411
Total liabilities and stockholders' equity	$ 27,376,352	$ 16,807,446

See accompanying notes to consolidated financial statements.

OCUGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year ended December 31,	
	2020	**2019**
Revenues		
Collaboration revenue	$ 42,620	$ —
Total revenues	42,620	—
Operating expenses		
Research and development	6,353,287	8,085,522
In-process research and development	7,000,000	—
General and administrative	7,974,050	6,077,097
Total operating expenses	21,327,337	14,162,619
Loss from operations	(21,284,717)	(14,162,619)
Other income (expense)		
Change in fair value of derivative liabilities	—	(3,187,380)
Loss on debt conversion	—	(341,136)
Interest income	1,065	1,214
Interest expense	(720,963)	(1,767,836)
Other income (expense)	182,662	(784,873)
Total other income (expense)	(537,236)	(6,080,011)
Net loss	$ (21,821,953)	$ (20,242,630)
Deemed dividend related to Warrant Exchange	(12,546,340)	—
Net loss to common stockholders	$ (34,368,293)	$ (20,242,630)
Shares used in calculating net loss per common share — basic and diluted	112,236,110	13,893,819
Net loss per share of common stock — basic and diluted	$ (0.31)	$ (1.46)
Net loss	$ (21,821,953)	$ (20,242,630)
Other comprehensive income (loss)		
Foreign currency translation adjustment	—	(451)
Comprehensive loss	$ (21,821,953)	$ (20,243,081)

See accompanying notes to consolidated financial statements.

OCUGEN, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Treasury Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	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	—	—	—	884,089	—	—	884,089
Issuance of common stock for subscription agreement	80,569	806	—	999,194	—	—	1,000,000
Conversion of debt	1,125,673	11,256	—	13,968,532	—	—	13,979,788
Issuance of common stock and warrants for Pre-Merger Financing	4,385,964	43,860	—	13,106,596	—	—	13,150,456
Issuance of stock for reverse asset acquisition, net of $2.6 million of costs	1,651,748	16,517	—	3,549,271	—	—	3,565,788
Reclassification of Series B Warrants from liability to equity	—	—	—	11,255,740	—	—	11,255,740
Issuance of common stock for warrant exercises, net	40,542,222	405,422	—	(222,388)	—	—	183,034
Repurchase of treasury stock	—	—	(47,864)	—	—	—	(47,864)
Foreign currency translation	—	—	—	—	(451)	—	(451)
Net loss	—	—	—	—	—	(20,242,630)	(20,242,630)
Balance at December 31, 2019	**52,746,728**	**$ 527,467**	**$ (47,864)**	**$ 62,018,632**	**$ —**	**$ (51,479,824)**	**$ 11,018,411**
Stock-based compensation expense	—	—	—	660,317	—	—	660,317
Warrant Exchange	21,920,820	219,208	—	(5,197,084)	—	—	(4,977,876)
Issuance of common stock for subscription agreements and warrant exercises	1,328,405	13,284	—	318,472	—	—	331,756
At-the-market common stock issuance, net of $1.5 million of equity issuance costs	108,137,431	1,081,375	—	35,258,411	—	—	36,339,786
Net Loss	—	—	—	—	—	(21,821,953)	(21,821,953)
Balance at December 31, 2020	**184,133,384**	**$ 1,841,334**	**$ (47,864)**	**$ 93,058,748**	**$ —**	**$ (73,301,777)**	**$ 21,550,441**

See accompanying notes to consolidated financial statements.

OCUGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (21,821,953)	$ (20,242,630)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	102,110	60,608
Non-cash interest expense	720,963	1,733,521
Non-cash lease expense	189,424	250,361
In-process research and development expense	7,000,000	—
Change in fair value of derivative liability	—	3,187,380
Stock-based compensation expense	660,317	884,089
Loss on debt conversion	—	341,136
Other non-cash	(349,409)	4,803
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(369,846)	(1,007,367)
Accounts payable and accrued expenses	(540,847)	(1,628,621)
Other assets	(104,000)	(227,172)
Lease obligations	(195,489)	(249,389)
Net cash used in operating activities	(14,708,730)	(16,893,281)
Cash flows from investing activities		
Purchase of property and equipment	(306,825)	(29,446)
Payment of reverse asset acquisition costs	—	(2,327,273)
Net cash used in investing activities	(306,825)	(2,356,719)
Cash flows from financing activities		
Financing lease principal payments	(23,856)	(25,866)
Proceeds from issuance of common stock	37,822,025	1,183,034
Payment of equity issuance costs	(1,477,806)	—
Proceeds from issuance of debt	921,415	6,800,000
Payments of debt issuance costs	(5,740)	(99,202)
Repayments of debt	(5,625,000)	(5,290,000)
Purchases of treasury stock	—	(47,864)
Proceeds from Pre-Merger Financing	—	22,546,353
Net cash provided by financing activities	31,611,038	25,066,455
Net increase in cash, cash equivalents and restricted cash	16,595,483	5,816,455
Cash, cash equivalents and restricted cash at beginning of period	7,595,068	1,778,613
Cash, cash equivalents and restricted cash at end of period	$ 24,190,551	$ 7,595,068
Supplemental disclosure of non-cash transactions:		
Issuance of Warrant Exchange Promissory Notes	$ 5,625,000	$ —
Obligation settled with common stock	$ 331,218	$ —
Purchase of property and equipment	$ 213,625	$ —
Conversion of convertible notes	$ —	$ 13,979,788
Right-of-use assets related to operating leases	$ 179,599	$ 470,356
Equity issuance costs	$ 4,029	$ 1,150,000
Reverse asset acquisition costs	$ —	$ 2,252,795

See accompanying notes to consolidated financial statements.

OCUGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business

Ocugen, Inc., together with its wholly owned subsidiaries (“Ocugen” or the “Company”), is a biopharmaceutical company focused on developing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19. The Company is located in Malvern, Pennsylvania.

Ocugen is co-developing COVAXIN, a whole-virion inactivated COVID-19 vaccine candidate, with Bharat Biotech International Limited ("Bharat Biotech") for the U.S. market. COVAXIN is being developed to prevent COVID-19 infection in humans and is formulated with the inactivated SARS-CoV-2 virus, an antigen, and an adjuvant. In February 2021, the Company entered into a Co-Development, Supply and Commercialization Agreement (the "Covaxin Agreement") with Bharat Biotech, pursuant to which the Company obtained an exclusive right and license under certain of Bharat Biotech's intellectual property rights, with the right to grant sublicenses to develop, manufacture, and commercialize COVAXIN for the prevention of COVID-19 in humans in the United States, its territories and possessions (the “Ocugen Covaxin Territory”). COVAXIN has been granted approval for emergency use in India. A Phase 3 clinical trial is ongoing in India. The Company is currently evaluating the clinical and regulatory path for COVAXIN in the United States including obtaining Emergency Use Authorization ("EUA") from the U.S. Food and Drug Administration (the "FDA") and, eventually, biologic license application (“BLA”) approval in the U.S. market, as well as the Company's commercialization strategy, if authorized or approved. See Note 16 for additional information about the terms, rights, and obligations under the Covaxin Agreement.

Ocugen is developing a breakthrough modifier gene therapy platform to generate therapies designed to fulfill unmet medical needs in the area of retinal diseases, including inherited retinal diseases ("IRDs") and dry age-related macular degeneration ("AMD"). Ocugen's modifier gene therapy platform is based on nuclear hormone receptors (“NHRs”), which have the potential to restore homeostasis, the basic biological processes in the retina. Unlike single-gene replacement therapies, which only target one genetic mutation, Ocugen believes that its gene therapy platform, through its use of NHRs, represents a novel approach in that it may address multiple retinal diseases with one product.

OCU400 is the Company's first product candidate being developed with the Company's modifier gene therapy platform. OCU400 is a novel gene therapy product candidate with the potential to be broadly effective in restoring retinal integrity and function across a range of genetically diverse IRDs, including retinitis pigmentosa ("RP") and leber congenital amaurosis ("LCA"). OCU400 has received four Orphan Drug Designations from the FDA for the treatment of certain disease genotypes: nuclear receptor subfamily 2 group E member 3 ("*NR2E3*"), centrosomal protein 290 ("*CEP290*"), rhodopsin ("*RHO*"), and phosphodiesterase 6B ("*PDE6ß*") mutation-associated inherited retinal degenerations. Ocugen is planning to initiate two Phase 1/2a clinical trials for OCU400 in the United States in the second half of 2021. OCU400 additionally received Orphan Medicinal Product Designation from the European Commission, based on the recommendation of the European Medicines Agency, for RP and LCA in February 2021, which Ocugen believes further supports the broad spectrum application of OCU400 to treat many IRDs. Ocugen is currently evaluating options to commence OCU400 clinical trials in Europe in 2022. Ocugen's second gene therapy candidate, OCU410, is being developed to utilize the nuclear receptor genes RAR-related orphan receptor A ("*RORA*") for the treatment of dry AMD. This candidate is currently in preclinical development. Ocugen is planning to initiate a Phase 1/2a clinical trial for OCU410 in 2022.

Ocugen is also conducting preclinical development for its biologic product candidate, OCU200. OCU200 is a novel fusion protein designed to treat diabetic macular edema, diabetic retinopathy, and wet AMD. Ocugen had a pre-Investigational New Drug ("IND") meeting with the FDA in November 2020 and received guidance on IND-enabling preclinical studies to support the Phase 1/2a study. Ocugen expects to initiate IND-enabling preclinical studies for OCU200 in 2021. Ocugen plans to initiate a Phase 1/2a clinical trial for OCU200 in 2022.

Ocugen was developing OCU300, a small molecule therapeutic for the treatment of symptoms associated with ocular graft-versus-host disease. The Phase 3 clinical trial for OCU300 was discontinued in 2020 based on results of a pre-planned interim sample size analysis conducted by an independent Data Monitoring Committee, which indicated the trial was unlikely to meet its co-primary endpoints upon completion. Ocugen is no longer pursuing the development of this product candidate.

Merger with Histogenics

On September 27, 2019, the Company, which was formerly known as Histogenics Corporation ("Histogenics"), completed a reverse merger (the "Merger") with Ocugen OpCo, Inc. ("OpCo") in accordance with the terms of the Agreement and Plan of

Merger and Reorganization, dated as of April 5, 2019, by and among OpCo, Restore Merger Sub, Inc., the Company's wholly owned subsidiary ("Merger Sub"), and the Company, as amended (the "Merger Agreement") pursuant to which Merger Sub merged with and into OpCo, with OpCo surviving as the Company's wholly owned subsidiary. Immediately after completion of the Merger, the Company changed its name to Ocugen, Inc. and the business previously conducted by OpCo became the business conducted by the Company. OpCo is deemed to be the accounting acquirer. Accordingly, the historical financial statements of OpCo became the Company's historical financial statements, including the comparative prior periods. See Note 3 for additional information.

Going Concern Consideration

The audited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") assuming the Company will continue as a going concern. As of December 31, 2020, the Company had cash, cash equivalents, and restricted cash of approximately $24.2 million, and since that date the Company has received net proceeds of $4.8 million from the sale of the Company's common stock in an at-the-market offering ("ATM") commenced in August 2020 and net proceeds of $21.2 million from the sale of the Company's common stock in a registered direct offering (the "Registered Direct Offering"). See Note 9 for additional information about the August 2020 ATM. See Note 16 for additional information about the Registered Direct Offering. As a result of the Company's cash, cash equivalents, and restricted cash balance as of December 31, 2020 and the net proceeds received subsequent to December 31, 2020 from the August 2020 ATM and the Registered Direct Offering, the Company believes that its cash, cash equivalents, and restricted cash will enable the Company to fund its operating expenses and capital expenditure requirements through at least one year from the date the audited consolidated financial statements are issued.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements included herein have been prepared in conformity with GAAP and under the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). The consolidated financial statements include the accounts of Ocugen, Inc. and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. Certain prior year amounts have been reclassified to conform with current year presentation.

Use of Estimates

In preparing 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 estimation of clinical trial accruals, warrant transactions, asset held for sale, and the valuation of debt and equity instruments, including embedded derivatives, and stock-based compensation.

Collaboration Arrangements

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

The Company has two agreements accounted for as collaborative agreements within the scope of ASC 808. See Note 4 for additional information.

Exit and Disposal Activities

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

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

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

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, and an impairment loss would be recognized to the extent the carrying amount exceeds the asset's fair value less cost to sell.

As of December 31, 2019, the Company had an intangible asset held for sale. The intangible asset qualified and was recorded as held for sale as of the date of the Merger and was carried at its original fair value less cost to sell of $7.0 million. The Company concluded during the year ended December 31, 2020, that a sale of the intangible asset held for sale was no longer probable to be completed within one year from the date the intangible asset was initially recorded as held for sale. As such, the carrying value of the intangible asset was reduced to zero with the corresponding charge of $7.0 million recognized as in-process research and development expense during the year ended December 31, 2020 as the in-process research and development does not have an alternative future use.

Although the Company has concluded that a sale of the intangible asset is no longer probable to be completed within one year from the date the intangible asset was initially recorded as held for sale, the Company is party to an Asset Purchase Agreement (as defined within Note 3) related to the intangible asset as of December 31, 2020, and continues to market the asset for sale. In the event of a sale of the intangible asset under the Asset Purchase Agreement or to another party, the Company will account for the sale in the period in which the sale occurs.

Fair Value Measurements

The company follows the provisions of the FASB 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 carrying value of certain financial instruments, including cash and cash equivalents, accounts payable, and accrued expenses approximates their fair values due to the short-term nature of these instruments.

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)

As of December 31, 2020, the Company believes the fair values using Level 2 inputs of the PPP Note and the borrowings under the EB-5 Loan Agreement (both as defined in Note 10) approximate their carrying values. See Note 10 for additional information.

Derivative Instruments

The Company does not have derivative hedging instruments used to mitigate risk. The Company evaluates all financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument, in accordance with FASB ASC Topic 815, *Derivatives and Hedging*. The Company additionally follows the provisions of ASC Topic 815-40, *Derivatives and Hedging — Contracts in Entity's Own Equity* for warrants issued, which is the authoritative guidance on accounting for derivative financial instruments indexed and potentially settled in a company's own stock. In order to determine if a contract is considered indexed to the Company's own stock for the purposes of determining liability versus equity classification, the Company performs a two-step analysis: (i) evaluate whether the contract contains any exercise contingencies and, if so, whether they disqualify the contract from being classified as equity; and (ii) assess whether the settlement terms are consistent with equity classification.

For derivative instruments that are accounted for as liabilities, including liability-designated warrants, the derivative instrument is initially recorded at its fair value as a derivative liability and is then revalued at each reporting date, with changes in the fair value reported as other income (expense) in the consolidated statements of operations and comprehensive loss. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period.

The Company had derivative instruments that were fair valued on a recurring basis using Level 3 inputs during the year ended December 31, 2019. There were no derivative instruments fair valued on a recurring basis using Level 3 inputs during the year ended December 31, 2020.

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 may include bank demand deposits, marketable securities with maturities of three months or less at purchase, and money market funds that invest primarily in certificates of deposit, commercial paper, and U.S. government and U.S. government agency obligations. The Company's restricted cash balance consists of cash held to collateralize a corporate credit card account.

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

	As of December 31,	
	2020	2019
Cash and cash equivalents	$ 24,039,325	$ 7,444,052
Restricted cash	151,226	151,016
Total cash, cash equivalents and restricted cash	$ 24,190,551	$ 7,595,068

Property and Equipment, Net

Property and equipment is recorded at cost. Significant additions or improvements are capitalized, and expenditures for repairs and maintenance are charged to expense as incurred. Gains and losses on disposal of assets are included in the consolidated statements of operations and comprehensive loss. Depreciation is calculated using the straight-line method and is recognized over the expected useful life of the underlying asset. Then Company's property and equipment includes office equipment, lab

equipment, leasehold improvements, and a right-of-use asset under the Company's financing lease. The Company's office equipment includes computers and other office technology equipment with a useful life of five years as well as furniture and fixtures with a useful life of seven years. The Company's lab equipment has a useful life of five years. Leasehold improvements are amortized over the shorter of their useful lives or the remaining lease term. If a leasehold improvement transfers ownership to the Company at the end of the lease term, the leasehold improvement is amortized over its useful life. The right-of-use asset under the Company's financing lease is amortized over five years, which represents the estimated useful life of the underlying leased equipment. See Note 6 for additional information about the Company's financing lease.

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 not to account for separately for all classes of underlying assets. Lease expense for variable lease components is recognized when the obligation is probable.

Operating leases are included in other assets and operating lease obligations on the Company’s consolidated balance sheets. Operating lease right-of-use assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. Operating lease payments are recognized as lease expense on a straight-line basis over the lease term. The Company primarily leases real estate classified as operating leases. FASB ASC Topic 842, *Leases* ("ASC 842") requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. 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 the 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 Company’s leases as the reasonably certain threshold has not been 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 an 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 is probable. Variable lease payments include the Company's proportionate share of utilities and other operating expenses and are presented as operating expenses in the Company’s consolidated statements of operations and comprehensive loss in the same line item as expense arising from fixed lease payments.

Stock-based compensation

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, *Compensation—Stock Compensation* (“ASC 718”). ASC 718 requires all stock-based payments to employees, including grants of employee stock options and modifications to existing agreements, to be recognized in the consolidated statements of operations and comprehensive loss based on their fair values. The Company uses the Black-Scholes option-pricing model to determine the fair value of options granted. The Company recognizes forfeitures as they occur.

The Company’s stock-based awards are subject to service-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. Stock-based awards generally vest over a one to three year requisite service period and have a contractual term of 10 years.

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 the Company’s Black-Scholes option-pricing model represent management’s best estimates and involve a number of variables, uncertainties, assumptions and the application of management’s judgment, as they are inherently subjective. If any assumptions change, the Company’s stock-based compensation expense could be materially different in the future.

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 No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.

Expected Volatility. The expected volatility is based on historical volatilities of Ocugen and similar entities within Ocugen's industry for periods commensurate with the expected term assumption.

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.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or the Company's tax returns. Under this method, deferred tax assets and liabilities are determined based on the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established.

The Company accounts for uncertain tax positions recognized in the consolidated financial statements by prescribing a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Segment Information

As of December 31, 2020, the Company viewed its operations and managed its business as one operating segment consistent with how the Company's chief operating decision-maker, the Company's Chief Executive Officer, makes decisions regarding resource allocation and assessing performance. As of December 31, 2020, substantially all of the Company's assets were located in the United States.

Recently Adopted Accounting Standards

In August 2018, the FASB issued Accounting Standards Update ("ASU") No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. This standard modifies certain disclosure requirements on fair value measurements and was effective for the Company on January 1, 2020. The adoption of this standard did not have a material impact on the Company's disclosures.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606.* This standard clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, ASC 606 guidance should be applied, including recognition, measurement, presentation, and disclosure requirements. The standard adds unit-of-account guidance to ASC 808 to align with the guidance in ASC 606 when an entity is assessing whether the collaborative arrangement or a part of the collaborative arrangement is within the scope of ASC 606. The standard also precludes a company from presenting transactions with collaborative arrangement participants that are not directly related to sales to third parties with revenue from contracts with customers recognized under ASC 606 if the collaborative arrangement participant is not a customer. This standard was effective for the Company on January 1, 2020. Consistent with the guidance in this standard, the Company assesses whether collaboration arrangements are within the scope of ASC 606. For collaboration arrangements that are not within the scope of ASC 606, applicable transactions with collaborative arrangement participants are presented as collaboration revenue rather than revenue from contracts with customers. See above and Note 4 for additional information.

Recent Accounting Pronouncements

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

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

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*. This standard will have an effective and transition date of January 1, 2024. Early adoption is permitted beginning January 1, 2021. This standard simplifies an issuer's accounting for convertible instruments by eliminating two of the three models in ASC 470-20 that require separate accounting for embedded conversion features as well as simplifies the settlement assessment that entities are required to perform to determine whether a contract qualifies for equity classification. This standard also requires entities to use the if-converted method for all convertible instruments in the diluted earnings per share calculation and include the effect of potential share settlement (if the effect is more dilutive) for instruments that may be settled in cash or shares, except for certain liability-classified share-based payment awards. The standard requires new disclosures about events that occur during the reporting period and cause conversion contingencies to be met and about the fair value of a public business entity's convertible debt at the instrument level, among other things. The Company does not currently expect the adoption of this standard to have a material impact on its consolidated financial statements.

3. Merger and Pre-Merger Financing

Pre-Merger Financing

In June 2019, OpCo 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, OpCo issued 2.2 million shares of common stock to the Investors, (ii) on October 4, 2019, the Company issued 2.2 million shares of the Company's common stock to the Investors and (iii) on October 4, 2019, the Company issued three series of warrants to purchase shares of the Company’s common stock (the “Series A Warrants,” the “Series B Warrants” and the “Series C Warrants” and collectively, the “Pre-Merger Financing Warrants”) in exchange for an aggregate purchase price of $25.0 million (the "Pre-Merger Financing"). See Note 11 for additional information.

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 OpCo’s outstanding shares of common stock and securities convertible into or exercisable for OpCo’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 OpCo 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.

In accordance with FASB ASC Topic 805, *Business Combinations* (“ASC 805”), the Company concluded that, while Histogenics was the legal acquirer, OpCo was the accounting acquirer due to the fact that (i) OpCo’s shareholders had the majority of the voting rights in Ocugen, (ii) OpCo held all of the board seats of the combined company, and (iii) OpCo management held all key positions in the management of the combined company. The Company further concluded that Histogenics did 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 was accounted for as a reverse asset acquisition.

NeoCart

Histogenics' product, NeoCart, is an innovative cell therapy that utilizes various aspects of its restorative cell therapies platform to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee. In December 2017, Histogenics entered into the License and Commercialization 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. In December 2018, after receiving feedback from the FDA regarding the need for an additional clinical trial prior to submission of a BLA, Histogenics discontinued the development of NeoCart.

In connection with the Merger, on May 8, 2019, Histogenics entered into an asset purchase agreement (the "Asset Purchase Agreement") with Medavate Corp., pursuant to which Histogenics agreed to sell substantially all of its assets relating to its NeoCart program for $6.5 million. The parties subsequently amended the Asset Purchase Agreement to increase the purchase price to $7.0 million with the purchase price increasing 10% per month (or any portion thereof) starting October 31, 2019 if the closing date of the Asset Purchase Agreement did not occur prior to October 31, 2019. The Company may terminate the Asset Purchase Agreement at any time without recourse. The Asset Purchase Agreement closing date did not occur as of December 31, 2020 and the Company has not terminated the Asset Purchase Agreement as of December 31, 2020.

The NeoCart asset was held for sale as of December 31, 2019. The NeoCart asset qualified as held for sale as of the date of the Merger and was carried at its original fair value less cost to sell based on a quoted price of $7.0 million, which was an observable Level 2 fair value input. The Company concluded during the year ended December 31, 2020, that a sale of the NeoCart asset was no longer probable to be completed within one year from the date of the Merger and therefore the NeoCart asset did not qualify as held for sale as of December 31, 2020. See Note 2 for additional information.

4. License and Development Agreements

Collaboration Agreement with Advaite, Inc.

In April 2020, the Company entered into a collaboration agreement (the "Advaite Agreement") with Advaite, Inc. ("Advaite") with respect to the development of Advaite's RapCov COVID-19 Testing Kit (the "COVID-19 Test"). Advaite was co-founded and is being managed by Mr. Karthik Musunuri, the son of the Company's Chief Executive Officer, Chairman of the Board and co-founder, Dr. Shankar Musunuri. Pursuant to the Advaite Agreement, the Company has provided, and will continue to provide as required in the future, certain production, research and development, technical, regulatory, and quality support services to Advaite in connection with the development and commercialization of the COVID-19 Test (the "Ocugen Services"). Advaite is responsible for the research, development, and seeking to obtain regulatory approval of the COVID-19 Test, and where regulatory approval is obtained, commercialize the COVID-19 Test. In January 2021, the COVID-19 Test received EUA from the FDA.

Advaite will solely own all data and materials, including the COVID-19 Test, generated by the Company and its representatives solely in the course of the performance of the Ocugen Services. Advaite is responsible for all preparation and submission of regulatory materials for the COVID-19 Test to regulatory authorities, and Advaite holds all regulatory approvals of the COVID-19 Test in its name and owns all related submissions.

The Company is entitled to receive cost reimbursements from Advaite for (a) costs incurred by the Company related to its personnel who are subject matter experts involved in providing the Ocugen Services ("SME Costs"); and (b) Advaite's pro-rata share of all costs, other than SME Costs, incurred by the Company in providing the Ocugen Services. As partial consideration for the Company's performance of the Ocugen Services, Advaite will pay to the Company a quarterly royalty in the range of mid-to-high single digits based on net sales of the COVID-19 Tests.

The Advaite Agreement is a collaborative arrangement within the scope of ASC 808. Cost reimbursements are recorded as a reduction in research and development expense in the period incurred. Royalty payments are recorded as collaboration revenue in the period in which the underlying sale occurs. For the year ended December 31, 2020, the Company recorded $0.3 million as a reduction of research and development expense. For the year ended December 31, 2020, the Company recorded $42,620 as collaboration revenue in connection with the Advaite Agreement.

The Advaite Agreement expires on April 29, 2021, unless extended upon mutual agreement of both the Company and Advaite. Except as otherwise specified in the terms of the Advaite Agreement, Advaite's obligation to make royalty payments to the Company will survive expiration of the Advaite Agreement.

Co-Development and Commercialization Agreement with CanSino Biologics Inc.

In September 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.

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 costs and expenses of its development activities in and for China, Hong Kong, Macau, and Taiwan (the "CanSinoBIO Territory") and Ocugen will be responsible for all costs and expenses of its development activities for any global location outside the CanSinoBIO Territory (the "Ocugen OCU400 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 OCU400 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, as amended, between Ocugen and The Schepens Eye Research Institute, Inc ("SERI"). The CanSinoBIO Agreement may be terminated by either party in its entirety upon (a) a material breach of the CanSinoBIO 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 by CanSinoBIO under the circumstances described in clause (a) or (b), 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.

License Agreement with The Schepens Eye Research Institute

In December 2017, the Company entered into an exclusive license agreement with SERI, which was amended in January 2021 (as so amended the "SERI Agreement"). The SERI Agreement gives the Company an exclusive, worldwide, sublicensable license to patent rights, biological materials and technical information for nuclear hormone receptor genes Nuclear Receptor Subfamily 1 Group D Member 1, *NR2E3* (OCU400), *RORA* (OCU410), Nuclear Protein 1, Transcriptional Regulator, and Nuclear Receptor Subfamily 2 Group C Member 1. The January 2021 amendment to the SERI Agreement additionally grants the Company rights in co-owned intellectual property pursuant certain patent applications and provisional patent applications. Under the SERI Agreement, the Company may make, have made, use, offer to sell, sell, and import licensed products. Under this agreement, the Company must use commercially reasonable efforts to bring one or more licensed products to market as soon as reasonably practicable. The Company is additionally party to a research agreement (the "Sponsored Research Agreement") with SERI, under which the Company incurs research and development expenses for work performed. The Sponsored Research Agreement will expire in June 2023. The Company may terminate the Sponsored Research Agreement at any time upon providing 60 days notice to SERI or upon mutual consent of both SERI and the Company.

SERI maintains control of patent preparation, filing, prosecution, and maintenance. The Company is responsible for SERI's out-of-pocket expenses related to the filing, prosecution, and maintenance of the licensed patent rights. In the event that SERI decides to discontinue the prosecution or maintenance of the licensed patent rights, the Company has the right, but not the obligation, to file for, or continue to prosecute, maintain, or enforce such licensed patent rights.

The SERI Agreement is a collaborative arrangement within the scope of ASC 808. Payments pursuant to the SERI Agreement are recorded as research and development expense in the period the obligation is incurred. The SERI Agreement requires the Company to pay licensing fees for patent rights granted, an annual license maintenance fee of $25,000 the first two calendar years following the expiration or termination of the Sponsored Research Agreement and an annual license maintenance fee of $0.1 million for each calendar year thereafter, payment of up to $6.0 million upon the achievement of certain development and regulatory milestones, payment of up to $10.1 million upon the achievement of certain commercial milestones, and royalties in the low-single digits based on net sales. The Company has made no milestone or royalty payments to date pursuant to the SERI Agreement.

The SERI Agreement will expire on the expiration date of the last to expire licensed patents right. The Company may terminate the license upon 180 days' prior written notice. SERI may immediately terminate the SERI Agreement if the Company ceases to carry on its business with respect to the licensed patent rights, fail to make payments within thirty days of receiving a written notice of missed payment, fail to comply with the Company's diligence obligations, default on its obligation to procure and maintain insurance, one of its officers is convicted of felony related to the licensed products, the Company breaches any material obligation of the agreement and does not cure such breach within 90 days or if the Company becomes bankrupt or insolvent.

License Agreement with the University of Illinois at Chicago

In February 2016, the Company entered into an exclusive license agreement (the "UIC Agreement") with the University of Illinois at Chicago ("UIC"). This agreement gave the Company an exclusive, worldwide, non-transferable, sublicensable license to patents and patent rights for OCU300 to make, have made, use, import, sell, and offer for sale products claimed by and/or incorporating or derived from the licensed patents. The UIC Agreement additionally gave the Company joint patent rights for patents and patent applications covering inventions or discoveries that were jointly conceived and reduced to practice by the Company and UIC.

As a result of the Company's discontinuation of the Phase 3 clinical trial for OCU300, the Company terminated the UIC Agreement effective in December 2020. Upon the termination of the UIC Agreement, all rights granted under the UIC Agreement reverted back to UIC. Joint patent rights for patents and patent applications covering inventions or discoveries that were jointly conceived by the Company and UIC remain co-owned by both the Company and UIC subsequent to the termination of the UIC Agreement.

License Agreement with the University of Colorado

In March 2014, the Company entered into an exclusive license agreement with University of Colorado ("CU"), which was amended in January 2017 and clarified by a letter of understanding in November 2017 (as so amended and clarified the "CU Agreement"). The CU Agreement gives the Company an exclusive, worldwide, sublicensable license to patents for OCU200 to make, have made, use, import, offer to sell, sell, have sold, and practice the licensed products in all therapeutic applications. Under the CU Agreement, the Company must use commercially reasonable efforts to develop, manufacture, sublicense, market, and sell the licensed products. Under the agreement, the Company assumed primary responsibility for preparing, filing, and prosecuting broad patent claims for OCU200 for CU's benefit. Further, the Company assumed primary responsibility for all patent activities, including all costs associated with the perfection and maintenance of the patents for OCU200.

The CU Agreement requires the payment of certain development and regulatory milestone aggregating to $1.5 million, annual minimum payments of $20,000 beginning in the third year after the effective date and increasing to a percentage rate in the mid-twenties of the previous year's royalty payments (as applicable), royalties in the low single digits on net sales, and royalties in the mid-teens on sublicense income of OCU200. The Company has made no milestone or royalty payments to date pursuant to the CU Agreement.

The CU Agreement will expire on the later of the expiration date of the last to expire licensed patent or the end of any relevant statutory or regulatory exclusivity period. The Company may terminate the CU Agreement upon 60 days' prior written notice. CU may terminate the CU Agreement upon 60 days' notice if the Company fails to make payments within 60 days of such payment's due date, breach and do not cure any diligence obligation, provide any materially false report, or otherwise materially breach and do not cure any material provision of the CU Agreement.

5. Property and Equipment

The major components of property and equipment as of December 31, 2020 and 2019 consist of the following:

	As of December 31,	
	2020	2019
Office equipment	$ 165,755	$ 113,553
Lab equipment	452,128	130,132
Leasehold improvements	176,964	41,010
Financing lease right-of-use asset	63,817	63,817
Total property and equipment	858,664	348,512
Less: accumulated depreciation	(225,697)	(126,048)
Total property and equipment, net	$ 632,967	$ 222,464

Depreciation expense during each of the years ended December 31, 2020 and 2019 was $0.1 million.

6. Leases

Operating Leases

The Company has commitments under operating leases for certain facilities used in its operations including for the use of laboratory, office, and storage space. On October 9, 2020 (the "Effective Date"), the Company entered into a lease agreement (the "Lease Agreement") with WPT Land 2 LP (the "Landlord") for a laboratory, office, and storage space located in Malvern, Pennsylvania. The Lease Agreement was determined to have two lease components per ASC 842, a laboratory space lease component (the "Initial Premises") and an office, storage, and future expanded laboratory space lease component (the "Expansion Premises"), with varying commencement dates. The Initial Premises commencement date occurred in December 2020. The Expansion Premises commencement date did not occur as of December 31, 2020. The Lease Agreement has an initial term of seven-years and the Company has the option to extend the Lease Agreement for one additional five-year term. The option for extension has been excluded from the lease term (and lease liability) for the Lease Agreement as the reasonably certain threshold is not met.

The Company had a former lease agreement with the Landlord for the Company's former office space. Pursuant to the terms of the Lease Agreement, the Company terminated the former lease agreement with the Landlord without penalty upon the commencement of the Expansion Premises in January 2021. The termination date of the former lease agreement is January 31, 2021 and the termination was accounted for as a modification per ASC 842 as the contractual lease term was shortened. The Company has no remaining lease payments as of December 31, 2020 for the former lease agreement. The Company additionally terminated the lease agreement for the Company's former laboratory space effective December 31, 2020. The Company has no remaining lease payments as of December 31, 2020 for the former laboratory space lease agreement.

The components of lease expense were as follows:

	Year ended December 31,	
	2020	2019
Operating lease cost	$ 189,424	$ 250,361
Variable lease cost	84,790	79,700
Total lease cost	$ 274,214	$ 330,061

Supplemental balance sheet information related to leases was as follows:

	As of December 31,	
	2020	2019
Right-of-use assets, net	$ 433,649	$ 344,574
Current lease obligations	$ 44,248	$ 172,310
Non-current lease obligations	389,317	163,198
Total lease liabilities	$ 433,565	$ 335,508

Supplemental information related to leases was as follows:

	Year ended December 31,	
	2020	2019
Weighted-average remaining lease terms—operating leases (years)	6.9	2.0
Weighted-average discount rate—operating leases	4.6 %	7.6 %

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

For the years ending December 31,	Amount
2021	$ 61,688
2022	69,399
2023	71,502
2024	73,605
2025	75,708
Thereafter	157,725
Total	$ 509,627
Less: present value adjustment	(76,062)
Present value of minimum lease payments	$ 433,565

The future minimum operating lease payments excludes payments for the Expansion Premises for which the commencement date did not occur as of December 31, 2020. The estimated aggregate base rent payments for the Expansion Premises are $1.4 million.

Financing Leases

In June 2018, the Company leased specialized research equipment under a lease classified as a financing lease. The leased equipment is included in property and equipment, net and is amortized on a straight-line basis over five years. Financing lease liabilities are included in other liabilities on the Company's consolidated balance sheets. The interest rate related to the lease obligation is 7.6% and the maturity date is July 2021. The Company has a de minimis amount of remaining payments under the financing lease as of December 31, 2020.

7. Accrued Expenses

Accrued Expenses are as follows:

	As of December 31,	
	2020	2019
Accrued expenses:		
Research and development	$ 512,026	$ 271,322
Clinical	117,012	421,788
Professional fees	405,001	917,568
Employee-related	963,117	624,420
Severance-related (1)	711,596	—
Other	221,643	34,947
Total accrued expenses	$ 2,930,395	$ 2,270,045

(1) See Note 8 for additional information regarding severance-related accrued expenses.

8. Exit and Disposal Activities

On June 15, 2020, the Company communicated notice to five employees of termination of their employment as a result of the Company's discontinuation of the Phase 3 clinical trial for OCU300. This reduction represented one-third of the Company’s workforce at the time of communication. All terminations were “without cause” and each employee received termination benefits upon departure. The termination dates varied for each employee and ranged from June 30, 2020 to December 31, 2020.

For the year ended December 31, 2020, the Company recognized $0.2 million of severance-related charges within general and administrative expense and $0.9 million of severance-related charges within research and development expense. The Company expects to pay severance benefits of $0.7 million during 2021.

The following table outlines the components of the severance-related charges:

	Amount
Accrued Severance at December 31, 2019	$ —
Severance-related charges	1,115,679
Severance-related payments	(404,083)
Accrued Severance at December 31, 2020	$ 711,596

9. Equity Transactions

At-the-Market Offerings

During the year ended December 31, 2020, the Company sold an aggregate of 108.1 million shares of common stock in separate ATMs commenced in May 2020, June 2020, and August 2020. During the year ended December 31, 2020, the Company sold 34.3 million shares under the May 2020 ATM, 24.8 million shares under the June 2020 ATM, and 49.0 million shares under the August 2020 ATM. During the year ended December 31, 2020, the Company received net proceeds of $36.3 million, after deducting commissions, fees and expenses of $1.5 million.

The offerings were made pursuant to the Company's effective "shelf" registration statement on Form S-3 filed with the SEC on March 27, 2020, the base prospectus contained therein dated May 5, 2020, and the prospectus supplements related to the offerings dated May 8, 2020, June 12, 2020, and August 17, 2020. As of December 31, 2020, the Company had sold all of the shares of common stock available for issuance under the prospectus supplements filed on May 8, 2020 and June 12, 2020 in connection with the May 2020 and June 2020 ATMs. As of December 31, 2020, the Company had remaining capacity to issue

up to $8.3 million of common stock under the prospectus supplement filed on August 17, 2020 in connection with the August 2020 ATM.

Subscription Agreements

On June 6, 2020, the Company entered into a subscription agreement with an accredited investor for the issuance of 1.3 million shares of the Company's common stock in a private placement. The shares of common stock were issued as part of a transaction in settlement of an outstanding obligation of the Company to the accredited investor, in which (i) the Company agreed to make certain cash payments, (ii) the Company issued the 1.3 million shares of common stock in exchange for the accredited investor's agreement to cancel $0.3 million of the outstanding obligation and (iii) the accredited investor agreed to cancel an additional portion of the amount owed by the Company representing a discount of $0.2 million.

On April 22, 2020, the Company entered into a subscription agreement with an accredited investor for the sale of 1,000 shares of the Company's common stock in a private placement for an aggregate offering price of $395. This private placement constituted a Dilutive Issuance (as defined in Note 11) and resulted in adjustments to the Series A Warrants.

On April 5, 2019, OpCo entered into a subscription agreement (the "April 2019 Subscription Agreement") with existing investors for the sale of 0.1 million shares of common stock for $1.0 million, including the sale of 40,286 shares of common stock for $0.5 million to a member of the Board of Directors. This capital raise triggered the conversion features on the convertible debt described further in Note 10.

10. Debt

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

	As of December 31,	
	2020	2019
PPP Note	$ 421,415	$ —
EB-5 Loan Agreement borrowings	1,635,747	1,072,123
Total carrying value of debt, net	$ 2,057,162	$ 1,072,123

PPP Note

On April 30, 2020, the Company was granted a loan from Silicon Valley Bank ("SVB"), in the aggregate amount of $0.4 million, pursuant to the Paycheck Protection Program (the “PPP”) of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the “CARES Act”). On June 5, 2020, the PPP Flexibility Act of 2020 (the "PPPFA") was signed into law amending the original terms of the PPP. Among other things, the PPPFA extended the deferral period for monthly principal and interest payments from six months to either (i) the date the Small Business Administration ("SBA") compensates the lender for any forgiven amounts or (ii) 10 months after the end of the borrower's loan forgiveness covered period. The PPPFA also extended the covered period for qualifying expenses from eight weeks to the earlier of 24 weeks or December 31, 2020. Certain amounts of the loan may be forgiven if they are used for qualifying expenses as described by the CARES Act.

The loan was in the form of a promissory note dated April 30, 2020 in favor of SVB (the "PPP Note"). The PPP Note matures on April 30, 2022 and bears interest at a rate of 1.0% per annum. Principal and interest payments are payable monthly commencing on either (i) the date the SBA compensates SVB for any forgiven amounts or (ii) 10 months after the end of the Company's covered period, which ended in October 2020. If the PPP Note is fully forgiven, the Company will not be responsible for any payments. The Company did not provide any collateral or guarantees for the loan, nor did the Company pay any facility charge to obtain the loan. The PPP Note provides for customary events of default, including, among others, failure to make payment, bankruptcy, breaches of representations, and material adverse events.

At December 31, 2020, the carrying value of the PPP Note was $0.4 million.

Warrant Exchange Promissory Notes

On April 22, 2020, in connection with the Warrant Exchange (as defined in Note 11), the Company issued to Investors certain promissory notes (the "Warrant Exchange Promissory Notes") with an aggregate principal amount of $5.6 million. The Warrant

Exchange Promissory Notes had a maturity date of April 21, 2021 and did not bear interest. The Warrant Exchange Promissory Notes were recorded at a fair value of $5.0 million. The difference of $0.6 million between the fair value and the aggregate principal amount of $5.6 million was recorded as a debt discount and accreted to interest expense over the life of the Warrant Exchange Promissory Notes. The accretion amounted to $0.6 million for the year ended December 31, 2020.

The Company was entitled to prepay the Warrant Exchange Promissory Notes in whole or in part at any time without penalty or premium. In the event that the Company consummated a financing transaction that generated cash to the Company, the Company was required to use 20% of the net proceeds of such transaction to prepay a portion of the outstanding amount under each Warrant Exchange Promissory Note if the transaction occurred on or prior to August 22, 2020, and 30% of the net proceeds to prepay a portion of the outstanding amount under each Warrant Exchange Promissory Note if that transaction occurred after August 22, 2020. As a result of the net proceeds from the ATMs discussed in Note 9 , the Company made payments to the Warrant Exchange Promissory Note holders of $5.6 million during the year ended December 31, 2020, causing the Warrant Exchange Promissory Notes to be repaid in full and no longer outstanding at December 31, 2020.

EB-5 Loan

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

Under the terms and conditions of the EB-5 Loan Agreement, the Company borrowed $1.0 million in 2016 and an additional $0.5 million on March 26, 2020. Issuance costs were recognized as a reduction to the loan balance and are amortized to interest expense over the term of the loan.

The carrying values of the EB-5 Loan Agreement borrowings as of December 31, 2020 and 2019 are summarized below:

	As of December 31,	
	2020	2019
Principal outstanding	$ 1,500,000	$ 1,000,000
Plus: accrued interest	181,053	127,777
Less: unamortized debt issuance costs	(45,306)	(55,654)
Carrying value of debt	$ 1,635,747	$ 1,072,123

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 the "Senior Secured Convertible Notes"). Immediately prior to the Merger, the Investors offset $5.3 million from the amount to be received under the Pre-Merger Financing and the Senior Secured Convertible Notes were deemed to have been repaid and cancelled. The accretion of the original issue discount to interest expense amounted to $0.8 million during the year ended December 31, 2019.

Convertible Promissory Notes

On April 4, 2019, the Company issued a convertible promissory note (the "Convertible Promissory Note") to an existing stockholder for $0.9 million at an interest rate of 5% per annum. On May 16, 2019, the Convertible Promissory Note was converted into equity. OpCo issued 0.1 million 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.

Convertible Notes

During the years ended December 31, 2019 and 2018, the Company issued convertible notes (the "Convertible Notes") to new and existing stockholders in the Company, including Convertible Notes in the aggregate principal amount of $3.5 million to members of the Board of Directors. As of December 31, 2019, all of the Convertible Notes had been converted and were no longer outstanding.

At issuance, the following amounts were recorded:

Note Issuance Date	Convertible Note Principal Amount	Fair Value of Embedded Derivatives	Debt Issuance Costs	Carrying Value upon Issuance
January 2018	$ 5,000,000	$ (2,657,711)	$ (35,969)	$ 2,306,320
June 2018	1,000,000	(724,216)	(3,000)	272,784
November 2018	1,150,400	(21,127)	(50,646)	1,078,627
December 2018	150,000	(2,857)	(14,310)	132,833
January 2019	450,000	(182,882)	(29,358)	237,760
February 2019	1,000,000	(302,379)	(55,875)	641,746
Total	$ 8,750,400	$ (3,891,172)	$ (189,158)	$ 4,670,070

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

If the Company received 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 above a certain amount of gross proceeds, the principal amount and all interest accrued but not paid through the closing date of the qualified equity financing was to automatically convert into the same class of equity securities as those issued in the qualified equity financing ("Conversion Feature"). The price per share varied among the Convertible Notes ranging from a 0% to 30% discount to the lowest price per share being paid by investors in the qualified equity financing.

The Company bifurcated the Conversion Feature for the January 2018, June 2018, January 2019, and February 2019 Convertible Notes and classified it as a derivative liability because the conversion feature did not have a fixed conversion price and conversion would be settled in a variable number of shares of common stock. There was no bifurcated conversion feature for the November 2018 and December 2018 Convertible 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 Convertible 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 Convertible Notes with subsequent changes in fair value recorded on the Company's consolidated statements of operations and comprehensive loss as other income (expense). The fair value at the issuance of each Convertible Note and at the end of each reporting period were estimated using an income approach model. Inputs used in the valuation were unobservable and therefore considered Level 3 in the fair value hierarchy. The debt discount was accreted into interest expense over the expected time until conversion of the Convertible Notes. The accretion amounted to $0.6 million for the year ended December 31, 2019. There was no accretion during the year ended December 31, 2020 as all Convertible Notes had been converted and were no longer outstanding as of December 31, 2019.

As a result of the April 2019 Subscription Agreement as described and defined within Note 9, the triggers for conversion were met on the Convertible Notes. On April 5, 2019, the Convertible Notes were modified to change the discount percentage from the 0% discount per the terms of the November 2018 and December 2018 Convertible Notes and the 15% discount per the terms of the January 2019 and February 2019 Convertible Notes to 30% at the time of conversion. The Company issued 1.1 million shares of common stock 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 conversion 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.

Principal Maturities

Debt maturities (excluding interest) are summarized below:

	For the years ending December 31,						
	2021	2022	2023	2024	2025	Thereafter	Total
Principal maturities	$ 234,119	$ 187,296	$ —	$ —	$ —	$ 1,500,000	$ 1,921,415

11. Warrants

Pre-Merger Financing Warrants

On September 27, 2019, Ocugen completed the Merger with OpCo. Immediately prior to the Merger, Ocugen and OpCo completed the Pre-Merger Financing, a previously announced private placement transaction with certain Investors pursuant to the Financing SPA, whereby, among other things, the Company agreed to issue the Pre-Merger Financing Warrants.

On November 5, 2019, the Company entered into an agreement with each Investor that amended the terms of each of the Pre-Merger Financing Warrants held by each such Investor (collectively, the "Warrant Amendments"). The terms of the Pre-Merger Financing Warrants and the Warrant Amendments are discussed below. There were no Pre-Merger Financing Warrants outstanding at December 31, 2020.

Series A Warrants

The Series A Warrants had an initial exercise price per share of $7.13, were exercisable upon issuance, and had a term of 60 months from the date of issuance. The Series A Warrants were exercisable for up to 8.8 million shares of Ocugen common stock.

The Series A Warrants had an anti-dilution adjustment whereby if Ocugen had issued or sold, entered into a definitive, binding agreement pursuant to which Ocugen would have been required to issue or sell or would have been 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 would have been reduced to such lower price per share and (ii) the number of shares issuable upon exercise of the Series A Warrants would have been 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.

All of the Series A Warrants were outstanding and exercisable as of December 31, 2019. Pursuant to the Warrant Exchange (as defined below), no Series A Warrants were outstanding as of December 31, 2020.

Series B Warrants

The Series B Warrants had an exercise price of $0.01, were exercisable after the completion of a 10 trading-day period following the effectiveness of a registration statement covering the resale of common stock into which such warrants were exercisable and were to expire on 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 were initially exercisable by the holders for 8.0 million shares of common stock.

Additionally, each Series B Warrant included a Reset Period pursuant to which the number of shares issuable upon exercise of the Series B Warrants was increased during certain Reset Periods (as defined in the Series B Warrants). The Reset Period concluded in November 2019 and resulted in an aggregate of 12.6 million additional shares of common stock becoming issuable upon exercise of the Series B Warrants. There were 1,000 Series B Warrants outstanding at December 31, 2019. There were no Series B Warrants outstanding at December 31, 2020.

Series C Warrants

The Series C Warrants were exercisable upon issuance for up to 50.0 million shares of common stock at an initial exercise price of $7.13 per share. Each of the Series C Warrants was amended pursuant to the Warrant Amendments 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 20.0 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. There were 1,000 Series C Warrants outstanding at December 31, 2019. There were no Series C Warrants outstanding at December 31, 2020.

Accounting for the Pre-Merger Financing Warrants

As of December 31, 2019, the Pre-Merger Financing Warrants were classified as equity. At issuance, the Series B Warrants were classified as a liability on the consolidated balance sheet as they did not meet the derivative scope exception to be accounted for within stockholders' equity. The Series B Warrants were initially measured at fair value and marked to market each reporting period. Upon the completion of the Reset Period in November 2019, the Series B Warrants were reassessed and determined to meet the derivative scope exception allowing for equity classification. The Series B Warrants were marked to market a final time and the remaining liability balance was reclassified to equity.

The fair value of the Series B Warrants was calculated using a Monte Carlo simulation while estimating the stock price during the 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 Reset Period, and additional shares issued from escrow. The methodology for measuring fair value was sensitive to the expected stock volatility assumption input. The volatility used in the fair value estimate at issuance was 96.0%. Inputs used in the valuation were unobservable and were therefore classified as Level 3 fair value inputs. The fair value of the Series B Warrants upon the end of the Reset Period was based on a Black-Scholes valuation model, which is classified as Level 3 in the fair value hierarchy.

The following table provides a roll-forward of the Series B Warrant liability:

	Amount
Balance at January 1, 2019	$ —
Fair value at issuance (September 27, 2019)	9,387,760
Change in fair value of embedded derivatives	1,867,980
Amount reclassified to equity	(11,255,740)
Balance at December 31, 2019	$ —

Warrant Exchange

On April 22, 2020, the Company entered into a subscription agreement as discussed within Note 9. The subscription agreement constituted a Dilutive Issuance (as defined above) and resulted in adjustments to the number of issuable Series A Warrants and the exercise price under the Series A Warrants.

Contemporaneously with the subscription agreement, the Company and OpCo entered into Amendment and Exchange Agreements (each an "Exchange Agreement" and collectively, the "Exchange Agreements") with the Investors. Pursuant to the Exchange Agreements, the Company, OpCo, and the Investors agreed, among other things, after giving effect to the Dilutive Issuance, to amend the Series A Warrants to provide for an adjustment to the number of common stock issuable upon the exercise of the Series A Warrants. Concurrently with such amendments, the Investors exchanged the Series A Warrants for (i) an aggregate of 21.9 million shares of common stock and (ii) the Warrant Exchange Promissory Notes (collectively the "Warrant Exchange"). Following the consummation of the Warrant Exchange and the concurrent exercise of the remaining Series B Warrants and Series C Warrants, there were no Pre-Merger Financing Warrants outstanding at December 31, 2020.

The Company accounted for the Warrant Exchange by recognizing the fair value of the consideration transferred in excess of the carrying value of the Series A Warrants as a reduction of additional paid-in capital. The fair value of the consideration transferred to settle the Series A Warrants was approximately $13.6 million, comprised of $8.6 million in shares of common stock and the fair value of the Warrant Exchange Promissory Notes of $5.0 million utilizing Level 2 inputs. The fair value of consideration transferred to settle the Series A warrants was in excess of the fair value of the Series A Warrants immediately

prior to the transaction by approximately $12.5 million. The excess consideration was accounted for as a deemed dividend to the warrant holders and is reflected as an additional net loss attributed to common stockholders in the calculation of basic and diluted net loss per common share for the year ended December 31, 2020. The fair value of the Series A Warrants immediately prior to the Warrant Exchange was $1.1 million, which was estimated using a Black-Scholes valuation model utilizing Level 3 inputs.

OpCo Warrants

Prior to 2018, OpCo issued warrants to investors of the Company pursuant to a stockholders' agreement and to two employees of the Company pursuant to their respective employment agreements. As of December 31, 2020 and 2019, 0.9 million warrants to purchase common stock were outstanding and exercisable and had a weighted average exercise price of $5.67 per share. The warrants expire between 2026 and 2027.

12. Stock-Based Compensation

Stock-based compensation expense for options granted are reflected in the consolidated statements of operations and comprehensive loss as follows:

	Year ended December 31,	
	2020	2019
General and administrative	$ 348,810	$ 362,833
Research and development	311,507	521,256
Total	$ 660,317	$ 884,089

As of December 31, 2020, the Company had $1.1 million of unrecognized compensation expense related to options outstanding under its equity plans. This expense is expected to be recognized over a weighted average period of two years as of December 31, 2020.

Equity Plans

The Company maintains two equity compensation plans, the 2014 Ocugen OpCo, Inc. Stock Option Plan (the “2014 Plan”) and the Ocugen, Inc. 2019 Equity Incentive Plan (the “2019 Plan”, collectively with the 2014 Plan, the "Plans"), which replaced the Histogenics Corporation 2013 Equity Incentive Plan (the "2013 Plan").

In December 2019, Ocugen’s stockholders approved the adoption of the 2019 Plan and the 2013 Plan was frozen. No additional awards have been or will be made under the 2013 Plan and any remaining authorized shares under the 2013 Plan were recycled into the 2019 Plan. On the first business day of each fiscal year, pursuant to the "Evergreen" provision of the 2019 Plan, the aggregate number of shares that may be issued under the 2019 Plan will automatically increase by a number equal to the lesser of 4% of the total number of shares of Company common stock outstanding on December 31st of the prior year, or a number of shares of Company common stock determined by the Board or Directors.

As of December 31, 2020, the 2014 Plan provides for the granting of up to 0.8 million equity awards in respect to Ocugen's common stock. As of December 31, 2020, the 2019 Plan provides for the granting of up to 4.2 million equity awards in respect of Ocugen's common stock, inclusive of equity awards that were previously available for issuance under the 2013 Plan and the additional shares authorized for issuance pursuant to the 2019 Plan's "Evergreen" provision on January 1, 2020.

As of December 31, 2020, an aggregate of 0.4 million and 3.8 million shares of Company common stock were issuable upon the exercise of outstanding stock options under the 2014 Plan and 2019 Plan, respectively.

Options to Purchase Common Stock

The assumptions utilized in the fair value calculation for options to purchase common stock as of December 31, 2020 and 2019 are as follows:

	Year ended December 31,	
	2020	2019
Weighted average expected option term (years)	6.0	6.0
Range of expected stock price volatility	110% - 117%	89% - 110%
Weighted average expected stock price volatility	112%	109%
Range of risk-free interest rate	0.3% – 1.7%	1.5% – 2.4%
Expected dividend rate	0%	0%

The following table summarizes the stock option activity under the Plans:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2019	731,189	$ 4.59	8.0	$ 24,028
Granted	4,082,950	$ 0.41		
Forfeited	(589,706)	$ 2.55		
Options outstanding at December 31, 2020	4,224,433	$ 0.84	8.9	$ 5,496,219
Options exercisable at December 31, 2020	512,288	$ 3.48	6.8	$ 286,223

The weighted average grant date fair value of stock options granted during the years ended December 31, 2020 and 2019 were $0.34 and $0.84, respectively. The total fair value of stock options vested during the years ended December 31, 2020 and 2019 were $0.5 million and $1.0 million, respectively.

13. Income Taxes

For the years ended December 31, 2020 and 2019, the Company did not recognize any current or deferred income tax expense or benefit due to the current and historical losses incurred by the Company. Losses before income taxes were $21.8 million and $20.2 million for the years ended December 31, 2020 and 2019, respectively, substantially all of which were incurred in the United States.

On March 27, 2020, the United States enacted the CARES Act. The Cares Act includes provisions relating to refundable payroll tax credits, deferment of the employer portion of certain payroll taxes, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The Company considered the tax related provisions under the CARES Act and noted that the effect of such provisions was not expected to have a material impact on the Company’s results of operations, cash flows, and consolidated financial statements.

The reconciliation of federal statutory income tax to the Company's provision for income taxes is as follows:

	As of December 31,	
	2020	2019
Expected provision at statutory rate	21.0 %	21.0 %
State tax - net of federal benefit	7.5 %	5.3 %
Tax credits	2.8 %	3.2 %
Permanent differences	(1.0)%	(8.1)%
Other	1.1 %	2.9 %
Change in valuation allowance	(31.4)%	(24.3)%
Total provision for income taxes	— %	— %

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities as of December 31, 2020 and 2019 are comprised of the following:

	As of December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 35,714,104	$ 31,575,288
Capital loss carryforwards	7,298,024	7,298,052
Start-up costs	11,234,623	11,234,751
Accruals and reserves	397,982	166,611
Intellectual property amortization	2,285,247	555,352
Stock-based compensation expense	1,290,212	1,123,100
Tax credits	2,541,244	1,926,677
Lease liability	125,266	96,895
Total deferred tax assets	60,886,702	53,976,726
Valuation allowance	(60,761,412)	(53,877,168)
Deferred tax assets, net of allowance	$ 125,290	$ 99,558
Deferred tax liabilities:		
Lease right-of-use assets	(125,290)	(99,558)
Net deferred tax assets	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets. Management has considered the Company's history of cumulative net losses, estimated future taxable income, and prudent and feasible tax planning strategies and has concluded that it is more likely than that the Company will not realize the benefits of its deferred tax assets. Accordingly, a full valuation allowance has been established against these net deferred tax assets as of December 31, 2020 and 2019, respectively. The Company's valuation allowance increased during 2020 by approximately $6.9 million primarily due to the generation of net operating losses and research and development and orphan drug credit carryforwards.

As of December 31, 2020 and 2019, the Company had U.S. federal net operating loss ("NOL") carryforwards of $128.0 million and $113.6 million, respectively, which may be available to offset future income tax liabilities. The Tax Cut and Jobs Act, which was enacted in December 2017 (the "TCJA"), will generally allow federal losses generated after 2017 to be carried over indefinitely, but will generally limit the NOL deduction to the lesser of the NOL carryover or 80% of a corporation's taxable income (subject to Section 382 of the Internal Revenue Code of 1986, as amended ("IRC")). In addition, there will be no carryback for losses generated after 2017. Losses generated prior to 2018 will generally be deductible to the extent of the lesser of a corporation's NOL carryover or 100% of a corporation's taxable income and will be available for twenty years from the period the loss was generated. The Company has federal NOLs generated after 2017 of $75.4 million, which do not expire. The federal NOLs generated prior to 2018 of $52.6 million will expire at various dates through 2037.

As of December 31, 2020 and 2019, the Company also had U.S. state NOL carryforwards of $126.7 million and $112.4 million, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2040.

As of December 31, 2020 and 2019, the Company had federal tax credit carryforwards of approximately $2.2 million and $1.6 million, respectively, which are available to offset future federal tax liabilities which expire at various dates through 2040. As of December 31, 2020 and 2019, the Company had state tax credit carryforwards of approximately $0.5 million and $0.4 million, respectively, which are available to reduce future tax liabilities which expire at various dates through 2035.

Under the provisions of the IRC, the NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Utilization of U.S. federal and state NOL and tax credit carryforwards may be subject to a substantial annual limitation under Section 382 and Section 383 of the IRC, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and tax credit carryforwards that can be utilized annually to offset future taxable income and tax

liabilities, respectively. The Company acquired a significant amount of federal and state NOL carryforwards and federal and state tax credit carryforwards as a result of the Merger.

The Company has not yet conducted a comprehensive study to assess whether a change of ownership has occurred, or whether there have been multiple ownership changes since its formation. Any limitation may result in expiration of a portion of the NOL carryforward or tax credit carryforwards before utilization, which would be offset by a change in the Company's valuation allowance. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has not yet conducted a study of tax credit carryforwards. Such a study, once undertaken by the Company, may result in an adjustment to our tax credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company’s tax credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheets or consolidated statements of operations and comprehensive loss if an adjustment is required.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	Year ended December 31,	
	2020	2019
Gross unrecognized tax benefits at beginning of year	$ 303,050	$ —
Additions for tax positions taken in a prior year	—	303,050
Additions for tax positions taken in the current year	—	—
Reductions for tax positions taken in the prior year due to settlement	—	—
Reductions for tax positions taken in the prior year due to statutes lapsing	—	—
Gross unrecognized tax benefits at end of year	$ 303,050	$ 303,050

The uncertain tax positions giving rise to the unrecognized tax benefits of $0.3 million at December 31, 2020 relate to the timing of certain income and deductions for federal income tax purposes taken by Histogenics prior to the Merger. The reversal of unrecognized tax benefits would not have any impact on the effective tax rate in the future and is not expected to create cash liability.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In a normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company’s tax years are still open under status from 2017 to present.

14. Net Loss per Share of Common Stock

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2020 and 2019:

	Year ended December 31,	
	2020	2019
Net loss—basic and diluted	$ (21,821,953)	$ (20,242,630)
Deemed dividend related to Warrant Exchange (Note 11)	(12,546,340)	—
Net loss to common stockholders	$ (34,368,293)	$ (20,242,630)
Shares used in calculating net loss per common share—basic and diluted	112,236,110	13,893,819
Net loss per common share—basic and diluted	$ (0.31)	$ (1.46)

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

	Year ended December 31,	
	2020	2019
Options to purchase common stock	4,224,433	731,189
Warrants	870,017	9,643,945
Total	5,094,450	10,375,134

15. Commitments and Contingencies

Commitments

The Company has commitments under certain license agreements, lease agreements, debt agreements, and separation agreements. Commitments under certain license agreements include annual payments, payments upon the achievement of certain milestones, and royalty payments based on net sales of licensed products. See Note 4 for additional information about commitments under license agreements. Commitments under lease agreements include future minimum lease payments for both operating and financing leases. See Note 6 for additional information about commitments under lease agreements. Commitments under debt agreements include payments for any amount of principal and accrued interest under the PPP Note that is determined to be not forgiven by the SBA as well as the future payment of principal and accrued interest under the EB-5 Loan Agreement. See Note 10 for additional information about commitments under debt agreements. Commitments under separation agreements include severance payments to be paid in 2021 as a result of the reduction in force in connection with the Company's discontinuation of the Phase 3 clinical trial for OCU300. See Note 8 for additional information about commitments under separation agreements.

Contingencies

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

16. Subsequent Events

Covaxin Agreement

On February 2, 2021, the Company entered into the Covaxin Agreement with Bharat Biotech to co-develop COVAXIN, a whole-virion inactivated COVID-19 vaccine being developed to prevent COVID-19 infection, for the U.S. market. Pursuant to the Covaxin Agreement, the Company obtained an exclusive right and license under certain of Bharat Biotech’s intellectual property rights, with the right to grant sublicenses, to develop, manufacture, and commercialize COVAXIN, a whole-virion inactivated vaccine candidate for the prevention of COVID-19 in humans in the Ocugen Covaxin Territory. In consideration of the license and other rights granted by Bharat Biotech to the Company, the parties agreed to share any profits generated from the commercialization of COVAXIN in the Ocugen Covaxin Territory, with the Company retaining 45% of such profits, and Bharat Biotech receiving the balance of such profits.

Under the Covaxin Agreement, the Company and Bharat Biotech will collaborate to develop COVAXIN for their respective territories. Except with respect to U.S. manufacturing rights under certain circumstances as described below, the Company has the exclusive right and is solely responsible for researching, developing, manufacturing, and commercializing COVAXIN for the Ocugen Covaxin Territory. Bharat Biotech has the exclusive right and is solely responsible for researching, developing, manufacturing, and commercializing COVAXIN outside of the Ocugen Covaxin Territory.

Bharat Biotech has agreed to provide to the Company all preclinical and clinical data, and to transfer to the Company certain proprietary technology owned or controlled by Bharat Biotech, that is necessary for the successful commercial manufacture and supply of COVAXIN to support commercial sale in the Ocugen Territory, including pursuant to any EUA for the Ocugen Covaxin Territory approved by the FDA. In certain circumstances set forth in the Covaxin Agreement, and until the Company is capable and primarily responsible for the manufacture and supply of COVAXIN for the Ocugen Covaxin Territory, Bharat Biotech has the exclusive right to manufacture COVAXIN for the Ocugen Covaxin Territory and is responsible for manufacturing and supplying clinical testing materials required for the Company’s development activities, and all of the

Company’s requirements of commercial quantities of COVAXIN. The parties will enter into supply agreements setting forth the terms of such supply. Bharat Biotech has agreed to provide a specified minimum number of doses in calendar year 2021.

The Covaxin Agreement continues in effect for the commercial life of COVAXIN, subject to the earlier termination of the Covaxin Agreement in accordance with its terms. The Covaxin Agreement also contains customary representations and warranties made by both parties, and customary provisions relating to indemnification, limitation of liability, confidentiality, information and data sharing, and other matters.

The Company is currently evaluating the clinical and regulatory path for COVAXIN in the United States including obtaining EUA from the FDA and, eventually, BLA approval in the U.S. market, as well as the Company's commercialization strategy, if authorized or approved. The impact of COVAXIN on the consolidated financial statements will be dependent the clinical, regulatory, and commercialization pathway for COVAXIN.

Registered Direct Offering

On February 7, 2021, the Company entered into a Securities Purchase Agreement pursuant to which the Company agreed to issue and sell in a Registered Direct Offering, 3.0 million shares of the Company's common stock at an offering price of $7.65 per share. The closing of the Registered Direct Offering occurred on February 10, 2021. The Company received net proceeds of $21.2 million from the sale of 3.0 million shares in the Registered Direct Offering, after deducting placement agent fees and related offering expenses of $1.7 million.

COVAXIN Preferred Stock Purchase Agreement

On March 1, 2021, the Company entered into a Preferred Stock Purchase Agreement, pursuant to which the Company agreed to issue and sell 0.1 million shares of the Company’s newly designated Series B Convertible Preferred Stock, par value $0.01 per share (the “Series B Preferred Stock”), at a price per share equal to $109.60, to Bharat Biotech. The Company is issuing the shares of Series B Preferred Stock as an advance payment for the supply of COVAXIN to be provided by Bharat Biotech pursuant to a supply agreement (the "Supply Agreement") expected to be entered into with respect to the parties' Covaxin Agreement.

Each share of Series B Preferred Stock is convertible, at the option of Bharat Biotech, into 10 shares of the Company’s common stock only after (i) the Company’s receipt of stockholder approval to increase the number of authorized shares of common stock under its Sixth Amended and Restated Certificate of Incorporation and (ii) the Company’s receipt of shipments by Bharat Biotech of the first 10.0 million doses of COVAXIN manufactured by Bharat Biotech pursuant to the Supply Agreement.

Exhibit 3.5

OCUGEN, INC.

**CERTIFICATE OF DESIGNATION OF PREFERENCES,
RIGHTS AND LIMITATIONS
OF
SERIES B CONVERTIBLE PREFERRED STOCK**

PURSUANT TO SECTION 151 OF THE
DELAWARE GENERAL CORPORATION LAW

The undersigned, Shankar Musunuri, does hereby certify that:

1. He is the Chief Executive Officer of Ocugen, Inc., a Delaware corporation (the "Corporation").

2. The Corporation is authorized to issue 10,000,000 shares of preferred stock, 30,000 of which are designated as Series A Convertible Preferred Stock.

3. The following resolutions were duly adopted by the board of directors of the Corporation (the "Board of Directors"):

WHEREAS, the certificate of incorporation of the Corporation provides for a class of its authorized stock known as preferred stock, consisting of 10,000,000 shares, $0.01 par value per share, issuable from time to time in one or more series;

WHEREAS, the Board of Directors is authorized, without further stockholder approval, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences, and rights of the shares of each such series and any qualifications, limitations or restrictions thereof; and

WHEREAS, it is the desire of the Board of Directors, pursuant to such authority, to fix the rights, preferences, restrictions and other matters relating to a series of the preferred stock, which shall consist of up to 54,745 shares of the preferred stock which the Corporation has the authority to issue, as follows:

NOW, THEREFORE, BE IT RESOLVED, that the Board of Directors does hereby provide for the issuance of a series of preferred stock for cash or exchange of other securities, rights or property and does hereby fix and determine the rights, preferences, restrictions and other matters relating to such series of preferred stock as follows:

TERMS OF PREFERRED STOCK

Section 1. Definitions. For the purposes hereof, the following terms shall have the following meanings:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 of the Securities Act.

"Alternate Consideration" shall have the meaning set forth in Section 7(d).

"Bharat" shall mean Bharat Biotech International Limited.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Certificate of Incorporation" means the Sixth Amended and Restated Certificate of Incorporation of Ocugen, Inc., as amended from time to time.

"Closing" means the closing of the purchase and sale of the Preferred Stock pursuant to Section 1 of the Purchase Agreement.

"Closing Date" means the Trading Day on which this Certificate of Designation has been filed with the Secretary of State of the State of Delaware, the Purchase Agreement has been executed and delivered by the applicable parties thereto and all conditions precedent to the Corporation's obligations to deliver the Preferred Stock have been satisfied or waived.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the Corporation's common stock, par value $0.01 per share, and stock of any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Corporation or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, rights, options, warrants or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Conversion Date" shall have the meaning set forth in Section 6(a).

"Conversion Events" shall have the meaning set forth in Section 6(a).

"Conversion Ratio" shall have the meaning set forth in Section 6(a).

"Conversion Shares" means, collectively, the shares of Common Stock issuable upon conversion of the shares of Preferred Stock in accordance with the terms hereof.

"Conversion Shares Registration Statement" means a registration statement that registers the resale of all Conversion Shares of the Holders, who shall be named as "selling stockholders" therein and meets the requirements of the Purchase Agreement.

"Co-Development Agreement" means the Co-Development, Supply and Commercialization Agreement, dated February 2, 2021, among the Corporation and Bharat.

"Delaware Courts" shall have the meaning set forth in Section 11(d).

"Distribution" shall have the meaning set forth in Section 7(b).

"Effective Date" means the date that the Conversion Shares Registration Statement filed by the Corporation pursuant to the Purchase Agreement is first declared effective by the Commission.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Fundamental Transaction" shall have the meaning set forth in Section 7(d).

"Holder(s)" shall have the meaning given such term in Section 2.

"Liquidation" shall have the meaning set forth in Section 5.

"Notice of Conversion" shall have the meaning set forth in Section 6(a).

"Original Issue Date" means the date of the first issuance of any shares of the Preferred Stock regardless of the number of transfers of any particular shares of Preferred Stock and regardless of the number of certificates which may be issued to evidence such Preferred Stock.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Preferred Stock" shall have the meaning set forth in Section 2.

"Purchase Agreement" means the Series B Preferred Stock Purchase Agreement, dated March 1, 2021, among the Corporation and the original Holder, as amended, modified or supplemented from time to time in accordance with its terms.

"Purchase Rights" shall have the meaning set forth in Section 7(b).

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Share Delivery Date" shall have the meaning set forth in Section 6(b)(i).

"Shares" means the shares of Preferred Stock issued to the original Holder pursuant to the Purchase Agreement.

"Standard Settlement Period" shall have the meaning set forth in Section 6(b)(i).

"Subscription Amount" shall mean, as to each Holder, the aggregate amount to be paid for the Shares purchased pursuant to the Purchase Agreement, in United States dollars and in immediately available funds.

"Successor Entity" shall have the meaning set forth in Section 7(e).

"Trading Day" means a day on which the principal Trading Market is open for business.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE MKT, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange (or any successors to any of the foregoing).

"Transaction Documents" means this Certificate of Designation, the Purchase Agreement, all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated pursuant to the Purchase Agreement.

"Transfer Agent" means Broadridge Corporate Issuer Solutions, Inc., the current transfer agent of the Corporation, with a mailing address of 1717 Arch St., Ste. 1300, Philadelphia, PA 19103 and an email address relating to issuances of issuance@broadridge.com, and any successor transfer agent of the Corporation.

Section 2. Designation, Amount and Par Value. The series of preferred stock of the Corporation shall be designated as its Series B Convertible Preferred Stock (the "Preferred Stock") and the number of shares so designated shall be 54,745 shares (which shall not be subject to increase without the written consent of holders of a majority of the then-outstanding shares of Preferred Stock (each, a "Holder" and collectively, the "Holders")). Each share of Preferred Stock shall have a par value of $0.01 per share. The Preferred Stock will initially be issued in book-entry form.

Section 3. Dividends. Except for stock dividends or dividends for which adjustments are to be made pursuant to Section 7, Holders shall be entitled to receive, and the Corporation shall pay, dividends on shares of Preferred Stock equal (on an as-if-converted-to-Common-Stock basis) to and in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock. No other dividends shall be paid on shares of Preferred Stock.

Section 4. Voting Rights. Except as otherwise provided herein or as otherwise required by law, the Preferred Stock shall have no voting rights. However, as long as any shares of Preferred Stock are outstanding, the Corporation shall not, without the affirmative vote of the Holders of a majority of the then-outstanding shares of the Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Preferred Stock or alter or amend this Certificate of Designation, (b) amend the Certificate of Incorporation or the bylaws of the Corporation in any manner that adversely affects any rights of the Holders, (c) increase the number of authorized shares of Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

Section 5. Liquidation. Upon any liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary (a "Liquidation"), the Holders shall be entitled to receive out of the assets of the Corporation available for distribution to its stockholders the same amount that a holder of Common Stock would receive if the Preferred Stock were fully converted (disregarding for such purposes any conversion limitations hereunder) to Common Stock which amounts shall be paid pari passu with all holders of Common Stock. The Corporation shall deliver written notice of any such Liquidation, not less than 45 days prior to the payment date stated therein, to each Holder.

Section 6. Conversion.

a) Conversions at Option of Holder. Each share of Preferred Stock shall be convertible, at any time and from time to time from but only after the occurrence of (i) the Corporation's receipt of stockholder approval to increase the authorized but unissued shares of Common Stock under the Certificate of Incorporation to such number of shares of Common Stock as shall be sufficient to convert the total issued and outstanding shares of Preferred Stock into shares of Common Stock pursuant to this Section 6(a) and the filing with the Delaware Secretary of State of an amendment to the Certificate of Incorporation to effect such increase and (ii) the Corporation's receipt of shipments by Bharat of the first 10 million doses of COVAXIN manufactured by Bharat pursuant to a supply agreement to be entered into in connection with the Co-Development Agreement (collectively, the "Conversion Events"), at the option of the Holder thereof, into shares of Common Stock on a one-for-ten basis (the "Conversion Ratio"). Holders shall effect conversions by providing the Corporation with the form of conversion notice attached hereto as Annex A (a "Notice of Conversion"). Each Notice of Conversion shall specify the number of shares of Preferred Stock to be converted, the number of shares of Preferred Stock owned prior to the conversion at issue, the number of shares of Preferred Stock owned subsequent to the conversion at issue and the date on which such conversion is to be effected, which date may not be prior to the date the applicable Holder delivers by facsimile such Notice of Conversion to the Corporation (such date, the "Conversion Date"). If no Conversion Date is specified in a Notice of Conversion, the Conversion Date shall be the date that such Notice of Conversion to the Corporation is deemed delivered hereunder. No ink-original Notice of Conversion shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Conversion form be required. The calculations and entries set forth in the Notice of Conversion shall control in the absence of manifest or mathematical error. To effect conversions of shares of Preferred Stock, a Holder shall not be required to surrender any certificate(s) representing the shares of Preferred Stock to the Corporation unless all of the shares of Preferred Stock represented thereby are so converted, in which case such Holder shall deliver the certificate representing such shares of Preferred Stock promptly following the Conversion Date at issue.

b) Mechanics of Conversion

i. Delivery of Conversion Shares Upon Conversion. Not later than the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined below) after each Conversion Date (the "Share Delivery Date"), the Corporation shall deliver, or cause to be delivered, to the converting Holder (A) Conversion Shares which, on or after the earlier of (i) the six month anniversary of the Original Issue Date or (ii) the Effective Date, shall be free of restrictive legends and trading restrictions (other than those which may then be required by the Purchase Agreement) representing the number of Conversion Shares being acquired upon the conversion of the Preferred Stock, and (B) a bank check in the amount of declared but unpaid dividends, if any. On or after the earlier of (i) the six month anniversary of the Original Issue Date or (ii) the Effective Date, the Corporation shall deliver the Conversion Shares required to be delivered by the Corporation under this Section 6 electronically through the Depository Trust Company or another established clearing corporation performing similar functions. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Corporation's primary Trading Market with respect to the Common Stock as in effect on the Conversion Date.

ii. Obligation Absolute; Partial Liquidated Damages. The Corporation's obligation to issue and deliver the Conversion Shares upon conversion of Preferred Stock in accordance with the terms hereof are absolute and unconditional, irrespective of any action or inaction by a Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by such Holder or any other Person of any obligation to the Corporation or any violation or alleged violation of law by such Holder or any other person, and irrespective of any other circumstance which might otherwise limit such obligation of the Corporation to such Holder in connection with the issuance of such Conversion Shares; provided, however, that such delivery shall not operate as a waiver by the Corporation of any such action that the Corporation may have against such Holder. Nothing herein shall limit a Holder's right to pursue actual damages for the Corporation's failure to deliver Conversion Shares within the period specified herein and such Holder shall have the right to pursue all remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief. The exercise of any such rights shall not prohibit a Holder from seeking to enforce damages pursuant to any other Section hereof or under applicable law.

iii. Reservation of Shares Issuable Upon Conversion. The Corporation covenants that it will make reasonable efforts, including, without limitation, engaging in reasonable efforts to obtain the requisite stockholder approval of any necessary amendment to the Certificate of Incorporation, to reserve and keep available out of its authorized and unissued shares of Common Stock for the sole purpose of issuance upon conversion of the Preferred Stock as herein provided, free from preemptive rights or any other actual contingent purchase rights of Persons other than the Holder (and the other holders of the Preferred Stock), not less than such aggregate number of shares of the Common Stock as shall (subject to the terms and conditions set forth in the Purchase Agreement) be issuable (taking into account the adjustments and restrictions of Section 7) upon the conversion of the then outstanding shares of Preferred Stock. The Corporation covenants that all shares of Common Stock that shall be so issuable shall, upon issue, be duly authorized, validly issued, fully paid and nonassessable and, if the Conversion Shares Registration Statement is then effective under the Securities Act, shall be registered for public resale in accordance with such Conversion Shares Registration Statement (subject to such Holder's compliance with its obligations under the Purchase Agreement and applicable securities laws).

iv. Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the conversion of the Preferred Stock. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such conversion, the Corporation shall at its election, either (a) pay cash equal to such fraction multiplied by the closing price of the Common Stock on the Trading Market on the Trading Day immediately preceding the Share Delivery Date or (b) round up to the next whole share

v. Transfer Taxes and Expenses. The issuance of Conversion Shares on conversion of this Preferred Stock shall be made without charge to any Holder for any documentary stamp or similar taxes that may be payable in respect of the issue or delivery of such Conversion Shares, provided that the Corporation shall not be required to pay any tax that may be payable in respect of any transfer involved in the issuance and delivery of any such Conversion Shares upon conversion in a name other than that of the Holders of such shares of Preferred Stock and the Corporation shall not be required to issue or deliver such Conversion Shares unless or until the Person or Persons requesting the issuance thereof shall have paid to the Corporation the amount of such tax or shall have established to the satisfaction of the Corporation that such tax has been paid. The Corporation shall pay all Transfer Agent fees required for same-day processing of any Notice of Conversion and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required doe same-day electronic delivery of the Conversion Shares.

Section 7. Certain Adjustments.

a) Stock Dividends and Stock Splits. If the Corporation, at any time while this Preferred Stock is outstanding: (i) pays a stock dividend or otherwise makes a dividend or dividends payable in shares of Common Stock on shares of Common Stock or any other Common Stock Equivalents (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Corporation upon conversion of, or payment of a dividend on, this Preferred Stock), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of a reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues, in the event of a reclassification of shares of the Common Stock, any shares of capital stock of the Corporation, then the Conversion Ratio shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding any treasury shares of the Corporation) outstanding immediately before such event, and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to this Section 7(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 7(a) above, if at any time the Corporation grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder of will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete conversion of such Holder's Preferred Stock (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such

record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights.

c) Pro Rata Distributions. During such time as this Preferred Stock is outstanding, if the Corporation declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Preferred Stock, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete Conversion of this Preferred Stock (without regard to any limitations on Conversion hereof) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution.

d) Fundamental Transaction. If, at any time while this Preferred Stock is outstanding, (i) the Corporation, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Corporation with or into another Person, (ii) the Corporation, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Corporation or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Corporation, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Corporation, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent conversion of this Preferred Stock, the Holder shall have the right to receive, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction, the number of shares of Common Stock of the successor or acquiring corporation or of the Corporation, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Preferred Stock is convertible immediately prior to such Fundamental Transaction. For purposes of any such conversion, the determination of the Conversion Ratio shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Corporation shall apportion the Conversion Ratio among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holders shall be given the same choice as to the Alternate Consideration they receive upon any conversion of this Preferred Stock following such Fundamental Transaction. To the extent necessary to effectuate the foregoing provisions, any successor to the Corporation or surviving entity in such Fundamental Transaction shall file a new Certificate of Designation with the same terms and conditions and issue to the Holders new preferred stock consistent with the foregoing provisions and evidencing the Holders' right to convert such preferred stock into Alternate Consideration. The Corporation shall cause any successor entity in a Fundamental Transaction in which the Corporation is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Corporation under this Certificate of Designation and the other Transaction Documents (as defined in the Purchase Agreement) in accordance with the provisions of this Section 7(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the holder of this Preferred Stock, deliver to the Holder in exchange for this Preferred Stock a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Preferred Stock which is convertible for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the

shares of Common Stock acquirable and receivable upon conversion of this Preferred Stock (without regard to any limitations on the conversion of this Preferred Stock) prior to such Fundamental Transaction, and with a conversion price which applies the conversion price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such conversion price being for the purpose of protecting the economic value of this Preferred Stock immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Certificate of Designation and the other Transaction Documents referring to the "Corporation" shall refer instead to the Successor Entity), and may exercise every right and power of the Corporation and shall assume all of the obligations of the Corporation under this Certificate of Designation and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Corporation herein.

f) Calculations. All calculations under this Section 7 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 7, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding any treasury shares of the Corporation) issued and outstanding.

g) Notice to the Holders.

i. Adjustment to Conversion Ratio. Whenever the Conversion Ratio is adjusted pursuant to any provision of this Section 7, the Corporation shall promptly deliver to each Holder a notice setting forth the Conversion Ratio after such adjustment and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Conversion by Holder. If (A) the Corporation shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Corporation shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Corporation shall authorize the granting to all holders of the Common Stock of rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Corporation shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Corporation is a party, any sale or transfer of all or substantially all of the assets of the Corporation, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property or (E) the Corporation shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Corporation, then, in each case, the Corporation shall cause to be filed at each office or agency maintained for the purpose of conversion of this Preferred Stock, and shall cause to be delivered to each Holder at its last address as it shall appear upon the stock books of the Corporation, at least twenty (20) calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange, provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Corporation or any of the Subsidiaries, the Corporation shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to convert the Preferred Stock (or any part hereof) during the 20-day period commencing on the date of such notice through the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 8. Miscellaneous.

a) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Conversion, shall be in writing and delivered personally, by facsimile, or sent by a nationally recognized overnight courier service, addressed to the Corporation, at the address set forth above Attention: Chief Financial Officer, e-mail address sanjay@ocugen.com or such other e-mail address

or address as the Corporation may specify for such purposes by notice to the Holders delivered in accordance with this Section 11. Any and all notices or other communications or deliveries to be provided by the Corporation hereunder shall be in writing and delivered personally, by email, or sent by a nationally recognized overnight courier service addressed to each Holder at the email address or address of such Holder appearing on the books of the Corporation, or if no such email address or address appears on the books of the Corporation, at the principal place of business of such Holder, as set forth in the Purchase Agreement. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via email at the email address set forth in this Section 8(a) prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via email at the email address set forth in this Section 8(a) on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given.

b) Absolute Obligation. Except as expressly provided herein, no provision of this Certificate of Designation shall alter or impair the obligation of the Corporation, which is absolute and unconditional, to pay liquidated damages and accrued dividends, as applicable, on the shares of Preferred Stock at the time, place, and rate, and in the coin or currency, herein prescribed.

c) Lost or Mutilated Preferred Stock Certificate. If a Holder's Preferred Stock certificate shall be mutilated, lost, stolen or destroyed, the Corporation shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated certificate, or in lieu of or in substitution for a lost, stolen or destroyed certificate, a new certificate for the shares of Preferred Stock so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such certificate, and of the ownership hereof reasonably satisfactory to the Corporation.

d) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Certificate of Designation shall be governed by and construed and enforced in accordance with the internal laws of the State of Delaware, without regard to the principles of conflict of laws thereof. Each party agrees that all legal proceedings concerning the interpretation, enforcement and defense of the transactions contemplated by any of the Transaction Documents (whether brought against a party hereto or its respective Affiliates, directors, officers, shareholders, employees or agents) shall be commenced in the Court of Chancery of the State of Delaware or the federal courts sitting in the State of Delaware (the "Delaware Courts"). Each party hereto hereby irrevocably submits to the exclusive jurisdiction of the Delaware Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of such Delaware Courts, or such Delaware Courts are improper or inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Certificate of Designation and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by applicable law. Each party hereto hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Certificate of Designation or the transactions contemplated hereby. If any party shall commence an action or proceeding to enforce any provisions of this Certificate of Designation, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding.

e) Waiver. Except as otherwise set forth herein, any of the rights, powers, preferences and other terms of the Preferred Stock set forth herein may be waived on behalf of all holders of Preferred Stock by the affirmative written consent or vote of the holders of at least a majority of the shares of Preferred Stock then outstanding. Any waiver by the Corporation or a Holder of a breach of any provision of this Certificate of Designation shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Certificate of Designation or a waiver by any other Holders. The failure of the Corporation or a Holder to insist upon strict adherence to any term of this Certificate of Designation on one or more occasions shall not be considered a waiver or deprive that party (or any other Holder) of the right thereafter to insist upon strict

adherence to that term or any other term of this Certificate of Designation on any other occasion. Any waiver by the Corporation or a Holder must be in writing.

f) Severability. If any provision of this Certificate of Designation is invalid, illegal or unenforceable, the balance of this Certificate of Designation shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law.

g) Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day.

h) Headings. The headings contained herein are for convenience only, do not constitute a part of this Certificate of Designation and shall not be deemed to limit or affect any of the provisions hereof.

i) Status of Converted or Redeemed Preferred Stock. Shares of Preferred Stock may only be issued pursuant to the Purchase Agreement. If any shares of Preferred Stock shall be converted, redeemed or reacquired by the Corporation, such shares shall resume the status of authorized but unissued shares of preferred stock and shall no longer be designated as Series B Convertible Preferred Stock.

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RESOLVED, FURTHER, that the Chairman, the president or any vice-president, and the secretary or any assistant secretary, of the Corporation be and they hereby are authorized and directed to prepare and file this Certificate of Designation of Preferences, Rights and Limitations in accordance with the foregoing resolution and the provisions of Delaware law.

IN WITNESS WHEREOF, the undersigned have executed this Certificate this 18th day of March 2021.

/s/ Shankar Musunuri

Name: Shankar Musunuri
Title: Chief Executive Officer

ANNEX A

NOTICE OF CONVERSION

(TO BE EXECUTED BY THE REGISTERED HOLDER IN ORDER TO CONVERT SHARES OF PREFERRED STOCK)

The undersigned hereby elects to convert the number of shares of Series B Convertible Preferred Stock indicated below into shares of common stock, par value $0.01 per share (the "Common Stock"), of Ocugen, Inc., a Delaware corporation (the "Corporation"), according to the conditions hereof, as of the date written below. If shares of Common Stock are to be issued in the name of a Person other than the undersigned, the undersigned will pay all transfer taxes payable with respect thereto and is delivering herewith such certificates and opinions as may be required by the Corporation in accordance with the Purchase Agreement. No fee will be charged to the Holders for any conversion, except for any such transfer taxes.

Conversion calculations:

Date to Effect Conversion:

Number of shares of Preferred Stock owned prior to Conversion:

Number of shares of Preferred Stock to be Converted:

Number of shares of Common Stock to be Issued:

Number of shares of Preferred Stock subsequent to Conversion:

Address for Delivery:
or
DWAC Instructions:
Broker no:
Account no:

[HOLDER]

By: _____
Name:
Title:

Exhibit 4.1

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Ocugen, Inc. (the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, par value $0.01 per share. As used in this summary, the terms "Ocugen," "the Company," "we," "our" and "us" refer to Ocugen, Inc.

The following is a description of the material terms and provisions relating to our common stock. The following description is a summary that is not complete and is subject to and qualified in its entirety by reference to our Sixth Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") and our amended and restated bylaws (the "Bylaws"), and to provisions of the Delaware General Corporation Law (the "DGCL"). Copies of our Certificate of Incorporation and our Bylaws, each of which may be amended from time to time, are included as exhibits to the Annual Report on Form 10-K to which this description is an exhibit.

General

Our authorized capital stock consists of 210,000,000 shares, 200,000,000 of which are designated as common stock with a par value of $0.01 per share and 10,000,000 of which are designated as preferred stock with a par value of $0.01.

Common Stock

Shares of our common stock have the following rights, preferences and privileges:

Voting Rights

Each holder of common stock is entitled to one vote per share on all matters submitted to a vote of stockholders. We have not provided for cumulative voting in the election of directors. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election. Except as otherwise required by law, holders of our common stock are not entitled to vote on any amendment to the Certificate of Incorporation that relates solely to the terms of an outstanding series of preferred stock if the holders of such series are entitled to vote thereon pursuant to the Certificate of Incorporation or any certificate of designation.

Dividends

Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of assets legally available at the times and in the amounts that our board of directors may determine from time to time. The timing, declaration, amount and payment of future dividends will depend on our financial condition, earnings, capital requirements and debt service obligations, as well as legal requirements, regulatory constraints, industry practice and other factors that its board of directors deems relevant. Our board of directors will make all decisions regarding our payment of dividends from time to time in accordance with applicable law.

Liquidation

Upon our liquidation, dissolution or winding-up, the holders of common stock are entitled to share ratably in all assets remaining after payment of all liabilities and the liquidation preferences of any outstanding preferred stock.

No Preemptive or Similar Rights

The holders of our common stock do not have any preemptive rights or preferential rights to subscribe for shares of our capital stock or any other securities. Our common stock is not subject to any redemption or sinking fund provisions.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc.

Listing

Our common stock is listed on The NASDAQ Capital Market under the symbol "OCGN."

Preferred Stock

Pursuant to our Certificate of Incorporation, our board of directors has the authority, without further approval by our stockholders, to designate and issue up to 10,000,000 shares of preferred stock in one or more series.

Series A Convertible Preferred Stock

Our board of directors has provided for the issuance of Series A Convertible Preferred Stock ("Series A Preferred") pursuant to the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (the "Series A Certificate of Designation"). Up to 30,000 shares are designated as Series A Preferred. Holders of Series A Preferred are entitled to receive dividends on Series A Preferred equal (on an as-converted to common stock basis) to and in the same form as dividends actually paid on shares of common stock, when and if such dividends are paid. Except as provided by law and certain protective provisions set forth in the Series A Certificate of Designation, the Series A Preferred has no voting rights. Upon our liquidation or dissolution, holders of Series A Preferred will be entitled to receive the same amount that a holder of common stock would receive if the preferred stock were fully converted to common stock. Shares of Series A Preferred are convertible to common stock at the option of the holder, on the terms and subject to the conditions set forth in the Series A Certificate of Designation.

Series B Convertible Preferred Stock

Our board of directors has provided for the issuance of Series B Convertible Preferred Stock ("Series B Preferred") pursuant to the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (the "Series B Certificate of Designation") in connection with a Preferred Stock Purchase Agreement between us and Bharat Biotech International Limited ("Bharat Biotech").

Each share of Series B Preferred is convertible, at the option of the holder, into 10 shares of the Company's common stock only after (i) the Company's receipt of stockholder approval to increase the number of authorized shares of common stock under its Sixth Amended and Restated Certificate of Incorporation and (ii) the Company's receipt of shipments by Bharat Biotech of the first 10 million doses of COVAXIN manufactured by Bharat Biotech, and further on the terms and subject to the conditions set forth in the Series B Certificate of Designation. The conversion rate of the Series B Preferred is subject to adjustment in the event of a stock dividend, stock split, reclassification or similar event with respect to the Company's common stock.

Holders of Series B Preferred are entitled to receive dividends on Series B Preferred equal (on an as-converted to common stock basis) to and in the same form as dividends actually paid on shares of common stock, when and if such dividends are paid. Except as provided by law and certain protective provisions set forth in the Series B Certificate of Designation, the Series B Preferred has no voting rights. Upon the Company's liquidation or

dissolution, holders of Series B Preferred will be entitled to receive the same amount that a holder of common stock would receive if the preferred stock were fully converted to common stock.

Anti-Takeover Effects of Provisions of Our Certificate of Incorporation, our Bylaws and Delaware Law

Various provisions contained in the Certificate of Incorporation, the Bylaws and Delaware law could delay, deter or discourage some transactions involving an actual or potential change in control of Ocugen, including acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of its potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Certificate of Incorporation and Bylaws

Preferred Stock

The Certificate of Incorporation authorizes our board of directors to establish one or more series of preferred stock and to determine, with respect to any series of preferred stock, the preferences, rights and other terms of such series. Under this authority, our board of directors could create and issue a series of preferred stock with rights, preferences or restrictions that have the effect of discriminating against an existing or prospective holder of our capital stock as a result of such holder beneficially owning or commencing a tender or exchange offer for a substantial amount of common stock. One of the effects of authorized but unissued and unreserved shares of preferred stock may be to render it more difficult for, or to discourage an attempt by, a potential acquiror to obtain control of us by means of a merger, tender or exchange offer, proxy contest or otherwise, and thereby protect the continuity of the company's management. The issuance of shares of preferred stock may have the effect of delaying, deferring or preventing a change in control of us without any action by our stockholders.

Classified Board

The Certificate of Incorporation and the Bylaws provide that the directors, other than those who may be elected by the holders of any series of preferred stock under specified circumstances, shall be divided into three classes. Such classes shall be as nearly equal in number of directors as reasonably possible. The election of the classes is staggered, such that only approximately one third of our board of directors is up for election in any given year. Each director shall serve for a term ending on the third annual meeting of stockholders following the annual meeting of stockholders at which such director was elected. Each director shall serve until such director's successor shall have become duly elected and qualified, or until such director's prior death, resignation, retirement, disqualification or other removal.

Election of Directors

The Certificate of Incorporation does not provide for cumulative voting in the election of directors. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Board Vacancies; Removal

The Certificate of Incorporation provides that any vacancy occurring on our board of directors will be filled by a majority of directors then in office, even if less than a quorum. The Certificate of Incorporation also provides that our directors can only be removed for cause upon the vote of more than two-thirds of the votes entitled to be cast by holders of all the then-outstanding shares of capital stock, voting together as a single class.

Special Meetings of Stockholders; Number of Directors and No Action by Written Consent of Stockholders

The Certificate of Incorporation and the Bylaws provide that only the board of directors, the chairman of the board of directors or the president may call a special meeting of our stockholders. The Bylaws provide that the authorized number of directors be changed only by resolution of the board of directors. The Bylaws provide that the stockholders may act only duly called annual or special meeting and no action may be effected by written consent.

Advance Notification of Shareholder Nominations and Proposals

The Bylaws establish advance notice procedures with respect to shareholder proposals and the nomination of persons for election as directors, other than nominations made by or at the direction of our board of directors.

Amendments to Certificate of Incorporation and Bylaws

The amendment of any of the above provisions (except for the provision making it possible for the board of directors to issue undesignated preferred stock) and the exclusive form and indemnification provisions described below, would require approval by a stockholder vote by the holders of at least a two thirds of the voting power of the then outstanding voting stock.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the DGCL which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Exclusive Jurisdiction for Certain Actions

The Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action arising pursuant to any provision of the DGCL, or (iv) any action asserting a claim 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 of 1933, as amended, or the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction.

The enforceability of similar federal court 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 this type of provision to be inapplicable or unenforceable. If a court were to find either of the choice of forum provisions contained in the Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

The 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 us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim.

Indemnification

The Certificate of Incorporation includes provisions that limit the liability of our directors for monetary damages for breach of their fiduciary duty as directors, except for liability that cannot be eliminated under the DGCL. Accordingly, our directors will not be personally liable for monetary damages for breach of their fiduciary duty as directors, except for liabilities:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- for unlawful payments of dividends or unlawful stock repurchases or redemptions, as provided under Section 174 of the DGCL; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment or repeal of these provisions will require the approval of the holders of shares representing at least two-thirds of the shares entitled to vote in the election of directors, voting as one class. The Certificate of Incorporation and Bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. The Certificate of Incorporation and Bylaws also permit us to purchase insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions as its officer, director, employee or agent, regardless of whether Delaware law would permit indemnification. We have entered into separate indemnification agreements with our directors and executive officers that require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors and to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified. We believe that the limitation of liability provision in the Certificate of Incorporation and the indemnification agreements facilitate our ability to continue to attract and retain qualified individuals to serve as directors and officers.

The limitation of liability and indemnification provisions in the Certificate of Incorporation and Bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Exhibit 4.8

NEITHER THIS WARRANT NOR THE SHARES OF COMMON STOCK PURCHASABLE UPON EXERCISE HEREOF HAVE BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 OR THE SECURITIES LAWS OF ANY STATE. THESE SECURITIES MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR AN EXEMPTION THEREFROM UNDER SUCH ACT AND APPLICABLE STATE SECURITIES LAWS. BY ACQUIRING THIS WARRANT, THE WARRANTHOLDER REPRESENTS THAT THE WARRANTHOLDER WILL NOT SELL OR OTHERWISE DISPOSE OF THIS WARRANT OR THE SHARES PURCHASABLE UPON EXERCISE HEREOF WITHOUT REGISTRATION OR OTHER COMPLIANCE WITH THE AFORESAID ACTS AND THE RULES AND REGULATIONS THEREUNDER.

Warrant No. [Date]
Warrant Holder:

OCUGEN, INC.

COMMON STOCK PURCHASE WARRANT

1. Issuance of Warrant

1.1 Number of Shares Subject to Warrant. Subject to the terms and conditions herein set forth, (the "Warrantholder") is entitled to purchase from Ocugen, Inc. (the "Company"), a Delaware corporation, an aggregate of [___] fully paid and non-assessable shares (which number of shares is subject to adjustment as described below) (the "Shares") of the Company's Common Stock, $0.001 par value per share(the "Common Stock"), upon surrender of this Warrant to the Company prior to the Expiration Date (as defined below) and upon payment of the Purchase Price (as defined below).

1.2. Expiration Date. This Warrant shall terminate at the earlier to occur of (a) 5:00 p.m., Eastern Time, on [____]; (b) 5:00 p.m., Eastern Time, on the day preceding the first closing of an offering by the Company of its Common Stock to the public pursuant to an effective registration statement under the Securities Act of 1933 (the "Act") or any comparable document under any similar federal statute then in force; or (c) 5:00 p.m., Eastern Time, on the day preceding the first closing of any consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, in which the shareholders of the Company immediately prior to such consolidation, merger or reorganization, hold less than 50% of the resulting or surviving corporation's voting power immediately after such consolidation, merger or reorganization (solely in respect of their equity interests in this Company), the sale, lease, or other disposition of all or substantially all of the assets or business of the Company (other than to a parent, subsidiary or otherwise in a transaction for the purpose of a corporate reorganization rather than a *bona fide* sale), or the transfer by shareholders of the Company (in one or a series of related transactions) to one person or entity or group of related persons and/or entities of shares constituting not less than a majority of the outstanding voting capital stock of the Company except to the extent any merger or reorganization for the sole purpose of changing the state of incorporation of the Company or for other internal restructuring purposes (such earlier date being hereinafter referred to as the "Expiration Date"). The Company shall notify the Warrantholder, at least 15 days before the first closing of any of the events specified in clauses (b) or (c) above, of the proposed date of such closing. The Company shall not be required to deliver an additional notice if the date of the closing is thereafter delayed.

1.3 Purchase Price. This Warrant is exercisable in whole or in part at an exercise price per share equal to $[___] (such price from time to time subject to adjustment in accordance with Section 2 hereof, and, as such price may from time to time be so adjusted, hereinafter called the "Purchase Price"). [Notwithstanding anything to the contrary contained herein, this Warrant may be exercised, in whole or in part, by presentation and surrender of this Warrant to the Company at its principal executive offices with a written notice of the holder's intention to effect

a cashless exercise. In the event of a cashless exercise, the holder of this Warrant shall receive a number of shares of Common Stock computed using the following formula:

$$X = \frac{Y\,(A-B)}{A}$$

Where:

x = the number of the Shares to be issued to the Holder.

Y = the number of the Shares purchasable under this Warrant

A = the fair market value of one Share on the date of determination

B = the per share Purchase Price (as adjusted to the date of such calculation).

For purposes of this Section 1.3, the per share fair market value of the Shares shall mean:

(i) If the Company's Common Stock is publicly traded, the per share fair market value of the Shares shall be the average of the closing prices of the Common Stock as quoted on the Over-the-Counter Bulletin Board, or the principal exchange on which the Common Stock is listed, in each case for the fifteen trading days ending five trading days prior to the date of determination of fair market value;

(ii) If the Company's Common Stock is not so publicly traded, the per share fair market value of the Shares shall be such fair market value as is determined in good faith by the Board of Directors of the Company after taking into consideration factors it deems appropriate, including, without limitation, recent sale and offer prices of the capital stock of the Company in private transactions negotiated at arm's length.][1]

2. Adjustments.

2.1. Stock Split, Subdivision or Combination of Common Stock or Stock Dividend.

(a) Stock Split, Subdivision or Combination. In the event that the Company, at any time or from time to time while this Warrant is outstanding, shall split, subdivide or combine its Common Stock (by reclassification or otherwise than by payment of a dividend in Common Stock), the number of Shares subject to purchase under this Warrant (i) shall be proportionately increased and the Purchase Price shall be proportionately decreased, in case of a split or subdivision of Common Stock, as of the effective date of such stock split or subdivision, or, if the Company shall take a record of the holders of its Common Stock for the purpose of so splitting or subdividing, as at such record date, whichever is earlier; or (ii) shall be proportionately decreased and the Purchase Price per Share shall be proportionately increased, in the case of a combination of Common Stock, as at the effective date of such combination or, if the Company shall take a record of holders of its Common Stock for the purpose of so combining, as at such record date, whichever is earlier.

(b) Stock Dividends. In the event that the Company, at any time or from time to time while this Warrant is outstanding, shall pay a dividend payable in, or make any other distribution (except any distribution specifically provided for in Section 2.1(a) hereof) in the nature of a dividend of Common Stock, then the Purchase Price shall be adjusted, from and after the date of determination of shareholder entitled to receive such dividend or distribution, to that price determined by multiplying the Purchase Price in effect immediately prior to such date of determination by a fraction, the numerator of which shall be the total number of shares of Common Stock outstanding immediately prior to such dividend or distribution, and the denominator of which shall be the total number of shares of Common Stock outstanding immediately after such dividend or distribution. The Warrantholder shall thereafter be entitled to purchase, at the Purchase Price resulting from such adjustment, the

[1] Included in certain of the common stock purchase warrants.

number of shares of Common Stock (calculated to the nearest whole share) obtained by multiplying the Purchase Price in effect immediately prior to such adjustment by the number of shares of Common Stock issuable upon the exercise hereof immediately prior to such adjustment, and dividing the product so obtained by the Purchase Price resulting from such adjustment.

2.2. Asset or Capital Dividend. In the event that the Company, at any time or from time to time while this Warrant is outstanding, shall make a distribution of its assets to the holders of its Common Stock as a dividend in liquidation or partial liquidation or as a return of capital other than as a dividend payable out of funds legally available for dividends under the laws of the Commonwealth of Pennsylvania, the Company shall promptly thereafter provide written notice of such to the Warrantholder in accordance with Section 9 below. In such event, the Warrantholder shall, upon exercise and payment of the Purchase Price within 14 business days after notification from the Company, be entitled to receive, in addition to the number of Shares receivable thereupon, and without payment of any additional consideration therefor, a sum equal to the amount of such assets as would have been payable to the Warrantholder had the Warrantholder been the holder of record of such Shares on the record date for such distribution; and an appropriate provision therefor shall be made for the Warrantholder to be made a party to any such distribution.

2.3. Adjustments for Consolidation, Merger, Sale of Assets, Reorganization or Reclassification. In the event that the Company, at any time or from time to time while this Warrant is outstanding, (a) shall consolidate with or merge into any other entity and shall not be the continuing or surviving corporation of such consolidation or merger; (b) shall permit any other entity to consolidate with or merge into the Company and the Company shall be the continuing or surviving entity but, in connection with such consolidation or merger, the Common Stock shall be changed into or exchanged for capital stock or other securities or property of any other entity; or (c) shall effect a capital reorganization or reclassification of the Common Stock (other than one deemed to result in the issue of additional Common Stock), then, and in each such event, lawful provision shall be made so that the Warrantholder shall be entitled to receive upon the exercise hereof at any time after the consummation of such consolidation, merger, transfer, reorganization or reclassification, in lieu of the Shares issuable upon exercise of this Warrant prior to such consummation, the capital stock and other securities and property to which the Warrantholder would have been entitled upon such consummation if the Warrantholder had exercised this Warrant immediately prior thereto.

2.4. Certificate of Adjustment. The Company shall, within a reasonable time period after written request at any time by the Warrantholder, furnish or cause to be furnished to the Warrantholder a certificate setting forth adjustments of the Purchase Price and of the number of Shares issuable upon exercise of this Warrant and the amount, if any, of other property at the time receivable upon the exercise of this Warrant.

2.5. No Other Adjustment. The number of Shares for which this Warrant is exercisable and the Purchase Price shall not be adjusted except in the manner and upon the terms and conditions set forth in Section 2 of this Warrant.

3. No Fractional Shares. No fractional Shares will be issued in connection with any exercise hereof. In lieu of any fractional Shares which would otherwise be issuable, the Company shall pay cash equal to the product of such fraction multiplied by the fair market value per Share, as determined in good faith by the Company's Board of Directors, on the date of exercise.

4. No Shareholder Rights. This Warrant shall not entitle the Warrantholder to any of the rights of a shareholder of the Company.

5. Reservation of Shares. The Company covenants that the Shares of Common Stock issuable upon the exercise of this Warrant have been duly authorized and reserved and, when issued and paid for, will be validly issued, fully paid and non-assessable. The issuance of this Warrant shall constitute full authority to those officers of the Company who are charged with the duty of executing stock certificates to execute and issue the necessary certificates for Shares upon the exercise of this Warrant.

6. Exercise of Warrant.

6.1. Time and Manner of Exercise. This Warrant may be exercised at any time or from time to time on or after the date hereof, but in no event later than the Expiration Date. In order to exercise this Warrant, in whole or in part, the Warrantholder shall deliver to the Company, at its address specified in Section 9 below: (a) a written subscription in the form of Annex A hereto of the Warrantholder's election to exercise this Warrant, specifying the number of Shares to be purchased; (b) a wire transfer or a certified or official bank check or checks payable to the order of the Company in an amount equal to the product of the Purchase Price and the number of Shares to be purchased at such time pursuant to the Warrant; (c) a Joinder to the Shareholders Agreement dated as of the date hereof among the Company and its shareholders (the "Shareholders Agreement"), becoming a party thereto as a holder of Common Stock, to the extent the Warrantholder is not then a party thereto with respect to the Shares; and (d) this Warrant. Upon receipt of such items, the Company shall, as promptly as practicable, and in any event within ten business days thereafter, issue or cause to be issued and delivered to the Warrantholder a certificate or, if requested by the Warrantholder, multiple certificates representing the aggregate number of full Shares issuable upon such exercise, together with cash in lieu of any fraction of a share, as provided in Section 3 above. This Warrant shall be deemed to have been exercised and such certificate or certificates shall be deemed to have been issued, and the Warrantholder or any other person so designated to be named therein shall be deemed to have become a holder of record of such shares for all purposes, as of the date that the items listed in clauses (a) through (d) above are received by the Company as aforesaid. If this Warrant shall have been exercised in part, the Company shall, at the time of delivery of such certificate or certificates, deliver to the Warrantholder a new Warrant evidencing the rights of the Warrantholder to purchase the unpurchased Shares, or such other securities as may become subject to the right to purchase by the Warrantholder under the terms hereof, which new Warrant shall in all other respects be identical to this Warrant.

6.2. Payment of Taxes and Expenses. All Shares issuable upon the exercise of this Warrant shall be validly issued, fully paid and non-assessable, and the Company shall pay all expenses in connection with, and all taxes and other governmental charges that may be imposed in respect of, the issue or delivery thereof, other than any federal, state or local income tax or other tax based upon gross or net income, owed by the Warrantholder on account of such issuance or delivery. The Company shall not be required, however, to pay any tax or other charge imposed in connection with any transfer involved in the issue of any certificate for Shares in any name other than that of the registered Warrantholder, and in such case the Company shall not be required to issue or deliver any stock certificate until such tax or other charge has been paid or it has been established to the Company's reasonable satisfaction that no such tax or other charge is due.

7. Replacement of Warrant. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of any such loss, theft or destruction of this Warrant, on delivery of an indemnity agreement or security reasonably satisfactory in form and amount to the Company or, in the case of any such mutilation, upon surrender and cancellation of such Warrant, the Company, at the expense of the Warrantholder, will execute and deliver, in lieu thereof, a new Warrant.

8. Transfer of Warrant. This Warrant and all rights hereunder are not transferable unless the Warrantholder obtains the written consent of the Company. Upon the Company's written consent and surrender of this Warrant properly endorsed; the Warrant may be transferred provided that: (a) such transfer must be effected in accordance with applicable securities laws and (b) the Company is, within a reasonable time after such transfer, furnished with written notice of the name and address of the transferee. Upon surrender of this Warrant, the Company, at the expense of the transferee or transferor hereof, as the transferee and transferor may decide between themselves, will issue and deliver to, on the order of the transferee, a new Warrant in the name of such transferee or as such transferee (on payment by such transferee of any applicable transfer taxes) may direct, calling in the aggregate on the face thereof for the number of Shares called for on the face of this Warrant upon surrender. Each taker and holder of this Warrant, by taking or holding the same, consents and agrees that this Warrant, when so endorsed in blank, shall be deemed negotiable, and, when so endorsed such holder hereof may be treated by the Company and all other persons dealing with this Warrant as the absolute owner hereof for any purposes and as the person entitled to exercise the rights represented by this Warrant, or to the transfer hereof on the books of the Company, any notice to the contrary notwithstanding; but until each such transfer on such books, the Company may

treat the registered holder hereof as the owner hereof for all purposes. Any attempted assignment in violation of this Section 8 shall be null and void.

9. Notices. All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified; (b) three days after having been sent by certified mail, return receipt requested, postage prepaid; (c) one business day after deposit with a nationally recognized overnight courier, specifying next day delivery, or (d) the business day on which delivered by confirmed facsimile. Notices shall be delivered to the following addresses:

If to the Company, to:

Ocugen, Inc.
One Great Valley Parkway, Suite# 8
Malvern, PA 19355
Attn: Shankar Musunuri

With a copy to:

***
***
***
Attn: ***.
Fax: ***

If to the Warrantholder, to the most recent address on file in the books and records of the Company.

10. Miscellaneous. This Warrant shall be governed by the laws of the State of Delaware. The headings in this Warrant are for purposes of convenience and reference only and shall not be deemed to constitute a part hereof. Neither this Warrant nor any term hereof may be changed, waived, discharged or terminated orally but only by an instrument in writing signed by the Company and the registered Warrantholder. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision hereof.

IN WITNESS WHEREOF, the Company has executed and issued this Warrant as of the date first above written.

OCUGEN, INC.

By: _____
Shankar Musunuri
Title: Chairman and Chief Executive Officer

[signature page to Common Stock Purchase Warrant]

FORM OF SUBSCRIPTION

To: Ocugen, Inc.

The undersigned, the holder of the within Warrant, hereby irrevocably elects to exercise the purchase right represented by such Warrant for, and to purchase thereunder, ____ shares of Common Stock of Ocugen, Inc. and herewith tenders payment of $____ in full payment of the purchase price for such shares, and requests that the certificates for such shares be issued in the name of, and delivered to, the undersigned.

Date: _____

_____
Signature of Warrantholder

_____
Name of Warrantholder (Please Print)

_____

_____
(Address)

Exhibit 10.7

OCUGEN, INC.
2019 Equity Incentive Plan

RESTRICTED STOCK UNIT GRANT NOTICE AND
RESTRICTED STOCK UNIT AGREEMENT

Ocugen, Inc (the "Company"), pursuant to its 2019 Equity Incentive Plan (the "Plan"), hereby grants to the individual listed below ("Participant") an award of the number of Restricted Stock Units set forth below (the "Restricted Stock Units"). The Restricted Stock Units are subject to the terms and conditions set forth in this Restricted Stock Unit Grant Notice (the "Grant Notice"), the Restricted Stock Unit Agreement attached hereto as Exhibit A (the "Agreement") and the Plan, each of which is incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Grant Notice and the Agreement.

Participant:	[_____]
Grant Date:	[_____]
Total Number of Restricted Stock Units:	will vest in _____ equal annual installments on each anniversary of the Grant Date over the _____ (___) year period
Vesting Schedule:	

By Participant's signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and the Grant Notice. Participant has reviewed the Agreement, the Plan and the Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing the Grant Notice and fully understands all provisions of the Grant Notice, the Agreement and the Plan.

OCUGEN, INC.

Name: Shankar Musunuri

Title: Chairman, CEO and Co-Founder

PARTICIPANT

Name:

EXHIBIT A
TO RESTRICTED STOCK UNIT GRANT NOTICE

RESTRICTED STOCK UNIT AGREEMENT

1. Award of Restricted Stock Units. The Company has granted to the Participant the number of Restricted Stock Units set forth in the Grant Notice, upon the terms and conditions set forth in the Grant Notice, the Plan and this Agreement. Each Restricted Stock Unit represents the right to receive one Share at the times and subject to the conditions set forth herein.

2. Date of Grant. The Restricted Stock Units were granted on the Grant Date set forth in the Grant Notice.

3. Vesting of Restricted Stock Units.

(a) Vesting. Subject to the continued service of the Participant with the Company through the relevant vesting dates, the Restricted Stock Units shall become vested in such amounts and at such times as are set forth in the Grant Notice.

(b) Service with Affiliates. Solely for purposes of this Agreement, service with the Company will be deemed to include service with any Affiliate of the Company (for only so long as such entity remains an Affiliate of the Company).

(c) Effect of Termination of Service. If the Participant's service with the Company ceases for any reason, the unvested portion of the Restricted Stock Units shall be forfeited immediately.

4. Settlement of Restricted Stock Units.

(a) Shares will be issued in respect of vested Restricted Stock Units within sixty (60) days following the applicable vesting date. For avoidance of doubt, this deadline is intended to comply with the "short-term deferral" exemption from Section 409A of the Code.

(b) The Restricted Stock Units will not confer on the Participant any rights as a stockholder of the Company until Shares are actually issued in settlement of such Restricted Stock Units.

(c) Notwithstanding the foregoing, to the extent provided in Prop. Treas. Reg. § 1.409A-1(b)(4)(ii) or any successor provision, the Company may delay settlement of Restricted Stock Units if it reasonably determines that such settlement would violate federal securities laws or any other applicable law.

5. Non-Transferability of Restricted Stock Units. The Restricted Stock Units may not be sold, pledged, assigned, hypothecated, gifted, transferred or disposed of in any manner, either voluntarily or involuntarily, by operation of law or otherwise, other than by will or by the laws of descent and distribution.

6. Investment Representations. The Participant represents and warrants to the Company that the Participant is acquiring the Restricted Stock Units (and upon settlement of the Restricted Stock Units, may be acquiring Shares) for investment for the Participant's own account, not as a nominee or agent, and not with a view to, or for resale in connection with, any distribution thereof. As a further condition to the settlement of the Restricted Stock Units, the Board may require that certain agreements, undertakings, representations, certificates, legends and/or information or other matters, as the Board may deem necessary or advisable, be executed, agreed to and/or provided to the Company to assure compliance with all such applicable laws or regulations.

7. Tax Consequences. The Participant acknowledges that the Company has not advised the Participant regarding the Participant's income tax liability in connection with the grant of the Restricted Stock Units and that the Company does not guarantee any particular tax treatment. The Participant acknowledges that the

Participant has reviewed with the Participant's own tax advisors the tax treatment of the Restricted Stock Units and is relying solely on those advisors in that regard. The Participant understands that the Participant (and not the Company) will be responsible for the Participant's own tax liabilities arising in connection with the Restricted Stock Units.

8. No Continuation of Service. Neither the Plan nor this Agreement will confer upon the Participant any right to continue in the employment or service of the Company or any of its Affiliates, or limit in any respect the right of the Company or its Affiliates to discharge the Participant at any time, with or without Cause and with or without notice.

9. Withholding. The Company is hereby authorized to withhold from any consideration payable or property transferable to the Participant any taxes required to be withheld in connection with the Restricted Stock Units.

10. Company Policies. In consideration for the grant of the Restricted Stock Units, the Participant agrees to be subject to the policies of the Company regarding clawback, securities trading and hedging or pledging of securities, as in effect from time to time.

11. The Plan. The Participant has received a copy of the Plan, has read the Plan and is familiar with its terms, and hereby accepts the Restricted Stock Units subject to the terms and provisions of the Plan. Pursuant to the Plan, the Board is authorized to interpret the Plan and to adopt rules and regulations not inconsistent with the Plan as it deems appropriate. The Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Board with respect to questions arising under the Plan, the Grant Notice or this Agreement.

12. Entire Agreement. The Grant Notice and this Agreement, together with the Plan, represents the entire agreement between the parties with respect to the subject matter hereof and supersedes any prior agreement, written or otherwise, relating to the subject matter hereof.

13. Amendment. Except as otherwise provided herein, in the Grant Notice or in the Plan, or as would otherwise not have a material adverse effect on the Participant, this Agreement may only be amended by a writing signed by each of the parties hereto.

14. Governing Law. This Agreement will be construed in accordance with the laws of the State of [_____], without regard to the application of the principles of conflicts of laws.

15. Execution. The Grant Notice may be executed, including execution by facsimile or electronic signature, in one or more counterparts, each of which will be deemed an original, and all of which together shall be deemed to be one and the same instrument.

Exhibit 10.12

LEASE AGREEMENT

WPT LAND 2 LP,
as Landlord

AND

OCUGEN, INC.,
as Tenant

AT

261 Great Valley Parkway
Malvern, Pennsylvania 19355

LEASE AGREEMENT

INDEX

THIS LEASE AGREEMENT (the "**Lease**") is made by and between **WPT LAND 2 LP**, a Delaware limited partnership ("**Landlord**") and **Ocugen, Inc.**, a Delaware corporation ("**Tenant**") and is dated as of the date on which this Lease has been fully executed by the last of Landlord and Tenant (the "**Effective Date**").

For good and valuable consideration of the rents and covenants hereinafter set forth, the receipt and sufficiency of which are acknowledged, and the promises set forth herein, intending to be legally bound, Landlord hereby leases to Tenant, and Tenant hereby rents from Landlord, the following described Premises (as defined below) upon the following terms and conditions. Accordingly, Landlord and Tenant agree as follows:

1. Basic Lease Terms and Definitions.

(a) Premises:

(i) 261 Great Valley Parkway, consisting of 4,206 rentable square feet of space located in the Building (as defined below), as shown on **Exhibit "A"** (the "**Initial Premises**").

(ii) 263 Great Valley Parkway, consisting of 12,195 rentable square feet of space located in the Building, as shown on **Exhibit "A"** (the "**Expansion Premises**").

(iii) For purposes of this Lease, for the period from the Initial Premises Commencement Date (as defined below) to and including the day immediately preceding the Expansion Premises Commencement Date (as defined below), the term "**Premises**" as used herein shall mean and include only the Initial Premises. From and after the occurrence of the Expansion Premises Commencement Date, the term "**Premises**" as used herein shall mean and include both the Initial Premises and the Expansion Premises.

(b) Building: 257-275 Great Valley Parkway, Malvern, Pennsylvania 19355, situate in East Whiteland Township, Chester County, consisting of 71,122 rentable square feet of space (the "**Building**"), being located on the Property (as defined below) known as Chester County UPI No. 42-4-15.47.

(c) Term:

(i) The "**Initial Premises Term**" shall be eighty-four (84) consecutive full calendar months commencing on the Initial Premises Commencement Date (as defined below) (plus any partial month from the Initial Premises Commencement Date until and including the last day preceding the next full calendar month during the Term) and shall expire on the Expiration Date (as defined below).

(ii) The "**Expansion Premises Term**" shall commence on the Expansion Premises Commencement Date (as defined below) and shall expire on the Expiration Date.

(iii) For purposes of this Lease, for the period from the Initial Premises Commencement Date to and including the day immediately preceding the Expansion Premises Commencement Date, the term "**Term**" as used herein shall mean and include only the Initial Premises Term. From and after the occurrence of the Expansion Premises Commencement Date, the term "**Term**" as used herein shall mean and include both the Initial Premises Term and the Expansion Premises Term.

(d) Commencement Date:

(i) The "**Initial Premises Commencement Date**" shall be the earlier to occur of: (i) the date that Landlord achieves Substantial Completion (as defined below) of the Initial Premises Work (as defined below) and delivers vacant possession of the Premises to Tenant; or (ii)

the date on which Tenant occupies any part of the Initial Premises for the conduct of its business.

(ii) The "**Expansion Premises Commencement Date**" (or "**EPCD**") shall be the earlier to occur of: (i) the date that Landlord achieves Substantial Completion of the Expansion Premises Work (as defined below); or (ii) the date on which Tenant occupies any part of the Expansion Premises for the conduct of its business.

(e) **Expiration Date**: The "**Expiration Date**" shall be the last day of the Initial Premises Term, as the same may be extended or earlier terminated in accordance with this Lease.

(f) **Minimum Annual Rent**:

(i) The "**Initial Premises Minimum Annual Rent**" shall be payable in monthly installments commencing on the Initial Premises Commencement Date as follows:

Lease Months	Rent/Square Foot	Monthly	Annualized
Months 1-12 ("**Year One**")	$16.00	$5,608.00	$67,296.00
Months 13-24 ("**Year Two**")	$16.50	$5,783.25	$69,399.00
Months 25-36 ("**Year Three**")	$17.00	$5,958.50	$71,502.00
Months 37-48 ("**Year Four**")	$17.50	$6,133.75	$73,605.00
Months 49-60 ("**Year Five**")	$18.00	$6,309.00	$75,708.00
Months 61-72 ("**Year Six**")	$18.50	$6,484.25	$77,811.00
Months 73-84 ("**Year Seven**")	$19.00	$6,659.50	$79,914.00

Notwithstanding the foregoing, if the Initial Premises Commencement Date shall not occur on the first day of a calendar month, the period beginning on the date that the Initial Premises Commencement Date occurs and ending on the last day of the month in which the Initial Premises Commencement Date occurs shall be identified as the "**Initial Premises Stub Period**". Rent (as defined hereunder) for the Initial Premises Stub Period will be calculated based upon Monthly Rent (as defined hereunder) that will be payable on and immediately following the Initial Premises Commencement Date prorated for the number of days in such Initial Premises Stub Period assuming a thirty (30) day calendar month regardless of the month in which such Initial Premises Stub Period occurs. Accordingly, in the event of an Initial Premises Stub Period, on the Initial Premises Commencement Date, Tenant shall pay Landlord Monthly Rent for the Initial Premises Stub Period an amount equal to (x) One Hundred Eighty-Six and 93/100 Dollars ($186.93) times (y) the number of days comprising the Initial Premises Stub Period plus all other charges comprising Rent, as defined in this Lease, similarly prorated for the Initial Premises Stub Period.

(ii) The "**Expansion Premises Minimum Annual Rent**" shall be payable in monthly installments commencing on the Expansion Premises Commencement Date as follows:

Lease Months	Rent/Square Foot	Monthly	Annualized
EPCD – the last day of Year One	$14.50	$14,735.63	$176,827.50
Year Two	$15.00	$15,243.75	$182,925.00
Year Three	$15.50	$15,751.88	$189,022.50
Year Four	$16.00	$16,260.00	$195,120.00
Year Five	$16.50	$16,768.13	$201,217.50
Year Six	$17.00	$17,276.25	$207,315.00
Year Seven	$17.50	$17,784.38	$213,412.50

Notwithstanding the foregoing, if the Expansion Premises Commencement Date shall not occur on the first day of a calendar month, the period beginning on the date that the Expansion Premises Commencement Date occurs and ending on the last day of the month in which the Expansion Premises Commencement Date occurs shall be identified as the "**Expansion Premises Stub**

Period". Rent for the Expansion Premises Stub Period will be calculated based upon Monthly Rent that will be payable on and immediately following the Expansion Premises Commencement Date prorated for the number of days in such Expansion Premises Stub Period assuming a thirty (30) day calendar month regardless of the month in which such Expansion Premises Stub Period occurs. Accordingly, in the event of an Expansion Premises Stub Period, on the Expansion Premises Commencement Date, Tenant shall pay Landlord Monthly Rent for the Expansion Premises Stub Period an amount equal to (x) Four Hundred Ninety-One and 19/100 Dollars ($491.19) times (y) the number of days comprising the Expansion Premises Stub Period plus all other charges comprising Rent, as defined in this Lease, applicable to the Expansion Premises, similarly prorated for the Expansion Premises Stub Period, plus all other charges comprising Rent, as defined in this Lease, applicable to the Initial Premises, without any proration.

(iii) For purposes of this Lease, for the period from the Initial Premises Commencement Date to and including the day immediately preceding the Expansion Premises Commencement Date, the term "**Minimum Annual Rent**" as used herein shall mean and include only the Initial Premises Minimum Annual Rent. From and after the occurrence of the Expansion Premises Commencement Date, the term "**Minimum Annual Rent**" as used herein shall mean and include both the Initial Premises Minimum Annual Rent and the Expansion Premises Minimum Annual Rent.

(g) Annual Operating Expenses:

(i) Landlord's good faith estimate of annual payments of Operating Expenses (as defined below) applicable to the Initial Premises ("**Initial Premises Annual Operating Expenses**") for the Lease Year (as defined below) of Year One is Six and 45/100 Dollars ($6.45) per rentable square foot of the Initial Premises, which amount includes the expenses and charges set forth in Section 6(b) below. Accordingly, from and after the Initial Premises Commencement Date, during Year One, Initial Premises Annual Operating Expenses are expected to be, based on the above estimate, Twenty-Seven Thousand One Hundred Twenty-Eight and 70/100 Dollars ($27,128.70), payable in equal monthly installments of Two Thousand Two Hundred Sixty and 73/100 Dollars ($2,260.73). All of the amounts set forth above in this Section 1(g)(i) are and shall be subject to adjustment and reconciliation as provided in this Lease.

(ii) Landlord's good faith estimate of annual payments of Operating Expenses applicable to the Expansion Premises ("**Expansion Premises Annual Operating Expenses**") for Year One is Six and 45/100 Dollars ($6.45) per rentable square foot of the Expansion Premises, which amount includes the expenses and charges set forth in Section 6(b) below. Accordingly, from and after the Expansion Premises Commencement Date, during Year One, Expansion Premises Annual Operating Expenses are expected to be, based on the above estimate, Seventy-Eight Thousand Six Hundred Fifty-Seven and 75/100 Dollars ($78,657.75), payable in equal monthly installments of Six Thousand Five Hundred Fifty-Four and 81/100 Dollars ($6,554.81). All of the amounts set forth above in this Section 1(g)(ii) are and shall be subject to adjustment and reconciliation as provided in this Lease.

(iii) For purposes of this Lease, for the period from the Initial Premises Commencement Date to and including the day immediately preceding the Expansion Premises Commencement Date, the term "**Annual Operating Expenses**" as used herein shall mean and include only the Initial Premises Annual Operating Expenses. From and after the occurrence of the Expansion Premises Commencement Date, the term "**Annual Operating Expenses**" as used herein shall mean and include both the Initial Premises Annual Operating Expenses and the Expansion Premises Annual Operating Expenses.

(h) **Tenant's Share**:

(i) "**Tenant's Initial Premises Share**" is 5.91%, obtained by dividing the rentable square feet of the Initial Premises by the rentable square feet of the Building.

(ii) "**Tenant's Expansion Premises Share**" is 17.15%, obtained by dividing the rentable square feet of the Expansion Premises by the rentable square feet of the Building.

(iii) For purposes of this Lease, for the period from the Initial Premises Commencement Date to and including the day immediately preceding the Expansion Premises Commencement Date, the term "**Tenant's Share**" as used herein shall mean and include only Tenant's Initial Premises Share. From and after the occurrence of the Expansion Premises Commencement Date, the term "**Tenant's Share**" as used herein shall mean and include both Tenant's Initial Premises Share and Tenant's Expansion Premises Share which, in the aggregate, is 23.06%, obtained by dividing the total rentable square feet of the Initial Premises and the Expansion Premises by the rentable square feet of the Building.

(i) **Use**: Tenant's "**Use**" shall be general office, laboratory and storage space use, and uses incidental thereto, but for no other use or purpose whatsoever.

(j) **Security Deposit**: The parties hereto acknowledge that Landlord is currently holding Forty-Six Thousand and 00/100 Dollars ($46,000.00) as a security deposit (the "**Existing Security Deposit**") delivered by Tenant to Landlord in accordance with the Other Lease (as defined below). Landlord agrees to use the Existing Security Deposit as a portion of the Security Deposit (as defined below) under this Lease. At the time of signing this Lease, Tenant shall deposit with Landlord an additional One Hundred Four Thousand and 00/100 Dollars ($104,000.00) which, together with the Existing Security Deposit, shall be the initial "**Security Deposit**" in the amount of One Hundred Fifty Thousand and 00/100 Dollars ($150,000.00) to be retained by Landlord as cash security for the faithful performance and observance by Tenant of the provisions of this Lease. Within thirty (30) days following the expiration of Year One, Landlord shall, provided no Event of Default has occurred and is then existing, return a Fifty Thousand and 00/100 Dollar ($50,000.00) portion of the Security Deposit to Tenant and retain the remaining One Hundred Thousand and 00/100 Dollars ($100,000.00) to be held as the "**Security Deposit**" as required under this Lease for Year Two. Within thirty (30) days following the expiration of Year Two, Landlord shall, provided no Event of Default has occurred and is then existing, return a Fifty Thousand and 00/100 Dollar ($50,000.00) portion of the Security Deposit to Tenant and retain the remaining Fifty Thousand and 00/100 Dollars ($50,000.00) to be held as the "**Security Deposit**" as required under this Lease for the balance of the Term and any extension or renewal thereof. Notwithstanding the foregoing, if at any time prior to the first day of Year Three, Tenant provides evidence to Landlord that Tenant's auditors have removed their "going concern" assumption with respect to the long-term viability of Tenant's business operations from Tenant's publicly filed financial statements, and provided no Event of Default has occurred and is then existing, Landlord shall accept Fifty Thousand Dollars ($50,000.00) as the Security Deposit and promptly return the then remaining balance to Tenant.

(k) **Addresses for Notices**:

If to Landlord:

c/o Workspace Property Trust
700 Dresher Road, Suite 150
Horsham, PA 19044
Attention: Anthony A. Nichols, Jr.,
Senior Vice-President
E-mail: tnichols@workspaceproperty.com

With a copy to:

Workspace Property Trust
5 Great Valley Parkway, Suite 209
Malvern, PA 19355
Attention: Catherine Bianco,
Director of Leasing
Email: cbianco@workspaceproperty.com

And an additional copy to:

McCausland Keen + Buckman
80 West Lancaster Avenue, 4th Floor
Devon, PA 19333
Attention: Stephan K. Pahides, Esq.
Email: spahides@mkbattorneys.com

If to Tenant:

Prior to the Initial Premises Commencement Date:

Ocugen, Inc.
5 Great Valley Parkway, Suite 160
Malvern, PA 19355
Attention: Dr. Shankar Musunuri
E-mail: shankar.musunuri@ocugen.com

On and after the Initial Premises Commencement Date:

The Premises.

(l) **Broker**: None.

(m) **Guarantor**: None.

(n) **Contents**: The following are attached to and made a part of this Lease:

Exhibits:	"A":	Plan Showing Initial Premises and Expansion Premises
	"B":	Building Rules
	"C":	Payment Rider
	"D":	Cleaning Schedule
	"E":	Tenant Estoppel Certificate Form
	"F":	Tenant's Concept Plan

2. **Premises**. Landlord leases to Tenant and Tenant leases from Landlord the Premises, together with the right in common with others to use the Common Areas (as defined below). Subject to Landlord's completion of Landlord's Work as provided for in Section 29 below, Tenant accepts the Premises, Building and Common Areas in their "**AS IS**" "**WHERE IS**" condition, without relying on any representation, covenant or warranty by Landlord other than as expressly set forth in this Lease. Landlord and Tenant stipulate and agree to the rentable square footages set forth in Section 1(a) and Section 1(b) above for all purposes with respect to this Lease. Following: (i) the Initial Premises Commencement Date, Tenant shall have access to the Initial Premises; and (ii) the Expansion Premises Commencement Date, Tenant shall have access to both the Initial Premises and the Expansion Premises, in each case twenty-four (24) hours per day, seven (7) days per week, fifty-two (52) weeks per year, subject to events beyond the reasonable control of Landlord and closures of the Premises permitted under this Lease. "**Common Areas**" means all areas and facilities as provided by Landlord from time to time for the use or enjoyment of all tenants in the Building or Property, including, if applicable and without limitation, driveways, sidewalks, parking areas, loading areas, landscaped areas, mechanical and fan rooms, electrical and telephone closets, structural components of the Building excluding the Building Structure (as defined below), and all other general Building or Property components, facilities, and fixtures that serve or are available to more than one (1) tenant at the Property. "**Land**" means the lot or plot of land on which the Building is situated, or the portion thereof allocated by Landlord to the Building. "**Property**" means the Land, the Building, adjoining parking areas, sidewalks, driveways, landscaping and additional buildings situated thereon, and the Common Areas.

3. Use.

(a) Tenant shall occupy and use the Premises only for the Use specified in Section l(i) above, and pursuant to the Building Rules (as defined hereunder). Without limiting the generality of the foregoing, Tenant shall not use the Premises for any retail sales. Tenant has reviewed and investigated the Building and the Property, and Tenant has determined, on its own judgment, that the Premises are suitable for Tenant's Use. Tenant understands, agrees and acknowledges that neither Landlord nor its Agents (as defined below) have made any representation or warranty of any kind with respect to the Premises, the Building or the Property that Tenant's intended Use is permitted under applicable East Whiteland Township zoning ordinances or regulations with respect to the Property and Tenant waives any implied warranty of Landlord of suitability or fitness of the Premises, Building or the Property for the Use or for any other particular intended commercial purpose, except as expressly set forth in this Lease. Tenant shall not permit any conduct or condition which may endanger, disturb or otherwise interfere with any other Building occupant's normal operations or with the management of the Building. Tenant and its employees, agents and invitees may use all Common Areas only for their intended purposes. Subject to Tenant's use of the Common Areas and the terms of this Lease, Landlord shall have exclusive control of all Common Areas at all times. "**Building Rules**" means the rules and regulations attached to this Lease as **Exhibit "B"** as they may be amended from time to time, in Landlord's reasonable discretion upon written notice to Tenant. In the event of any conflict between the terms of the Building Rules and the terms of this Lease, the terms of this Lease shall control. Excepting any initial occupancy permit(s) from East Whiteland Township which, to the extent required by any Law (as defined below), shall be Landlord's obligation to obtain as part of the Landlord's Work, Tenant shall be responsible, at its sole cost and expense, to obtain all required permits and approvals required by East Whiteland Township and all permits and licenses required by the Commonwealth of Pennsylvania for Tenant's Use including, without limitation, the operation of its business and the construction or installation of any Alterations (as defined below) to the Premises installed by or on behalf of Tenant, but the failure of Tenant to obtain any or all such licenses, permits and approvals shall not affect the validity of this Lease. Tenant shall be responsible, at its sole cost and expense, to confirm Tenant's Use is permitted under all applicable zoning codes and ordinances of East Whiteland Township, but if Tenant's Use is not permitted by right, this Lease shall remain in full force and effect, Tenant shall not apply for any zoning change or variance without Landlord's written consent, in Landlord's sole discretion, and if Landlord consents, Tenant shall be responsible, at its sole cost and expense, for applying for and pursuing such zoning relief. For purposes of this Lease, "**Agents**" of a party means such party's employees, agents, servants, representatives, independent contractors, subcontractors, designees or licensees and in the case of Landlord only, shall include without limitation, Workspace Property Management, L.P., Workspace Property Trust, L.P., and any other associated or affiliated entity.

(b) Tenant and its employees, agents and invitees shall have the right, at Tenant's sole risk and responsibility, and pursuant to the Building Rules, to use, on a non-exclusive basis in common with other tenants and visitors of the Building, Tenant's Share of all unreserved, uncovered parking spaces on the Property (the "**Parking Area**"). Notwithstanding the foregoing, Landlord shall provide Tenant's Share of parking spaces in the Parking Area totaling forty-two (42) parking spaces for Tenant's use during the Term, at no additional cost to Tenant. Notwithstanding the foregoing, Landlord is under no obligation to enforce Tenant's parking rights granted hereunder and Landlord shall have no liability to Tenant for any unauthorized parking of any vehicles within the Parking Area. Tenant will, upon request, promptly furnish to Landlord the license plate numbers of the vehicles operated by Tenant and its subtenants, invitees, concessionaires, licensees and their respective officers, agents and employees. The Parking Area provided for herein is provided as a license solely for the accommodation of Tenant and other Building occupants or invitees, and Landlord assumes no responsibility or liability of any kind whatsoever from whatever cause with respect to the vehicle Parking Area and all other parking areas, including adjoining streets, sidewalks and passageways, or the use thereof by Tenant or Tenant's employees, customers, agents, contractors or invitees. Tenant may not assign, transfer, sublease or otherwise alienate the use of the Parking Area without Landlord's prior written consent except in connection with an assignment, transfer or sublease of this Lease approved by Landlord or permitted under Section 18(b) below.

(c) Without the prior written consent of Landlord, and except as required under applicable Law (as defined below) or regulatory agency rules (including those of the Securities and Exchange Commission), Tenant shall not Publicize (as defined hereunder) in any medium this Lease or the negotiations for, or the terms, conditions or provisions included herein, provided however, that Tenant may announce the fact that this Lease has been signed and the size of the Premises. "**Publicize**" as used in the preceding sentence means public dissemination of information for

marketing or promotional purposes, whether by press release, in printed or digital marketing materials, on a website, or otherwise. Subject to Tenant's prior approval, not to be unreasonably conditioned, withheld or delayed, Landlord shall have the right to Publicize any trademark, trade name, trade dress or any name, picture or logo which is commonly identified with Tenant, however no such use shall be construed to grant to Landlord any rights in or to any such trademark, trade name, trade dress or any name, picture or logo of Tenant. Landlord may also: (i) include Tenant's name in any description of this Lease in any offering materials related to the sale or other transfer of the Building; (ii) disclose the details of this Lease to prospective lenders, purchasers or other transferees of Landlord's interest in the Property; (iii) photograph the Premises, which images may include Tenant's trademark, trade name, trade dress or any name, picture or logo which is commonly identified with Tenant, for Landlord's use in its website or printed promotional and marketing materials (however, such use shall not be construed to grant to Landlord any rights in or to any such trademark, trade name, trade dress or any name, picture or logo of Tenant); and (iv) publicize this Lease after the Initial Premises Commencement Date. Any press release issued by either party regarding this Lease shall be subject to the prior approval of both parties, which approval shall not be unreasonably withheld, delayed or conditioned.

(d) Landlord hereby discloses to Tenant that the Premises and Building are a portion of a larger development known as the Great Valley Corporate Center (the "**GVCC**"), which consists of certain improvements for the benefit of all owners and occupants of properties within the GVCC. Pursuant to certain recorded instruments with respect to the GVCC, owners of properties within the GVCC are assessed certain association fees and other charges, which fees and charges are included as part of the Operating Expenses.

4. Term; Option to Renew; Possession.

(a) Subject to Section 29 below: (i) the Initial Premises Term shall commence on the Initial Premises Commencement Date; and (ii) the Expansion Premises Term shall commence on the Expansion Premises Commencement Date, and each shall end on the Expiration Date unless sooner terminated in accordance with this Lease. If Landlord is delayed in delivering possession of all or any portion of the Initial Premises to Tenant for any or no reason, this Lease will not be void or voidable, except as expressly set forth in this Lease, nor will Landlord be liable to Tenant for any loss or damage resulting therefrom, but in that event, the Initial Premises Term will commence on the date Landlord delivers possession of the Initial Premises to Tenant with the Substantial Completion of the Initial Premises Work, which date will then become the Initial Premises Commencement Date (and the Expiration Date will be extended so that the length of the Term remains unaffected by such delay), and the Monthly Rent due for any partial month shall be prorated on a per diem basis as provided in Section 1(f) above. If Landlord is delayed in delivering possession of all or any portion of the Expansion Premises to Tenant for any or no reason, this Lease will not be void or voidable, except as expressly set forth in this Lease, nor will Landlord be liable to Tenant for any loss or damage resulting therefrom, but in that event, the Expansion Premises Term will commence on the date Landlord delivers possession of the Expansion Premises to Tenant with the Substantial Completion of the Expansion Premises Work, which date will then become the Expansion Premises Commencement Date (but in no event shall the Expiration Date be extended), and the Monthly Rent due for any partial month shall be prorated on a per diem basis as provided in Section 1(f) above. Notwithstanding anything contained in this Lease to the contrary, (a) if Tenant (or anyone having rights under or through Tenant) shall operate its business within all or any part of the Initial Premises prior to Landlord achieving Substantial Completion of the Initial Premises Work, then the Initial Premises Commencement Date shall be deemed to occur on such date that Tenant (or anyone claiming under or through Tenant) commences business operations within all or any part of the Initial Premises; and, (b) if Tenant (or anyone having rights by, under or through Tenant) shall operate its business within all or any part of the Expansion Premises prior to Landlord achieving Substantial Completion of the Expansion Premises Work, then the Expansion Premises Commencement Date shall be deemed to occur on such date that Tenant (or anyone claiming by, under or through Tenant) commences business operations within all or any part of the Expansion Premises. Within ten (10) days after receipt of a request from Landlord, Tenant shall execute and deliver a certificate in form and substance reasonably required by Landlord confirming the Initial Premises Commencement Date and the Expiration Date, and the Expansion Premises Commencement Date, but the failure to do so shall not alter the terms of this Lease, and in such event, Landlord's determination of such dates shall be deemed accepted. For purposes of this Lease, and any renewal thereof, the term "**Lease Year**" means the period from the Initial Premises Commencement Date through the succeeding twelve (12) full calendar months (including for Year One, any partial month from the Initial Premises Commencement Date until the first day of the first full calendar month) and each successive twelve (12) month period thereafter during the Term, and any renewal thereof.

(b) Landlord shall not be liable for any loss or damage to Tenant resulting from any delay in delivering possession of any part of the Premises to Tenant due to the holdover of any existing tenant, any event of Force Majeure (as defined below), any Tenant Delay (as defined below), or any other circumstances outside of Landlord's reasonable control (collectively, an "**Excused Delay**"), nor shall any such Excused Delay affect the continuation or validity of this Lease. In the event Landlord shall be actually delayed in delivering any part of the Premises as the result of any event due to, or act or omission by, or caused by, Tenant or Tenant's Agents (a "**Tenant Delay**"), either the: (i) Initial Premises Commencement Date; or (ii) the Expansion Premises Commencement Date, as the case may be, will be the date, as reasonably determined by Landlord, that Landlord would have delivered possession of such applicable portion of the Premises to Tenant in the condition required under this Lease but for such Tenant Delay.

(c) As Landlord's performance of: (i) the Initial Premises Work; and (ii) the Expansion Premises Work nears completion, in each case, Landlord shall notify Tenant of the date that is thirty (30) days before the expected date of Substantial Completion for the applicable portion of the Premises (the "**Early Entry Date**"), as reasonably determined by Landlord. Tenant and its Agents shall, at all reasonable times from and after the Early Entry Date, have the right, at Tenant's own risk, expense and responsibility, to enter the then applicable portion of the Premises for the limited purpose of taking measurements and installing its fixtures, furnishings and equipment (including, without limitation, its telecommunication, data, computer, telephone and/or antenna wiring, cabling, conduit and the like) (collectively, the "**FFE**"), so long as: (i) Tenant obtains Landlord's prior written consent, not to be unreasonably withheld or delayed; (ii) Tenant uses contractors and workers who are compatible with the contractors and workers engaged by Landlord including, without limitation, Contractor (as defined below), so as to avoid any labor disturbance; and, (iii) Tenant and all parties entering such portion of the Premises or any part thereof on Tenant's behalf do not materially or unreasonably interfere with the performance of the Landlord's Work, as the case may be. In the event Landlord is unable to Substantially Complete the Landlord's Work because of any inability to access the Premises caused by Tenant or its Agents, then such delay shall be deemed a Tenant Delay. Any such entry into either the Initial Premises or any part thereof prior to the Initial Premises Commencement Date, or to the Expansion Premises or any part thereof prior to the Expansion Premises Commencement Date, shall be subject to the reasonable consent, direction and control of both the Landlord and the Contractor, and Tenant shall abide by the terms and conditions of this Lease including, without limitation, providing evidence of required insurance for Tenant and all of Tenant's Agents, as if the Term of this Lease had already commenced, except that, unless caused by a Tenant Delay, Tenant shall have no obligation to pay Rent or any portion thereof until after Initial Premises Commencement Date, or the Expansion Premises Commencement Date, as the case may be, each in accordance with the terms of this Lease. At no time prior to the Initial Premises Commencement Date or the Expansion Premises Commencement Date, as applicable, may Tenant commence business operations within the Initial Premises or Expansion Premises, as applicable. Tenant's installation of its FFE shall not be considered an installation of an Alteration, provided that the installation and removal of all of such FFE will not affect any Building Structure or portion thereof on the Property, any Building System (as defined below) or any other equipment or facilities serving the Building or any Building occupant. All FFE installed by or on behalf of Tenant shall be removed from the Premises by Tenant at the expiration or earlier termination of this Lease in accordance with Section 21(a) below. Tenant's failure to comply with the terms and conditions of this Section 4(c) shall be deemed a default by the Tenant under this Lease entitling Landlord to exercise all legal and equitable remedies available to Landlord. Except to the extent caused by the gross negligence or willful misconduct of Landlord or its Agents, Tenant will indemnify, defend, and hold harmless Landlord, the Landlord Additional Insureds (as defined below) and their respective Agents from and against any and all claims, actions, damages, proceedings, costs, liability and expense (including reasonable fees of attorneys, investigators and experts) which may be asserted against, imposed upon, or incurred by Landlord or any of the Landlord Additional Insureds or their respective Agents on account of the loss of life, personal injury or damage to property in or about the Premises, to the extent caused by Tenant's (or its Agents) access of and to the Initial Premises prior to the Initial Premises Commencement Date, and/or the Expansion Premises prior to the Expansion Premises Commencement Date, in each case whether in contract or tort. Tenant's obligations pursuant to this Section 4(c) shall survive the expiration or earlier termination of this Lease. In case any action or proceeding is brought against Landlord or any of the Landlord Additional Insureds or their respective Agents by reason of any such claim, Tenant, upon notice from Landlord or any of the Landlord Additional Insureds or their respective Agents, will, at Tenant's sole cost and expense, resist and defend such action or proceeding with counsel reasonably acceptable to Landlord and such Landlord Additional Insureds and their respective Agents.

(d) Reference is hereby made to that certain other Lease Agreement dated December 19, 2016, as amended (the "**Other Lease**") now existing by and between Tenant and Landlord for Suite 150 and Suite 160, aggregating approximately 8,038 rentable square feet at Landlord's building located at 5 Great Valley Parkway, Malvern, PA 19355 (the "**Other Space**"). Provided that Tenant surrenders the Other Space no later than the fifth (5th) day after the Expansion Premises Commencement Date in the condition required by the Other Lease, and no Event of Default by Tenant has occurred and is continuing under the Other Lease (the "**Other Lease Termination Conditions**"), the Other Lease for the Other Space shall be deemed terminated without the need for any additional documentation confirming such termination, without penalty to Tenant effective as of the Expansion Premises Commencement Date, and the parties hereto agree Landlord shall adjust the Other Security Deposit as provided for in Section 1(j) above. Tenant agrees that Tenant's obligation to pay Rent for the Expansion Premises shall commence on the Expansion Premises Commencement Date, regardless of whether Tenant has vacated the Other Space. Tenant shall surrender the Other Space to Landlord in the condition required under the Other Lease; provided, however, the parties hereto agree that Tenant shall have no obligation to remove any Alterations or Landlord's Work (as such capitalized terms are defined under the Other Lease), and that Tenant shall only be obligated to remove from the Other Space all wiring and cables, furniture, trade fixtures, equipment and other personal property installed by Tenant. Further, from and after the fifth (5th) day after the Expansion Premises Commencement Date, any failure of Tenant to vacate the Other Space in accordance with the Other Lease shall be deemed an Event of Default by the Tenant under the Other Lease and, in addition, Tenant will in all respects be deemed to be a "Holdover" pursuant to Section 21(b) of the Other Lease, and in which case Tenant shall be required to pay to Landlord holdover rent due under the Other Lease for the Other Space in addition to all Rent due with respect to all of the Premises under this Lease. Notwithstanding anything to the contrary contained in the Other Lease, if the Expansion Premises Commencement Date does not occur until after the expiration date of the Other Lease, then Tenant shall not be deemed a "Holdover" pursuant to Section 21(b) of the Other Lease and the term of the Other Lease shall be extended until the fifth (5th) day after the Expansion Premises Commencement Date. Notwithstanding anything to the contrary contained herein, in the event Tenant terminates this Lease prior to the occurrence of the Initial Premises Commencement Date pursuant to Section 4(f) below, the Other Lease shall not terminate and will continue to be valid and binding between the parties with respect to the Other Space.

(e) Provided that (i) this Lease is then in effect, (ii) no Event of Default has occurred and is continuing prior to the Expiration Date of the Term, and (iii) Tenant (or an Affiliate) occupies all of the Premises, Tenant shall have the right and option to extend the Term of this Lease for one (1) additional period of sixty (60) months (the "**Renewal Term**"), commencing as of the date immediately following the Expiration Date of the Term, on the same terms and conditions as are in effect on the last day of the Term (except that the Minimum Annual Rent shall be increased as set forth below in Section 4(e)(i) of this Lease, no abatement or allowances shall be continued, and Tenant shall not have any further renewal rights), exercisable by giving Landlord prior written notice of Tenant's election to extend the Term (the "**Renewal Notice**"), on or prior to the date which is twelve (12) months prior to the Expiration Date of the Term; it being agreed that time is of the essence (the "**Renewal Option**"). If and when the Renewal Term is in effect, all references to the Term of this Lease shall be deemed to mean the Renewal Term. This Renewal Option is personal to Tenant and is non-transferable to any assignee, subtenant or other party (or than an Affiliate).

(i) The Minimum Annual Rent for each year of the Renewal Term shall be equal to the greater of (y) the Minimum Annual Rent payable in the immediately preceding Lease Year, with annual increases at the rate of [***] per rentable square foot; or (z) one hundred percent (100%) of the FMR value of the Premises (with yearly escalations) applicable at the time Tenant exercises such option (but in no event prior to the date that is twelve (12) months before the Expiration Date of the Term). Unless Landlord accepts as Tenant's Minimum Annual Rent obligation for each year of the additional period an amount equal to the Minimum Annual Rent payable in the immediately preceding Lease Year, with annual increases of [***] per rentable square foot (the **"Prior Rent Alternative"),** within thirty (30) days after Landlord receives notice of Tenant's Renewal Notice, but in no event prior to the date that is twelve (12) months before the Expiration Date of the Term, Landlord will give notice to Tenant (the **"Rent Notice")** of Landlord's opinion of the FMR and comparing the FMR to the Minimum Annual Rent payable in the immediately preceding Lease Year. If Tenant does not respond to the Rent Notice within fifteen (15) days after receiving it, Landlord's opinion of the FMR shall be deemed accepted as the Minimum Annual Rent due for each Lease Year of the Renewal Term. If, during such fifteen (15) day period, Tenant gives Landlord notice that Tenant contests Landlord's determination of the FMR (an **"Objection Notice"),** which notice must contain therein Tenant's opinion of the FMR (including yearly escalations), the parties shall then negotiate to determine a FMR (with yearly

escalations) acceptable to both parties to arrive at a mutually agreeable Minimum Annual Rent for each Lease Year of the Renewal Term, which, in no event, shall be less than the Prior Rent Alternative. If and when the parties come to an agreement, they will both execute an amendment to this Lease establishing the Minimum Annual Rent for each Lease Year of the Renewal Term. If, within fifteen (15) days after Landlord's receipt of the Objection Notice, the parties have not signed such an amendment to this Lease, then each of the Renewal Option and the Renewal Notice shall be terminated and void, and Tenant shall not have any right to renew the Term.

(ii) As used in this Lease, the term **"FMR"** shall mean, as of the date in question, the then current annual rental charge, including provisions for subsequent increases and other adjustments for leases or agreements to lease then currently being negotiated, or executed in comparable space located in the Building, the office park of which the Building is a part, and leases or agreements to lease then currently being negotiated or executed for comparable space located elsewhere in office buildings located in the GVCC / Route 202 submarket, for a term commencing on or about the then scheduled Expiration Date of this Lease. In determining FMR, the following factors, among others, shall be taken into account and given effect: size, location of premises, lease term, condition of the building, condition of the premises, economic concessions (including free rent, tenant improvements being performed by landlords for tenants, or tenant improvement allowances being granted by landlords to tenants), then being granted by landlords to tenants and services provided by landlords.

(f) Landlord shall use commercially reasonable efforts to achieve Substantial Completion of the Initial Premises Work by January 1, 2021. Notwithstanding anything in this Lease to the contrary, in the event that Substantial Completion of the Initial Premises Work is not achieved by February 15, 2021 for reasons other than any Excused Delay, then Landlord shall provide Tenant with one (1) day's abatement of Rent for each day of delay after February 15, 2021 until Substantial Completion of the Initial Premises Work is achieved. Further, notwithstanding anything to the contrary contained herein and without limiting Tenant's remedies under the preceding sentence, in the event that Substantial Completion of the Initial Premises Work is not achieved by June 1, 2021 for reasons other than any Excused Delay, then Tenant shall have the option to terminate this Lease upon written notice to Landlord, provided that if Substantial Completion of the Initial Premises Work is achieved within fifteen (15) days after Landlord's receipt of Tenant's termination notice, then such termination notice shall be null and void and this Lease shall continue in full force and effect. If this Lease is terminated as provided in the previous sentence, the parties shall be discharged from all obligations under this Lease, except that Landlord shall immediately return any prepaid Rent and the One Hundred Four Thousand and 00/100 Dollars ($104,000.00) portion of the Security Deposit previously deposited with Landlord by Tenant. Tenant acknowledges that in the event this Lease is terminated, Landlord shall retain the Existing Security Deposit as security for and under the Other Lease, which shall remain in full force and effect as set forth in Section 4(d) above.

5. **Rent; Taxes**. This is a "triple net" lease and the Minimum Annual Rent payments due from Tenant do not include any Annual Operating Expenses, other additional Rent, or utilities and services, which amounts are Tenant's responsibility as set forth herein. Accordingly, Tenant agrees to pay to Landlord, without demand, deduction or offset, Minimum Annual Rent, Annual Operating Expenses, and other additional Rent for the Term, in advance, on the first (1st) day of each calendar month during the Term (collectively, the "**Monthly Rent**"), to Landlord's address set forth on the "**Payment Rider**" attached hereto as **Exhibit "C"** (unless Landlord designates otherwise in writing to Tenant) or if required by Landlord to an account selected by Landlord by direct payment, in which event Tenant shall execute and deliver a direct payment authorization within five (5) days after receipt of Landlord's notice; provided that Monthly Rent for the first (1st) full month of the Term shall be paid to Landlord concurrent with the signing of this Lease. If either the Initial Premises Commencement Date or the Expansion Premises Commencement Date is not the first (1st) day of the month, the monthly installment of Minimum Annual Rent for that partial month shall be apportioned on a per diem basis and shall be paid on or before the Initial Premises Commencement Date and/or the Expansion premises Commencement Date, as the case may be. Tenant shall pay Landlord a service and handling charge equal to [***] of any Rent not paid within five (5) days after the date due, which amount shall be considered part of Tenant's Rent obligation. In addition, any Rent, including such charge, not paid within five (5) days after the due date will bear interest at the at the rate of [***] per month (the "**Interest Rate**") from the date due to the date paid, which amount shall be considered part of Tenant's Rent obligation. The payment of interest on such amounts will not extend the due date of any amount owed. Notwithstanding the foregoing, Landlord shall waive the first late charge and interest payment in any twelve (12)-month period during the Term provided the delinquent payment is made within five (5) days after Tenant's receipt of written notice thereof. Tenant shall pay before delinquent all taxes or

other charges levied or assessed upon, measured by, or arising from: (a) the conduct of Tenant's business; (b) Tenant's leasehold estate; or (c) Tenant's property. Additionally, Tenant shall pay to Landlord all sales, use, transaction privilege, or other excise tax that may at any time be levied or imposed upon, or measured by, any amount payable by Tenant under this Lease. For purposes of this Lease, "**Rent**" means the Minimum Annual Rent, Annual Operating Expenses, and any other additional amounts of money payable by Tenant to Landlord under this Lease.

6. Operating Expenses.

(a) The amount and percentage of the Annual Operating Expenses set forth in Section 1(g) and Section 1(h) above represents Tenant's Share of the estimated Operating Expenses for the calendar year in which the Term commences. Landlord shall provide annually prior to January 1 of each calendar year a reasonable estimate of the Annual Operating Expenses due for such calendar year, and Tenant shall pay Tenant's Share of such estimate in equal installments on a monthly basis as part of Rent. Landlord may adjust such amount from time to time if the estimated Annual Operating Expenses increase or decrease. Landlord may also invoice Tenant separately from time to time for Tenant's Share of any extraordinary or unanticipated Operating Expenses. By April 30th of each calendar year (and as soon as practical after the expiration or earlier termination of this Lease or, at Landlord's option, after a sale of the Building or the Property), Landlord shall provide Tenant with a statement of Operating Expenses representing Tenant's Share for the preceding calendar year or part thereof. Within thirty (30) days after delivery of the statement to Tenant, Landlord or Tenant shall pay to the other the amount of any overpayment or deficiency then due from one to the other or, at Landlord's option, Landlord may credit Tenant's account for any overpayment. If Tenant does not give Landlord notice within sixty (60) days after receiving Landlord's statement that Tenant disagrees with the statement and specifying the items and amounts in dispute, Tenant shall be deemed to have waived the right to contest the statement. Landlord's and Tenant's obligation to pay any overpayment or deficiency due to the other pursuant to this Section 6 shall survive the expiration or earlier termination of this Lease. Notwithstanding any other provision of this Lease to the contrary, Landlord may, in its reasonable discretion, determine from time to time the method of computing and allocating Operating Expenses, including the method of allocating Operating Expenses to various types of space within the Building to reflect any disparate levels of services provided to different types of space, and if the scope of the services performed for any building on the Property (including the Building) is disproportionately more or less than for others, Landlord shall equitably allocate the costs based on the scope of the services being performed for each building on the Property (including the Building). If the Building is not fully occupied during any period, Landlord may make a reasonable adjustment based on occupancy in computing the Operating Expenses for such period so that Operating Expenses are computed as though the Building had been fully occupied; provided, however, that Landlord shall not recover more than one hundred percent (100%) of Operating Expenses. If Landlord shall fail to render a statement for Tenant's Share of Operating Expenses to Tenant within twenty-four (24) months following the applicable calendar year in which such Operating Expenses were incurred, then Landlord shall be deemed to have waived its right to collect such sums from Tenant hereunder in respect thereof.

(b) "**Operating Expenses**" means all costs, fees, charges and expenses incurred or charged by Landlord in connection with the ownership, operation, maintenance and repair of, and services provided to, the Property, including, but not limited to, and to the extent not otherwise payable by Tenant pursuant to this Lease, (i) the charges, at standard retail rates, for all utilities and services provided to Tenant and other occupants of the Building by Landlord pursuant to Section 7 of this Lease, (ii) the cost of insurance carried by Landlord pursuant to Section 8 of this Lease together with the cost of any deductible paid by Landlord in connection with an insured loss, (iii) Landlord's cost to Maintain (as defined hereunder) the Property pursuant to Section 9 of this Lease, including without limitation, fire protection, trash collection, janitorial services pursuant to Section 7(c) below, water, sewer, heating, ventilation and air conditioning ("**HVAC**") systems, roof maintenance, exterior landscaping, snow and ice removal, and Common Area cleaning and exterminating, (iv) a non-reconcilable amount equal to the charges incurred by Landlord for personnel, vehicles, and supplies used or attributable to the Premises equal to a fixed amount of [***] per rentable square foot of the Premises (the "**Tenant Services Fee**"), (v) all levies, taxes (including real estate taxes, sales taxes and gross receipt taxes), assessments, liens, license and permit fees, together with the reasonable cost of contesting any of the foregoing, which are applicable to the Term, and which are imposed by any authority or under any Law, or pursuant to any recorded covenants or agreements including, without limitation, all GVCC fees, upon or with respect to the Property pursuant to Section 5 of this Lease, or any improvements thereto, or directly upon this Lease or the Rent or upon

amounts payable by any subtenants or other occupants of the Premises, or against Landlord because of Landlord's estate or interest in the Property, (vi) the annual amortization (over their estimated economic useful life or payback period, whichever is shorter) of the costs (including reasonable financing charges) of capital improvements or replacements (a) required by any Law, (b) made for the purpose of reducing Operating Expenses, or (c) made for the purpose of directly enhancing the safety of tenants in the Building, (vii) a management and administrative fee equal to [***] from the Property (the "**Management Fee**") (and Tenant shall be responsible to pay Landlord Tenant's Share thereof as part of its Monthly Rent payment), and (viii) costs to process the certification or re-certification of the Building pursuant to any applicable environmental rating system (such as Energy Star or LEED), including, applying, reporting, tracking and related reasonable consultant's fees associated therewith.

(c) The foregoing Section 6(b) notwithstanding and except as otherwise provided herein, Operating Expenses will not include: (i) depreciation on the Building, (ii) financing and refinancing costs (except as provided above), interest on debt or amortization payments on any Mortgage (as defined hereunder), or rental under any ground or underlying lease, (iii) leasing commissions, advertising expenses, tenant improvements or other costs directly related to the leasing of the Property, (iv) income, excess profits, corporate capital stock tax or transfer tax, imposed or assessed upon Landlord, unless such tax or any similar tax is levied or assessed in lieu of all or any part of any taxes includable in Operating Expenses above, (v) the cost of services and utilities which are Tenant's responsibility, which shall be paid by Tenant directly to the utility and service providers of such utilities and services as set forth in Section 7 below unless left unpaid by Tenant, (vi) administrative wages and salaries or any other general and administrative overhead of Landlord in excess of the Management Fee and the Tenant Services Fee; (vii) wages, salaries, fringe benefits and other labor costs of all persons above the level of senior project manager engaged by Landlord for the operation, maintenance, repair and replacement of the Property; (viii) legal fees and other expenses incurred in connection with disputes with prospective tenants or tenants or occupants other than Tenant in the Building; (ix) costs of services provided to other tenants of the Building or services to which Tenant is not entitled (including costs specially billed to and paid by specific tenants); (x) any expenses for which Landlord has received actual reimbursement (including, without limitation, insurance proceeds); (xi) the cost of fees and fines in connection with any violation by Landlord of any applicable Laws with respect to any ADA or accessibility violations to improvements constructed by Landlord; (xii) late fees, penalties and/or interest solely in connection with Landlord's late payment of Operating Expenses (including real estate taxes); and (xiii) any item that, if included in Operating Expenses, would involve a double collection for such item by Landlord. If Landlord elects to prepay real estate taxes during any discount period, Landlord shall be entitled to the benefit of any such prepayment. Landlord shall have the right to directly perform (by itself or through an affiliate) any services provided under this Lease, provided however, that the Landlord's charges included in Operating Expenses for any such services shall not exceed competitive market rates for comparable services.

(d) The parties agree that Tenant's Share reflects and will be continually adjusted to reflect the ratio of the rentable square feet of the area rented to Tenant (including, if applicable, an allocable share of all Common Areas) as the numerator, as compared with the total number of rentable square feet of the entire Building (or additional buildings that are or may be constructed within the Property), as the denominator, measured outside wall to outside wall, but excluding therefrom any storage areas. Landlord shall have the right to make changes or revisions in the Common Areas of the Building or the Land so as to provide additional leasing area. Landlord shall also have the right to construct additional buildings in the Property for such purposes as Landlord may deem appropriate, and subdivide the lands for that purpose if necessary, and upon so doing, the Property shall become the subdivided lot on which the Building in which the Premises is located. Tenant understands that as a result of changes in the layout of the Common Areas from time to time occurring due to, by way of example and not by way of limitation, the rearrangement of corridors, the aggregate of all Building tenant proportionate shares may be equal to, less than or greater than one hundred percent (100%).

(e) No more than [***] times during the Term and any extension or renewal thereof, in addition to Tenant's right to contest any statement of Landlord's Operating Expenses provided for in Section 6(a) above, if Tenant provides written notice to Landlord within sixty (60) days after receipt of Landlord's statement of Operating Expenses representing Tenant's Share for the preceding calendar year or part thereof that Tenant disagrees with such statement for Operating Expenses, and specifies the items and amounts in dispute, Tenant shall have the right, at its sole cost and expense, to examine Landlord's books and records relating to the determination of Operating Expenses for such calendar year, and commence and diligently complete an audit of such charges (an "**Audit**"); provided, however, that

(1) Tenant shall give Landlord a minimum of [***] prior written notice of its intent to exercise such right, (2) the inspection may not take place outside of normal business hours at Landlord's corporate offices, at Tenant's sole cost, (3) Tenant shall use reasonable efforts to not interfere with Landlord's normal business activities, taking into account the workload of Landlord's employees involved in responding to the Audit request; and (4) an Event of Default under this Lease has not occurred and is then continuing. The Audit of Landlord's records may be conducted only by a certified public accountant, subject to Landlord's approval, which approval shall not be unreasonably withheld. Any accounting firm selected by Tenant in connection with the Audit (a) shall be a reputable independent nationally or regionally recognized certified public accounting firm which has previous experience in auditing financial operating records of landlords of office/flex buildings; (b) shall not currently or previously have been providing accounting and/or lease administration services to Tenant and shall not have provided accounting and/or lease administration services to Tenant in the past three (3) years; (c) shall not be retained by Tenant on a contingency fee basis (i.e. Tenant must be billed based on the actual time and materials that are incurred by the accounting firm in the performance of the Audit, and a statement signed by an officer of Tenant confirming such agreement between Tenant and auditor, shall be provided to Landlord prior to the commencement of the Audit); and (d) at Landlord's option, both Tenant and its agent shall be required to execute a commercially reasonable confidentially agreement prepared by Landlord. The foregoing Audit shall be completed, and the results delivered to Landlord, within [***]after the date Tenant receives Landlord's statement of Operating Expenses for the preceding calendar year (subject to delay due to any event caused by Landlord or Landlord's Agents), or Tenant shall be deemed to have waived the right to contest the statement. Landlord and Tenant shall work together in good faith to resolve any issues raised in Tenant's Audit. In the event Tenant timely completes its Audit and it reveals an overpayment by Tenant of Tenant's Share of Annual Operating Expenses (an "**Overcharge**"), and Landlord in good faith agrees with such determination, the amount due to Tenant (if any) shall be credited against no more than [***] of Tenant's monthly Minimum Annual Rent next coming due for each month following the determination of such Overcharge until such time as Tenant is reimbursed in full, and if the Audit reveals that Tenant was undercharged during any given year (an "**Undercharge**"), Tenant shall promptly pay to Landlord the amount of such Undercharge. Landlord shall additionally reimburse Tenant in the event of an Overcharge of greater than [***] for the out of pocket costs incurred in connection with such Audit in an amount not to exceed [***]. If the parties are unable to resolve the dispute within thirty (30) days after completion of Tenant's Audit, then, at Tenant's request, a certified public accounting firm selected by Landlord and subject to requirements (a), (b), and (c) above as to Landlord, and reasonably approved by Tenant, shall, at Tenant's cost, conduct an audit of the relevant Operating Expenses (the "**Neutral Audit**"). Tenant shall pay all costs and expenses of the Neutral Audit unless the final determination in such Neutral Audit is that Landlord Overcharged Tenant for Tenant's Share of Operating Expenses in the statement for the year being audited by more than [***], in which case Landlord shall pay all costs and expenses of the Neutral Audit in an amount not to exceed [***]. In any event, Landlord will reimburse or provide a credit for any Overcharge of Operating Expenses and Tenant shall pay to Landlord any Undercharge of Operating Expenses.

7. Utilities; Services.

(a) With the exception of Tenant's Share of any utilities and services expressly included as part of the Operating Expenses in Section 6(b) above and Section 7(c) below, Tenant shall directly pay for electricity and gas for and to the Premises, power, telephone, internet and other communication services for the Premises, and any other utilities or services supplied to the Premises. Except to the extent Landlord elects to provide any such services and invoice Tenant for the cost or include the cost as part of Tenant's Share of Operating Expenses, Tenant shall obtain such services in its own name and timely pay all charges directly to the provider(s). If a sub-meter is utilized to measure Tenant electricity and gas usage at the Premises, the cost of such actual measured amount, with Landlord's standard administrative fee equal to five percent (5%), shall be billed by Landlord directly to Tenant as a charge separate and distinct from Tenant's Share of Operating Expenses. If a separate dedicated meter is utilized to measure Tenant's electricity and gas usage at the Premises, Tenant shall pay all charges incurred directly to the applicable utility or service provider. Landlord shall have the exclusive right to select, and to change, the companies providing such services to the Building or Premises. Any wiring, cabling or other equipment necessary to connect Tenant's telecommunications equipment shall be Tenant's responsibility and shall be installed by Tenant in a manner reasonably approved by Landlord. Landlord shall not be responsible or liable for any interruption in such services, nor shall any such interruption affect the continuation or validity of, or constitute a Landlord default under, this Lease. Notwithstanding anything contained herein to the contrary, if any interruption of services or utilities to the Premises

occurs as a result of the gross negligence or willful misconduct of Landlord or its employees, agents or contractors, and continues beyond five (5) business days from the date of such interruption and renders all or a material portion of the Premises untenantable (meaning that Tenant is unable to use, and does not use, such space in the normal course of its business for Tenant's Use), then Tenant shall notify Landlord in writing that Tenant intends to abate Rent. If such service or utility has not been restored within two (2) business days of Landlord's receipt of Tenant's notice, then Rent shall abate proportionately with respect to the portion of the Premises rendered untenantable on a per diem basis for each day after such two (2) business-day period during which such portion of the Premises remains untenantable.

(b) If because of Tenant's density, use, equipment or other Tenant circumstances, Tenant's consumption of any utility or other service included as part of Operating Expenses or demands on the Building Systems are excessive when compared with other occupants of the Property, or are in excess of those of a typical user of office space in the Building, or in buildings in the East Whiteland Township area, or cause extraordinary maintenance and repair issues beyond those customarily and routinely incurred by Landlord to operate the Building Systems, Landlord may adjust the Annual Operating Expenses due from Tenant from time to time or may install supplemental equipment and meters at Tenant's expense, and may invoice Tenant separately for, and Tenant shall pay on demand, the cost of Tenant's excessive consumption or use, or such additional equipment, as reasonably determined by Landlord. Landlord shall have the option, at any time during the Term or any extension thereof, to exclude any utility service from Operating Expenses, in which case, Landlord may either: (i) provide any such services and invoice Tenant for the cost; or (ii) require Tenant to obtain service in its own name and timely pay all charges directly to the provider.

(c) Landlord will furnish the following services for the normal use and occupancy of the Premises for Tenant's Use, the costs of which are included as part of Operating Expenses: (i) electric and gas service and power for the Common Areas; (ii) water for the Premises, (iii) sanitary-sewer for the Premises, (iv) trash removal and janitorial services pursuant to the cleaning schedule attached hereto and made a part hereof as **Exhibit "D"**, (v) HVAC, and (v) such other services Landlord reasonably determines are appropriate or necessary, all in a manner comparable to that of similar buildings in the area. If Tenant requests, and if Landlord is able to furnish services in addition to those identified above, Tenant shall pay Landlord's reasonable charge with Landlord's standard administrative fee for such supplemental services. Tenant acknowledges that Landlord has no obligation to provide any additional services in or about the Premises or the Building, its Parking Area or access areas, or in or about the Land.

(d) Landlord shall provide Tenant with keys to unlock exterior doors for entry into the Building. Other than such exterior locks, Landlord shall have no obligation to provide surveillance or security systems in or about the Premises or the Building, the Parking Area, or access areas, or in or about the Land, and Landlord shall have no liability and Tenant hereby waives all claims in connection with the decision whether or not to provide such services, or the failure of any security personnel, mechanical surveillance or other security or surveillance measures to prevent the occurrence of any theft, vandalism or any other criminal or like causes (or the failure to apprehend the perpetrators of such acts), whether provided by Tenant or Landlord. Tenant shall defend, indemnify, and hold Landlord, the Landlord Additional Insureds and their respective Agents harmless from any such claims made by any of Tenant's or Tenant's Agent's employee, licensee, invitee, contractor, agent or other person whose presence in, on or about the Premises or the Building is attendant to the business of Tenant. Tenant shall have the right, at its sole cost and expense and only after providing written notice to Landlord, to install, maintain, operate, repair, update and replace its own security system on the Premises, including without limitation, card access readers for entry into the Premises, and interior and exterior cameras (collectively, the "**Security System**"), subject to Landlord's approval of the location and installation methods of such Security System, not to be unreasonably withheld or delayed. Any such installation of Tenant's Security System shall be an Alteration and shall be subject to all applicable provisions of Section 12 and Section 13 of this Lease. Tenant shall provide to Landlord cards compatible with the card access readers, keys or combinations, as the case may be, to permit Landlord to access all parts of the Premises, subject to the terms of this Lease. Subject to the final sentence of this Section 7(d), the Security System shall remain the personal property of Tenant and Tenant shall be required remove the Security System prior to the expiration or earlier termination of this Lease. Removal shall be performed in a manner which will not impair the integrity of, damage or adversely affect the Property, and Tenant shall immediately repair any resulting damage and restore the Property to the condition it was found prior to the installation of the Security System, and otherwise in accordance with reasonable procedures established by Landlord. If Tenant fails to remove the Security System within ten (10) days after the expiration date or

earlier termination of this Lease, then in addition to Landlord's other remedies, Landlord may deem the Security System abandoned by Tenant, at which time the Security System shall, at Landlord's sole discretion, become the exclusive property of Landlord, and Landlord may take any action or no action with respect to such Security System including, without limitation, using or removing such Security System, and if it elects to remove the Security System, repair any resulting damage and restore the Property to the condition it was found prior to the installation of the Security System, all at Tenant's sole cost and expense, all in accordance with the terms of Section 21(a) below. Notwithstanding the foregoing, any time prior to the expiration or earlier termination of this Lease, Landlord may request that Tenant leave the Security System, in good working order, on the Property at the expiration or earlier termination of this Lease, which request may be granted by Tenant in its sole discretion, and if Tenant agrees to such request, the Security System shall become the sole and exclusive property of Landlord without any payment to Tenant.

(e) Tenant, at Tenant's sole cost and expense, shall have the right to install a generator to exclusively service the Premises, together with one generator pad and a sound attenuation house (not to exceed forty-five (45) contiguous useable square feet of ground area and twelve (12) feet in height), reasonably necessary for Tenant's business operations in the Premises for emergency, electrical back-up purposes, including one above-ground diesel fuel tank, a conduit (no greater than six inches (6") in diameter) and wires running within the said conduit to connect the generator to Tenant's equipment in the Building and the Building Systems, to the extent required, a muffler with a sound/noise level not to exceed sixty (60) decibels of a distance of not more than twenty (20) feet from the equipment (the sixty (60) decibels maximum sound level applies to all equipment noise, including HVAC), and all related equipment and apparatus (the "**Generator**"), strictly under and subject to the following conditions:

(i) Before beginning the installation of the Generator, which Tenant shall perform in a good and workmanlike manner and in compliance with the following standards, Tenant shall first obtain Landlord's written approval, not to be unreasonably withheld or delayed, and in connection therewith Tenant shall provide to Landlord final plans and specifications prepared by an engineer reasonably approved by Landlord and setting forth in detail the design, location, size, method of installation, screening and all related equipment and apparatus for Landlord's review and written approval, together with evidence reasonably satisfactory to Landlord that all Laws and industry standards have been satisfied. Landlord's approval shall not constitute a representation or warranty by Landlord that Tenant's plans and specifications comply with any Laws or industry standards as such compliance shall be the sole responsibility of Tenant. Landlord, at Landlord's sole and reasonable discretion, shall determine the type of screening required to be maintained around the Generator and the places and method of penetrating the exterior of the Building to connect the Generator to the Premises, at Tenant's sole cost and expense;

(ii) At least three (3) business days prior to the Generator installation, Tenant shall notify Landlord of the date and time of the installation and such installation shall be fully coordinated with Landlord. Such installation shall not damage the Building or materially interfere with the use of any portion of the Building during the hours of 8:00 a.m. to 6:00 p.m. Monday through Friday (legal holidays excepted) ("**Normal Business Hours**") while such installation is taking place;

(iii) Tenant shall have the obligation to perform and shall pay all costs and expenses in connection with, arising out of, or related to the Generator including without limitation the installation, use, operation, insurance, maintenance, repair, tangible personal property taxes, and, to the extent necessary and appropriate, replacement, as may be needed to keep the Generator in a safe, good, orderly condition and repair. In connection with the Generator, Tenant shall reimburse Landlord for the actual reasonable third party costs and expenses of Landlord's consultants, architects, engineers, contractors and attorneys within thirty (30) days of receipt of an invoice with respect thereto;

(iv) Tenant shall properly fuel and immediately notify Landlord verbally and in writing and remove from the area and otherwise remediate any spills or other leaks of fluid from the Generator or otherwise connected therewith and shall otherwise comply with all Environmental Laws (as defined hereunder), industry standards and the Building Rules, as reasonably imposed by Landlord. All testing of the Generator shall be performed after Normal Business Hours and in accordance with a schedule to be submitted in advance to and approved in writing by Landlord. Landlord shall have the right, during the Term, to relocate the Generator, at Landlord's sole cost and expense. Landlord shall have the right, during the Term, to require Tenant to modify the Generator sound attenuation housing

and exhaust system if, in Landlord's sole and absolute discretion, noise or exhaust fumes are interfering with other tenants and occupants in the Building or the Property;

(v) Subject to the final sentence of this Section 7(e)(v), the Generator shall remain the personal property of Tenant and Tenant shall be required remove the Generator prior to the expiration or earlier termination of this Lease. Removal shall be performed in a manner which will not impair the integrity of, damage or adversely affect the Property, and Tenant shall immediately repair any resulting damage and restore the Property to the condition it was found prior to the installation of the Generator, and otherwise in accordance with reasonable procedures established by Landlord. If Tenant fails to remove the Generator within ten (10) days after the expiration date or earlier termination of this Lease, then in addition to Landlord's other remedies, Landlord may deem the Generator abandoned by Tenant, at which time the Generator shall, at Landlord's sole discretion, become the exclusive property of Landlord, and Landlord may take any action or no action with respect to such Generator including, without limitation, using or removing such Generator, and if it elects to remove the Generator, repair any resulting damage and restore the Property to the condition it was found prior to the installation of the Generator, all at Tenant's sole cost and expense, all in accordance with the terms of Section 21(a) below. Notwithstanding the foregoing, any time prior to the expiration or earlier termination of this Lease, Landlord may request that Tenant leave the Generator on the Property at the expiration or earlier termination of this Lease, which request may be granted by Tenant in its sole discretion, and if Tenant agrees to such request, the Generator shall become the sole and exclusive property of Landlord without any payment to Tenant; and,

(vi) All applicable terms and conditions of this Lease shall apply to the Generator. The obligations of Tenant under this Section 7(e) shall survive the expiration or earlier termination of this Lease.

8. Insurance; Waivers; Indemnification.

(a) Landlord will at all times during the Term carry a policy of insurance which insures the Building, including the Premises, if any, against loss or damage by fire or other casualty (namely, the perils against which insurance is afforded by a standard fire insurance policy); provided, however, that Landlord will not be responsible for, and will not be obligated to insure against, any loss of or damage to any personal property or trade fixtures of Tenant or any alterations which Tenant may make to the Premises or any loss suffered by Tenant due to business interruption. All insurance maintained by Landlord pursuant to this Section 8 may be effected by blanket insurance policies.

(b) Prior to Tenant's entry onto the Premises, Tenant will obtain and have and thereafter keep in full force and effect at all times until the expiration of the Term of this Lease, insurance coverage as follows:

(i) Comprehensive general liability insurance policy on an ISO CG 00 01 form, on an occurrence basis, providing coverage for claims for bodily injury, personal injury and property damage occurring on, in or about the Premises with a per occurrence/per offense limit of at least Three Million and 00/100 Dollars ($3,000,000.00) with no deductible or self-insured retention unless specifically approved by Landlord. Defense costs shall be in addition to the policy limits. Such insurance shall provide coverage for all of Tenant's operations and shall include contractual liability coverage, including coverage applicable to the Tenant's indemnity requirements herein, and shall include an endorsement naming Landlord, Workspace Property Management, L.P., Workspace Property Trust, L.P. and each of their respective directors, officers, shareholders, members, employees, associated and affiliated entities, ground lessors, any Mortgagees(s) (as defined hereunder), and any other party as designated by Landlord (hereinafter "**Landlord Additional Insureds**") as additional insureds on a primary and non-contributory basis for all liability, claims, costs, damages, and expenses arising out or resulting from Tenant's acts, omissions, operations, occupancy, use, control, and/or tenancy of the Premises. This insurance may be effected by a combination of a primary general liability policy and an excess liability policy provided the limit of the primary general liability policy is not less than One Million and 00/100 Dollars ($1,000,000.00) per occurrence and the excess liability policy follows form. Any aggregate under the policy(ies) shall apply separately to the Premises. Such policy(ies) shall include a severability of interest condition or clause providing coverage to each insured as if such insured was the only insured under the policy.

(ii) Workers' compensation insurance in statutory amounts and in accordance with the laws of the Commonwealth of Pennsylvania and employers' liability insurance with limits not less than Five Hundred Thousand

and 00/100 Dollars ($500,000.00) bodily injury by accident and bodily injury by disease. Such insurance shall cover all individuals employed at or retained on behalf of Tenant with respect to the Premises. Such insurance shall include a waiver of subrogation against Landlord and the Landlord Additional Insureds.

(iii) All risk or "special form" property insurance upon property of every description and kind owned by Tenant and/or under Tenant's care, custody or control and/or for which Tenant is responsible located at the Premises or for which Tenant is legally liable or installed by or on behalf of Tenant. Such insurance shall be in an amount equal to the full replacement cost thereof. Such policy shall also include coverage for business interruption and extra expense in an amount and with coverage adequate to indemnify Tenant for its loss of business and costs of operations for a period of at least twelve (12) months. The deductible under such policy shall not exceed Five Thousand and 00/100 Dollars ($5,000.00) unless specifically approved by Landlord.

(iv) Insurance for such other hazards and in such amounts as Landlord may reasonably require and as at the time are commonly insured against with respect to property similar in character, general location and use and occupancy to the Premises or as required by any Mortgagee in amounts reasonably determined by Landlord. If, by reason of changed economic conditions, the insurance amounts referred to in this Section 8(b) become inadequate, Tenant agrees to increase the amounts of such insurance promptly upon Landlord's reasonable request. If the forms of policies, endorsements, certificates, or evidence of insurance required by this Section 8(b) are superseded or discontinued, Landlord may require other equivalent or better forms.

All of Tenant's insurance policies shall be issued by insurers authorized to issue such insurance, licensed to do business and admitted in the state in which the Property is located and rated at least A-VIII in the most current edition of *Best's Insurance Reports,* shall be in a form and with terms and conditions reasonably acceptable to Landlord, shall include a waiver of subrogation against Landlord and the Landlord Additional Insureds, to the extent permitted by Law, and shall provide an undertaking by the insurers to provide (or if the carriers are unwilling or unable to provide such notice, Tenant or Tenant's insurance broker shall provide) at least thirty (30) days prior written notice to Landlord and Landlord's Mortgagee prior to any material change, reduction in coverage required hereunder, or cancellation of any of the insurance policies required herein (ten (10) days in the event of non-payment of premium). Tenant shall deliver to Landlord, within five (5) days after the date of this Lease or any earlier date on which Tenant accesses the Premises, and at least five (5) days prior to the date of each policy renewal, a certificate of insurance, in a form reasonably acceptable to Landlord, evidencing such coverage and including all policy forms and endorsements requested by Landlord. Tenant shall provide complete copies of its insurance policies to Landlord within fifteen (15) days of Landlord's request. It is understood and agreed that Tenant's insurance policies shall be primary to any separate coverage carried by Landlord or any Landlord Additional Insured. Any other insurance carried by Landlord and the Landlord Additional Insureds shall be excess of and non-contributory with Tenant's insurance. The minimum limits of Tenant's liability insurance and other requirements designated in this Section 8 shall in no way limit or diminish Tenant's liability including Tenant's indemnification obligations under this Lease. Further, in the event Tenant maintains insurance with limits greater than those required herein, the limits required herein shall be deemed amended to be such higher limit and Landlord and the Landlord Additional Insureds shall be entitled to the benefit of such higher limit and coverage to the fullest extent of such insurance. Acceptance by Landlord of delivery of any certificates of insurance does not constitute approval or agreement by Landlord that the insurance requirements in this Section 8(b) have been met, and failure of Landlord to demand such evidence of full compliance with these insurance requirements or failure of Landlord to identify a deficiency from certificates or evidence provided will not be construed as a waiver of Tenant's obligation to maintain such insurance.

Tenant's insurance obligations set forth herein shall continue in effect throughout the Term and after the Term as long as Tenant, or anyone claiming by, through or under Tenant, occupies all or any part of the Premises.

(c) Tenant will not do or allow anything to be done on the Premises which will increase the rate of insurance on the Building from that of a general office/flex building. If any use of the Premises by Tenant results in an increase in the insurance rate(s) for the Building, Tenant will pay Landlord, as additional Rent, within thirty (30) days after being billed, any resulting increase in premiums irrespective of whether Landlord shall have consented to Tenant's act. If Tenant installs, or causes the installation of, any electrical equipment which overloads the electrical lines, Tenant shall, at its own expense, make all changes to its Premises and install any fire extinguishing equipment and/or other safeguards that Landlord's insurance underwriters or applicable fire, safety and building codes and

regulations may require. Nothing herein contained shall be deemed to constitute Landlord's consent to such overloading.

(d) Tenant shall not be permitted to satisfy any of its insurance obligations set forth in this Lease through any self-insurance or self-insured retention, unless expressly consented to by Landlord in writing, which consent may be granted or withheld in Landlord's sole discretion.

(e) Tenant shall waive, and release Landlord and the Landlord Additional Insureds for any loss or damage to property, and any resulting loss of use of such property, arising out of fire or other casualty coverable by a standard "Causes of Loss-Special Form" property insurance policy with such endorsements and additional coverages as are considered good business practice in Tenant's business, even if such loss or damage shall be brought about by the fault or negligence of Landlord or any of the Landlord Additional Insured or their respective Agents. Landlord shall waive and release Tenant for any loss or damage to its property arising out of fire or other casualty coverable by a standard "Causes of Loss-Special Form" property insurance policy; provided, however, such waiver by Landlord shall not be effective with respect to Tenant's liability described in Section 9(b) and Section 10(d) hereof nor shall it apply with respect to loss, damage, cost or expense arising out of or resulting from Tenant's operations or activities at the Premises. This waiver and release is effective regardless of whether the releasing party actually maintains the insurance described above in this Section 8(e) and is not limited to the amount of insurance actually carried, or to the actual proceeds received after a loss. Each party shall have its insurance company that issues its property coverage waive any rights of subrogation and shall have the insurance company include an endorsement acknowledging this waiver, if necessary. Tenant assumes all risk of damage of Tenant's property within or at the Property and any resulting loss of use or business interruption, including, but not limited to, any loss or damage caused by water leakage, fire, windstorm, explosion, theft, act of any other tenant, or other cause. Landlord and Tenant acknowledge that the insurance requirements of this Lease reflect their mutual recognition and agreement that each party will look to its own insurance and that each can best insure against loss to its property and business no matter what the cause.

(f) Subject to Section 8(e) above, and except to the extent caused by the gross negligence or willful misconduct of Landlord, any of the Landlord Additional Insureds or their Agents, Tenant will indemnify, defend, and hold harmless Landlord, the Landlord Additional Insureds and their Agents from and against any and all claims, actions, damages, proceedings, costs, liability and expense (including reasonable fees of attorneys, investigators and experts) which may be asserted by any of Tenant's customers, guests, visitors, clients, patrons, invitees or any other third-party against, imposed upon, or incurred by Landlord, any of the Landlord Additional Insureds or their Agents and arising out of or in connection with loss of life, personal injury, damages, or property damage in or about the Premises or arising out of the occupancy or use of the Property by Tenant or its Agents, whether in contract or tort, occasioned wholly or in part by any act or omission of Tenant or its Agents, and whether prior to, during or after the Term. Tenant's obligations pursuant to this Section 8(f) shall survive the expiration or termination of this Lease. In case any action or proceeding be brought against Landlord, any of the Landlord Additional Insureds or their Agents by reason of any such claim, Tenant, upon notice from Landlord, any of the Landlord Additional Insureds or their Agents, will, at Tenant's expense, resist and defend such action or proceeding with counsel reasonably acceptable to Landlord, such Landlord Additional Insureds and their Agents.

9. Maintenance and Repairs.

(a) Landlord shall Maintain the Building footings, foundation, structural steel columns and girders (the "**Building Structure**") at Landlord's sole cost and expense. Subject to reimbursement as an Operating Expense, Landlord shall Maintain: (i) the exterior utility lines and facilities to the point of connection to/distribution within the Building (unless maintained by the applicable utility company); (ii) the Building (including the roof but excluding the Building Structure), including the Premises (except to the extent of Tenant's obligations set forth in Section 9(b) hereof); (iii) the Building Systems; (iv) the Common Areas; and, (v) any other improvements owned by Landlord located on the Property. If Tenant becomes aware of any condition that is Landlord's responsibility to repair, replace or maintain, Tenant shall promptly notify Landlord of such condition. Moreover, regardless of who bears responsibility for any repair, replacement or maintenance, Tenant shall immediately notify Landlord if Tenant becomes aware of any areas of water intrusion or mold growth in or about the Premises. The cost of repairs to the Common Areas will be included as an Operating Expense, except where the repair has been made necessary by misuse or neglect by Tenant or Tenant's Agents, in which event Landlord will nevertheless make the repair but Tenant will

pay to Landlord, as additional Rent, upon demand, the cost incurred by Landlord to complete such repairs. "**Maintain**" means to provide such maintenance, repair and, to the extent necessary and appropriate, replacement, as may be needed to keep the subject property in good working order or condition. Maintenance also includes utilizing such building-performance assessment tools and energy-optimizing practices that Landlord in its discretion reasonably deems necessary and appropriate for planning, designing, installing, testing, operating and maintaining the Building Systems and Common Areas in an energy efficient manner and providing a safe and comfortable work environment, with a view toward achieving improved overall Building performance and minimizing the Building's impact on the environment. "**Building Systems**" means any electrical, mechanical, structural, plumbing, HVAC, sprinkler, life safety or Building access systems, if any, serving the Building and the Premises. Landlord shall deliver the Building Systems serving the Premises in good working order on each of the Initial Premises Commencement Date and/or the Expansion Premises Commencement Date, as applicable.

(b) Except as provided in Section 9(a) above, Tenant, at its sole cost and expense, shall Maintain the Premises and all fixtures and equipment in the Premises. Tenant, at its sole cost and expense, shall keep the Premises in a neat and orderly condition. Alterations, repairs and replacements to the Property, including the Premises, made necessary because of Tenant's Alterations or installations, any use or circumstances special or particular to Tenant, or any act or omission of Tenant or its Agents shall be made at the sole cost and expense of Tenant to the extent not covered by any applicable insurance proceeds paid to Landlord.

(c) Notwithstanding anything to the contrary contained herein, if Landlord decides an HVAC unit requires replacement, in its sole discretion, Landlord agrees to install, subject to Tenant's reimbursement as set forth below, replacements of any existing HVAC units on the Effective Date servicing the Premises which are no longer usable. Each replacement HVAC unit shall be paid for by Landlord, who shall be reimbursed by Tenant on the basis of an amortization of the full cost of each such replacement HVAC over a seven (7) year period on a straight line basis. Tenant shall make such reimbursement payments to Landlord on a monthly basis, as an Operating Expense, in accordance with the amortization as aforesaid. Tenant's reimbursement obligation set forth herein shall exist during the Term and any extension or renewal thereof. By way of illustration only, if a replacement HVAC unit is installed thirty-six (36) months prior to the expiration of the Term or any extension or renewal thereof, Tenant's reimbursement obligation shall only occur for the first thirty-six (36) months of the seven (7) year amortization period. Notwithstanding the foregoing, under no circumstances will Landlord be responsible for the replacement, installation or cost of any supplemental HVAC units or any HVAC units installed by Tenant during the Term or any extension or renewal thereof.

10. Compliance.

(a) Tenant will, at its sole cost and expense, promptly comply with all Laws now or subsequently pertaining to Tenant's use or occupancy of the Premises including, without limitation, those relating to ADA (as defined below) and any other Laws regarding accessibility, with respect to the Premises. Tenant will pay any taxes or other charges that may now or hereafter be applied or charged on or against Tenant's property or trade fixtures or relating to Tenant's use of the Premises. Neither Tenant nor its Agents shall use the Premises in any manner that under any Law would require Landlord to make any alteration to or in the Building or Common Areas (without limiting the foregoing, Tenant shall not use the Premises in any manner that would cause the Premises or the Property to be deemed a "place of public accommodation" under the ADA if such use would require any such Alteration). Landlord shall be responsible for compliance with the ADA, and any other Laws regarding accessibility, with respect to the Common Areas and the Building. Tenant shall be responsible for compliance with the ADA, and any other Laws regarding accessibility with respect to the Premises. Notwithstanding anything to the contrary contained in this Lease, Tenant shall not be required to make any Alterations or changes to the Premises, Building or Property to comply with such Laws unless caused by Tenant's act or failure to act as required hereunder, and any such required Alterations or changes shall be performed by or on behalf of Landlord, at Tenant's sole cost and expense. "**ADA**" means the Americans with Disabilities Act of 1990 (42 U.S.C. § 1201 et seq.), as amended and supplemented from time to time and all other federal, state and municipal laws relating to access. As used herein, "**Law**" or "**Laws**" means any and all present or future federal, state, municipal, county and other local laws, statutes, ordinances, rules, orders, regulations, directives, subdivisions, guidelines, common law, and any and all governmental, quasi-governmental, judicial or administrative orders, directives, decrees, judgments, injunctions, and agreements, and any and all other requirements of federal, state or local governmental authorities, bureaus, agencies, or offices having jurisdiction over the Property, or of any private association or contained in any restrictive covenants or other declarations or

agreements, now or subsequently pertaining to the Property or the use and occupation of the Property including, without limitation, Tenant's Use.

(b) Tenant will comply, and will cause its Agents to comply, with the Building Rules. Landlord may adopt, and Tenant shall comply with, reasonable rules and regulations to promote energy efficiency, sustainability and environmental standards for the Property, as the same may be changed from time to time upon reasonable notice to Tenant.

(c) Tenant agrees that (i) no activity will be conducted on the Premises that will use or produce any Hazardous Materials (as defined hereunder), except for activities which are part of the ordinary course of Tenant's business and are conducted in accordance with all Environmental Laws (as provided herein) ("**Permitted Activities**"); (ii) the Premises will not be used for storage of any Hazardous Materials, except for materials used in the Permitted Activities which are properly stored in a manner and location complying with all Environmental Laws; (iii) no portion of the Premises or Property will be used by Tenant or Tenant's Agents for the disposal of Hazardous Materials; (iv) Tenant will deliver to Landlord copies of all Material Safety Data Sheets and other written information prepared by manufacturers, importers or suppliers of any chemical; (v) Tenant will immediately notify Landlord of any violation by Tenant or Tenant's Agents of any Environmental Laws or the release or suspected release of Hazardous Materials in, under or about the Premises or the Property, and Tenant shall immediately deliver to Landlord a copy of any notice, filing or permit sent or received by Tenant with respect to the foregoing; and (vi) Tenant will cooperate with Landlord, any Mortgagee or any purchaser of the Property in their environmental assessments of the Property, including without limitation, participation in interviews regarding the uses and environmental conditions at or affecting the Property, and providing reasonable access to the Premises. "**Environmental Laws**" means all present or future federal, state or local laws, ordinances, rules or regulations (including the rules and regulations of the federal Environmental Protection Agency and comparable state agency) relating to the protection of human health or the environment. "**Hazardous Materials**" means pollutants, contaminants, toxic or hazardous wastes or other materials the removal of which is required or the use of which is regulated, restricted, or prohibited by any Environmental Law. If at any time during or after the Term, any portion of the Property is found to be contaminated by Tenant or Tenant's Agents or subject to conditions prohibited in this Lease caused by Tenant or Tenant's Agents, Tenant will indemnify, defend and hold Landlord, the Landlord Additional Insureds and their respective Agents harmless from all claims, demands, actions, liabilities, costs, expenses, attorneys' fees, damages and obligations of any nature arising from or as a result thereof, and Landlord shall have the right to direct remediation activities, all of which shall be performed at Tenant's cost. Tenant's obligations pursuant to this Section 10(c) shall survive the expiration or earlier termination of this Lease. Notwithstanding anything contained in this Section 10(c) to the contrary, Tenant shall have no liability under this Section 10(c) with respect to Hazardous Materials existing or generated, at, in, on, under or in connection with the Premises (a) prior to the Initial Premises Commencement Date or Expansion Premises Commencement Date, as applicable, or (b) resulting solely from the acts or omissions of Landlord or its agents, employees, contractors or invitees during the Term, and in no event shall any costs, expenses, attorneys' fees, or other monetary obligations of any nature arising from or as a result thereof be included as part of Tenant's Share of Operating Expenses, provided, however, Tenant shall be liable for, and responsible for the costs resulting from, any exacerbation of such conditions or Hazardous Materials. Landlord represents to Tenant that, as of the Effective Date, Landlord has received no written notice from any governmental agency having jurisdiction over the Premises that any Hazardous Materials exist in the Premises in violation of any Environmental Laws in, on or under the Premises, the Building or the Common Areas.

(d) Tenant shall be responsible for controlling and managing its employees, customers, patrons, visitors, invitees and guests' access to the Premises, at Tenant's sole cost and expense.

11. **Signs**. Landlord will furnish and install, at its sole cost and expense, Tenant Building standard vinyl identification signage on or beside the main entrance door to both the Initial Premises and the Expansion Premises and on Landlord's existing monument sign located on the Property, all in accordance with Landlord's standard graphics program for the Building and in accordance with all applicable Laws and regulations including, without limitation, the requirements of East Whiteland Township. Except as expressly permitted in this Section 11, Tenant shall not place any signs, graphics, notice, picture, placard or poster, or any advertising matter whatsoever on the exterior of the Premises, Building, or the Property, or make or permit any changes in or to Tenant's signage, without the prior written consent of Landlord, in its sole discretion, other than signs that are located wholly within the interior of the Premises

and not visible from the exterior of the Premises. Landlord shall have the right to install and maintain signs on the exterior and interior of the Building. Tenant shall maintain all signs installed by Tenant in good condition. Tenant shall remove its signs at the termination of this Lease, shall repair any resulting damage, and shall restore the Premises and/or the Property to its condition existing prior to the installation of Tenant's signs. Tenant will not have the right to have additional names placed on the Building monument sign without Landlord's prior written consent, in its sole discretion. Tenant shall bear the cost of any additional names placed on the Building monument sign approved by Landlord or any changes required to any existing sign due to a name change by Tenant. In the event that Tenant desires to change its name on the Building monument sign or on any sign, Tenant shall provide an explanation to Landlord of the circumstances prompting the need for such name change. If any sign for which this Lease requires Landlord's approval has not been approved by Landlord is displayed, then Landlord shall, upon reasonable prior notice to Tenant, have the right to remove such sign at Tenant's sole cost and expense or to require Tenant to do the same. Tenant expressly acknowledges and agrees that the location of the panel on Landlord's existing monument sign shall not be guaranteed, and Landlord shall have the absolute right from time to time, in its sole discretion, to relocate the position of Tenant's sign panel on the monument sign.

12. Alterations.

(a) Except for non-structural Alterations that (i) do not exceed Ten Thousand and 00/100 Dollars ($10,000.00) in the aggregate, (ii) are not visible from the exterior of the Premises, (iii) do not affect any Building System, the roof, or the structural strength of the Building (iv) do not require penetrations into the floor, ceiling or walls, and (v) do not require work within the walls, below the floor or above the ceiling ("**Cosmetic Alterations**", which shall not require Landlord's consent), Tenant shall not make or permit any Alterations in or to the Premises without first obtaining Landlord's consent, which consent shall not be unreasonably withheld or delayed, and any such Alterations shall not affect the structural elements of the Building, the Common Areas or Building Systems, or would otherwise require a building permit. With respect to any Alterations made by or on behalf of Tenant (whether or not the Alteration requires Landlord's consent): (u) not less than ten (10) days prior to commencing any Alteration, Tenant shall deliver to Landlord for Landlord's review and approval the plans, specifications and necessary permits for the Alterations (the "**Alteration Plans**"), together with certificates evidencing that Tenant's contractors and subcontractors have adequate insurance coverage naming the Landlord Additional Insureds, as their interests may appear, as additional insureds; (v) Tenant shall obtain Landlord's prior written approval of any contractor or subcontractor which such approval shall not be unreasonably withheld, conditioned or delayed; (w) the Alteration shall be constructed with new materials, in a good and workmanlike manner, and in compliance with all Laws and the plans and specifications delivered to, and, if required above, approved by Landlord; (x) the Alteration shall be performed in accordance with Landlord's reasonable requirements relating to sustainability and energy efficiency; (y) Tenant shall pay Landlord all reasonable out-of-pocket costs and expenses in connection with Landlord's review of Tenant's plans and specifications, and of any supervision or inspection of the construction Landlord deems necessary; and (z) upon Landlord's request Tenant shall, prior to commencing any Alteration, provide Landlord reasonable security against liens arising out of such construction. "**Alteration(s)"** means any addition, alteration or improvement to the Premises or Property excluding Landlord's Work, and Tenant's FFE. Any Alteration by Tenant shall be the property of Tenant until the expiration or termination of this Lease; at that time without payment by Landlord the Alteration shall remain on the Property and become the property of Landlord unless Landlord, promptly after Tenant's written request, which request may be made at the time Tenant submits its Alteration Plans to Landlord for Landlord's review, gives notice to Tenant to remove any of such Alterations at the expiration of this Lease, in which event Tenant will remove them, will repair any resulting damage and will restore the Premises to the condition existing prior to Tenant's installation of such Alteration(s), all in accordance with the terms of Section 21(a) below. Notwithstanding anything to the contrary in this Lease or in any other writing signed by Landlord, neither this Lease nor any other writing signed by Landlord shall be construed as evidencing, indicating, or causing an appearance that any Alterations to be done, or caused to be done, by Tenant is or was in fact for the immediate use and benefit of Landlord.

(b) For any Alterations (other than Cosmetic Alterations), Tenant shall pay Landlord a construction supervision fee equal to five percent (5%) of Tenant's total hard construction costs. Landlord's review or approval of any Alterations or plans or specifications therefor shall not be a representation or warranty of Landlord that such Alterations, plans or specifications are fit for any use or comply with any Laws, and Tenant shall have no right to rely upon any review or approval. Landlord shall have no liability to Tenant or any third party by reason of such review or approval, and any such review and approval shall be for Landlord's own benefit.

(c) All workmen and mechanics performing any Alterations must work in harmony and not interfere with labor employed by Landlord, Landlord's contractors (including, without limitation, the Contractor) or labor employed by any other tenants or their contractors. If at any time during the course of the installation of any Alterations, any workmen or mechanics performing the Alterations are unable to work in harmony, or interfere, with labor employed by Landlord, Landlord's contractors (including, without limitation, the Contractor) or by any other tenants or their contractors, then the approval granted by Landlord to Tenant for the subject Alterations may be withdrawn by Landlord upon forty eight (48) hours' written notice to Tenant, and Tenant shall thereafter cause the Alterations to cease and shall, at Landlord's sole option, restore the Premises to the condition as existed prior to the commencement of such Alterations. Tenant shall indemnify, defend and hold Landlord, the Landlord Additional Insureds, and their respective Agents harmless from and against any claim, liability or other losses in any way arising from labor disharmony in connection with any Alterations or any other contractors or employees of Tenant, its subtenants, successors or assigns. Landlord reserves the right to require Tenant to use contractors designated by Landlord, in its sole discretion, for Alterations that are performed in secure areas of the Building or other portions of the Building outside of the Premises or which impact any Building Systems, provided the rates of such contractors are commercially market rates.

13. **Mechanics' Liens**. Except to the extent contracted for by Landlord, the interest of Landlord in the Premises and the Property shall not be subject in any way to any liens, including real estate commission liens and construction liens for improvements to or other work performed by or on behalf of Tenant. Tenant shall promptly pay for all labor, services, materials, supplies or equipment furnished to Tenant in or about the Premises. Tenant shall keep the Premises and the Property free from any liens arising out of any labor, services, materials, supplies or equipment furnished or alleged to have been furnished to Tenant. Tenant shall take all steps permitted by law in order to avoid the imposition of any such liens including a written provision in all construction contracts for suppliers of labor, services, materials and equipment, approved in writing by Landlord prior to execution, that this Lease prohibits mechanics/construction liens against the Premises and the Property. Should any such lien or notice of such lien be filed against the Premises or the Property, Tenant shall discharge the same by satisfying or bonding over such lien within fifteen (15) days after Tenant has notice that the lien or claim is filed regardless of the validity of such lien or claim. It is further understood and agreed that under no circumstance is the Tenant to be deemed the agent of Landlord for any Alteration, repair, or construction within the Premises, the same being done at the sole expense and request of Tenant and not as an express or implied agent of Landlord. All contractors, materialmen, suppliers, mechanics, and laborers are hereby charged with notice that they must look only to Tenant for the payment of any charge for work done or materials furnished upon the Premises in connection with any Alterations, repair or construction by Tenant within the Premises during the Term.

14. **Landlord's Rights**.

(a) Tenant shall permit Landlord and its Agents to enter the Premises at all reasonable times following reasonable notice (except in an emergency) to inspect, perform any work to Maintain, or make alterations to the Premises (other than alterations for subsequent tenants) or Property, to exhibit the Premises for the purpose of sale or financing, and, during the last twelve (12) months of the Term and any renewal thereof, to exhibit the Premises to any prospective tenant. Landlord will make reasonable efforts not to inconvenience Tenant or interfere with Tenant's business operations therein, in exercising its rights under this Section 14, but Landlord shall not be liable for any interference with Tenant's occupancy resulting from Landlord's entry. Tenant will provide Landlord or its designees free and unfettered access to any mechanical or utility rooms, conduits, risers or the like located within the Premises. Landlord, its lender, and any authorized representative or similar party, and any prospective tenant, shall have the right to enter the Premises at reasonable times and upon reasonable prior notice to perform inspections, surveys, measurements or such other reasonable activities as may be necessary to prepare the Premises for occupancy by the succeeding tenant. Tenant will have no claims, including claims for interruption of Tenant's business, or cause of action against Landlord by reason of entry for such purposes. Notwithstanding the foregoing, except in an emergency, neither Landlord nor its lender, authorized representative or similar party shall enter any "clean space" or R&D space within the Premises without Tenant's prior consent, which consent shall not be unreasonably withheld or delayed, and only then accompanied by a Tenant representative at all times, provided, however, Landlord shall not be required to reschedule any such scheduled entry if Tenant's representative becomes unavailable during such time.

(b) In addition to any other rights provided for herein, Landlord reserves the following rights, exercisable without liability to Tenant for damage or injury to property, person, or business and without effecting an eviction, constructive or actual, or disturbance of Tenant's use or possession or giving rise to any claim: (i) to name the Building and to change the name or street address of the Building or the roads leading to and from the Building or the Land; (ii) to relocate various facilities within the Building and on the Land, including, without limitation, lobby areas, mechanical areas, entrances or passageways, doors or doorways, corridors, elevators, stairs, toilets or other Common Areas; access to and from the Building; or the configuration of the Parking Area or other parking areas; (iii) to install vending machines of all kinds in the Building and to receive all of the revenue derived therefrom; (iv) when reasonably necessary to temporarily close the Parking Area or any part thereof, walkways, drives, entrances, doors, corridors, elevators or other facilities, provided alternate parking areas, driveways and entrances are provided, to the extent necessary; (v) to subdivide the Property; (vi) to subject all or any part of the Property to a condominium regime; (vii) to pursue, or allow any tenant or prospective Property purchaser to pursue, any variance or other zoning relief which Landlord shall, in its good faith judgment, determine to be advisable; (viii) to unilaterally alter Tenant's ingress and egress to the Building or make any change in operating conditions to restrict pedestrian, vehicular or delivery ingress and egress to a particular location, or at any time close temporarily any Common Areas to make repairs or changes therein or to effect construction, repairs or changes within the Building or on the Land on which the Building is located, or to discourage non-tenant parking, and may do such other acts in and to the Common Areas as in Landlord's sole judgment may be desirable to improve their convenience; (ix) to use and/or allow others to use the roof of the Building or any portion of the Land on which the Building is located; (x) to limit the space on the directory of the Building to be allotted to Tenant; and, (xi) to grant to anyone the right to conduct any particular business or undertaking in the Building; provided, however, that Landlord's rights under this Section 14(b) shall not adversely affect Tenant's access to or use of the Premises for Tenant's Use in any material way.

(c) No rights, easements or licenses are acquired in the Property or any land adjacent to the Property by Tenant by implication or otherwise except as expressly set forth in this Lease. Any diminution or shutting off of light air or view by any structure which may be erected on lands adjacent to the Building shall in no way affect this Lease or impose any liability on Landlord.

(d) If Tenant breaches any covenant or condition of this Lease beyond applicable notice and cure periods, in addition to all other remedies available to Landlord under this Lease, Landlord may, on prior notice to Tenant (except that no notice need be given in case of emergency), cure such breach at the expense of Tenant, and the reasonable amount of all expenses, including attorney's fees, incurred by Landlord in so doing (whether paid by Landlord or not) will be deemed payable on demand as additional Rent.

(e) As additional security for the faithful performance and observance by Tenant of all of the terms, provisions and conditions of this Lease, Tenant hereby grants to and creates on behalf of Landlord a security interest in all of Tenant's FFE, decorations, Alterations, machinery, installations, additions and improvement in and to the Premises. Accordingly, this Lease constitutes a security agreement under the Pennsylvania Uniform Commercial Code. The security interest herein granted, and any security interest of Landlord granted by statute shall be subordinate, solely as to FFE and other personalty, to any purchase money security interest given by Tenant in connection with the financing of the purchase of the item of personalty in question. Tenant agrees from time to time to execute and deliver such security agreements and financing statements as Landlord shall reasonably require to evidence and/or perfect the lien of the security interest granted herein, within ten (10) days after Landlord's request therefor. Upon the occurrence of an Event of Default (as defined hereunder), Landlord may, at its option, foreclose on said security and apply the proceeds of the sale of the property covered thereby for the payment of all Rent due under this Lease or any other sum owed by Tenant under the terms of Section 22 below including, but not limited to, any damages or deficiencies resulting from any reletting of the Premises, whether said damage or deficiency accrued before or after summary proceedings or other re-entry by Landlord. Tenant covenants that it shall keep and maintain all FFE and other personalty at the Premises, whether or not the property of Tenant, in good, substantial and efficient operating condition (including replacement of same when necessary) at Tenant's sole cost and expense, at all times during the Term of this Lease. Upon Tenant's request, Landlord shall execute a lien subordination agreement concerning any purchase money security interest given by Tenant in connection with the financing of the purchase of Tenant's FFE and other personalty in favor of any lender to Tenant (a "**Lien Subordination Agreement**"), and Tenant acknowledges that Landlord will incur costs in connection with the review and negotiation of such Lien Subordination Agreement. Accordingly, Tenant shall promptly pay to Landlord the amount of all costs (including, without

limitation, Landlord's reasonable attorney's fees) actually incurred by Landlord in connection with any Lien Subordination Agreement. Without limiting the generality of the foregoing, Tenant shall pay such amount even in the event that the proposed Lien Subordination Agreement is not effectuated. Tenant understands, certifies and agrees Landlord will not execute any waiver of liens in connection with any Tenant financing.

(f) In the event Tenant requests Landlord to enter into an access agreement with a telecommunications or other data service provider, Tenant acknowledges that Landlord will incur costs in connection with the review and negotiation of such agreement. Accordingly, Tenant shall promptly pay to Landlord the amount of all reasonable out-of-pocket costs (including, without limitation, Landlord's reasonable attorney's fees) actually incurred by Landlord in connection with any such telecommunications or other data service provider access agreement. Without limiting the generality of the foregoing, Tenant shall pay such amount even in the event that the proposed agreement is not effectuated.

15. **Damage by Fire or Other Casualty**. If the Premises or Common Areas shall be damaged or destroyed by fire or other casualty, Tenant shall promptly notify Landlord, and Landlord, subject to the conditions set forth in this Section 15, shall repair such damage and restore the Premises or Common Areas to substantially the same condition in which they were immediately prior to such damage or destruction (including Landlord's Work), but not including the repair, restoration or replacement of any FFE or any Alterations installed by or on behalf of Tenant. Landlord shall notify Tenant, within thirty (30) days after the date of the casualty, if Landlord anticipates that the restoration will take more than one hundred eighty (180) days from the date of the casualty to complete; in such event, either Landlord or Tenant (unless the damage was intentionally caused by Tenant) may terminate this Lease effective as of the date of casualty by giving notice to the other within ten (10) days after Landlord's notice or, if neither party terminates this Lease as aforementioned, and such restoration is not completed within such two hundred seventy (270) day period, then Tenant may terminate this Lease upon thirty (30) days' written notice to Landlord at any time prior to the completion. If a casualty occurs during the last twelve (12) months of the Term, either party may terminate this Lease unless Tenant has the right to extend the Term for at least three (3) more years and does so within thirty (30) days after the date of the casualty. Moreover, Landlord may terminate this Lease if the loss is not covered by the insurance required to be maintained by Landlord under this Lease or if any holder of a Mortgage on the Land or Building does not permit or release insurance proceeds for such repair or restoration. Tenant will receive a proportionate abatement of Minimum Annual Rent and Annual Operating Expenses to the extent all or a portion of the Premises is rendered untenantable as a result of any such casualty.

16. **Condemnation**. If (a) all of the Premises are Taken (as defined hereunder), (b) any part of the Premises is Taken and the remainder is insufficient in Landlord's opinion for the reasonable operation of Tenant's business, or (c) any of the Property is Taken, and, in Landlord's opinion, it would be impractical or the condemnation proceeds are insufficient to restore the remainder, then this Lease shall terminate as of the date the condemning authority takes possession. If this Lease is not terminated, to the extent that proceeds are paid to Landlord and made available by the holder of a Mortgage on the Land or the Building, Landlord shall restore the Building to a condition as near as reasonably possible to the condition prior to the Taking, the Minimum Annual Rent shall be abated for the period of time all or a part of the Premises is untenantable in proportion to the square foot area untenantable, and this Lease shall be amended appropriately including, without limitation, the proportionate reduction of Tenant's Share. The compensation awarded for a Taking shall belong to Landlord. Except for any relocation benefits to which Tenant may be entitled, Tenant hereby assigns all claims against the condemning authority to Landlord, including, but not limited to, any claim relating to Tenant's leasehold estate. "**Taken**" or "**Taking**" means acquisition by a public authority having the power of eminent domain by condemnation or conveyance in lieu of condemnation.

17. **Quiet Enjoyment**. Landlord covenants that Tenant, upon performing all of its covenants, agreements and conditions of this Lease, shall have quiet and peaceful possession of the Premises as against anyone claiming by or through Landlord, subject, however, to the terms of this Lease.

18. **Assignment and Subletting**.

(a) Except as provided in Section 18(b) below, Tenant shall not enter into nor permit any Transfer (as defined hereunder) voluntarily or by operation of law, without the prior written consent of Landlord, which consent shall not be unreasonably withheld or delayed. Without limitation, Tenant agrees that Landlord's consent shall not be

considered unreasonably withheld if (i) the proposed transferee is an existing tenant of Landlord or an affiliate of Landlord, (ii) the business, business reputation, or creditworthiness of the proposed transferee is unacceptable to Landlord, in Landlord's reasonable discretion, (iii) Landlord or an affiliate of Landlord has comparable space available for lease by the proposed transferee, (iv) the proposed transferee is a governmental agency or a quasi-governmental entity or any other person or entity entitled, directly or indirectly, to diplomatic or sovereign immunity, regardless of whether the proposed transferee agrees to waive such diplomatic or sovereign immunity, or shall not be subject to the service of process in, or the jurisdiction of the courts of, the Commonwealth of Pennsylvania; or (v) an Event of Default by Tenant exists, or Tenant is in default under this Lease. A consent to one Transfer shall not be deemed to be a consent to any subsequent Transfer. In no event shall any Transfer relieve Ocugen, Inc. and any subsequent Tenant from any obligation under this Lease. Landlord's acceptance of Rent from any person shall not be deemed to be a waiver by Landlord of any provision of this Lease or to be a consent to any Transfer. Any Transfer not in conformity with this Section 18 shall be void at the option of Landlord or its Mortgagee. "**Transfer**" means (i) any assignment, transfer, pledge or other encumbrance of all or a portion of Tenant's interest in this Lease, (ii) any sublease, license or concession of all or a portion of Tenant's interest in the Premises, or (iii) any transfer of a controlling interest in Tenant. For the purpose of this definition, "transfer of a controlling interest of Tenant" means either (i) ownership or voting control, directly or indirectly, of at least fifty (50%) percent of all equity or other beneficial interest or (ii) the power to direct the management and policies of such entity.

(b) Landlord's consent shall not be required in the event of any Transfer by Tenant to an Affiliate (as defined hereunder) provided that (i) the Affiliate has a tangible net worth at least equal to that of Tenant as of the Effective Date of this Lease, (ii) Tenant provides Landlord notice of the Transfer at least seven (7) days prior to the effective date of the Transfer, together with current financial statements of the Affiliate certified by an executive officer of the Affiliate and a copy of the proposed Transfer documents, and (iii) in the case of an assignment or sublease, Tenant delivers to Landlord an assumption agreement or a sublease (as applicable) executed by Tenant and the Affiliate, together with a certificate of insurance and appropriate endorsements evidencing the Affiliate's compliance with the insurance requirements of Tenant under this Lease. Landlord's consent shall also not be required with respect to the sale or transfer of stock in Tenant whose stock or ownership interests are publicly-traded on a nationally-recognized exchange. "**Affiliate**" means (1) any corporation, partnership, limited liability company or other entity controlling, controlled by, under common control of Tenant, or an affiliate, subsidiary or parent of Tenant, (2) any successor to the business of Tenant by merger, consolidation or reorganization, or (3) any purchaser of all or substantially all of the assets of Tenant or seventy-five percent (75%) or more of the stock or other ownership interest of Tenant (or Tenant's parent) as a going concern.

(c) The provisions of Section 18(a) above notwithstanding, if Tenant proposes to Transfer all of the Premises (other than to an Affiliate), Landlord may terminate this Lease, either conditioned on execution of a new lease between Landlord and the proposed transferee or without that condition. If Tenant proposes to enter into a Transfer for either the Initial Premises or the Expansion Premises, as the case may be (other than to an Affiliate), Landlord may amend this Lease to remove either the Initial Premises or the Expansion Premises, as the case may be (the "**Recapture Space**"), either conditioned on execution of a new lease between Landlord and the proposed transferee or without that condition. If this Lease is not so terminated or amended, Tenant shall pay to Landlord, immediately upon receipt, the excess of (i) all compensation received by Tenant for the Transfer over (ii) the Rent allocable to the Premises transferred. If Landlord recaptures the Recapture Space, Tenant shall be solely responsible, at its cost and expense, for all Alterations required to separate the Recapture Space from the balance of the Premises, if any, including, but not limited to, construction of demising walls and separation of utilities.

(d) If Tenant requests Landlord's consent to a Transfer, Tenant shall provide Landlord, at least fifteen (15) days prior to the proposed Transfer, current financial statements of the transferee certified by an executive officer of the transferee, a complete copy of the proposed Transfer documents, and any other information Landlord reasonably requests. If Landlord fails to approve such Transfer within fifteen (15) days after Landlord's receipt of all requested materials, Landlord's consent to such Transfer shall be deemed rejected. Immediately following any approved assignment or sublease, Tenant shall deliver to Landlord an assumption agreement or a sublease (as applicable) reasonably acceptable to Landlord executed by Tenant and the transferee, together with a certificate of insurance evidencing the transferee's compliance with the insurance requirements of Tenant under this Lease. Each sublease will provide that such subtenant's rights will be no greater than those of Tenant, and that the sublease is subject and subordinate to this Lease and to the matters to which this Lease is or will be subordinate, and that upon an Event of

Default, Landlord may, at its option, have such subtenant attorn to Landlord or, subject to the following sentence, require that such subtenant pay its rent due to Tenant under such sublease directly to Landlord, provided, however, in such case Landlord will not (i) be liable for any previous act or omission of Tenant under such sublease or, (ii) be subject to any offset not expressly provided for in this Lease or by any previous prepayment of more than one month's rent under such sublease. If this Lease shall be assigned, or if the Premises or any part thereof shall be sublet or occupied by any party or parties other than Tenant, Landlord may, during any Event of Default, collect directly from any such assignee or subtenant of Tenant, or any other party occupying the Premises or any part thereof through or under Tenant, all rents that become due and payable for the use of the Premises or any part thereof by such party under such assignment agreement or sublease, and apply the net amount collected to the Rent herein reserved, but no such assignment, subletting, occupancy or collection of any such amount shall be deemed a waiver of the Tenant's obligations under this Section 18, nor shall it be deemed an acceptance of the assignee, subtenant or occupant as the "Tenant" hereunder, nor a release of Tenant from the full performance by Tenant of all the terms, conditions and covenants of this Lease. The liability of Tenant and each assignee or subtenant will be joint, several and primary for the observance of all the provisions, obligations and undertakings of this Lease, including the payment of Rent without abatement or reduction of any kind or nature through the entire Term, as the same may be renewed, extended or otherwise modified. The proposed assignee or subtenant will use the Premises for the permitted Use only.

(e) Tenant acknowledges that Landlord will incur costs in connection with any Transfer under this Lease. Accordingly, Tenant shall promptly pay to Landlord the amount ("**Transfer Charge**") of all reasonable out-of-pocket costs (including, without limitation, Landlord's reasonable attorney's fees) actually incurred by Landlord in connection with any Transfer, not to exceed [***] per Transfer so long as Tenant uses Landlord's Consent to Transfer form, substantially unchanged. Without limiting the generality of the foregoing, Tenant shall pay the Transfer Charge even in the event that (i) a proposed Transfer is not effectuated or (ii) a Transfer is permitted herein without need for Landlord's consent.

19. Subordination; Mortgagee's Rights.

(a) Tenant accepts this Lease subject and subordinate to any Mortgage of the entire Building and/or Land affecting the Premises, which may now or in the future be secured upon the Building and/or Land, and to all renewals, modifications, consolidations, replacements and extensions thereof, provided that Tenant's right of possession of the Premises shall not be disturbed by the Mortgagee so long as an Event of Default does not exist and Tenant is not in default under this Lease. This clause shall be self-operative, and although no instrument or act on the part of Tenant will be necessary to effectuate such subordination, Tenant will, nevertheless, in confirmation of such subordination, within ten (10) days after request, execute and deliver any further instruments confirming the subordination of this Lease and any further instruments of attornment that the Mortgagee may reasonably request. However, any Mortgagee may at any time subordinate its Mortgage to this Lease, without Tenant's consent, by giving notice to Tenant, and this Lease shall then be deemed prior to such Mortgage without regard to their respective dates of execution and delivery; provided that such subordination shall not affect any Mortgagee's rights with respect to condemnation awards, casualty insurance proceeds, intervening liens or any right which shall arise between the recording of such Mortgage and the execution of this Lease. Notwithstanding the foregoing, the party holding the instrument to which this Lease is subordinate shall have the right to recognize and preserve this Lease in the event of any foreclosure sale or possessory action, and in such case this Lease shall continue in full force and effect at the option of the party holding the superior lien and Tenant shall attorn to such party and shall execute, acknowledge and deliver any instrument that has for its purpose and effect the confirmation of such attornment within ten (10) days after request. Tenant waives the protection of any statute or rule of law that gives or purports to give Tenant any right to terminate this Lease or surrender possession of the Premises upon the transfer of Landlord's interest. "**Mortgage**" means any mortgage, deed of trust or other lien or encumbrance on Landlord's interest in the Property or any portion thereof, including without limitation any ground or master lease if Landlord's interest is or becomes a leasehold estate. "**Mortgagee**" means the holder of any Mortgage, including any ground or master lessor if Landlord's interest is or becomes a leasehold estate.

(b) Intentionally omitted.

(c) The provisions of Section 15 and Section 16 above notwithstanding, Landlord's obligation to restore the Premises after a casualty or condemnation shall be subject to the consent and prior rights of any Mortgagee.

(d) Tenant shall send to each Mortgagee of any Mortgage covering the Property or any part thereof (after notification of the identity of such mortgagee and the mailing address thereof) copies of all notices that Tenant sends to Landlord; such notices to said Mortgagee shall be sent concurrently with the sending of the notices to Landlord and in the same manner as notices are required to be sent pursuant to Section 25 hereof. Tenant will accept performance of any provision of this Lease by such Mortgagee as performance by, and with the same force and effect as though performed by, Landlord.

20. Tenant's Certificate; Financial Information; Confidentiality.

(a) Within ten (10) days after Landlord's request from time to time, (a) Tenant shall execute, acknowledge and deliver to Landlord, for the benefit of Landlord, Mortgagee, any prospective Mortgagee, and any prospective purchaser of Landlord's interest in the Property, an estoppel certificate in the form of attached **Exhibit "E"** (or other commercially reasonable form requested by Landlord), modified as necessary to accurately state the facts represented, and (b) Tenant shall furnish to Landlord, Landlord's Mortgagee, prospective Mortgagee and/or prospective purchaser reasonably requested financial information, but not more than twice per year; provided, that if Tenant is a publicly traded company or the financial information of Tenant is consolidated with a publicly traded Affiliate of Tenant, then publication by Tenant or such publicly traded company of its financials on its website shall be considered delivery by Tenant of requested financials hereunder. Landlord agrees to keep any private financial information provided to it by Tenant confidential (except for disclosure to the parties listed in Section 20(b) below), and any Mortgagee, prospective Mortgagee and/or prospective purchaser, and any such party with which Landlord shares such information shall be instructed by Landlord of the obligation to keep such information confidential**.**

(b) Tenant agrees not to disclose the terms, covenants, conditions or other facts with respect to this Lease, including the Minimum Annual Rent and additional Rent, to any person, corporation, partnership, association, newspaper, periodical or other entity, except to Tenant's accountants, attorneys, lenders, consultants and representatives (who shall also be required to keep the terms of this Lease confidential) or as required by Law. This non-disclosure and confidentiality agreement will be binding upon Tenant without limitation as to time, and a breach of this Section 20(b) will constitute a material breach under this Lease. In addition, Tenant's employees, contractors and Agents shall keep all of the terms and conditions of this Lease, including any billing statements and/or any backup supporting those statements, confidential.

21. Surrender.

(a) On the date on which this Lease expires or terminates, Tenant shall return possession of the Premises to Landlord in good broom-clean condition, except for ordinary wear and tear, and except for casualty damage or other conditions that Tenant is not required to remedy under this Lease. Notwithstanding anything to the contrary contained in this Lease, prior to the expiration or earlier termination of this Lease (unless Landlord in writing directs Tenant otherwise at least thirty (30) days before the expiration date of the Term or any extension or renewal thereof), Tenant shall remove from the Premises all Alterations (subject to Section 12(a) above) and its FFE, partitions, signage, and all other personal property installed by Tenant or its assignees or subtenants. Tenant shall not be required to remove any improvements made to the Premises as part of Landlord's Work other than Tenant specific equipment or any unusual configuration for first class office/flex space that was installed to the Premises for Tenant's specific Use and business operations, and any raised flooring, vaults, and modifications to the Building's utility and mechanical systems ("**Tenant Specific Equipment**"). Tenant shall also cap or terminate all telephone, computer and data connections at service entry panels in accordance with all applicable Laws. Tenant shall repair any damage resulting from any and all such removal(s) and shall restore the Premises to good order and the condition existing prior to Landlord's installation of any such Tenant Specific Equipment and Tenant's installation of any Alterations and/or FFE. Any of the Alterations, FFE, Tenant Specific Equipment or Tenant's personal property not removed or restored as required herein shall be deemed abandoned, and Landlord, at Tenant's expense, may remove, store, sell or otherwise dispose of such property in such manner as Landlord may see fit and retain such property as its property or sell such property and keep the proceeds. If Tenant does not return possession of the Premises to Landlord in the condition required under this Lease, Tenant shall pay Landlord all resulting damages Landlord may incur. Tenant's failure to comply with the terms

and conditions of this Section 21(a) shall also be deemed an Event of Default by the Tenant under this Lease, entitling Landlord to exercise all legal and equitable remedies available to Landlord.

(b) If Tenant remains in possession of the Premises or any part thereof after the expiration or earlier termination of this Lease ("**Holdover**"), without the written consent of Landlord, Tenant's occupancy of the Premises shall be that of a tenancy at sufferance. Tenant's occupancy during any Holdover period shall otherwise be subject to the provisions of this Lease (unless clearly inapplicable), except that the Monthly Rent shall be one hundred fifty percent (150%) of the Monthly Rent payable for the last full month immediately preceding the Holdover for the first month of any such Holdover, and two hundred percent (200%) of the Monthly Rent payable for the last full month immediately preceding the Holdover thereafter, plus in each case, all other charges payable hereunder, and upon all the terms hereof applicable to such a tenancy at sufferance. No Holdover or payment by Tenant after the expiration or termination of this Lease shall operate to extend the Term or prevent Landlord from immediate recovery of possession of the Premises by summary proceedings or otherwise. Nothing contained herein shall be deemed to authorize Tenant to remain in occupancy of the Premises after the Expiration Date or sooner termination of the Term. Any provision in this Lease to the contrary notwithstanding, any Holdover by Tenant shall constitute an Event of Default entitling Landlord to exercise, without obligation to provide Tenant any notice or cure period, all of the remedies available to Landlord upon an Event of Default, and, if Tenant fails to surrender the Premises to Landlord on or any time after the Expiration Date in the condition required under this Lease within thirty (30) days after Landlord provides notice to Tenant to vacate (which notice may be provided to Tenant any time prior to the Effective Date, provided, however, in no event shall Tenant be required to surrender the Premises prior to the Expiration Date), Tenant shall also be liable for, and agrees to hold Landlord harmless from and against, all liabilities, obligations, damages, penalties, claims, costs, charges and expenses, including attorneys' fees and consequential damages, that Landlord suffers as a result of the Holdover, including any claims made by any succeeding tenant based on such delay.

22. Defaults - Remedies.

(a) It shall be an "**Event of Default**" following the expiration of all applicable notice and cure periods set forth below:

(i) If Tenant does not pay in full when due any and all Rent and, except as provided in Section 22(d) below, Tenant fails to cure such default on or before the date that is five (5) business days after Landlord gives Tenant written notice of default;

(ii) If Tenant enters into or permits any Transfer in violation of Section 18 above;

(iii) If Tenant fails to observe and perform or otherwise breaches any other provision of this Lease, and, except as provided in Section 22(d) below, Tenant fails to cure the default on or before the date that is thirty (30) days after Landlord gives Tenant written notice of default; provided, however, if the default cannot reasonably be cured within thirty (30) days following Landlord's giving of notice, Tenant shall be afforded additional reasonable time (not to exceed ninety (90) days following Landlord's notice) to cure the default if Tenant begins to cure the default within thirty (30) days following Landlord's notice and continues diligently in good faith to completely cure the default;

(iv) If Tenant becomes insolvent or makes a general assignment for the benefit of creditors or offers a settlement to creditors, or if a petition in bankruptcy or for reorganization or for an arrangement with creditors under any federal or state law is filed by or against Tenant, or a bill in equity or other proceeding for the appointment of a receiver for any of Tenant's assets is commenced, or if any of the real or personal property of Tenant shall be levied upon; provided that any proceeding brought by anyone other than Landlord or Tenant under any bankruptcy, insolvency, receivership or similar law shall not constitute an Event of Default until such proceeding has continued unstayed for more than sixty (60) consecutive days; or

(v) If Tenant vacates any portion of the Premises for thirty (30) or more consecutive days, except in the event of casualty, condemnation, Force Majeure, or in connection with the performance of a permitted Alteration.

Any notice periods provided for in this Lease shall run concurrently with any statutory notice periods and any notice sent hereunder may be sent simultaneously with or incorporated into any such statutory notice.

(b) If an Event of Default occurs, Landlord shall, at any time thereafter, with or without notice or demand and without limiting Landlord in the exercise of any other right or remedy which Landlord may have by reason of such default (with such remedies being cumulative and not exclusive), have the following rights and remedies:

(i) Landlord, without any obligation to do so, may elect to cure the default on behalf of Tenant, in which event Tenant shall reimburse Landlord upon demand for any sums paid or costs incurred by Landlord (together with an administrative fee of ten percent (10%) thereof) in curing the default, plus interest at the Interest Rate from the respective dates of Landlord's incurring such costs, which sums and costs together with interest at the Interest Rate shall be deemed additional Rent;

(ii) To enter, re-enter and repossess the Premises, by breaking open locked doors if necessary, without terminating this Lease, and remove all persons and all or any property from the Premises, by action at law, without being liable for prosecution or damages, in which case Landlord shall be entitled to enforce all of Landlord's rights and remedies under this Lease, including the right to recover the Rent and all other amounts due hereunder as they become due. Landlord may, at Landlord's option, make alterations and repairs in order to relet the Premises and relet all or any part(s) of the Premises for Tenant's account. Tenant agrees to pay to Landlord on demand any deficiency (taking into account all reasonable costs incurred by Landlord) that may arise by reason of such reletting. In the event of reletting without termination of this Lease, Landlord may at any time thereafter elect to terminate this Lease for such previous breach. No re-entry or taking possession of the Premises by Landlord pursuant to this Section 22(b)(ii) or other action on Landlord's part shall be construed as an election to terminate this Lease unless a written notice of such intention is sent to Tenant or unless the termination hereof is decreed by a court of competent jurisdiction. Landlord's election not to terminate this Lease pursuant to this Section 22(b)(ii) or pursuant to any other provision of this Lease shall not preclude Landlord from subsequently electing to terminate this Lease or pursuing any of its other remedies;

(iii) To accelerate the whole or any part of the Rent for the balance of the Term as provided in Section 22(b)(iv) below, along with all sums past due, and declare the same to be immediately due and payable. In determining the amount of any future payments due Landlord as a result of increases in Annual Operating Expenses, Landlord may make such determination based upon the amount of Annual Operating Expenses paid by Tenant for the full year immediately prior to such Event of Default;

(iv) To terminate this Lease and the Term by any lawful means without any right on the part of Tenant to save the forfeiture by payment of any sum due or by other performance of any condition, term or covenant broken, in which case Tenant shall promptly surrender possession of the Premises to Landlord. In such event, Landlord shall be entitled to recover from Tenant all damages incurred by Landlord by reason of Tenant's Event of Default including, but not limited to, the cost of recovering possession of the Premises; expenses of re-letting, including necessary renovation and alteration of the Premises, reasonable attorneys' fees, and any real estate commission actually paid; the "worth at the time of award" established by the court having jurisdiction thereof of the amount by which the unpaid rent and other charges due for the balance of the Term after the time of Tenant's default exceeds the amount of such rental loss for the same period that Tenant proves by clear and convincing evidence could have been reasonably avoided; and that portion of any leasing commission paid by Landlord, if any, applicable to the unexpired Term of this Lease (which shall be calculated based on the assumption that any leasing commission applicable to the Term would have been evenly and equally amortized in monthly payments over the number of months contained in the Term at an interest rate of seven percent (7%) per annum). For purposes of this Section 22(b)(iv), "**worth at the time of award**" of the amount referred to above shall be computed by discounting each amount by a rate equal to the Prime Rate at the time of the award plus three percent (3%), but in no event more than an annual rate of ten percent (10%). As used herein, the "**Prime Rate**" means the then current prime rate published in the Wall Street Journal provided, however, if the Wall Street Journal no longer publishes a prime rate then the Prime Rate shall be an equivalent rate established by a financial institution or financial publication designated by Landlord;

(v) Maintain Tenant's right to possession, in which case this Lease shall continue in effect, whether or not Tenant shall have abandoned the Premises. In such event Landlord shall be entitled to enforce all of Landlord's rights and remedies under this Lease, including the right to recover the Rent and all other amounts due hereunder as and when they become due;

(vi) Landlord may immediately proceed to collect or bring action for the whole Rent or such part thereof as aforesaid, as well as for liquidated damages provided for hereinafter, as being rent in arrears, or may enter judgment therefor in an amicable action as herein elsewhere provided for in case of rent in arrears, or may file a Proof of Claim in any bankruptcy or insolvency proceeding for such rent, or Landlord may institute any other proceedings, whether similar to the foregoing or not, to enforce payment thereof;

(vii) Landlord shall have the right of injunction, in the event of a breach or threatened breach by Tenant of any of the agreements, conditions, covenants, or terms hereof, to restrain the same and the right to invoke any remedy allowed by law or in equity, whether or not other remedies, indemnity or reimbursements are herein provided. The rights and remedies given to Landlord in this Lease are distinct, separate, and cumulative remedies, and no one of them, whether or not exercised by Landlord, shall be deemed to be in exclusion of any of the others; and,

(viii) Pursue any other remedy now or hereafter available under the laws or judicial decisions of the Commonwealth of Pennsylvania. The expiration or termination of this Lease and/or the termination of Tenant's right to possession shall not relieve Tenant from liability under any indemnity provisions of this Lease as to matters occurring or accruing during the Term hereof or by reason of Tenant's occupancy of the Premises.

(c) In addition to the rights and remedies provided in Section 22(b) above, if an Event of Default occurs relating to Tenant's non-payment of the Rent due hereunder, Tenant hereby authorizes any attorney of any court of record of the Commonwealth of Pennsylvania to appear for Tenant and to **CONFESS JUDGEMENT** against Tenant, and in favor of Landlord, **FOR ALL RENT DUE HEREUNDER PLUS COSTS AND AN ATTORNEY'S COLLECTION COMMISSION EQUAL TO THE GREATER OF TEN PERCENT (10%) OF ALL RENT OR FIVE THOUSAND 00/100 DOLLARS ($5,000.00)**, plus damages and all reasonable attorney's fees, costs and expenses, for which this Lease or a true and correct copy hereof shall be good and sufficient warrant. **TENANT UNDERSTANDS THAT THE FOREGOING PERMITS LANDLORD TO ENTER A JUDGMENT AGAINST TENANT WITHOUT PRIOR NOTICE OR HEARING. ONCE SUCH A JUDGMENT HAS BEEN ENTERED AGAINST TENANT, ONE OR MORE WRITS OF EXECUTION OR WRITS OF GARNISHMENT MAY BE ISSUED THEREON WITHOUT FURTHER NOTICE TO TENANT AND WITHOUT A HEARING, AND, PURSUANT TO SUCH WRITS, LANDLORD MAY CAUSE THE SHERIFF OF THE COUNTY IN WHICH ANY PROPERTY OF TENANT IS LOCATED TO SEIZE TENANT'S PROPERTY BY LEVY OR ATTACHMENT. IF THE JUDGMENT AGAINST TENANT REMAINS UNPAID AFTER SUCH LEVY OR ATTACHMENT, LANDLORD CAN CAUSE SUCH PROPERTY TO BE SOLD BY THE SHERIFF EXECUTING THE WRITS, OR, IF SUCH PROPERTY CONSISTS OF A DEBT OWED TO TENANT BY ANOTHER ENTITY, LANDLORD CAN CAUSE SUCH DEBT TO BE PAID DIRECTLY TO LANDLORD IN AN AMOUNT UP TO BUT NOT TO EXCEED THE AMOUNT OF THE JUDGMENT OBTAINED BY LANDLORD AGAINST TENANT, PLUS THE COSTS OF THE EXECUTION.** Such authority shall not be exhausted by one (1) exercise thereof, but judgment may be confessed as aforesaid from time to time as often as any of the Rent and other sums shall fall due or be in arrears, and such powers may be exercised as well after the expiration of the initial Term of this Lease and during any extended Term of this Lease and after the expiration of any extended Term of this Lease.

(d) Any provision to the contrary in this Section 22 notwithstanding, (i) Landlord shall not be required to give Tenant any notice and opportunity to cure provided in Section 22(a)(i) above more than twice in any consecutive twelve (12) month period, and thereafter Landlord may declare an Event of Default without affording Tenant any of the notice and cure rights provided under this Lease, (ii) Landlord shall not be required to give any additional notice prior to exercising its rights if Tenant fails to comply with the provisions of Sections 8, 12, 13, 18, 20, 26 of this Lease within the appliable notice, consent, cure or other time periods expressly set forth in such sections, and (iii) Landlord may, in the event of an emergency, cure any Tenant default without providing notice thereof to Tenant.

(e) No waiver by Landlord of any breach by Tenant shall be a waiver of any subsequent breach, nor shall any forbearance by Landlord to seek a remedy for any breach by Tenant be a waiver by Landlord of any rights and remedies with respect to such or any subsequent breach. Efforts by Landlord to mitigate the damages caused by Tenant's default shall not constitute a waiver of Landlord's right to recover damages hereunder. No right or remedy herein conferred upon or reserved to Landlord is intended to be exclusive of any other right or remedy provided herein or by law, but each shall be cumulative and in addition to every other right or remedy given herein or now or hereafter existing at law or in equity. No payment by Tenant or receipt or acceptance by Landlord (or payment into a lockbox account) of a lesser amount than the total amount due Landlord under this Lease shall be deemed to be other than on account, nor shall any endorsement or statement on any check or payment be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of Rent due, or Landlord's right to pursue any other available remedy.

(f) If either party commences an action or proceeding against the other party arising out of or in connection with this Lease, the prevailing party shall be entitled to have and recover from the other party reasonable attorneys' fees, costs of suit, investigation expenses and discovery costs, including costs of appeal.

(g) IN ANY CIVIL ACTION, COUNTERCLAIM, OR PROCEEDING, WHETHER AT LAW OR IN EQUITY, WHICH ARISES OUT OF, CONCERNS, OR RELATES TO THIS LEASE, ANY AND ALL TRANSACTIONS CONTEMPLATED BY THIS LEASE, THE PERFORMANCE OF THIS LEASE, OR THE RELATIONSHIP CREATED BY THIS LEASE, WHETHER SOUNDING IN CONTRACT, TORT, STRICT LIABILITY, OR OTHERWISE, TRIAL SHALL BE TO A COURT OF COMPETENT JURISDICTION AND NOT TO A JURY. EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY.

(h) When this Lease and the Term or any extension thereof shall have been terminated on account of any Event of Default by Tenant, or when the Term or any extension thereof shall have expired, Tenant hereby authorizes any attorney of any court of record of the Commonwealth of Pennsylvania to appear for Tenant and for anyone claiming by, through or under Tenant and to **confess judgment** against all such parties, and in favor of Landlord, **in ejectment and for the recovery of possession of the Premises**, plus damages and all reasonable attorney's fees, costs and expenses, for which this Lease or a true and correct copy hereof shall be good and sufficient warrant. **TENANT UNDERSTANDS THAT THE FOREGOING PERMITS LANDLORD TO ENTER A JUDGMENT AGAINST TENANT WITHOUT PRIOR NOTICE OR HEARING. AFTER THE ENTRY OF ANY SUCH JUDGMENT AGAINST TENANT, A WRIT OF POSSESSION MAY BE ISSUED THEREON WITHOUT FURTHER NOTICE TO TENANT AND WITHOUT A HEARING.** If for any reason after such action shall have been commenced it shall be determined and possession of the Premises remain in or be restored to Tenant, Landlord shall have the right for the same default and upon any subsequent default(s) or upon the termination of this Lease or Tenant's right of possession as herein set forth, to again confess judgment as herein provided, for which this Lease or a true and correct copy hereof shall be good and sufficient warrant.

(i) The warrants to confess judgment set forth above shall continue in full force and effect and be unaffected by amendments to this Lease or other agreements between Landlord and Tenant even if any such amendments or other agreements increase Tenant's obligations or expand the size of the Premises.

(j) TENANT ACKNOWLEDGES AND AGREES THAT THE FOREGOING WARRANTS OF ATTORNEY ARE GIVEN IN CONNECTION WITH A COMMERCIAL TRANSACTION AND THAT LANDLORD'S PROPER EXERCISE OF THE WARRANTS OF ATTORNEY GRANTED HEREIN WOULD BE IN ACCORDANCE WITH TENANT'S REASONABLE EXPECTATIONS. TENANT EXPRESSLY AND ABSOLUTELY KNOWINGLY AND EXPRESSLY WAIVES AND RELEASES (i) ANY RIGHT, INCLUDING, WITHOUT LIMITATION, UNDER ANY APPLICABLE STATUTE, WHICH TENANT MAY HAVE TO RECEIVE A NOTICE TO QUIT PRIOR TO LANDLORD COMMENCING AN ACTION FOR REPOSSESSION OF THE PREMISES AND (ii) ANY RIGHT WHICH TENANT MAY HAVE TO NOTICE AND TO HEARING PRIOR TO A LEVY UPON OR ATTACHMENT OF TENANT'S PROPERTY OR THEREAFTER AND (iii) ANY PROCEDURAL ERRORS IN CONNECTION WITH THE ENTRY OF ANY SUCH JUDGMENT OR IN THE ISSUANCE OF ANY ONE OR MORE WRITS OF POSSESSION OR EXECUTION OR GARNISHMENT THEREON.

(k) Tenant expressly waives (i) the benefits of all laws, now or hereafter in force, exempting any property within the Premises or elsewhere from distraint, levy or sale; (ii) the right to any notice to remove as may be specified in the Pennsylvania Landlord and Tenant Act of April 6, 1951, as amended, or any similar or successor provision of law, and agrees that five (5) days' notice shall be sufficient in any case where a longer period may be statutorily specified; and (iii) any Pennsylvania statutory provisions dealing with termination rights due to casualty, condemnation, delivery of possession or any other matter dealt with by this Lease, all of which are superseded by the terms of this Lease.

23. **Tenant's Authority; OFAC**. Tenant represents and warrants to Landlord that: (a) Tenant is duly formed, validly existing and in good standing under the laws of the state under which Tenant is organized, and qualified to do business in the state in which the Property is located, and (b) the person(s) signing this Lease are duly authorized to execute and deliver this Lease on behalf of Tenant, and if Tenant is a corporation, partnership, joint venture, limited liability company, or other type of organization (each, an "**Entity**"), Tenant will, within fifteen (15) days after Landlord's request, provide Landlord with a resolution confirming the authorization. Tenant represents and warrants to Landlord (i) that neither Tenant nor any person or entity that directly owns a ten percent (10%) or greater equity interest in Tenant nor any of its officers, directors or managing members (collectively, "**Tenant and Others in Interest**") is a person or entity with whom U.S. persons or entities are restricted from doing business under regulations of the Office of Foreign Asset Control ("**OFAC**") of the Department of the Treasury (including those named on OFAC's Specially Designated and Blocked Persons List) or under any statute, executive order (including Executive Order 13224 signed on September 24, 2001 (the "**Executive Order**") and entitled "Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism"), or other governmental action, (ii) that Tenant and Others in Interest's activities do not violate the International Money Laundering Abatement and Financial Anti-Terrorism Act of 2001 or the regulations or orders promulgated thereunder (as amended from time to time, the "**Money Laundering Act**"), and (iii) that throughout the Term Tenant will comply with the Executive Order and the Money Laundering Act. Tenant certifies that it is not engaged in this transaction, directly or indirectly on behalf of, or instigating or facilitating this transaction, directly or indirectly on behalf of, any such person, group, entity, or nation. Tenant hereby agrees to defend, indemnify, and hold harmless Landlord from and against any and all claims, damages, losses, risks, liabilities, and expenses (including attorney's fees and costs) arising from or related to any breach of the foregoing certification.

24. **Liability of Landlord**. The word "Landlord" in this Lease includes the Landlord executing this Lease as well as its successors and assigns, each of which shall have the same rights, remedies, powers, authorities and privileges as it would have had it originally signed this Lease as Landlord. Any such person or entity, whether or not named in this Lease, shall have no liability under this Lease after it ceases to hold title to the Property, the Building or the Premises except for obligations already accrued (and, as to any unapplied portion of Tenant's Security Deposit, if applicable, Landlord shall be relieved of all liability upon transfer of such portion to its successors in interest). Tenant shall look solely to Landlord's successor in interest for the performance of the covenants and obligations of the Landlord hereunder which subsequently accrue. Landlord shall not be deemed to be in default under this Lease unless Tenant gives Landlord notice specifying the default and Landlord fails to cure the default within a reasonable period following Tenant's notice. In no event shall Landlord be liable to Tenant for any loss of business or profits of Tenant or for consequential, punitive or special damages of any kind. Anything in this Lease to the contrary notwithstanding, covenants, undertakings and agreements herein made on the part of Landlord are made and intended not as personal covenants, undertakings and agreements or for the purpose of binding Landlord personally or the assets of Landlord, except Landlord's interest in the Property, but are made and intended for the purpose of binding only Landlord's interest in the Property, as the same may from time to time be encumbered. Neither Landlord nor any principal of Landlord nor any owner of the Property, nor any of their respective partners, officers, employees, heirs, legal representatives, successors, and assigns, whether disclosed or undisclosed, shall have any personal liability with respect to any of the provisions of this Lease or the Premises; Tenant shall look solely to the equity of Landlord in the Property for the satisfaction of any claim by Tenant against Landlord.

25. **Notices**. Any notice, consent or other communication under this Lease shall be in writing and addressed to Landlord or Tenant at their respective addresses specified in Section 1(k) above (or to such other address as either may designate by notice to the other) with a copy of any default notice to any Mortgagee or other party designated in writing by Landlord. Each notice or other communication shall be deemed sent if sent by prepaid overnight delivery service or by certified mail, return receipt requested, postage prepaid or in any other manner, with delivery in any case evidenced by a receipt, and shall be deemed to have been delivered on the day of actual delivery to the intended

recipient (or if the day of actual delivery is not a business day, the first business day immediately following the day of actual delivery) or on the business day any attempted delivery is refused. The sending of notice by Landlord's or Tenant's attorneys, representatives and Agents under this Section 25 shall be deemed to be the acts of Landlord or Tenant, respectively. Delivery of notice through electronic messages sent to the email address(es) of Landlord or Tenant, their respective Affiliates, and legal counsel as set forth in Section 1(k), shall constitute delivery of notice so long as a copy of such electronic message is delivered by the sending party to the receiving party by prepaid overnight delivery service within one (1) business day after the date of such electronic message.

26. **Security Deposit.** The Security Deposit shall be retained by Landlord as cash security for the faithful performance and observance by Tenant of the provisions of this Lease. Tenant shall not be entitled to any interest on the Security Deposit. Landlord shall have the right to commingle the Security Deposit with its other funds. Landlord may use the whole or any part of the Security Deposit for the payment of any amount as to which Tenant is in default or to compensate Landlord for any loss or damage it may suffer by reason of Tenant's Event of Default under this Lease. If Landlord uses all or any portion of the Security Deposit as herein provided, within ten (10) days after demand, Tenant shall pay Landlord cash in an amount equal to that portion of the Security Deposit used by Landlord. If Tenant complies fully and faithfully with all of the provisions of this Lease, the Security Deposit shall be returned to Tenant within sixty (60) days after the Expiration Date, surrender of the Premises to Landlord in the condition required herein and final adjustment and reconciliation of Operating Expenses due and payable prior to the Expiration Date have occurred.

27. **Broker**. Tenant represents and warrants to Landlord that Tenant has not consulted or negotiated with any broker or finder with regard to this Lease. Landlord and Tenant each will indemnify the other against, and hold the other harmless from, any claims for fees or commissions from anyone with whom either of them has consulted or negotiated with regard to the Premises and this Lease, including attorneys' fees at all tribunal levels incurred in connection with the defense of any such claim.

28. **Mortgagee Approval.** If any Mortgagee shall have the right of approval of this Lease and such Mortgagee shall, subsequent to the execution hereof by all parties hereto, require a change or changes in this Lease as a condition of its approval thereof and if within thirty (30) days after notice from Landlord, Tenant fails or refuses to execute reasonable amendment(s) to this Lease accomplishing the change or changes which are stated by Landlord as being needed in connection with the approval of this Lease by the Mortgagee, Landlord shall have the right to cancel this Lease. It is understood and agreed that any such change or changes required by such Mortgagee shall not materially affect or alter: (i) the Minimum Annual Rent, Annual Operating Expenses, any additional Rent or Term; (ii) the size of the Premises; or (iii) Tenant's rights under this Lease.

29. **Landlord's Work**. Landlord shall have no obligations whatsoever to improve or pay for any improvements to the Premises for Tenant's use and occupancy thereof except as expressly set forth in this Section 29. Commencing promptly after the Effective Date, the parties shall proceed diligently and continuously to finalize the Initial Premises Work Final Plans (as defined below) and the Expansion Premises Work Final Plans (as defined below) with Polek Schwartz Architects ("**Architect**"), which Architect was selected and retained by Landlord and approved by Tenant prior to the Effective Date, and Landlord shall, subject to the provisions of this Section 29, construct and install or cause the construction and installation of all work and improvements required to complete: (1) the Initial Premises Work substantially in accordance with such Initial Premises Work Final Plans; and, (2) the Expansion Premises Work substantially in accordance with such Expansion Premises Work Final Plans. "**Initial Premises Work**" means the work and improvements made to design and construct the Initial Premises, all in accordance with the Final Plans, which work includes the installation of the following: (i) new store-front glass entrance door; (ii) new sidelights to match the existing lights at the new conference room and office; (iii) new plastic laminate kitchen millwork; (iv) new high-low water fountain; (v) new ADA accessible bathrooms; (vi) new building standard broadloom carpet in the office area, VCT at the bathrooms, kitchen, warehouse and janitorial closet, and sprayed epoxy flooring in laboratories; (vii) new 2x4 basket style LED lighting throughout the Initial Premises; (viii) creation of wall fed electric junction boxes for one set of workstations and a junction box in the ceiling for the center set of workstations (i.e. for a Tenant supplied power pole); (ix) creation of a new narrow electrical room along the length of the back wall of the Initial Premises to house the existing electrical equipment in the space as of the Effective Date; and (x) new demising wall and separation of utilities for the Initial Premises. "**Expansion Premises Work**" means the work and improvements made to design and construct the Expansion Premises, all in accordance with the Final Plans, which work includes the installation of the following: (i) new plastic laminate kitchen millwork; (ii) new building standard

broadloom carpet in the office area, and VCT at the kitchen; (iii) new 2x4 basket style LED lighting throughout the office areas of the Expansion Premises; and (iv) creation of wall or ceiling fed electric junction boxes for the proposed set of workstations. For purposes of this Lease, the term "**Landlord's Work**" as used herein may refer to either the Initial Premises Work, the Expansion Premises Work, or both, as the context requires. Landlord may use building standard materials for all improvements and work included as part of Landlord's Work.

(a) Within ten (10) business days following the Effective Date, Landlord shall cause Architect to prepare, and Landlord shall provide to Tenant: (1) initial complete, finished, detailed architectural drawings and specifications for the Initial Premises Work, including construction drawings and specifications, for all of the Initial Premises Work (collectively, the "**Initial Premises Working Plans**"); and, (2) initial complete, finished, detailed architectural drawings and specifications for the Expansion Premises Work, including construction drawings and specifications, for all of the Expansion Premises Work (collectively, the "**Expansion Premises Working Plans**"), each in substantial conformance with that certain plan prepared by or on behalf of Landlord and mutually approved by Landlord and Tenant prior to the Effective Date, identified as "Ocugen Expansion", prepared by Architect, dated August 13, 2020, Sheet No. SK-1, a copy of which is attached hereto and made a part hereof as **Exhibit "F"** (the "**Concept Plan**"). For purposes of this Lease, the term "**Working Plans**" as used herein may refer to either the Initial Premises Working Plans, the Expansion Premises Working Plans, or both, as the context requires. Landlord shall be responsible for the cost of the Concept Plan and all drafts of the Working Plans.

(i) Each of the Working Plans shall include sufficient detail and comply with all Laws for the issuance of building permits from East Whiteland Township for Landlord's Work ("**Building Permits**"). Tenant shall have five (5) business days from receipt of each such Working Plan to review and approve them or state any reasonable objections as set forth below in writing. Tenant's approval shall not be unreasonably conditioned or withheld provided the Working Plans are consistent with the applicable Landlord's Work and any objections shall be in writing with such specificity as to allow the necessary modifications by Landlord and/or Architect ("**Tenant's Objections**"). If Tenant returns either of the Working Plans to Landlord with Tenant's Objections within such five (5) business day period, Landlord or Architect shall revise such Working Plans incorporating Tenant's Objections (if required, "**Revised Working Plans**"), and submit the Revised Working Plans to Tenant within ten (10) business days after Landlord's receipt of Tenant's Objections. As to Tenant's Objections and Landlord's response, but not otherwise, this process shall be repeated (and each revised plan set shall be deemed Revised Working Plans) until the then current Revised Working Plans have been finally approved by Landlord and Tenant for Contractor's submission to East Whiteland Township for the issuance of Building Permits. If East Whiteland Township requires any changes to either of the Working Plans (or the then current Revised Working Plans, as the case may be) at any time, Landlord or Architect shall revise such plans incorporating East Whiteland Township's requested changes (which shall be deemed Revised Working Plans) and submit such Revised Working Plans to Tenant for Tenant's reasonable approval, and then provide copies thereof to Contractor for re-submission to East Whiteland Township. If Tenant fails to issue Tenant's Objections or otherwise respond to any submission within any such five (5) business day period as applicable, the then applicable Working Plans (or the then current Revised Working Plans, as the case may be) submitted for approval shall be deemed approved by Tenant, so long as East Whiteland Township approves such Working Plans (or the then current Revised Working Plans, as the case may be).

(ii) The "**Initial Premises Work Final Plans**" are the Initial Premises Working Plans (or the then current Revised Working Plans applicable to the Initial Premises Work, as the case may be) as so approved or deemed approved by Tenant and accepted by East Whiteland Township. The "**Expansion Premises Work Final Plans**" are the Expansion Premises Working Plans (or the then current Revised Working Plans applicable to the Expansion Premises Work, as the case may be) as so approved or deemed approved by Tenant and accepted by East Whiteland Township. For purposes of this Lease, the term "**Final Plans**" as used herein may refer to either the Initial Premises Work Final Plans, the Expansion Premises Work Final Plans, or both, as the context requires. As to both the Initial Premises Work and the Expansion Premises Work, in the event of any conflict or inconsistency between either of the Working Plans or any Revised Working Plans, and the Final Plans, the Final Plans shall govern and control. Each of the Final Plans may only be modified by Tenant with Landlord's prior written approval, in Landlord's reasonable discretion, and if approved by Landlord, Tenant shall be liable for any additional reasonable costs incurred in connection with such modifications requested by Tenant, and any delay solely and directly resulting from such modifications shall be deemed a Tenant Delay.

(iii) Notwithstanding anything herein contained to the contrary, if Landlord identifies Long Lead Time Items (as defined below) during its review of either of the Working Plans as set forth above or during the performance of any of Landlord's Work, Tenant understands, acknowledges and agrees that Landlord may substitute all such Long Lead Time Items with alternate materials, brands or finishes that are available and in stock by any applicable supplier or manufacturer of such item, in its reasonable discretion, subject to Tenant's reasonable approval. "**Long Lead Time Item(s)**" means any material, brand or finish that is a part or component of Landlord's Work that takes longer than six (6) weeks to obtain from any applicable supplier or manufacturer after the date such item was ordered.

(iv) Tenant understands, acknowledges and agrees Landlord's review or approval of either of the Working Plans, any Revised Working Plans and either of the Final Plans does not constitute a code review and shall not be a representation or warranty of Landlord that either of the Final Plans are fit for any use, comply with any Laws or other legal requirements, or satisfy all requirements of East Whiteland Township, and Tenant shall have no right to rely upon any review or approval thereof by Landlord. Landlord shall have no liability to Tenant or any third party by reason of such review or approval.

(v) Tenant shall have the right from time to time to request changes to either or both of the Final Plans ("**Change Orders**"). If, after approval of either of the Final Plans by Landlord and Tenant, Tenant requests any change or addition to the work and materials to be provided pursuant to either such Final Plans, and such changes (i) do not conform with all applicable Law, (ii) would, in Landlord's reasonable judgment, adversely affect the integrity or effectiveness of any Building Systems, including, without limitation, HVAC, electrical, plumbing, fire protection, sprinkler, security or life safety systems, or (iii) would impair the structural integrity of the Building, then such Change Order shall require Landlord's approval. Following receipt of Tenant's request for a Change Order, Landlord shall provide Tenant with a good faith estimate of the impact on cost and schedule, if any, of each proposed Change Order. Tenant shall have three (3) business days following receipt of the impact statement to either agree to the Change Order or retract its request for the Change Order. If Tenant maintains the Change Order, Landlord shall cause the Contractor to diligently process the Change Order and Tenant shall be responsible for any actual delay in the completion of Landlord's Work resulting from any Change Order requested by Tenant, which shall be a Tenant Delay. In the event the actual cost of Landlord's Work is increased as a result of a Change Order pursuant to this Section 29(b)(v), then Tenant shall be responsible for such increased cost, and Tenant shall pay the cost of the Change Order to Landlord within ten (10) business days after the Change Order and cost thereof is agreed to by Tenant.

(vi) Tenant designates [***] ("**Tenant's Authorized Representative**") as the person authorized to approve in writing all plans, drawings, specifications, charges and approvals pursuant to this Section 29 (and the act of the aforenamed person shall be sufficient to bind Tenant). Landlord designates [***] ("**Landlord's Authorized Representative**") as the person authorized to approve in writing all plans, drawings, specifications, charges and approvals pursuant to this Section 29 (and the act of the aforenamed person shall be sufficient to bind Landlord). Landlord or Tenant may designate a substitute authorized representative by prior written notice or email to the other party. Neither party shall be obligated to respond to any instructions, approvals, changes, or other communications from anyone claiming to act on the other party's behalf other than the applicable authorized representative. All references in this Section 29 to actions taken, approvals granted, or submissions made by Tenant shall mean that such actions, approvals or submissions have been taken, granted or made, in writing, by Tenant's Authorized Representative acting for Tenant, and all references in this Section 29 to actions taken, approvals granted, or submissions made by Landlord shall mean that such actions, approvals or submissions have been taken, granted or made, in writing, by Landlord's Authorized Representative acting for Landlord.

(b) Landlord will cause the Landlord's Work to be performed by a contractor selected and retained by Landlord, in its sole discretion (the "**Contractor**"). Landlord will cause the Contractor and its subcontractors to perform and complete the Landlord's Work, at Landlord's expense (except as to any Change Orders), in a good and workmanlike manner and in accordance with the Final Plans and all applicable Laws to achieve Substantial Completion thereof. During the performance of Landlord's Work, all of Landlord's contractors and workers including, without limitation, Contractor, shall be deemed Landlord Additional Insureds.

(c) "**Substantial Completion**" or "**Substantially Completed**" means (i) that the Landlord's Work has been completed by Contractor in accordance with the Final Plans and in compliance with all applicable Laws, subject only to completion of minor finishing, adjustment of equipment, and other minor construction aspects that do not affect Tenant's ability to conduct its business in the Premises pursuant to a mutually agreed-upon punch-list of incomplete items prepared by Landlord and Tenant during a walk-through of the Premises (the "**Punch List Items**"); and (ii) Landlord has obtained a temporary or final certificate of occupancy from East Whiteland Township as the case may be, indicating that the Initial Premises, or the Expansion Premises, as the case may be, may be lawfully occupied by Tenant for its Use. Landlord will use commercially reasonable efforts to complete the Punch-List Items as promptly as possible but in no event more than sixty (60) days after the Initial Premises Commencement Date and/or the Expansion Premises Commencement Date, as the case may be, absent any Excused Delay.

(d) If Landlord shall be actually and materially delayed in completing the Landlord's Work as a result of: (i) Tenant's failure to comply with any deadline specified in this Section 29, (ii) Tenant's failure to approve either of the Final Plans on or prior to the timelines provided herein, (iii) Tenant's changes to either or both of the Final Plans subsequent to the date that such plans or working drawings are approved by Landlord and Tenant including, without limitation, any Change Order, (iv) Tenant's failure to pay when due any sums payable by Tenant pursuant to this Section 29, (v) Tenant's request for materials, finishes or installations as part of the Landlord's Work which constitute Long Lead Time Item(s), (vi) any delay in obtaining any applicable permits with respect to the Landlord's Work caused by the act or omission of Tenant, (vii) acts or omissions by any person or firm employed or retained by Tenant, or (viii) interference with the progress of any Landlord's Work, or the scheduling thereof, occasioned by Tenant or any of Tenant's contractors or vendors not working in harmony with any person undertaking any part of the Landlord's Work including, without limitation, in violation of Section 4(c) above, such delay(s) shall be deemed a Tenant Delay, Landlord's Work shall be deemed to have been Substantially Completed on the date that they would have been substantially completed if such Tenant Delay had not occurred, and therefore, the Commencement Date will be deemed to be the date that Landlord would have achieved Substantial Completion had such Tenant Delay not occurred. The foregoing shall not be deemed a "Tenant Delay" unless and until Landlord has provided Tenant with written notice of such delay. The length of any Tenant Delay is to be measured by the duration of the actual delay in completion solely and directly caused by the event or conduct constituting Tenant Delay commencing as of the date of Landlord's notice thereof.

(e) Notwithstanding Landlord's obligation to perform or cause the performance of Landlord's Work on a "turnkey" no-cost to Tenant basis, Tenant shall, at its sole cost and expense, be responsible for the installation, completion and payment for the costs of the Generator expressly approved by Landlord as provided in Section 7(e) above, supplemental HVAC, installation of any security or access system, Tenant's telecommunications, voice and data installation and related wiring and cabling to be used at the Premises, all laboratory millwork, benching and equipment, and Tenant's acquisition, assembly, disassembly and installation of all FFE, all of which shall be deemed an Alteration in accordance with, but under and subject to Section 12 and Section 13 of this Lease.

30. Miscellaneous.

(a) The captions in this Lease are for convenience only, are not a part of this Lease and do not in any way define, limit, describe or amplify the terms of this Lease.

(b) This Lease represents the entire agreement between the parties hereto and there are no collateral or oral agreements or understandings between Landlord and Tenant with respect to the Premises or the Property. No representations or promises will be binding on the parties to this Lease except those representations and promises expressly contained in this Lease.

(c) This Lease shall not be modified in any manner except by an instrument in writing executed by the parties.

(d) The masculine (or neuter) pronoun and the singular number shall include the masculine, feminine and neuter genders and the singular and plural number. The word "**including**" followed by any specific item(s) is deemed to refer to examples rather than to be words of limitation. The word "**person**" includes a natural person, a

partnership, a corporation, a limited liability company, an association and any other form of business association or entity.

(e) Both parties having participated fully and equally in the negotiation and preparation of this Lease, this Lease shall not be more strictly construed, nor any ambiguities in this Lease resolved, against either Landlord or Tenant.

(f) Each covenant, agreement, obligation, term, condition or other provision contained in this Lease shall be deemed and construed as a separate and independent covenant of the party bound by, undertaking or making the same, not dependent on any other provision of this Lease unless otherwise expressly provided. All of the terms and conditions set forth in this Lease shall apply throughout the Term unless otherwise expressly set forth herein.

(g) If any provisions of this Lease shall be declared unenforceable in any respect, such unenforceability shall not affect any other provision of this Lease, and each such provision shall be deemed to be modified, if possible, in such a manner as to render it enforceable and to preserve to the extent possible the intent of the parties as set forth herein.

(h) This Lease shall be construed and enforced in accordance with the Laws of the Commonwealth of Pennsylvania (without the application of any conflict of laws principles).

(i) This Lease shall be binding upon and inure to the benefit of Landlord and Tenant and their respective permitted successors and assigns. All persons liable for the obligations of Tenant or Landlord under this Lease shall be jointly and severally liable for such obligations.

(j) Tenant shall not record this Lease, or any memorandum thereof, or otherwise file this Lease with any governmental authority, without Landlord's prior consent.

(k) Whenever it is provided that Landlord's or Tenant's consent is required, unless another standard is provided in this Lease with respect to such specific consent, neither Landlord nor Tenant, as applicable will unreasonably withhold, condition or delay such consent or approval (such consent or approval and such exercise of judgment being collectively referred to as "**consent**"). If Landlord delays, conditions or refuses such consent, Tenant waives any claim for money damages (including any claim for money damages by way of setoff, counterclaim or defense) based upon any claim or assertion that Landlord unreasonably withheld, conditioned or delayed consent. Tenant's sole remedy will be specific performance. Failure on the part of Tenant to seek relief within sixty (60) days after the date upon which Landlord has withheld, conditioned or delayed its consent will be deemed a waiver of any right to dispute the reasonableness of such withholding, conditioning or delaying of consent.

(l) This Lease may be executed in multiple counterparts, each of which, when assembled to include an original signature for each party contemplated to sign this Lease, will constitute a complete and fully executed original. All such fully executed counterparts will collectively constitute a single Lease agreement.

(m) Time periods for Landlord's or Tenant's performance under any provisions of this Lease, other than the payment of Rent, shall be extended for periods of time during which the non-performing party's performance is prevented, impeded or delayed due to circumstances beyond such party's control, including without limitation, including acts of God; any epidemic, pandemic or national health emergency (including without limitation, COVID-19 or any matter or issues similar to an epidemic or pandemic, or any governmental orders or directives with respect thereto); fire or other casualty; unreasonable governmental delay; governmental regulations, orders or shutdowns; inability to procure labor, materials, supplies, power or transportation despite reasonable efforts; strikes; unusual inclement weather; or, where applicable, the passage of time while waiting for an adjustment of insurance proceeds ("**Force Majeure**"). Any time limits required to be met by either party hereunder, whether specifically made subject to Force Majeure or not, except those related to the surrender of the Premises by the end of the Term or payment of Minimum Annual Rent or additional Rent, will, unless specifically stated to the contrary elsewhere in this Lease, be automatically extended by the number of days by which any required performance is delayed due to Force Majeure. The lack of capital shall not be an event of Force Majeure.

(n) Unless otherwise specified, in computing any period of time described herein, the day of the act or event after which the designated period of time begins to run is not to be included and the last day of the period so computed is to be included, unless such last day is a Saturday, Sunday or legal holiday for national banks in the Commonwealth of Pennsylvania (such day which is neither Saturday, Sunday or legal holiday), in which event the period shall run until the end of the next day which is neither a Saturday, Sunday, or a legal holiday.

(o) Time is of the essence with respect to the parties' obligations under this Lease.

(p) Each of Landlord and Tenant agrees that it will not raise or assert as a defense to any obligation under this Lease, or make any claim that this Lease is invalid or unenforceable, due to any failure of this document or this Lease to comply with ministerial requirements, including requirements for corporate seals, attestations, witnesses, notarizations or other similar requirements, and each party hereby waives the right to assert any such defense or make any claim of invalidity or unenforceability due to any of the foregoing.

(q) Landlord and Tenant expressly agree that if the signature of Landlord and/or Tenant on this Lease is not an original, but is a digital, mechanical or electronic reproduction (such as, but not limited to, an e-mail, PDF or DocuSign), then such digital, mechanical or electronic reproduction shall be as enforceable, valid and binding as, and the legal equivalent to, an authentic and traditional ink-on-paper original wet signature penned manually by its signatory.

(r) This Lease is submitted to Tenant on the understanding that it will not be considered an offer by Landlord and will not bind Landlord in any way until (a) Tenant has duly executed and delivered the required number of originals to Landlord and (b) Landlord has executed and delivered one of such originals to Tenant. Tenant's offer of this Agreement shall be irrevocable and open for acceptance by Landlord until 5:00 p.m. on the fifteenth (15th) day after execution and delivery hereof by Tenant, and if not accepted by then may be withdrawn by Tenant.

(s) Any State statutory provisions dealing with termination rights due to casualty, condemnation, delivery of possession or any other matter dealt with by this Lease are superseded by the terms of this Lease.

31. CONFESSION OF JUDGMENT acknowledgment.

(a) SECTION 22(c) OF THIS LEASE PROVIDES FOR THE CONFESSION OF JUDGMENT AGAINST TENANT FOR MONEY AND SECTION 22(h) OF THIS LEASE PROVIDES FOR THE CONFESSION OF JUDGMENT AGAINST TENANT FOR EJECTMENT. IN CONNECTION THEREWITH, TENANT, KNOWINGLY, VOLUNTARILY, INTENTIONALLY AND UPON ADVICE OF SEPARATE COUNSEL, UNCONDITIONALLY WAIVES ANY AND ALL RIGHTS IT MAY HAVE TO PRIOR NOTICE AND AN OPPORTUNITY FOR HEARING UNDER THE RESPECTIVE CONSTITUTIONS AND LAWS OF THE UNITED STATES AND THE COMMONWEALTH OF PENNSYLVANIA. WITHOUT LIMITATION OF THE FOREGOING, TENANT HEREBY SPECIFICALLY WAIVES ALL RIGHTS TENANT HAS OR MAY HAVE TO NOTICE AND OPPORTUNITY FOR A HEARING PRIOR TO EXECUTION UPON ANY JUDGMENT CONFESSED IN EJECTMENT OR FOR MONEY OR BOTH AGAINST TENANT BY LANDLORD HEREUNDER.

(b) TENANT (I) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF LANDLORD HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT LANDLORD WILL NOT SEEK TO EXERCISE OR ENFORCE ITS RIGHTS TO CONFESS JUDGMENT HEREUNDER, AND (II) ACKNOWLEDGES THAT THE EXECUTION OF THIS LEASE BY LANDLORD HAS BEEN MATERIALLY INDUCED BY, AMONG OTHER THINGS, THE INCLUSION IN THIS LEASE OF SAID RIGHTS TO CONFESS JUDGMENT AGAINST TENANT. TENANT FURTHER ACKNOWLEDGES THAT IT HAS HAD THE OPPORTUNITY TO DISCUSS SAID PROVISIONS WITH TENANT'S INDEPENDENT LEGAL COUNSEL AND THAT THE MEANING AND EFFECT OF SUCH PROVISIONS HAVE BEEN FULLY EXPLAINED TO TENANT BY SUCH COUNSEL.

SIGNATURES ON FOLLOWING PAGE

The parties to this Lease, intending to be legally bound, have executed and delivered this Lease as of the date on which this Lease has been fully executed and delivered by Landlord and Tenant.

LANDLORD:

WPT LAND 2 LP,
a Delaware limited partnership

By: WPT Land 2 GP LLC,
a Delaware limited liability company,
its sole general partner

Dated: 10/9/2020

By: /s/ Anthony A. Nichols, Jr.
Name: Anthony A. Nichols, Jr.,
Title: Senior Vice President

TENANT:

OCUGEN, INC.,
a Delaware corporation

Dated: 10/9/2020

By: /s/ Shankar Musunuri
Name: Dr. Shankar Musunuri
Title: CEO

Exhibit 21.1

Ocugen, Inc.
List of Subsidiaries

Name of Wholly-Owned Subsidiary	Jurisdiction of Organization
Ocugen Limited	Ireland
Ocugen OpCo, Inc.	Delaware
Histogenics Securities Corporation	Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-234127) of Ocugen, Inc.
(2) Registration Statement (Form S-3 No. 333-237456) of Ocugen, Inc.
(3) Registration Statement (Form S-8 No. 333-237454) pertaining to the Ocugen, Inc. 2019 Equity Incentive Plan and the Ocugen, Inc. 2014 Stock Incentive Plan

of our report dated March 19, 2021, with respect to the consolidated financial statements of Ocugen, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 19, 2021

Exhibit 31.1

CERTIFICATION

I, Shankar Musunuri, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 19, 2021 /s/ Shankar Musunuri, Ph.D., MBA

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

Exhibit 31.2

CERTIFICATION

I, Sanjay Subramanian, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 19, 2021 /s/ Sanjay Subramanian

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

Exhibit 32.1

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

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

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

The Annual Report on Form 10-K for the year ended December 31, 2020 (the Form 10-K) 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-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 19, 2021

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

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

Date: March 19, 2021

/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-K 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-K), irrespective of any general incorporation language contained in such filing.