# EX-10.1 3 ocgn-20210331x10qxex101.htm EX-10.1

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

Exhibit 10.1

### CO-DEVELOPMENT, SUPPLY AND COMMERCIALIZATION AGREEMENT

THIS CO-DEVELOPMENT, SUPPLY AND COMMERCIALIZATION AGREEMENT (this "Agreement") dated as of January 31, 2021 (the "Effective Date") is entered into by and between Ocugen, Inc., with an address at 263 Great Valley Parkway, Malvern, PA 19355, USA (together with its Affiliates, subsidiaries, successors and permitted assigns, "Ocugen"), and Bharat Biotech International Limited, whose registered office address is at Genome Valley, Shameerpet, Hyderabad – 500 078 Telagana India (together with its Affiliates, subsidiaries, successors and permitted assigns, "BBIL"). Ocugen and BBIL may be referred to herein as a "Party" or, collectively, as "Parties".

#### BACKGROUND

WHEREAS, BBIL is a global leader in vaccine innovation and has unique expertise with respect to vaccines and biotherapeutics research and product development, manufacturing, supply and distribution;

WHEREAS, Ocugen is a biopharmaceutical company focused on discovering, developing and commercializing transformative therapies;

WHEREAS, BBIL has certain rights to the Product, that it developed in collaboration with the Indian Council of Medical Research - National Institute of Virology, and BBIL desires to collaborate and cooperate with Ocugen to Develop, Manufacture and Commercialize the Product for use in the Field in and for the Ocugen Territory; and

WHEREAS, on the terms and subject to the conditions set forth herein, BBIL is willing to grant Ocugen the exclusive right under the BBIL Technology and the BBIL Patent Rights to Develop, Manufacture and Commercialize the Product for use in the Field in and for the Ocugen Territory.

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

# ARTICLE I DEFINITIONS

As used in this Agreement, the following words shall have the following meanings:

- 1.1. "Adverse Event" means any untoward medical occurrence in a patient who is administered the Product, whether or not considered related to the Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease associated with the use of the Product.
- 1.2. "Affiliate" means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with such first Person. For purposes of this definition only, the term "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means direct or indirect ownership of fifty percent (50%) or more, including ownership by one or more trusts with substantially the same beneficial interests, of the voting and equity rights of such Person, or the power to direct the management of such Person.
- 1.3. "Applicable Laws" means any national, international, federal, state or local laws, treaties, statutes, ordinances, rules and regulations, including any rules, regulations, guidance, guidelines or requirements of any Governmental Authority, Regulatory Authority, national securities exchanges or securities listing organizations, that are in effect from time to time during the Term and apply to a particular activity hereunder.

- 1.4. "BBIL Development Activities" means all Development activities to be conducted by or on behalf of BBIL as specified in the Development Plan pursuant to this Agreement.
- 1.5. "BBIL Patent Rights" means all Patent Rights, but excluding Joint Program Patent Rights, that are (a) Controlled by BBIL or its Affiliates as of the Effective Date and are set forth on Schedule 1.5, (b) conceived or reduced to practice by BBIL or its Affiliates in the conduct of the BBIL Development Activities pursuant to the Development Plan or otherwise pursuant to this Agreement, or (c) conceived or reduced to practice by BBIL or its Affiliates outside of this Agreement during the Term, in each case of (a), (b), and (c) to the extent necessary or useful for the research, Development, Manufacture, or Commercialization of the Product in the Field in the Territory.
- 1.6. "BBIL Technology" means any Technology, but excluding Joint Program Technology, that is (a) Controlled by BBIL or its Affiliates as of the Effective Date, (b) discovered, developed, made, created or reduced to practice by BBIL or its Affiliates in the conduct of the BBIL Development Activities pursuant to the Development Plan or otherwise pursuant to this Agreement, or (c) discovered, developed, made, created or reduced to practice by BBIL or its Affiliates outside of this Agreement during the Term, in each case of (a), (b), and (c) to the extent necessary or useful for the research, Development, Manufacture, or Commercialization of the Product in the Field in the Territory.
  - 1.7. "BBIL Territory" means the entire world excluding the Ocugen Territory.
- 1.8. "BLA" means a Biologics License Application, as defined in the FDCA and regulations promulgated thereunder, or similar application, or any successor application or procedure required to sell the Product in the Ocugen Territory.
- 1.9. "**Business Day**" means any day other than Saturday, Sunday, or any day that banks are authorized or required to be closed in New York, New York or in Hyderabad, India.
- 1.10. "Calendar Quarter" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31, except that the first Calendar Quarter will commence on the Effective Date and the last Calendar Quarter will end upon the end of the Term.
- 1.11. "Calendar Year" means each respective period of twelve (12) consecutive months ending on December 31, except that the first Calendar Year will commence on the Effective Date and the last Calendar Year will end upon the end of the Term.
- 1.12. "Claims" means all demands, claims and liabilities (whether criminal or civil, in contract, tort, or otherwise) for losses, damages, legal costs, or other expenses of any nature whatsoever, and all costs and expenses (including legal costs) incurred in connection therewith.
- 1.13. "Clinical Data" means any and all data (together with all Clinical Trial reports and the results of analyses thereof) derived or generated from any preclinical studies or any Clinical Trial involving the Product conducted by or on behalf of a Party or from the testing of subjects or the analysis of samples used in any such Clinical Trial.
- 1.14. "Clinical Trial" means, any research study of a therapeutic product with human subjects designed to provide specific data to determine either or both the safety and efficacy of such product. "Clinical Trial" includes any Phase 1 Clinical Trial, Phase 2 Clinical Trial or Phase 3 Clinical Trial.
- 1.15. "Clinical Trial Materials" means clinical testing materials, including clinical supplies of the Product in appropriate containers, for use in Clinical Trials.
  - 1.16. "CMA" means a Conditional Marketing Authorization granted by the EMA.
  - 1.17. "CMC Technology" means any Technology that relates to chemistry, manufacture and control for the Product.

- 1.18. "Commercialization" or "Commercialize" means any and all activities directed to the offering for sale and sale of the Product in the Ocugen Territory or the BBIL Territory, as applicable, including: (a) activities directed to marketing, promoting, detailing, warehousing, distributing, importing, exporting, selling and offering to sell the Product; (b) conducting post-registration efficacy and/or safety Clinical Trials with respect to the Product; (c) interacting with Regulatory Authorities regarding the foregoing; (d) seeking pricing approvals and reimbursement approvals (as applicable) for the Product; and (e) conducting such other post-registration Clinical Trials, including health-economic outcomes research, real-world evidence studies, or investigator-initiated studies. When used as a verb, to "Commercialize" and "Commercializing" means to engage in Commercialization and "Commercialized" has a corresponding meaning.
- 1.19. "Commercialization Plan" means a written plan for the Commercialization of the Product by a Party in and for the Ocugen Territory or the BBIL Territory, as applicable, during each three (3) year period beginning in the Calendar Year in which the First Commercial Sale of the Product occurs anywhere in such Territory, as such written plan may be amended, modified or updated by the responsible Party from time to time, and which written plan shall contain, among other things: (a) Commercialization objectives for the Product in such Territory; and (b) a projected timeline for achieving such objectives.
- 1.20. "Commercially Reasonable Efforts" means, with respect to the conduct by a Party of its activities and obligations hereunder, including as it relates to the Development, Manufacture or Commercialization of the Product in and for the Ocugen Territory or BBIL Territory, as applicable, the performance of such obligations or tasks by such Party, using a level of effort consistent with the exercise of good faith and prudent scientific and business judgment commonly used by a biopharmaceutical company of similar size and resources in the development, manufacture or commercialization of biologics and products of comparable market potential as the Product, taking into account all relevant factors, including as applicable, the stage of development, efficacy and safety relative to competitive products in the marketplace, actual or anticipated Regulatory Authority approved labeling, the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), the cost and likelihood of obtaining all Regulatory Approvals, and actual or projected profitability. For clarity, Commercially Reasonable Efforts shall be determined on a market-by-market basis for the Product, and it is anticipated that the level of efforts and resources may be different markets and may change over time, reflecting changes in the status of the Product.
- 1.21. "Confidential Information" means all (a) documents and information provided by or on behalf of one Party to the other Party in connection with or in furtherance of this Agreement, including at any meeting of the JSC, (b) the terms of this Agreement, and (c) all BBIL Technology, BBIL Patent Rights, Ocugen Technology, Ocugen Patent Rights, Joint Program Technology, Joint Program Patent Rights and Joint Program Materials that are disclosed or provided by or on behalf of a Party to the other Party, or to any of its employees, consultants or Affiliates during the Term.
- 1.22. "Control" or "Controlled" means, with respect to Technology or Patent Rights, the possession by a Party of the right to grant a license or sublicense to such Technology or Patent Rights as provided herein without the payment of consideration to, or violating the terms of any agreement or arrangement with any third party, and without violating any Applicable Laws. For clarity, neither a Party nor any of its Affiliates shall be deemed to Control any Technology or Patent Rights by virtue of the rights granted by the other Party under this Agreement.
- 1.23. "Cover" or "Covered" means, with respect to the Product, that the Manufacture, use, offer for sale, sale or import of the Product in a particular country by an unlicensed third party would infringe a Valid Claim.
- 1.24. "COVID-19" means SARS-CoV-2 or COVID-19, and any evolutions or mutations thereof or related or associated epidemics, pandemics or disease outbreaks.
- 1.25. "CTA" means a Clinical Trial application or any successor application or procedure required to initiate clinical testing of the Product in humans in the Territory, and all supplements and amendments to any of the foregoing.
  - 1.26. "Data" means, all results, data, and analyses thereof, including non-clinical data and Clinical Data.

- 1.27. "Development" or "Develop" means with respect to the Product and in accordance with the Development Plan, any and all activities directed to (a) research, non-clinical and pre-clinical studies, and IND-enabling studies, (b) clinical drug development activities that are undertaken with respect to the Product up through and including the date any Clinical Trials are completed, and (c) the preparation, filing and obtaining of INDs and Marketing Authorizations and all regulatory affairs related to the foregoing. When used as a verb, "Developing" means to engage in Development and "Developed" has a corresponding meaning. For clarity, "Development" shall exclude any Commercialization activities.
  - 1.28. "Development Activities" means the BBIL Development Activities and the Ocugen Development Activities.
- 1.29. "Development Plan" means a written plan for the Development of the Product by Ocugen, in and for the Ocugen Territory, and BBIL, in and for the BBIL Territory, for a Calendar Year or longer period, as such written plan may be amended, modified or updated by the Parties from time to time, and which written plan shall contain, among other things: (a) the Development objectives for the Product and the Development Activities to be performed by each Party for the Product in the Field in the Ocugen Territory or the BBIL Territory, as applicable; (b) the regulatory activities to be conducted by each Party in the Ocugen Territory or the BBIL Territory, as applicable; and (c) a projected timeline for such activities or to reach certain clinical milestones in the Ocugen Territory or specific countries within the BBIL Territory, as applicable.
- 1.30. "**Drug Approval Application**" means in any country in the Territory, an application for Marketing Authorization for a Product in such country, including: (a) in the United States, a BLA or EUA; (b) in the European Union, a MAA or CMA; (c) in any other country or jurisdiction in the Territory, a counterpart of a BLA, EUA, MAA or CMA in such country; and (d) all renewals, supplements and amendments to any of the foregoing.
  - 1.31. "EMA" means the European Medicines Agency or any successor agency or authority thereto.
- 1.32. "EUA" means Emergency Use Authorization, as defined in the FDCA and regulations promulgated thereunder, or similar request, application, authorization or procedure, or any successor request, application, authorization or procedure required or initially utilized to sell the Product in the Field in the Ocugen Territory.
- 1.33. "European Union" means the economic, scientific and political organization of member states known as the European Union, as its membership may be altered from time to time, or any successor thereto, and including, for purposes of this Agreement, the United Kingdom.
  - 1.34. "FDA" means the United States Food and Drug Administration, or any successor agency or authority thereto.
  - 1.35. "FDCA" means the United States Federal Food, Drug, and Cosmetic Act, as amended.
  - 1.36. "Field" means the prevention of COVID-19 in humans.
- 1.37. "First Commercial Sale" means with respect to the Product in any country in the Territory, the date of the first sale, transfer or disposition to an end user by a Party, its Affiliate or Sublicensee for value in that country after Marketing Authorization for the Product has been received in such country; *provided*, that the following shall not constitute a First Commercial Sale: (a) any sale of the Product by a Party, its Affiliate or Sublicensee to another Affiliate or Sublicensee of such Party; (b) any sale, transfer or disposition of the Product for research, preclinical, clinical, Development or regulatory purposes (including for use in Clinical Trials or pre-clinical studies); or (c) the sale, transfer or other disposition of the Product for a bona fide charitable purpose, including so-called "treatment IND sales," "named patient sales," "expanded access program" or "compassionate use sales" or to physicians or hospitals for promotional purposes (including free samples to a level and in an amount which is customary in the industry or which is reasonably proportional to the market for the Product).

- 1.38. "Force Majeure" means any occurrence beyond the reasonable control of a Party that prevents or substantially interferes with the performance by such Party of any of its obligations hereunder, including by reason of any act of God, flood, fire, explosion, earthquake, casualty, accident or pandemic (other than COVID-19), or war, revolution, civil commotion, act of terrorism, blockage or embargo, labor dispute, or any injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any Governmental Authority or of any subdivision, authority or representative of any such Governmental Authority.
  - 1.39. "GAAP" means United States generally accepted accounting principles applied on a consistent basis.
- 1.40. "Governmental Authority" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).
- 1.41. "IND" means (a) an Investigational New Drug Application as defined in the FDCA and regulations promulgated thereunder or any successor application or procedure required to initiate clinical testing of a product in humans in the United States; (b) an equivalent of an Investigational New Drug Application that is required in any other country or region in the Territory before beginning clinical testing of a product in humans in such country or region; and (c) all supplements and amendments to any of the foregoing.
- 1.42. "**Joint Program Materials**" means any tangible chemical, biological or physical materials that are collected, conceived, generated, developed or reduced to practice jointly by or on behalf of BBIL or its Affiliates' personnel, on the one hand, and Ocugen or its Affiliates' personnel, on the other hand, in the conduct of the Development Activities pursuant to the Development Plan.
- 1.43. "**Joint Program Patent Rights**" means any Patent Rights that contain one or more claims to the Joint Program Technology or Joint Program Materials.
- 1.44. "**Joint Program Technology**" means any (a) Technology that is conceived or first reduced to practice (actually or constructively), whether or not patentable, jointly by or on behalf of BBIL or its Affiliates' personnel, on the one hand, and Ocugen or its Affiliates' personnel, on the other hand (including any subcontractors or consultants to BBIL or Ocugen) in the conduct of or otherwise in connection with the performance of Development Activities pursuant to the Development Plan.
  - 1.45. "MAA" means a Marketing Authorization Application filed with the EMA.
  - 1.46. "Major Market Country" means India.
- 1.47. "Manufacture" means any activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, release, shipping, holding, conduct of Manufacture Process Development, stability testing, quality assurance and quality control of the Product. When used as a verb, "Manufacturing" means to engage in Manufacture and "Manufactured" has a corresponding meaning.
- 1.48. "Manufacture Process Development" means the process development, process qualification, and validation and scale-up of the process to manufacture the Product and analytic development and product characterization with respect thereto.
- 1.49. "Marketing Authorization" means the Regulatory Approval issued in respect of a Drug Approval Application filed by a Party or any of its Affiliates or Sublicensees that allows the marketing and sale of the Product for use in the Field in a country or region in the Territory.
- 1.50. "Ocugen Development Activities" means all Development activities to be conducted by or on behalf of Ocugen as specified in the Development Plan pursuant to this Agreement.
- 1.51. "Ocugen Patent Rights" means all Patent Rights, but excluding Joint Program Patent Rights, that are (a) conceived or reduced to practice by or on behalf of Ocugen or its Affiliates in the conduct of the Ocugen Development Activities pursuant to the Development Plan, or (b) conceived or reduced to practice by Ocugen or its Affiliates outside of this Agreement during the Term, in each case of (a) and (b) to the extent

necessary or useful for the research, Development, Manufacture, or Commercialization of the Product in the Territory.

- 1.52. "Ocugen Technology" means all Technology, but excluding Joint Program Technology, that is (a) discovered, developed, made, created or reduced to practice by Ocugen or its Affiliates in the conduct of the Ocugen Development Activities pursuant to the Development Plan, or (b) discovered, developed, made, created or reduced to practice by or on behalf of Ocugen or its Affiliates outside of this Agreement during the Term, in each case of (a) and (b) to the extent necessary or useful for the research, Development, Manufacture, or Commercialization of the Product in the Territory.
  - 1.53. "Ocugen Territory" means the United States.
- 1.54. "Patent Rights" means the rights and interests in and to issued patents and pending patent applications (which, for purposes of this Agreement, include certificates of invention, applications for certificates of invention and priority rights) in any country or region, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, all letters patent granted thereon, and all reissues, re-examinations and extensions thereof, and all foreign counterparts of any of the foregoing, and also including any and all utility models and registered designs.
- 1.55. "**Permits**" means all necessary consents, approvals and authorizations of all Governmental Authorities, Regulatory Authorities or other Persons in connection with the Development, Manufacture or Commercialization of the Product in each country and region of the applicable Territory.
- 1.56. "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.
- 1.57. "Phase 1 Clinical Trial" means a human clinical trial for a product in any country that would satisfy the requirements of 21 C.F.R. § 312.21(a).
- 1.58. "**Phase 2 Clinical Trial**" means a human clinical trial conducted in any country that would satisfy the requirements of 21 C.F.R. § 312.21(b) and is intended to explore one or more doses, dose responses, and duration of effect, and to generate initial evidence of clinical activity and safety, for a product in the target patient population.
- 1.59. "Phase 3 Clinical Trial" means a clinical trial in an extended human patient population designed to obtain data determining efficacy and safety of a product to support Marketing Authorization in the proposed therapeutic indication, as more fully defined in 21 C.F.R. § 312.21(c), or its successor regulation, or the equivalent in any foreign country.
- 1.60. "**Product**" means the advanced stage whole-viron inactivated vaccine candidate/product, commonly referred to as COVAXIN<sup>TM</sup>, and any and all improvements thereto made by BBIL or otherwise arising during the Term.
- 1.61. "**Product Trademark**" means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs and combinations thereof, in each case that are used by a Party in connection with the Development or Commercialization of the Product in the applicable Territory.
- 1.62. "**Regulatory Approval**" means, with respect to any country or region in the Territory, any approval, registration or authorization (including, for the avoidance of doubt, an EUA, CMA, or any equivalent authorization granted in any country or region in the Territory, as applicable) of any Regulatory Authority required for the Manufacture, use, storage, transport or Commercialization of the Product for use in the Field in such country or region of the Territory.
- 1.63. "**Regulatory Authority**" means any national, international, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority over

the distribution, importation, exportation, Manufacture, production, use, storage, transport, clinical testing, pricing, sale or reimbursement of the Product in the applicable Territory, including the FDA and the EMA in the applicable Territory.

- 1.64. "Regulatory Filing" means all applications, filings, submissions, approvals, licenses, registrations, Permits, notifications, authorizations (or waivers) and approvals (including all Regulatory Approvals) and all correspondence submitted to or received from any Regulatory Authority (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect to Clinical Trials or studies, or the Development, Manufacture or Commercialization of the Product and all Data contained in any of the foregoing made to or received from any Regulatory Authority in a given country, including BLAs, MAAs and INDs, regulatory drug lists, advertising and promotion documents, Manufacturing data, drug master files, Clinical Data, Adverse Event files and complaint files.
- 1.65. "Sale" means any transaction for which consideration is received by Ocugen, its Affiliates or Sublicensees for sale, use, lease, transfer or other disposition of the Product to or for the benefit of a third party. For clarity, the sale, use, lease, transfer or other disposition of the Product by Ocugen or any of its Affiliates or Sublicensees to another of these entities for resale by such entity to a third party shall not be deemed a Sale, provided such resale by these entities to or for the benefit of a third party has not occurred. For further clarity, the sale, transfer or other disposition of the Product by Ocugen or any of its Affiliates or Sublicensees to a wholesaler or a distributor for resale by such wholesaler or distributor shall not be deemed a Sale hereunder; but rather, the sale by the wholesaler or distributor to the end user shall be treated as a Sale by Ocugen, its Affiliates or Sublicensee, as applicable. For purposes of this definition, "Sale" shall not include the sale, transfer or disposition of the Product (a) for research, preclinical, clinical, Development or regulatory purposes (including for use in Clinical Trials or pre-clinical studies); or (b) for a bona fide charitable purpose, including so-called "treatment IND sales," "named patient sales," "expanded access program" or "compassionate use sales" or to physicians or hospitals for promotional purposes (including free samples to a level and in an amount which is customary in the industry or which is reasonably proportional to the market for the Product).
- 1.66. "**Senior Executives**" means, with respect to Ocugen, Shankar Musunuri, Ph.D., MBA, Chief Executive Officer of Ocugen, and with respect to BBIL, Dr. V. Krishna Mohan, Whole-time Director of BBIL.
- 1.67. "Serious Adverse Event" means any Adverse Event that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect, as defined more fully in 21 C.F.R. § 312.32.
- 1.68. "**Significant Development Event**" means any of the following material Development events: (a) any material interaction and/or written correspondence between a Party or any of its Affiliates and any Regulatory Authority with respect to the Product; or (b) any material event or result with respect to any Clinical Trial involving the Product.
- 1.69. "Sublicensee" means any person or entity (including Affiliates of the applicable Party) that is granted a sublicense as permitted by this Agreement (or an option to take such a sublicense), either directly by a Party or indirectly by any other Sublicensee hereunder.
- 1.70. "**Technology**" means, collectively, data, results, technology, inventions, discoveries, improvements, trade secrets and proprietary methods, whether or not patentable and in any tangible or intangible form, including: (a) methods of manufacture or use of, and structural and functional information pertaining to, biologics;(b) compositions of matter, data, formulations, processes, techniques, know-how and results; and (c) unregistered design rights, copyright, database rights, rights in respect of confidential information, rights under data exclusivity laws, rights under orphan drug laws, rights under unfair competition laws, property rights in biological or chemical materials, extension of the terms of any such rights, applications for and the right to apply any of the foregoing registered property and rights, and similar or analogous rights. For clarity, Technology excludes Patent Rights.

- 1.71. "**Territory**" means collectively or individually, as the context requires, the Ocugen Territory or the BBIL Territory.
  - 1.72. "United States" or "US" means the United States of America, its territories and possessions.
  - 1.73. "USD" or "\$" means the lawful currency of the United States.
- 1.74. "Valid Claim" means any claim of a pending patent application or an issued (or granted) and unexpired patent that (a) has not been finally cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction, (b) has not been permanently revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, (c) has not been rendered unenforceable through terminal disclaimer or otherwise, (d) is not lost through an interference proceeding, or foreign equivalent, that is unappealable or unappealed within the time allowed for appeal, and (e) in the case of a claim in a pending patent application, has been pending for not more than seven (7) years after the date of filing of the earliest patent application claiming priority with respect to such claim.
- 1.75. **Other Terms**. The definition of each of the following terms is set forth in the section of the Agreement indicated below:

Defined Term	Section		
Allowable Expenses	Exhibit B		
Annual Report	8.2		
BBIL	Preamble		
BBIL Indemnitees	13.1		
BBIL Indemnity Claim	13.1		
BBIL Trademarks	9.5		
Commercial Supply Agreement	7.2(a)		
Commercialization Expenses	Exhibit B		
Cost of Goods Sold	Exhibit B		
Damages Payment	13.7		
Development Expenses	Exhibit B		
Development Supply Agreement	7.1(a)		
Direct Labor Costs	Exhibit B		
Direct Material Costs	Exhibit B		
Disclosing Party	11.1		
Dispute	14.6		
Distribution Expenses	Exhibit B		
Indemnified Party	13.3		
Indemnifying Party	13.3		
Indemnity Claim	13.3		
JSC	2.1		
Losses	13.1		
Net Sales	Exhibit B		
Ocugen	Preamble		
Ocugen Development and Commercialization Costs	12.4(d)		
Ocugen Indemnitees	13.2		
Ocugen Indemnity Claim	13.2		
Ocugen Trademarks	9.5		
Operating Profit	Exhibit B		
Other Party	12.2		
Parties	Preamble		
Party	Preamble		
Product	Recitals		
Profit Share	8.1		
Public Statement	11.2		
Quarterly Report	8.2		
Receiving Party	11.1		
Retention Period	8.5		
Sales and Marketing Expenses	Exhibit B		
SEC	11.1(c)		

### ARTICLE II GOVERNANCE

- 2.1. <u>Joint Steering Committee</u>. Within [\*\*\*] after the Effective Date, the Parties shall establish a joint steering committee ("**JSC**") to facilitate the Development and Commercialization of the Product by Ocugen and BBIL pursuant to this Agreement. Each of Ocugen and BBIL agree to keep the JSC reasonably informed of its progress and activities under this Agreement, including pursuant to Section 2.9.
- 2.2. <u>Composition</u>. The JSC shall be comprised up to [\*\*\*] designated by Ocugen and up to [\*\*\*] designated by BBIL; [\*\*\*]. Each Party's representatives will be senior personnel (one of which may be a consultant) who possess a thorough understanding of the scientific and business issues relevant to this Agreement to enable such person to make decisions on behalf of such Party with respect to the issues falling within the jurisdiction of the JSC. Subject to the foregoing sentence, each Party may from time to time substitute its representatives on the JSC, in its sole discretion, effective upon notice to the other Party of such change. A secretary shall be appointed on an annual rotating basis by either Ocugen or BBIL, with Ocugen designating the first secretary.
  - 2.3. Functions and Powers of the JSC. The JSC shall have and perform the following responsibilities:
- (a) oversee the conduct of the Development Activities and the implementation and execution of the Development Plan;
  - (b) review and approve the Development Plan and all amendments thereto;
- (c) review and discuss the overall performance of Development Activities by the Parties and comparing same to the diligence obligations set forth in Section 4.3;
  - (d) review reports delivered to the JSC in accordance with this Agreement;
- (e) review or ensure the exchange of all Technology, proprietary materials, reports or other information submitted to each Party or the JSC pursuant to this Agreement;
- (f) subject to Section 14.6, resolve any dispute with respect to the Parties' rights and obligations under this Agreement;
- (g) establish subcommittees, direct and oversee any subcommittee on all significant issues, and resolve disputed matters that may arise at the subcommittees; and
- (h) perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as mutually determined by the Parties in writing.
- 2.4. <u>Meetings</u>. The JSC shall establish a schedule of times for regular meetings. Special meetings may be convened by any member of the JSC upon not less than thirty (30) days' written notice to the other members of the JSC. Until the First Commercial Sale of the Product in the Ocugen Territory, the JSC will meet at least once per [\*\*\*]. The JSC may conduct such meetings by telephone or audio, videoconference, or in person as determined by the Parties. Meetings of the JSC are effective only if at least one (1) representative of each Party participates in such meeting; *provided*, in the event of exigent circumstances, a Party may designate a substitute member to temporarily attend and perform the functions of such Party's designee(s) at any meeting of the JSC, which shall constitute participation in such meeting for purposes of this Section 2.4. Each Party may invite a reasonable number of participants, in addition to its representatives, to attend JSC meetings in a non-voting capacity; provided that such attendees shall be bound by confidentiality and non-use obligations at least as restrictive as those set forth in this Agreement.
- 2.5. <u>Minutes</u>. The secretary shall have responsibility for preparing, circulating and finalizing the agenda for and minutes from each JSC meeting. Minutes shall be circulated to each Party within [\*\*\*] after each meeting of the JSC, setting forth, *inter alia*, an overview of the discussions at the meeting and a list of any actions and decisions approved by the JSC and a list of any issues. Such minutes shall be effective only after

approval by both Parties in writing. With the sole exception of specific items of the meeting minutes to which the members cannot agree and that may not be resolved as provided in Section 2.7, definitive minutes of all JSC meetings shall be finalized no later than [\*\*\*] after the meeting to which the minutes pertain. If, at any time during the preparation and finalization of the JSC minutes, the Parties do not agree on any issue with respect to the minutes, such issue shall be resolved by the escalation process set forth in Section 2.7. The decision resulting from the escalation process shall be recorded by the secretary in amended finalized minutes for such meeting.

2.6. <u>Subcommittees</u>. The JSC may establish and disband subcommittees as deemed necessary by the JSC. Each such subcommittee will consist of an equal number of representatives designated by each Party, which number shall be mutually agreed by the Parties. Each Party may change its representatives on any subcommittee upon written notice to the other Party or send a substitute representative to any subcommittee meeting. Each Party's representatives and any substitute for a representative shall be bound by confidentiality and non-use obligations consistent with the terms of this Agreement. Except as expressly provided in this Agreement, no subcommittee has the authority to bind the Parties hereunder and each subcommittee will report and be subordinate to the JSC. If a dispute arises that cannot be resolved by a subcommittee, such dispute shall be referred to the JSC for resolution.

### 2.7. Decisions.

- (a) The JSC will act by consensus, with the representatives of each Party having, collectively, one (1) vote on behalf of that Party. The Parties shall cause their respective representatives on the JSC to use their good faith efforts to resolve all matters appropriately presented to them in an expeditious manner.
- (b) If the JSC is deadlocked on a decision within its purview and cannot come to a mutual agreement on such decision within [\*\*\*] after the matter has been brought to the JSC's attention, it shall be escalated to the Senior Executives for resolution. If consensus cannot be reached by the Senior Executives within [\*\*\*] after referral to the Senior Executives by the JSC, then the Parties will resolve such dispute in accordance with the terms of Section 14.5.
- 2.8. Scope of JSC Authority. The JSC and any subcommittees have only the powers assigned expressly to it in this Article II and elsewhere in this Agreement, and do not have any power to amend, modify, or waive compliance with this Agreement. Subject to the foregoing, each Party will be entitled to rely conclusively (without further evidence of any kind whatsoever) on any determination made by the JSC in accordance with this Agreement, and no Party will assert or attempt to assert that any action taken by the JSC that is within such scope of authority granted to the JSC under this Agreement is invalid or not binding on such Party. Each Party retains the rights, powers, and discretion granted to it under this Agreement and neither Party may delegate or vest such rights, powers, or discretion in the JSC or subcommittee unless expressly provided for in this Agreement or the Parties expressly so agree in writing.
- 2.9. <u>Reports</u>. At each regularly scheduled meeting of the JSC, each Party will provide to the JSC a progress update on such Party's activities under the Development Plan or Commercialization Plan, as applicable. Such progress update can take the form of a PowerPoint presentation. Each Party will endeavor to provide a copy of any such PowerPoint presentation to the JSC at least two (2) Business Days prior to the meeting of the JSC at which such presentation will be made. Such presentation will include a summary of the Development or Commercialization activities conducted by such Party pursuant to the Development Plan or Commercialization Plan, as applicable, since the prior meeting of the JSC.
- 2.10. <u>Expenses</u>. Each Party shall bear its own costs associated with its participation in the JSC or any subcommittee, including but not limited to the costs of travel and expenses directly associated with participation in the JSC or any subcommittee.

## ARTICLE III GRANT OF RIGHTS

3.1. <u>License Grants to Ocugen</u>. Subject to the provisions of this Agreement, BBIL hereby grants to Ocugen:

- (a) an exclusive (even as to BBIL), sublicensable (through multiple tiers) license under the BBIL Technology and the BBIL Patent Rights, to use, research, Develop (including to conduct the Ocugen Development Activities assigned to Ocugen in the Development Plan), Manufacture and Commercialize the Product in the Field in and for the Ocugen Territory; and
- (b) an exclusive (even as to BBIL), sublicensable (through multiple tiers) license, under BBIL's rights in the Joint Program Technology and Joint Program Patent Rights, to use, research, Develop (including to conduct the Ocugen Development Activities assigned to Ocugen in the Development Plan), Manufacture and Commercialize the Product in the Field in and for the Ocugen Territory.
- 3.2. <u>License Grant to BBIL</u>. Subject to the provisions of this Agreement, Ocugen hereby grants to BBIL a limited, non-exclusive, non-royalty bearing, non-sublicensable (except to Affiliates of BBIL) license under the Ocugen Technology and the Ocugen Patent Rights, to conduct the BBIL Development Activities assigned to BBIL in the Development Plan.
- 3.3. Ocugen Right to Sublicense. Ocugen shall have the right to grant sublicenses, in whole or in part, through one or more tiers, under the licenses granted to it under Section 3.1 to any of its Affiliates, and to any third party pursuant to a written agreement; provided that (a) any such sublicense shall be consistent with and subject to the terms and conditions of this Agreement, and (b) Ocugen shall remain responsible to BBIL for the performance of its Sublicensee(s) or any Affiliate to which it grants a sublicense with respect to Ocugen's obligations under the terms of this Agreement.
- 3.4. Ocugen Assistance. Ocugen shall provide BBIL with all documents, information and Data in its possession as reasonably requested by BBIL or that are otherwise necessary or useful for BBIL to conduct the BBIL Development Activities under Article IV, including without limitation all Joint Program Materials under the Control of Ocugen.
- 3.5. <u>BBIL Assistance</u>. BBIL shall provide Ocugen with all documents, information and Data in its possession as reasonably requested by Ocugen or that are otherwise necessary or useful for Ocugen to conduct the Ocugen Development Activities under Article IV, including without limitation all Joint Program Materials under the Control of BBIL.
- 3.6. <u>Non-Competition</u>. During the Term, except as set forth in this Agreement, Ocugen shall, not directly or indirectly (with, for the benefit of, using, or with the sponsorship of, any third party) Develop, Manufacture or Commercialize any COVID-19 vaccine candidate or similar product that competes, directly or indirectly, with the Product in the Ocugen Territory, except with the prior written consent of BBIL.

# ARTICLE IV CO-DEVELOPMENT OF THE PRODUCT

- 4.1. <u>Overview</u>. Consistent with the terms and conditions of this Agreement, the Parties shall collaborate with one another in the Field during the Term as it relates to the Development of the Product in and for their respective Territories. Ocugen will have the exclusive right and sole responsibility for (except as set forth in Article VII and, if applicable, as set forth in the Development Supply Agreement) the research and Development of the Product in the Field in and for the Ocugen Territory, and BBIL will have the exclusive right and sole responsibility for the research and Development of the Product in the Field in and for the BBIL Territory.
- 4.2. <u>Development Plan.</u> The initial Development Plan, attached hereto as <u>Exhibit A</u>, describes the BBIL Development Activities and the Ocugen Development Activities to be carried out by the Parties in and for their respective Territories from the Effective Date through the end of Calendar Year 2021. For each Calendar Year after 2021, the Parties shall jointly prepare an updated Development Plan and submit it to the JSC for its review and approval pursuant to Section 2.3(b). The Parties shall use Commercially Reasonable Efforts to collaborate on, prepare and submit each Development Plan to the JSC no later than [\*\*\*] days prior to the end of each Calendar Year starting with Calendar Year 2021. Any amendment, modification or update to any Development Plan shall be set forth in a written document prepared by one or both Parties and reviewed by the JSC, shall specifically state that it is an amendment, modification or update to the then-existing

Development Plan and shall be sent to the JSC members no later than [\*\*\*] days prior to the meeting of the JSC at which such amendment, modification or update is to be reviewed and approved.

#### 4.3. <u>Development Activities; Diligence</u>.

# (a) BBIL Development Activities.

- (i) BBIL will be responsible for the BBIL Development Activities set forth in the Development Plan, which shall include the conduct of Clinical Trials for the Product in and for the BBIL Territory.
- (ii) BBIL shall use Commercially Reasonable Efforts to conduct the BBIL Development Activities as set forth in the Development Plan (consistent with good scientific practice). BBIL shall make available to Ocugen all results, Data, and information arising from the BBIL Development Activities (including any Clinical Trial protocols for the Product); provided however, BBIL does not warrant the suitability of any Data submitted by BBIL to Ocugen to support Ocugen's Regulatory Filings for the Product in the Field in and for the Ocugen Territory.

#### (b) Ocugen Development Activities.

- (i) Ocugen will be responsible for the Ocugen Development Activities set forth in the Development Plan, which shall include the design and preparation of Clinical Trial protocols for the Product and the conduct of Clinical Trials for the Product in and for the Ocugen Territory.
- (ii) Ocugen shall use Commercially Reasonable Efforts to conduct the Ocugen Development Activities as set forth in the Development Plan (consistent with good scientific practice). Ocugen shall make available to BBIL all results, Data, and information arising from the Ocugen Development Activities (including any Clinical Trial protocols for the Product).
- 4.4. Ownership of Joint Technology and Joint Patent Rights. All Joint Program Technology and Joint Program Patent Rights shall be jointly owned by the Parties and each Party shall be free to practice such Joint Program Technology and Joint Program Patent Rights in its Territory, subject to any terms or conditions of this Agreement to the contrary.
- 4.5. <u>Costs of Development</u>. BBIL is solely responsible for all costs and expenses associated with the performance of the BBIL Development Activities and the Development of the Product in the Field in and for the BBIL Territory and Ocugen is solely responsible for all costs and expenses associated with the performance of the Ocugen Development Activities and the Development of the Product in the Field in and for the Ocugen Territory.
- 4.6. Engagement of Third Party Contractors. A Party may engage third party contractors to perform, as applicable, BBIL Development Activities or Ocugen Development Activities hereunder; *provided*, that with respect to any such subcontract, the applicable third party contractor shall execute an agreement containing provisions that (a) are consistent with the cooperation, records and reports, ownership, confidentiality and intellectual property provisions set forth in this Agreement, and (b) assign any and all intellectual property rights discovered or invented by the third party contractor thereunder to BBIL or Ocugen, as applicable.
- 4.7. <u>Compliance</u>. Each Party shall perform all Development Activities for which it is responsible under the Development Plan in a good scientific manner and in compliance with all Applicable Laws.
- 4.8. Records and Reports. Each Party shall maintain complete and accurate records of its Development Activities in accordance with good business practices and in sufficient detail, including in sufficient detail for the purpose of making patent filings and Regulatory Filings, in good scientific manner, or otherwise in a manner that reflects all work done and results achieved. Each Party may review and copy such records at reasonable times, and upon reasonable notice to the other Party. Each Party shall provide to the other Party, at least once each [\*\*\*] until the First Commercial Sale of the Product in the Ocugen Territory, a reasonably detailed report that summarizes: (a) all Development Activities conducted and the results obtained

by such Party with respect to the Product during the most recently completed Calendar Quarter; and (b) any Significant Development Events applicable to the Product.

4.9. <u>Further Cooperation</u>. Further to the Parties' respective obligations under Section 4.3, each Party shall share with the other Party all information it obtains in its conduct of the Development Activities, including but not limited to documents and Data in regard to pre-clinical activities, clinical activities, CMC Technology, Manufacture, and Regulatory Approval in or for its Territory.

# ARTICLE V REGULATORY ACTIVITIES

#### 5.1. BBIL Regulatory Activities.

- (a) BBIL shall have the exclusive right and sole responsibility for the preparation, submission and maintenance of all Regulatory Filings, and obtaining Regulatory Approvals for, the Product in the Field in and for the BBIL Territory. BBIL shall use Commercially Reasonable Efforts to seek and obtain Marketing Authorization for the Product in the Major Market Country, including, if applicable, obtaining accelerated review of such application for Marketing Authorization. All Regulatory Approvals for the Product in the BBIL Territory will be held by and in the name of BBIL or any of its Affiliates. BBIL shall solely and exclusively own all Regulatory Approvals obtained by BBIL in and for the BBIL Territory.
- (b) BBIL shall reasonably cooperate with any on-site inspection by a Regulatory Authority with respect to any Clinical Trial being conducted by Ocugen as it relates to BBIL's Manufacture of Clinical Trial Materials or finished Products pursuant to this Agreement, the Development Supply Agreement or the Commercial Supply Agreement, as applicable.

### 5.2. Ocugen Regulatory Activities.

- (a) Ocugen shall have the exclusive right and sole responsibility for the preparation, submission and maintenance of all Regulatory Filings, and obtaining Regulatory Approvals for, the Product in the Field in and for the Ocugen Territory. Ocugen shall use Commercially Reasonable Efforts to seek and obtain Marketing Authorization for the Product in the Ocugen Territory, including where applicable, obtaining accelerated review of application(s) for Marketing Authorization. All Regulatory Approvals for the Product in the Ocugen Territory will be held by and in the name of Ocugen or any of its Affiliates. Ocugen shall solely and exclusively own all Regulatory Approvals obtained by Ocugen in and for the Ocugen Territory.
- (b) For all Clinical Trials sponsored by Ocugen, to the extent permissible by the applicable Regulatory Authority, Ocugen shall have the right to include in any Regulatory Filing for Regulatory Approval of the Product in the Ocugen Territory, all Data and other information related to the use of the Product in the BBIL Territory and include such Data and other information in any subsequent interactions with such Regulatory Authority.

### 5.3. Regulatory Correspondence.

- (a) The Parties shall reasonably cooperate with and assist each other in compliance with all regulatory obligations to the extent arising out of or otherwise related to (i) the Product, or (ii) the performance of the Parties' respective obligations under this Agreement, including by providing to the other Party copies of all Regulatory Filings related to the Product for and in respect of its Territory, including in order to support Clinical Trials for the Product being undertaken and conducted by Ocugen.
- (b) Upon the reasonable request of Ocugen, BBIL shall reasonably respond to questions or comments from Regulatory Authorities in the Ocugen Territory as it relates to use of the Product in the Field. In the event that a Regulatory Authority requests any information that has not been provided to Ocugen by BBIL, to the extent such additional information is under the control of BBIL, BBIL shall provide such information to Ocugen at no additional cost. Upon the reasonable request of BBIL, Ocugen shall reasonably respond to questions or comments from Regulatory Authorities in the BBIL Territory as it relates to use of the Product in the Field. In the event that a Regulatory Authority requests any information that has not been



provided to BBIL by Ocugen, to the extent such additional information is under the control of Ocugen, Ocugen shall provide such information to BBIL at no additional cost.

5.4. <u>Responsibility for Regulatory Expenses</u>. Each Party shall be solely responsible for paying all costs and expenses incurred in connection with obtaining or maintaining Regulatory Approval of the Product in the Field in its Territory.

## ARTICLE VI COMMERCIALIZATION

- 6.1. Responsibility for Commercialization of the Product. Consistent with the terms and conditions of this Agreement, each Party shall be solely responsible for Commercialization of the Product in the Field in its Territory. For clarity, Ocugen shall be solely responsible for, and has exclusive rights with respect to, the Commercialization of the Product in the Field in and for the Ocugen Territory, and BBIL shall be solely responsible for, and has exclusive rights with respect to, the Commercialization of the Product in the Field in and for the BBIL Territory, in each case including all pre-marketing, marketing, promotion, sales, distribution, import and export activities (including securing reimbursement, sales and marketing and conducting any post-marketing trials or databases and post-marketing safety surveillance), maintaining all issued Marketing Authorizations, maintaining all pharmacovigilance systems and activities as required by Applicable Laws and the timing and launch of the Product in its applicable Territory. Each Party shall, and shall cause its Affiliates to, market and promote the Product only in the Field in its Territory.
- 6.2. <u>Commercialization Plan</u>. No later than [\*\*\*] prior to the anticipated First Commercial Sale of the Product in the Ocugen Territory or the BBIL Territory, as applicable, the responsible Party shall provide to the other Party its initial Commercialization Plan for its Territory. Thereafter, each Party shall provide the other Party with an updated Commercialization Plan no later than [\*\*\*].
- 6.3. <u>Responsibility for Commercialization Expenses</u>. Each Party shall be solely responsible for paying all costs and expenses incurred in connection with its Commercialization of the Product in the Field in its Territory.
- 6.4. <u>Commercialization Diligence</u>. Subject to the receipt of Marketing Authorization, Ocugen shall use Commercially Reasonable Efforts to market, promote, offer for sale, sell, and otherwise Commercialize the Product in the Field in and for the Ocugen Territory. Subject to the receipt of Marketing Authorization, BBIL shall use Commercially Reasonable Efforts to market, promote, offer for sale, sell, and otherwise Commercialize the Product in the Field in and for the Major Market Country in the BBIL Territory.
- 6.5. <u>Commercialization Reports</u>. Each Party shall maintain a record of all of its Commercialization activities in accordance with good business practices. No later than [\*\*\*], such Party shall provide to the other Party a reasonably detailed report that summarizes the Commercialization activities conducted by such Party during [\*\*\*].
- 6.6. <u>Compliance with Applicable Laws</u>. Each Party undertakes to Commercialize the Product in the Field in and for the applicable Territory entirely in accordance with the Marketing Authorization for the Product in such country of the Territory and in accordance with all Applicable Laws.
- 6.7. Adverse Events. BBIL shall be solely responsible for reporting to Regulatory Authorities all Adverse Events and Serious Adverse Events to the extent required by Applicable Laws, in each case for and in respect of the BBIL Territory. Ocugen shall be solely responsible for reporting to Regulatory Authorities all Adverse Events and Serious Adverse Events to the extent required by Applicable Laws, in each case for and in respect of the Ocugen Territory. In furtherance of the foregoing, during the Term, each Party shall be responsible for promptly notifying the other Party regarding any Adverse Event, whether actual or suspected, in respect of the Product that is suffered anywhere in the world and with respect to which such Party obtains information or knowledge (the "Reporting Party") as follows:
- (a) the Reporting Party shall report to the other Party by telephone (followed by written descriptions) or in writing any information regarding a Serious Adverse Event concerning drug reactions that are



life-threatening or cause death within [\*\*\*] after an initial determination by the Reporting Party that the Adverse Event constitutes a Serious Adverse Event;

- (b) the Reporting Party shall report to the other Party in writing any information about any Serious Adverse Event that does not fall within the scope of Section 6.7(a) within [\*\*\*] days after an initial determination by the Reporting Party that the Adverse Event constitutes a Serious Adverse Event; and
- (c) the Reporting Party shall report to the other Party by telephone (followed by written descriptions) or in writing any information regarding a non-serious Adverse Event that does not fall within the scope of Sections 6.7(a) or 6.7(b) within [\*\*\*] days after the date the Reporting Party receives the information.

A Reporting Party's reports delivered pursuant to this Section 6.7 shall contain any relevant information reasonably required by the other Party to meet the requirements of any Regulatory Authority in or for its Territory.

# ARTICLE VII MANUFACTURE AND SUPPLY OF THE PRODUCT

### 7.1. <u>Development Supply Agreement</u>.

- (a) Subject to Section 7.4, pursuant to a development supply agreement (the "**Development Supply Agreement**") to be entered into between the Parties, BBIL shall be responsible for the Manufacture and supply of all Clinical Trial Materials required for Ocugen's non-clinical and clinical Development of the Product in the Field in and for the Ocugen Territory (including the performance of the Ocugen Development Activities). The Parties will enter into the Development Supply Agreement within [\*\*\*] days after the Effective Date. The Development Supply Agreement shall contain mutually agreeable terms, including, among other things, that the maximum purchase price payable by Ocugen for Clinical Trial Materials manufactured and supplied thereunder shall not exceed [\*\*\*].
- (b) Except as set forth in the Development Supply Agreement, prior to the completion of the technology transfer as provided in Section 7.3(a), BBIL shall be responsible, in accordance with the Development Supply Agreement or as may otherwise be agreed between the Parties, to (i) Manufacture and supply Ocugen with such form and quantity of Clinical Trial Materials as Ocugen reasonably requires to conduct the Ocugen Development Activities and carry out Clinical Trials necessary to seek and obtain Regulatory Approval of the Product in the Field in and for the Ocugen Territory, and (ii) perform release and stability testing of the Product for use in the Field in and for the Ocugen Territory in accordance with FDA requirements and Applicable Law. In furtherance of the forgoing, within [\*\*\*] days after the Effective Date, and thereafter on an as needed basis during the Term or as may otherwise be discussed and agreed by the Parties at the JSC, BBIL shall share all CMC Technology and related information for the Product with Ocugen.

# 7.2. Commercial Supply Agreement.

- (a) Subject to this Section 7.2 and Section 7.4, subject to Ocugen's ability to qualify a secondary supplier in limited events of supply failure, pursuant to a commercial supply agreement (the "Commercial Supply Agreement") to be entered into between the Parties, BBIL shall be responsible for the Manufacture and supply of all of Ocugen's requirements of commercial quantities of the Product for Ocugen's Commercialization of the Product in the Field in and for the Ocugen Territory, subject to any reasonable limitations on BBIL's capacity (as more fully described in the Commercial Supply Agreement), until such time as the technology transfer described in Section 7.3(a) below has been completed. The Parties will enter into the Commercial Supply Agreement prior to the anticipated First Commercial Sale of the Product in the Ocugen Territory. Except as set forth in the Commercial Supply Agreement:
- (i) prior to the completion of the technology transfer as provided in Section 7.3(a), BBIL shall be responsible, at its sole cost and expense, for (x) the Manufacture and supply of the finished Product in its commercial packaging presentation, for use by Ocugen in the Field in the Ocugen Territory after Ocugen's receipt of an EUA, BLA or other Regulatory Approval for the Product in the Ocugen Territory, and (y) performing release and stability testing of the Product for use in the Field in the Ocugen Territory in accordance with FDA requirements and Applicable Law; and



- (ii) following the completion of the technology transfer as provided in Section 7.3(a), (x) Ocugen shall be responsible, at its sole cost and expense, for the Manufacture and supply of the finished Product in its commercial packaging presentation, for use by Ocugen in the Field in the Ocugen Territory after Ocugen's receipt of an EUA, BLA or other Regulatory Approval for the Product in the Ocugen Territory, (y) if required under the Commercial Supply Agreement, and subject to any reasonable limitations on Ocugen's capacity (as more fully described in the Commercial Supply Agreement), Ocugen shall be responsible for the Manufacture and supply of the finished Product in its commercial packaging presentation, for use by BBIL in the Field in and for the BBIL Territory, after BBIL's receipt of Regulatory Approval for the Product in the BBIL Territory.
- (b) The Commercial Supply Agreement shall contain mutually agreeable terms, including, among other things, that (i) notwithstanding the consummation of the technology transfer pursuant to Section 7.3, for and during the Calendar Year 2021, BBIL shall Manufacture and supply to Ocugen, its Affiliates or Sublicensees not less than (*i.e.*, at least) [\*\*\*] of finished commercial Product (sufficient for a minimum of [\*\*\*] patients) for Ocugen's, its Affiliates' and Sublicensees' use in the Field in and for the Ocugen Territory, (ii) the maximum purchase price payable by Ocugen for the Product manufactured and supplied thereunder shall not exceed [\*\*\*], and (iii) following the completion of the technology transfer as provided in Section 7.3, notwithstanding Ocugen's exclusive right to Manufacture the Product in and for the Ocugen Territory, BBIL shall continue to be a back-up supplier of the Product for Ocugen, its Affiliates or Sublicensees, as applicable, in and for the Ocugen Territory, provided that the purchase price payable by Ocugen for any such back-up supply shall be negotiated between the Parties prior to BBIL manufacturing such supply for Ocugen.

# 7.3. <u>Technology Transfer</u>.

- (a) Upon Ocugen's written request, BBIL shall (i) provide Ocugen with all preclinical and clinical Data (including Clinical Data) in support of US late-stage Clinical Trials being conducted by Ocugen or its designees, and (ii) transfer to Ocugen or its designated CMOs or CROs (which may be by electronic transfer (utilizing a secure portal) in accordance with a mutually agreed technology transfer plan or pursuant to a material transfer agreement), all BBIL Technology (including [\*\*\*]), in a form and format as necessary for the successful commercial manufacture and supply of the Product to support commercial sale of the Product in the Field in and for the Ocugen Territory. The technology transfer set forth in the preceding sentence shall be deemed completed as of such time as Ocugen (or its designees) are capable and primarily responsible for the Manufacture and supply of the Product for use by Ocugen in the Field in and for the Ocugen Territory.
- (b) Following the initial technology transfer to Licensee as provided in Section 7.3(a)(ii), upon Ocugen's request and on an as needed basis during the Term, BBIL shall transfer to Ocugen or its designee (in accordance with a mutually agreed technology transfer plan or material transfer agreement) all BBIL Technology (including the [\*\*\*]), reasonably necessary or useful to support the successful commercial Manufacture of the Product for commercial sale in and for the Ocugen Territory.
- (c) Upon Ocugen's reasonable request BBIL shall(i) provide such technical assistance and cooperation as may be reasonably requested by Ocugen or its designee in connection with the technology transfers contemplated by Section 7.3(a) or Section 7.3(b), and (ii) make its personnel reasonably available to consult with Ocugen or its designees with respect to the BBIL Technology. BBIL shall cause such personnel to respond to Ocugen's or its designees' reasonable requests and inquires pursuant to the preceding sentence within [\*\*\*].
- (d) Each Party shall be responsible for any and all costs and expenses incurred by it in connection with the transfer of BBIL Technology as contemplated by this Section 7.3.

### 7.4. Exclusivity.

(a) Prior to the completion of the technology transfer pursuant to Section 7.3(a), BBIL shall have the exclusive right to Manufacture the Product in the Field in and for the Ocugen Territory, subject to allowance for qualifying a secondary source to be set forth in the Commercial Supply Agreement; thereafter, BBIL shall have a non-exclusive right to Manufacture the Product in the BBIL Territory for the use and

Commercialization of such Product by Ocugen, its Affiliates or Sublicensees in and for the Ocugen Territory solely as may be requested by Ocugen, its Affiliates or Sublicensees pursuant to and in accordance with the terms of the Commercial Supply Agreement.

(b) Except as set forth in Section 7.4(a), from and after the completion of the technology transfer pursuant to Section 7.3(a), Ocugen shall have, except as otherwise set forth in the Commercial Supply Agreement, the sole and exclusive right to Manufacture the Product in the Field in and for the Ocugen Territory.

### ARTICLE VIII PROFIT SHARE

- 8.1. <u>Profit Share</u>. The Parties will share in Operating Profit with respect to Sales of the Product by Ocugen, its Affiliates and Sublicensees in the Field in and for the Ocugen Territory as follows: Ocugen will be entitled to forty-five percent (45%) and BBIL will be entitled to fifty-five percent (55%) thereof (the "**Profit Share**"). Procedures for calculating the Profit Share on a Calendar Quarter basis and other finance and accounting matters, are set forth in <u>Exhibit B</u> attached hereto, and to the extent not set forth in <u>Exhibit B</u> or elsewhere in this Agreement, will be established by the JSC.
- Sales Reports; Payments. Within [\*\*\*] after the end of each of the first three Calendar Quarters of each Calendar Year (each such report, a "Quarterly Report") and [\*\*\*] after the end of each such Calendar Year (each such report, an "Annual Report"), Ocugen shall provide a written report to BBIL showing:(a) the gross Sales and Net Sales of the Product in and for the Ocugen Territory through the end of such Calendar Quarter (or Calendar Year, if applicable); (b) the total amount of deductions from gross Sales taken to determine Net Sales of the Product in and for the Ocugen Territory for such Calendar Quarter (or Calendar Year, if applicable); (c) a calculation of Operating Profit in accordance with Exhibit B for such Calendar Quarter (or Calendar Year, if applicable), and (d) a calculation of the Profit Share payable to BBIL in respect of such Calendar Quarter (or Calendar Year, if applicable). In addition, each Annual Report will include any applicable adjustments to Operating Profit reported in the Quarterly Reports for such Calendar Year. Ocugen shall pay any Profit Share owed to BBIL within [\*\*\*] after the end of each of the first three Calendar Quarters of each Calendar Year and [\*\*\*] after the end of such Calendar Year in which Sales of the Product by Ocugen, its Affiliates or Sublicensees occur in the Ocugen Territory, commencing with the Calendar Quarter in which the First Commercial Sale of the Product in the Ocugen Territory occurs. To the extent that the actual Operating Profit for the first three Calendar Quarters of any Calendar Year were in excess of the Operating Profit included in the applicable Quarterly Reports, Ocugen will pay to BBIL, within [\*\*\*] after the end of the applicable Calendar Year, an amount equal to the Profit Share on such excess. To the extent that the actual Operating Profit for the first three Calendar Quarters of any Calendar Year were less than the Operating Profit included in the applicable Quarterly Reports, Ocugen may apply the amount of any overpayment as a credit against any Profit Share that may be payable to BBIL within [\*\*\*] after the end of the applicable Calendar Year, or if no Profit Share is payable, against the future Profit Share payments owed to BBIL under this Agreement. If no such future Profit Share payments are payable, then BBIL shall refund the overpayment to Ocugen within [\*\*\*] after the end of such Calendar Year.
- 8.3. <u>Mode of Payment; Currency</u>. All payments made by Ocugen under this Article VIII shall be made by wire transfer from a banking institution in USD in accordance with instructions given in writing from time to time by BBIL.
- 8.4. Withholding Taxes. If Applicable Laws require withholding of income or other taxes imposed upon any payments made by Ocugen to BBIL under this Agreement, including any VAT or sales tax, Ocugen shall (a) make such withholdings as may be required, (b) subtract such withholdings from such payments, (c) submit appropriate proof of payment of the withholding taxes to BBIL within a reasonable period of time, and (d) promptly provide BBIL with all official receipts with respect thereto.
- 8.5. <u>Books and Records; Audit.</u> Ocugen and its Affiliates and Sublicensees shall keep and maintain for [\*\*\*] from the end of the Calendar Year in which such Net Sales occur (the "**Retention Period**") materially complete and accurate records of gross Sales and Net Sales of the Product in the Ocugen Territory by, as applicable, Ocugen, its Affiliates and Sublicensees, in sufficient detail to allow Operating Profit and the Profit Share to be determined accurately. BBIL shall have the right during the applicable Retention Period, and at its cost, through an independent certified public accountant reasonably acceptable to Ocugen, to audit the relevant



records of Ocugen, its Affiliates and Sublicensees to verify that the amount of such payment was correctly determined. Ocugen, its Affiliates and Sublicensees shall each make its records reasonably available for audit by such independent certified public accountant during regular business hours at such place or places where such records are customarily kept, upon [\*\*\*] written notice from BBIL. Such audit right shall not be exercised by BBIL more than [\*\*\*] or more than [\*\*\*]. All records made available for audit shall be the Confidential Information of Ocugen. The results of each audit, if any, shall be binding on both Parties absent manifest error. In the event there was an underpayment by Ocugen hereunder, Ocugen shall promptly (but in any event no later than [\*\*\*] after Ocugen's receipt of the report so concluding) make payment to BBIL of any shortfall. BBIL shall bear the full cost of such audit unless such audit discloses an underreporting by Ocugen of the higher of (a) [\*\*\*], or (b) [\*\*\*] during the period audited, in which case Ocugen shall reimburse BBIL for all reasonable costs incurred by BBIL in connection with such audit. In the event the auditor finds an overpayment by Ocugen, Ocugen shall have the right to deduct the overpayment from any Profit Share payment due to BBIL by Ocugen or, if no such future Profit Share payments are payable, then BBIL shall refund the overpayment to Ocugen within [\*\*\*] after BBIL receives the audit report.

# ARTICLE IX INTELLECTUAL PROPERTY

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

#### 9.2. Patent Filing, Prosecution and Maintenance.

- (a) BBIL shall, acting through patent counsel of its choice: (i) endeavor to prepare, file, prosecute and maintain the BBIL Patent Rights and the Joint Program Patent Rights worldwide so as to secure the broadest protection reasonably and lawfully available; (ii) consult with Ocugen in relation to the preparation, filing, prosecution and maintenance of the BBIL Patent Rights and the Joint Program Patent Rights, as well as all changes to patent claims or specifications that would have the effect of reducing or limiting the extent of such patent coverage; and (iii) pay all fees and expenses to prepare, file, prosecute and maintain the BBIL Patent Rights and the Joint Program Patent Rights worldwide as and when due, *provided* Ocugen shall reimburse BBIL for the portion of such fees and expenses that are incurred by BBIL in, for or with respect to the Ocugen Territory. BBIL shall consult in good faith with Ocugen and Ocugen shall cooperate with and assist BBIL in all reasonable respects, in connection with BBIL's preparation, filing, prosecution and maintenance of such BBIL Patent Rights and Joint Program Patent Rights. If BBIL desires to abandon or to not maintain any of the Joint Program Patent Rights in the Field in and for the Ocugen Territory (or to cease funding any application or Patent Rights forming a part of such Joint Program Patent Rights), it shall give Ocugen [\*\*\*] prior written notice of same, and Ocugen shall have the right but not the obligation, beginning at the end of such [\*\*\*] period, to pursue preparing, filing, prosecuting or maintaining such Joint Program Patent Rights in the Field solely in and for the Ocugen Territory, at its sole cost and expense.
- (b) Ocugen shall, acting through patent counsel of its choice, endeavor to prepare, file, prosecute and maintain the Ocugen Patent Rights licensed to BBIL pursuant to this Agreement. If Ocugen desires to abandon or to not maintain any of the Ocugen Patent Rights in the Field in and for the BBIL Territory (or to cease funding any application or Patent Rights forming a part of such Ocugen Patent Rights), Ocugen shall give BBIL [\*\*\*] prior written notice of same, and BBIL shall have the right but not the obligation, beginning at the end of such [\*\*\*] period, to pursue preparing, filing, prosecuting or maintaining such Ocugen Patent Rights in the Field solely in and for the BBIL Territory, at BBIL's sole cost and expense.

#### 9.3. Enforcement and Defense.

- (a) Each Party shall inform the other Party promptly if it becomes aware of any infringement, potential infringement or misappropriation of any BBIL Patent Rights or Joint Program Patent Rights in the Field anywhere in the world, and the Parties shall consult with each other regarding a strategy for enforcement or defense and the best way to respond to such infringement. Notwithstanding the foregoing, as between the Parties, BBIL shall have the first right, but not the obligation, to address infringement of the BBIL Patent Rights and the Joint Program Patent Rights anywhere in the world by taking reasonable steps, which may include the institution of legal proceedings or other action, and to compromise or settle such infringement of the BBIL Patent Rights or the Joint Program Patent Rights, *provided* BBIL shall keep Ocugen informed about such infringement response and Ocugen shall provide all reasonable cooperation to BBIL in connection with such infringement response. In the event that BBIL initiates any such action, any damages or other payments recovered shall belong solely to BBIL. BBIL shall not take any position with respect to, or compromise or settle, any such infringement of the BBIL Patent Rights or Joint Program Patent Rights in any way that may derogate from Ocugen's rights in this Agreement, without the prior written consent of Ocugen, which consent shall not be unreasonably withheld, conditioned or delayed. If BBIL does not intend to enforce or defend any BBIL Patent Rights or Joint Program Patent Rights anywhere in the world, it shall promptly inform Ocugen of such fact. All costs relating to BBIL's infringement responses under this Section 9.3(a) shall be borne solely by BBIL.
- (b) If BBIL informs Ocugen that it does not intend to enforce or defend any BBIL Patent Rights or Joint Program Patent Rights, or ceases to diligently pursue infringement of any BBIL Patent Rights or Joint Program Patent Rights anywhere in the world in accordance with Section 9.3(a), then Ocugen shall have the right, but not the obligation, at its own expense, upon written notice to BBIL, to address such infringement of such BBIL Patent Rights or Joint Program Patent Rights by taking reasonable steps, which may include the institution of legal proceedings or other action, and to compromise or settle such infringement of such BBIL Patent Rights or Joint Program Patent Rights against the applicable third party, *provided* Ocugen shall keep BBIL informed about such infringement response and BBIL shall provide all reasonable cooperation to Ocugen in connection with such infringement response. In the event that Ocugen initiates any such action, any damages or other payments recovered shall belong solely to Ocugen. Ocugen shall not take any position with respect to, or compromise or settle, any such infringement of the BBIL Patent Rights or Joint Program Patent Rights in any way that may derogate from BBIL's rights in this Agreement, without the prior written consent of BBIL, which consent shall not be unreasonably withheld, conditioned or delayed. All costs relating to Ocugen's infringement responses under this Section 9.3(b) shall be borne solely by Ocugen.
- (c) If the alleged infringement of the BBIL Patent Rights or the Joint Program Patent Rights is both within and outside the Field, the Parties shall also cooperate with BBIL's other licensees (if any) in relation to any such action(s).
- (d) Each Party agrees to be joined in any suit to enforce the BBIL Patent Rights or Joint Program Patent Rights in the applicable Territory in accordance with Section 9.3(a) or Section 9.3(b), as applicable, subject to being indemnified and secured in a reasonable manner as to any costs, damages, expenses, or other liabilities such Party may incur in connection therewith or resulting therefrom which such Party is otherwise not required to incur under Section 9.3(a) or Section 9.3(b), as applicable, and such Party shall have the right to be separately represented in any such suit by its own counsel at its own expense.

#### 9.4. Infringement of Third-Party Rights.

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

in any such suit, proceeding or other action, and all expenses with respect to any such suit, proceeding or other action in the Ocugen Territory shall be borne equally by the Parties. Each Party shall promptly furnish the other Party with a copy of each communication relating to the alleged infringement that is received by such Party, including all documents filed in any litigation.

- (b) BBIL shall have the right to settle the related suit, proceeding or other action with the applicable third party, provided, that if the taking of any action or any proposed settlement involves the making of any statement, express or implied, concerning the validity of the BBIL Patent Rights or the Joint Program Patent Rights, Ocugen shall be notified before BBIL takes such action or makes such settlement.
- 9.5. <u>Product Trademarks</u>. BBIL may, in its sole discretion, select, and BBIL shall own, the Product Trademarks for use on Products in the Field in and for the BBIL Territory, and BBIL shall be responsible for the registration, prosecution, maintenance and enforcement thereof (such Product Trademarks, the "BBIL Trademarks"). Ocugen may, in its sole discretion, select, and Ocugen shall own, the Product Trademarks for use on Products in the Field in and for the Ocugen Territory, and Ocugen shall be responsible for the registration, prosecution, maintenance and enforcement thereof (such Product Trademarks, the "Ocugen Trademarks"); provided, that Ocugen shall (a) (i) notify BBIL of its choice of any Ocugen Trademark not less than [\*\*\*] before effecting its first filing of a Marketing Authorization for the Product in the Ocugen Territory; and (i) notify BBIL if it is required by any Regulatory Authority to alter, amend or change such Ocugen Trademark, or (b) if reasonably requested by BBIL, evaluate in good faith the use of a BBIL Trademark for the Product in the Ocugen Territory. If Ocugen uses a BBIL Trademark for the Product in the Ocugen Territory, BBIL shall grant to Ocugen an exclusive, royalty-free, sublicensable right to use such BBIL Trademark for the Development and Commercialization of the Product in the Ocugen Territory without any additional consideration due to BBIL, and BBIL shall register, prosecute, maintain and enforce such BBIL Trademark in the Ocugen Territory at BBIL's cost.

# ARTICLE X REPRESENTATIONS AND WARRANTIES

- 10.1. <u>Representations and Warranties of the Parties</u>. Each Party represents and warrants to the other Party as of the Effective Date that:
- (a) it is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, and has full power and authority to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement;
- (b) it has the full right, power, and authority to enter into this Agreement and to grant the rights and licenses granted by it under this Agreement;
- (c) there are no existing, or to its knowledge, threatened Claims pending with respect to the subject matter of this Agreement or its right to enter into and perform its obligations under this Agreement;
- (d) it has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;
- (e) this Agreement has been duly executed and delivered on behalf of it, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with its terms, subject to the general principles of equity and to the laws of bankruptcy, insolvency, moratorium, and other similar laws affecting the enforcement of creditors' rights generally, and to any applicable competition laws:
- (f) all Permits required to be obtained by it in accordance with the execution and delivery of this Agreement and the performance of its obligations under this Agreement have been or will be obtained, and in the case of Ocugen, all Permits have been or will be obtained in relation to its conduct of any and all activities described hereunder to be performed in or with respect to the Ocugen Territory; and
- (g) the execution and delivery of this Agreement and the performance of its obligations hereunder do not conflict with or constitute a default under any of its constitutional or formation agreements.



- 10.2. <u>BBIL's Additional Warranties</u>. BBIL further represents and warrants as of the Effective Date, and covenants as and to the extent applicable during the Term, that:
- (a) it has full right and authority to grant the licenses and rights granted under this Agreement, and no rights or licenses are required from BBIL, or to its knowledge, any other Person, in order for Ocugen to Develop, Manufacture and Commercialize the Product in the Field in and for the Ocugen Territory as contemplated under this Agreement other than the rights granted to Ocugen under Section 3.1;
- (b) to BBIL's knowledge, there are no Patent Rights Controlled by a third party that would be infringed by Ocugen's use of the BBIL Technology or Ocugen's practicing of the BBIL Patent Rights in the Field in and for the Ocugen Territory, and to BBIL's knowledge, no Claim or litigation has been brought or asserted (and BBIL has no knowledge of any Claim, whether or not brought or asserted, or of any facts or circumstances that exist that would reasonably be expected to give rise to any such Claim or litigation) by any Person alleging that (i) the BBIL Patent Rights are invalid or unenforceable or (ii) the conception, development, reduction to practice, disclosing, copying, making, assigning or licensing of the BBIL Technology or the BBIL Patent Rights existing as of the Effective Date as contemplated herein, violates, infringes, constitutes misappropriation of or otherwise conflicts or interferes with or would violate, infringe or otherwise conflict or interfere with, any intellectual property or proprietary right of any other Person;
- (c) to BBIL's knowledge, no Person is infringing or threatening to infringe, or misappropriating or threatening to misappropriate, the BBIL Patent Rights existing as of the Effective Date;
- (d) subject to Section 9.3(a), it has made and will use Commercially Reasonable Efforts to maintain the validity of the BBIL Patent Rights and, will not surrender its rights in any way so as to undermine the licenses granted to Ocugen in Section 3.1; and
- (e) BBIL has not employed (and to the best of its knowledge, has not used a contractor or consultant that has employed) and in the future will not employ (or to the best of its knowledge, use any contractor or consultant that employs) any Person debarred by the FDA, or any Person who is the subject of a FDA debarment or investigation or proceeding in the conduct of its Development Activities.
- 10.3. Ocugen's Additional Warranties. Ocugen further represents and warrants as of the Effective Date, and covenants as and to the extent applicable during the Term, that it has full right and authority to grant the licenses and rights granted under this Agreement, and no rights or licenses are required from Ocugen, or to its knowledge, any other Person, in order for BBIL to conduct the BBIL Development Activities assigned to BBIL in the Development Plan or otherwise in connection with the Development, Manufacture and Commercialization of the Product in the Field in and for the BBIL Territory as contemplated under this Agreement other than the rights granted to BBIL under Section 3.2.
- 10.4. No Other Warranties. Each Party understands that the Product is the subject of ongoing research and that neither Party can assure the safety, successful research or development, efficacy or usefulness of the Product. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS Article X, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY PATENT RIGHTS, LICENSES, TECHNOLOGY, PRODUCT, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH PARTY HEREBY DISCLAIMS WARRANTIES OF MERCHANTABILITY, SAFETY, TOXICITY, EFFICACY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. Ocugen acknowledges notwithstanding anything to the contrary contained in this Agreement that BBIL is providing all Data and documents to Ocugen under this Agreement on an 'as is' basis without any warranty as to its usefulness for any particular purpose and it shall be the responsibility of Ocugen to use such Data so provided only after conducting appropriate due diligence thereon.

#### ARTICLE XI CONFIDENTIAL INFORMATION

## 11.1. Confidential Information.

(a) <u>Confidentiality Obligations</u>. Each Party (the "**Disclosing Party**") may disclose to the other Party (the "**Receiving Party**") and the Receiving Party may acquire during the course and conduct of

activities under this Agreement, certain Confidential Information of the Disclosing Party in connection with this Agreement. The Receiving Party shall keep all the Disclosing Party's Confidential Information in confidence with the same degree of care with which the Receiving Party holds its own confidential information (but in no event less than a commercially reasonable degree of care), and take all reasonable steps necessary to prevent the unauthorized disclosure or use of any of the Disclosing Party's Confidential Information. The Receiving Party shall not use the Disclosing Party's Confidential Information except in connection with the performance of its obligations and exercise of its rights under this Agreement.

- (b) Exceptions. The provisions of Section 11.1(a) shall not apply to, and Confidential Information of the Disclosing Party shall not include, information which the Receiving Party can demonstrate by reasonable, written evidence: (a) was, prior to its receipt by the Receiving Party from the Disclosing Party, in the possession of the Receiving Party and at its free disposal; (b) is subsequently disclosed to the Receiving Party without any obligations of confidence by a third party who has not derived it directly or indirectly from the Disclosing Party; (c) is or becomes generally available to the public through no act or default of the Receiving Party or its agents, employees or Affiliates; or (d) is independently developed by the Receiving Party without use of, reference or access to, the Disclosing Party's Confidential Information.
- (c) <u>Permitted Disclosures</u>. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:
- (i) prosecuting or maintaining Patents Rights as permitted by this Agreement, provided that the Disclosing Party is informed of such requirement a reasonable period of time prior to the disclosure;
- (ii) Regulatory Filings for the Product that such Party has a license or right to Develop hereunder in a given country or jurisdiction;
  - (iii) prosecuting or defending litigation as permitted by this Agreement;
- (iv) complying with applicable court orders or governmental regulations, including mutually recognized securities laws and rules of securities exchanges;
- (v) disclosure to its employees, consultants, contractors and agents, and to Sublicensees (in the case of Ocugen), and those of its Affiliates, in each case on a need-to-know basis in connection with the research, Development, Manufacture, and Commercialization of the Product in accordance with the terms of this Agreement, in each case under obligations of confidentiality and non-use at least as stringent as those herein; and
- (vi) disclosure to potential and actual investors, acquirers, licensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration, in each case under written obligations of confidentiality and non-use at least as stringent as those herein.

Notwithstanding the foregoing, if a Party is, based on advice of legal counsel, required to make a disclosure of the other Party's Confidential Information pursuant to Sections 11.1(c)(iii) or 11.1(c)(iv), it shall, except where impracticable, give reasonable advance notice (not less than five (5) Business Days) to the other Party of such disclosure and use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own Confidential Information, but in no event less than reasonable efforts.

If information, which constitutes Confidential Information, is disclosed pursuant to Section 11.1(c) but such information does not thereby fall into any of the exceptions stated in Section 11.1(b), then notwithstanding such disclosure pursuant to Section 11.1(c), such information shall still constitute Confidential Information and the obligations of confidentiality and restriction on use under Section 11.1(a) shall still apply to it.

The Parties acknowledge that either or both Parties (or their respective parent companies) may be obligated to make filings (including, but not limited to, the filing of a copy of this Agreement) with the U.S. Securities and Exchange Commission (the "SEC") or other securities regulators or exchanges. Each Party shall be entitled to make such required filings, provided that it requests confidential treatment of at least the financial terms and sensitive technical terms of this Agreement to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing of this Agreement, the Party making such filing shall provide notice to the other Party with a copy of such disclosure and, if applicable, a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment not less than five (5) Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), and shall give good faith consideration to the other Party's comments thereon to the extent consistent with the legal requirements. No such notice shall be required if the substance of the description of or reference to this Agreement contained in the proposed filing has been included in any previous filing made by either Party hereunder or otherwise approved by the other Party.

- (d) Return of Confidential Information. Upon the termination of this Agreement for any reason, the Receiving Party shall return to the Disclosing Party, or destroy, at its option (subject to written confirmation of its action), Confidential Information of the Disclosing Party in its possession, and those portions of any documents or other materials that contain the Disclosing Party's Confidential Information, including all copies made and make no further use or disclosure thereof, *provided*, that the Receiving Party may retain one copy of the Confidential Information of the Disclosing Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with Applicable Laws and its obligations hereunder and for no other purpose.
- <u>Publicity</u>. Ocugen may issue a public announcement of the execution of this Agreement in a form mutually agreed by the Parties and substantially in the form attached hereto as Schedule 11.2. Thereafter, with respect to any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof (a "Public Statement"), (a) Ocugen may make Public Statements relating to the research, Development, Manufacture or Commercialization of the Product in and for the Ocugen Territory, including the publication of all results of research or Development Activities, any Clinical Trial conducted on the Product, Regulatory Filings, Regulatory Approvals or any health or safety matter related to the Product, all with respect to the Ocugen Territory, without BBIL's prior written consent; provided, that Ocugen shall not make any such Public Statement that includes any Confidential Information of BBIL without the prior written consent of BBIL to disclose such Confidential Information, and (b) BBIL may make Public Statements relating to the research, Development, Manufacture or Commercialization of the Product in the BBIL Territory, including the publication of all results of research or Development Activities, any Clinical Trial conducted on the Product, Regulatory Filings, Regulatory Approvals or any health or safety matter related to the Product, all with respect to the BBIL Territory, without Ocugen's prior written consent; provided, that BBIL shall not make any such Public Statement that includes any Confidential Information of Ocugen without the prior written consent of Ocugen to disclose such Confidential Information; provided that it is understood and agreed that BBIL shall not make any Public Statements relating to the amount of any Profit Share payments to be made or actually made under this Agreement, except as permitted pursuant to Section 11.1(c)(iv). If either Party requires the other Party's consent to issue a Public Statement or any portion thereof as provided above, such consent shall not be unreasonably withheld, conditioned or delayed by the other Party; and the issuing Party will provide the other Party with a copy of the proposed Public Statement as soon as reasonably practicable under the circumstances prior to its scheduled release (but in no event fewer than five (5) Business Days). If the reviewing Party provides any comments, the Parties will consult on such proposed Public Statement and amend accordingly. Each Party may repeat any information relating to this Agreement that has already been publicly disclosed in accordance with this Section 11.2, provided such information continues as of such time to be accurate.

#### 11.3. Publication.

(a) <u>Clinical Trials</u>. For the purposes of clarity, under Section 11.2(a), Ocugen shall have the right to (i) publish the results or summaries of results of all Ocugen sponsored or supported Clinical Trials, observational studies and other studies such as meta analyses, in each case conducted with respect to the Product and the protocols of such Clinical Trials on www.ClinicalTrials.gov and in each case publish the results, summaries and protocols of such Clinical Trials or studies on such other websites and repositories and at scientific congresses and in a peer-reviewed journal within such timescales as required by Applicable Law or

Ocugen's or its Affiliates' standard operating procedures, irrespective of the outcome of such Clinical Trials or studies; and (ii) publish the status of the Product in its annual and quarterly reports and updates regarding Ocugen's research and development pipeline. Each such publication or disclosure made in accordance with this Section 11.3(a) shall not be a breach of the confidentiality obligations provided in this Article XI and Ocugen shall be entitled to maintain or effect such publication or disclosure even following any termination of Ocugen's rights in respect of the Product. Any disclosure made under this Section 11.3(a) that includes any Confidential Information of BBIL (excluding any information that falls under the exceptions of Sections 11.1(b) and except as otherwise set forth in Section 11.1(c)) shall be subject to the provisions set forth in Section 11.3(b). For clarity, BBIL shall not have any publication rights with respect to the research, Development, Manufacture or Commercialization of the Product in and for the Ocugen Territory or with respect to any Confidential Information of Ocugen, except as set forth in Section 11.2(b).

- (b) Other Publications. With respect to any paper or presentation proposed for disclosure by Ocugen, its Affiliates or Sublicensees (or a third party to the extent such third party is required to obtain prior approval, review or comment of any paper or presentation for disclosure from Ocugen, its Affiliates or Sublicensees) that includes Confidential Information of BBIL (excluding any information that falls under the exceptions of Section 11.1(b) and except as otherwise set forth in Section 11.1(c)), BBIL may review and comment on the portion of such paper or presentation that includes any Confidential Information of BBIL, including requesting removal of such Confidential Information. For any proposed publication or presentation (including posters, slides, abstracts, and manuscripts), Ocugen shall provide a copy of the relevant portion of such paper or presentation at least twenty (20) days (ten (10) days for abstracts) prior to the date of submission for publication or the date of presentation, whichever is earlier, of any of such submitted materials. BBIL shall review such submitted materials and respond to Ocugen as soon as reasonably possible, but in any case, within twenty (20) days (ten (10) days for abstracts) after receipt thereof. At BBIL's reasonable request, Ocugen shall (a) delete from such proposed publication or presentation any Confidential Information of BBIL, or (b) delay the date of such submission for publication or the date of such presentation for sixty (60) days to permit BBIL to seek appropriate patent protection.
- 11.4. <u>Survival</u>. Each Party's obligations under this Article XI shall continue during the Term and for a period of [\*\*\*] thereafter.

# ARTICLE XII TERM AND TERMINATION

12.1. <u>Term.</u> This Agreement, and the licenses granted hereunder, shall come into effect on the Effective Date and, unless terminated earlier in accordance with this Article XII, shall continue in force and effect for the commercial life of the Product (the "**Term**").

#### 12.2. Other Bases of Termination.

- (a) Either Party may terminate this Agreement at any time by providing notice in writing to the other Party (the "Other Party"):
- (i) subject to Section 12.2(b), if the Other Party is in material breach of this Agreement and, in the case of a breach capable of remedy within [\*\*\*], the breach is not remedied within [\*\*\*] of the Other Party receiving written notice specifying the breach and requiring its remedy; or
- (ii) in the event that the Other Party or any of its Affiliates challenges or assists a third party in initiating or pursing a challenge of any Technology Controlled by such Party; or
- (iii) if (x) the Other Party makes a general assignment for the benefit of creditors, files a voluntary petition in bankruptcy, consents to an order for relief in connection with an involuntary petition in bankruptcy filed against such Other Party (or an involuntary petition in bankruptcy filed against such Other Party remains un-dismissed or un-stayed for a period of more than [\*\*\*]), (y) an order is made or a resolution is passed for the winding up of the Other Party (other than voluntarily for the purpose of solvent amalgamation or reconstruction), or (z) a liquidator, administrator, administrative receiver, receiver, or trustee is appointed in respect of the whole or any part of the Other Party's assets or business and such appointment is not withdrawn or stayed within a period of [\*\*\*].

- (b) In the event that either Party believes that such Party has cause to terminate this Agreement pursuant to Section 12.2(a)(i), prior to providing a notice of material breach as provided in Section 12.2(a)(i), such Party shall raise such issue by written notice to the Other Party, which shall not constitute a notice of material breach hereunder. If within [\*\*\*] following the Other Party's receipt of such notice, such Party believes that the Other Party has not remedied the issues identified by such Party in such notice, such Party may thereafter pursue the remedies provided to it under this Agreement, including pursuant to Section 12.2(a)(i); provided that, if the Other Party disputes in good faith whether such Party has cause to terminate this Agreement pursuant to Section 12.2(a)(i) and provides written notice of such dispute, which notice shall set forth the dispute in reasonable detail prior to the expiration of such [\*\*\*] period, then such dispute shall be escalated to the JSC, who shall attempt to resolve such dispute within ten (10) Business Days after the matter has been brought to the JSC's attention. If the JSC is deadlocked and cannot come to a mutual agreement on such decision within ten (10) Business Days, the matter shall be escalated to the Senior Executives for resolution; provided, however, if such dispute is not resolved by the Senior Executives within thirty (30) days following the date the matter was escalated, then such Party may thereafter pursue the remedies provided to it under this Agreement, including pursuant to Section 12.2(a)(i); provided further that the [\*\*\*] period set forth in the second sentence of this Section 12.2(b) will be tolled until such time as such dispute is resolved.
- 12.3. Sale of Remaining Inventory. Upon termination of this Agreement for any reason, Ocugen shall be entitled to sell, use, or otherwise dispose of (subject to payment of the Profit Share under Section 8.1) any unsold or unused stock of the Product for a period of eighteen (18) months after the effective date of termination, *provided* that Ocugen is then and remains during such eighteen (18) month period in compliance with all of the other terms and conditions of this Agreement.
- 12.4. <u>Consequences of Termination by BBIL Under 12.2(a)(i) and 12.2(a)(ii)</u>. If this Agreement is terminated by BBIL pursuant to Section 12.2(a)(i) or Section 12.2(a)(ii), then:
- (a) The licenses granted to Ocugen under Section 3.1(a) and Section 3.1(b) shall be terminated and be of no further force and effect, and to the extent permitted by Applicable Laws, Ocugen shall promptly assign to BBIL all Regulatory Filings (including any Regulatory Approvals) for the Product in the Field in and for the Ocugen Territory.
- (b) Within forty-five (45) days after such termination, Ocugen shall provide to BBIL a fair and accurate summary of the status and results of its Development, Manufacturing and Commercialization activities for the Product in the Field in and for the Ocugen Territory prior to the effective date of termination.
- (c) Ocugen shall use Commercially Reasonable Efforts to effect a timely transition to BBIL of all Development, Manufacturing and Commercialization activities and responsibilities for the Product in the Field in and for the Ocugen Territory as are in existence as of the date of termination in accordance with a transition plan to be mutually agreed by the Parties. Ocugen shall promptly discontinue and wind-down or transfer to BBIL, at Ocugen's cost, any clinical Development activities still ongoing and forward all interim and final reports and underlying Data from such activities to BBIL as part of such transition.
- (d) Effective upon such termination and request by BBIL for such license, Ocugen hereby grants to BBIL a perpetual, irrevocable, exclusive (even as to Ocugen) license, with the right to grant sublicenses, under Ocugen's rights in the Joint Program Technology and Joint Program Patent Rights, used in the Development, Manufacture or Commercialization of the Product in the Field in the Ocugen Territory on the date of termination, solely for BBIL to continue to Develop, Manufacture or Commercialize the Product in the Field in the Ocugen Territory. The foregoing license shall be royalty-bearing as follows: BBIL shall pay Ocugen a royalty of [\*\*\*] of the Net Sales of the Product by BBIL, its Affiliates or its Sublicensees in the Ocugen Territory (to the extent the Product is thereafter Commercialized by BBIL, its Affiliates or its Sublicensees in the Ocugen Territory) until such time as the amounts paid under this Section 12.4(d) equals: (i) [\*\*\*], less (ii) [\*\*\*] in accordance with the terms of Exhibit B (the "Ocugen Development and Commercialization Costs"). Thereafter, the license granted under this Section 12.4(d) shall be a fully paid-up, non-royalty bearing, perpetual, non-exclusive license in and for the Ocugen Territory.
- (e) Upon BBIL's request, Ocugen shall, as part of any transition plan mutually agreed by the Parties under Section 12.4(c), at BBIL's expense, transfer to BBIL (or its designee) any processes, documents, materials and other Technology, to the extent the foregoing is Controlled by Ocugen as of the



effective date of termination and used in the Manufacture of Products in the Field in and for the Ocugen Territory as of the date of termination.

- 12.5. <u>Consequences of Termination by Ocugen Under 12.2(a)(i) and 12.2(a)(ii).</u> If this Agreement is terminated by Ocugen pursuant to Section 12.2(a)(i) or Section 12.2(a)(ii), then:
- (a) The licenses granted to Ocugen under Section 3.1(a) and Section 3.1(b) shall continue to be valid in accordance with this Agreement, to the extent permitted by Applicable Laws; provided that Ocugen shall continue to pay the Profit Share to BBIL in accordance with Section 8.1 for the balance of the Term.
- (b) Within forty-five (45) days after such termination, Ocugen shall provide BBIL with a statement of [\*\*\*] in accordance with the terms of Exhibit B, within [\*\*\*] after receipt of such report, BBIL shall reimburse Ocugen all such [\*\*\*].
- 12.6. <u>No Further Obligations</u>. Except as provided in this Article XII, and except in respect of any accrued rights, upon the expiration or termination of this Agreement, neither Party shall be under any further obligation to the other.

# ARTICLE XIII INDEMNIFICATION; INSURANCE

- 13.1. <u>Indemnification of BBIL Indemnitees by Ocugen</u>. Ocugen shall indemnify, defend and hold harmless BBIL, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, the "**BBIL Indemnitees**"), against all liabilities, damages, losses and expenses (including reasonable attorneys' fees and expenses of litigation) (collectively, "**Losses**") incurred by or imposed upon the BBIL Indemnitees, or any of them, including as a direct result of Claims of third parties, including personal injury and product liability claims (collectively, "**BBIL Indemnity Claims**"), to the extent arising out of: (a) the Development, Manufacture or Commercialization of the Product by Ocugen or any of its agents in the Field in and for the Ocugen Territory; (b) any breach of this Agreement by Ocugen or any of its Affiliates or agents, including its representations, warranties and covenants; or (c) the gross negligence or willful misconduct of or fraud by any Ocugen Indemnitee or agent of Ocugen, excluding any Ocugen Indemnity Claim or Losses for which BBIL has an obligation to indemnify Ocugen Indemnitees pursuant to Section 13.2, as to which Claims or Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.
- 13.2. <u>Indemnification of Ocugen Indemnitees by BBIL</u>. BBIL shall indemnify, defend and hold harmless Ocugen, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, the "**Ocugen Indemnitees**"), against all Losses incurred by or imposed upon the Ocugen Indemnitees, or any of them, including as a direct result of Claims of third parties, including personal injury and product liability claims (collectively, "**Ocugen Indemnity Claims**"), to the extent arising out of: (a) any breach of this Agreement by BBIL or any of its Affiliates or agents, including its representations, warranties and covenants; or (b) the gross negligence or willful misconduct of or fraud by any BBIL Indemnitee or agent of BBIL, excluding any BBIL Indemnity Claim or Losses for which Ocugen has an obligation to indemnify BBIL Indemnitees pursuant to Section 13.1, as to which Claims or Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.
- Party") in respect of a BBIL Indemnity Claim or an Ocugen Indemnity Claim, as applicable (each, an "Indemnity Claim") shall give prompt written notice of such Indemnity Claim to the Party from whom indemnification is sought (the "Indemnifying Party"); provided, that the Indemnifying Party is not contesting its obligation under this Article XIII, and shall permit the Indemnifying Party to control the investigation, defense and settlement of such Indemnity Claim; and further provided, that the Indemnifying Party shall (a) act reasonably and in good faith with respect to all matters relating to the settlement or disposition of such Indemnity Claim as the settlement or disposition relates to such Indemnified Party and (b) not settle or otherwise resolve such Indemnity Claim without the prior written consent of such Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). Each Indemnified Party shall cooperate with the Indemnifying Party in its investigation, defense and settlement of any such Indemnity Claim in all

reasonable respects and shall have the right to be present in person or through counsel at all legal proceedings with respect to such Indemnity Claim. If the Indemnifying Party does not assume and conduct the defense of the Indemnity Claim as provided above, (i) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Indemnity Claim in any manner the Indemnified Party may deem appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (ii) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article XIII. The Indemnifying Party shall have no liability for any settlement of Indemnity Claims entered into by the Indemnified Party without the prior written consent of the Indemnifying Party.

- 13.4. <u>Limited Liability.</u> NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES OR ITS SUBLICENSEES FOR ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS OR LOST REVENUES, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 13.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER SECTIONS 13.1 OR 13.2, FOR DAMAGES AVAILABLE FOR A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OR A PARTY'S MATERIAL BREACH OF THE INTELLECTUAL PROPERTY OBLIGATIONS IN Article IX OR THE CONFIDENTIALITY OBLIGATIONS IN SECTION 11.1.
- 13.5. <u>Insurance</u>. Each Party shall procure and maintain insurance, including product liability insurance, or shall self-insure, in each case in a manner adequate to cover its obligations under this Agreement and consistent with normal business practices of prudent companies similarly situated at all times during the Term and for a period of [\*\*\*] thereafter. Ocugen shall be responsible to insure the Clinical Trial Materials and the Product supplied by BBIL pursuant to Sections 7.1 and 7.2 including product liability insurance in respect thereof for the Ocugen Territory. Each Party shall procure insurance or self-insure at its own expense. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article XIII; provided that BBIL shall not be liable for any Claim to the extent that the Losses in respect of which the Claim is made are covered by a policy of insurance, and actually paid by the insurance company to Ocugen net of any deductible under the insurance policies and less any taxation suffered on the proceeds and any reasonable out of pocket expenses suffered or incurred by Ocugen in connection with the Claim. Each Party shall provide the other Party with written evidence of such insurance or self-insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance.
- 13.6. <u>Maximum Liability</u>. Except to the extent of a Party's gross negligence or willful misconduct in the performance of this Agreement, or to the extent any BBIL Indemnity Claim or Losses in respect of a BBIL Indemnity Claim relates to or arises from or is in any way connected to the Ocugen Territory ([\*\*\*]), the maximum aggregate liability of either Party in respect of any Claim, including an Indemnity Claim, under this Agreement, notwithstanding anything to the contrary contained in this Agreement shall not exceed an amount equal to [\*\*\*] preceding the date on which the action or omission alleged to have caused such Claim or Indemnity Claim occurred.
- 13.7. Otherwise Compensated. If the Indemnifying Party makes any payment by way of Losses in respect of a Claim under this Agreement ("Damages Payment") and the Indemnified Party subsequently receives any monetary payment (exclusive of payments from the Indemnifying Party), which payment compensates the Indemnified Party for the same Loss as the Damages Payment, the Indemnified Party shall, once it has received such monetary payment, forthwith repay (net of any taxes actually paid or withheld with respect thereto) to the Indemnifying Party an amount equal to the amount (if any) by which the amount of the Damages Payment, aggregated with the amount of such monetary payment, exceeds the total amount of the Losses suffered by the Indemnified Party in respect of such Claim.
- 13.8. <u>No Double Recovery.</u> No Indemnified Party shall be entitled to recover damages or obtain payment, reimbursement, restitution or indemnity more than once for the same loss, damage, deficiency or breach.

- 13.9. <u>Mitigation Not Affected</u>. Both Parties shall procure that commercially reasonable steps are taken and commercially reasonable assistance is given to avoid or mitigate any Losses which, in the absence of mitigation, might give rise to a liability in respect of any Claim.
- 13.10. <u>Time Limitation for Claims</u>. BBIL shall not be liable for any Claim unless a notice of the Claim is given by Ocugen to BBIL specifying the matters set out in Section 13.11 and in the case of any Claims of third parties, including personal injury and product liability claims, within twelve (12) months from the expiry date of the shelf life of the Clinical Trial Materials or the Product supplied by BBIL under the Development Supply Agreement or Commercial Supply Agreement specified in Section 7.1 and 7.2, as the case may be.
- 13.11. <u>Notification of Claims</u>. Notice of any Claim shall be given by Ocugen to BBIL within the time limits specified in Section 13.10 and shall not be valid unless it specifies full information (to the extent available) in relation to the legal and factual basis of the Claim and the evidence on which Ocugen is making such Claim relies (including, where the Claim is the result of or in connection with a third party Claim, evidence of the third party Claim) and setting out Ocugen's good faith estimate of the amount of Losses which are, or are to be, the subject of the Claim (including any Losses which are contingent on the occurrence of any future event).

# ARTICLE XIV GENERAL / MISCELLANEOUS

- 14.1. Force Majeure. Neither Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed to be in breach of this Agreement, if such failure or delay is due to or results from a Force Majeure. In the event of a Force Majeure, the Party affected shall use Commercially Reasonable Efforts to cure or overcome the same and resume performance of its obligations hereunder. Notice of a Party's failure or delay in performance due to Force Majeure must be given to the other Party within thirty (30) days after its occurrence. All delivery dates under this Agreement that have been affected by such Force Majeure event shall be tolled for the duration of such Force Majeure. If a Force Majeure event persists for more than thirty (30) days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such Force Majeure event.
- 14.2. <u>Amendment; Waiver</u>. This Agreement may be amended, modified, superseded or canceled, and any of the terms of this Agreement may be waived, only by a writing signed by duly authorized representatives of both Ocugen and BBIL, or, in the case of waiver, by the Party or Parties waiving compliance. No failure or delay on the part of either Party to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy.
- 14.3. <u>Invalid Clauses</u>. If any provision or part of this Agreement is held to be invalid, amendments to this Agreement may be made by the addition or deletion of wording as appropriate to remove the invalid part or provision but otherwise retain the provision and the other provisions of this Agreement to the maximum extent permissible under Applicable Laws.
- 14.4. <u>Notices</u>. Any notice to be given under this Agreement shall be in writing and shall be sent by registered mail or e-mail (confirmed by registered mail) to the address of the relevant Party set out below, or to such other address or e-mail as that Party may from time to time notify to the other Party in accordance with this Section 14.4. The addresses and e-mails of the Parties are as follows:

in the case of Ocugen, to:

Shankar Musunuri

Chairman, CEO and Co-Founder Ocugen, Inc. 263 Great Valley Parkway Malvern, PA 19355, USA

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Tel: [***]
E-mail: [***]

with a copy to:

Rachael M. Bushey, Esq.

Troutman Pepper Hamilton Sanders LLP 3000 Two Logan Square
Philadelphia, PA 19104

Tel: [***]
E-mail: [***]

in the case of BBIL, to:

[***]
[***]
[***]
[***]
[***]
E-mail: [***]
E-mail: [***]
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Notices delivered in accordance with this Section 14.4 shall be deemed delivered, in the case of Ocugen, on receipt if received on a Business Day before 5:00pm Eastern Time at the location of delivery or if after 5:00pm Eastern Time, then on the following Business Day, or, in the case of BBIL if received on a Business Day before 5:00pm India Standard Time at the location of delivery or if after 5:00pm India Standard Time, then on the following Business Day. All notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement will be in the English language.

- 14.5. <u>Law and Jurisdiction</u>. The validity, construction and performance of this Agreement shall be governed by and construed in accordance with the laws of the United Kingdom, without regard to the application of principles of conflicts of law.
- Dispute Resolution. Subject to the decision-making provisions of Section 2.7 with respect to matters exclusively within the purview of the JSC, in the event of any dispute, difference or disagreement arising out of or relating to this Agreement ("Dispute"), the Parties shall seek to resolve the matter within the next thirty (30) days by referring it to the Senior Executives. The Senior Executives (or their designees) shall promptly meet in good faith to try to resolve the Dispute. If any such Dispute is not resolved by the Senior Executives through good faith discussions within such thirty (30) day period or in the event of any deadlock at the JSC which is not resolved by the Senior Executives in accordance with Section 2.7(b), such Dispute or deadlock shall be resolved by binding arbitration. Either Party may, on ten (10) days written notice to the other Party, initiate binding arbitration in accordance with the then-current arbitration rules of the United Nations Commission on International Trade Law. The arbitration shall be conducted in the English language by a single arbitrator who is mutually acceptable to both Parties and the award thus rendered shall be final and binding upon both Parties and enforceable in any court having jurisdiction thereof in accordance with its terms. The place of arbitration shall be Singapore. Each Party shall bear its own costs and expenses and attorneys' fees in connection with any such arbitration. If, despite the good faith efforts of the Parties, they are unable to mutually agree on a single arbitrator, then, in such event, the arbitration will be conducted by a panel of three (3) arbitrators, one selected by BBIL and one selected by Ocugen (in each case, who shall be appointed within (30) days of the determination that such arbitration will be conducted by a panel as opposed to a single arbitrator), and a third arbitrator, who shall act as the presiding arbitrator, selected by the two-Party appointed arbitrators within thirty (30) days after the selection of the second arbitrator.
- 14.7. <u>Entire Agreement</u>. This Agreement, including its Exhibits and Schedules, sets out the entire agreement between the Parties relating to its subject matter and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter, including that certain Mutual Nondisclosure Agreement entered into between the Parties as of August 26, 2020 and the Letter of



Intent dated 21 December 2020. The Parties acknowledge that they are not relying on any representation, agreement, term or condition which is not set out in this Agreement.

- 14.8. <u>Purposes and Scope</u>. The Parties understand and agree that the relationship between the Parties described herein is limited to the activities, rights and obligations as set forth in this Agreement. Nothing in this Agreement shall be construed (a) to create or imply a general partnership between the Parties, (b) to make either Party the agent of the other for any purpose, (c) to alter, amend, supersede or vitiate any other arrangements between the Parties with respect to any subject matter not covered hereunder, (d) to give either Party the right to bind the other, (e) to create any duties or obligations between the Parties except as expressly set forth herein, or (f) to grant any direct or implied licenses or any other rights other than as expressly set forth herein.
- 14.9. <u>Assignment and Successors</u>. Neither this Agreement nor any obligation of a Party hereunder may be assigned by either Party without the written consent of the other, which consent shall not be unreasonably withheld, conditioned or delayed, except that Ocugen may assign this Agreement and the rights, obligations and interests of Ocugen without such consent in whole or in part, to any of its Affiliates, *provided* that Ocugen shall remain liable and responsible to BBIL for the performance and observance of all such duties and obligations by such Affiliates. Without limiting the generality of the foregoing, with the prior written consent of BBIL, not be unreasonably withheld, conditioned or delayed, Ocugen may also assign this Agreement in whole, but not in part, to any purchaser of all or substantially all of its assets or all or substantially all of its assets to which this Agreement relates, or shares representing a majority of its common stock voting rights or to any successor company resulting from any merger, consolidation, share exchange or other similar transaction. Any permitted assignment to a third party shall be for the whole (and not part) of this Agreement.
- 14.10. Further Assurances and Actions. Each Party, upon the request of the other Party, whether before or after the Effective Date and without further consideration, will do, execute, acknowledge and deliver, or cause to be done, executed, acknowledged or delivered, all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney, instruments and assurances as may be reasonably necessary to effect complete consummation of the transactions contemplated by this Agreement, and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement. The Parties agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by this Agreement.
- 14.11. <u>Expenses</u>. Each of the Parties will bear its own direct and indirect expenses incurred in connection with the negotiation and preparation of this Agreement, the transactions contemplated hereby (including the Development Supply Agreement and the Commercial Supply Agreement) and, except as set forth in this Agreement, the performance of the obligations contemplated hereby and thereby.
- Interpretation. Except where the context expressly requires otherwise: (a) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation;" (b) all references herein to Articles, Sections, Exhibits and Schedules shall be deemed references to Articles and Sections of, and Exhibits and Schedules to, this Agreement; (c) all terms of an accounting or financial nature shall be construed in accordance with GAAP, as in effect from time to time; (d) countries shall include territories; (e) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof; (f) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa); (g) any reference herein to any Person will be construed to include the Person's successors and assigns; (h) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (i) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement; (j) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging); and (k) the term "or" will be interpreted in the inclusive sense (and/or) commonly associated with the term "or." The headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement. The words "agrees to", "will" and

"shall" are used in a mandatory, not a permissive, sense. The Parties agree that they have been represented by counsel during the negotiation and execution of this Agreement and therefore waive the application of any Applicable Law, regulation, holding or rule of construction providing that ambiguities in an agreement or other document will be construed against the Party drafting such agreement or document.

14.13. <u>Counterparts</u>. This Agreement may be executed in counterparts and delivered via facsimile, emailed PDF or other electronic means, each of which will be deemed to be an original, and both of which taken together, will constitute one (1) agreement binding on both Parties.

[remainder of this page intentionally left blank]

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

## OCUGEN, INC.

By: /s/ Shankar Musunuri

Name: Dr. Shankar Musunuri

Title: CEO

# BHARAT BIOTECH INTERNATIONAL LIMITED

By: /s/ V. Krishna Mohan

Name: Dr. V. Krishna Mohan Title: Whole-time Director

## **EXHIBIT A**

# **Initial Development Plan**

[\*\*\*]

#### **EXHIBIT B**

#### **Determination of Operating Profit**

1. <u>Definitions</u>. For purposes of this <u>Exhibit B</u>, and where otherwise used in the Agreement, the following terms shall have the following meanings:

"Allowable Expenses" means the sum of Development Expenses<sup>1</sup>, Costs of Goods Sold, Distribution Expenses, Sales and Marketing Expenses, direct administrative expenses and Commercialization Expenses.

"Commercialization Expenses" means all actual costs and expenses (including labor) that are attributable to Commercialization activities conducted by or on behalf of Ocugen, its Affiliates or Sublicensees, directly related or attributable thereto. Commercialization Expenses shall include: [\*\*\*].

"Cost of Goods Sold" means, to the extent sourced from BBIL or its Affiliates, the standard unit cost of the Manufacture of the Product (i.e., Direct Material Costs and Direct Labor Costs, plus Manufacturing overhead specifically attributable to the Product (and allocated to Ocugen, its Affiliates or Sublicensees as pass-through-costs), all calculated in accordance with GAAP). "Direct Material Costs" means the actual costs incurred in Manufacturing or purchasing materials, including freight-in costs, sales and excise taxes imposed thereon and customs duty and charges levied by government authorities, and all costs of packaging components (in any case, to the extent not deducted from Net Sales). "Direct Labor Costs" means the actual cost of employees engaged in direct Manufacturing activities and direct quality control and quality assurance activities who are directly employed in Manufacturing and packaging the Product. and a reasonable allocation of facilities costs, all in accordance with GAAP. To the extent that the Product is sourced from a third party manufacturer, the actual price paid by Ocugen, its Affiliates or Sublicensees to the third party for the Manufacture, supply and packaging of the Product shall be the Cost of Goods Sold.

"Development Expenses" means all costs and expenses actually incurred by Ocugen in connection with the Ocugen Development Activities performed by Ocugen, its Affiliates or agents in accordance with the Development Plan.

"**Distribution Expenses**" means Ocugen's, its Affiliates' and Sublicensees' reasonable costs and expenses (including labor) related to storage and distribution of the Product in and for the Ocugen Territory, including [\*\*\*].

"Net Sales" means the gross amount actually received by Ocugen, any of its Affiliates or Sublicensees (each, a "Seller") for Sales of the Product to third parties in the Ocugen Territory less the following accrued deductions (if and to the extent included in and not already deducted from the gross amounts invoiced or otherwise charged):

- (a) [\*\*\*];
- (b) [\*\*\*]:
- (c) [\*\*\*]·
- (d) [\*\*\*]:
- (e) [\*\*\*]:
- (f) [\*\*\*]
- (g) [\*\*\*].

Each of the above deductions to Net Sales shall be calculated in accordance with GAAP. In addition, if any Seller effects a sale, disposition or transfer of the Product to a customer in the Ocugen Territory other

<sup>&</sup>lt;sup>1</sup> Provided the same shall not exceed [\*\*\*].



than on customary commercial terms or as part of a package of products and services, the Net Sales of such Product to such customer shall be deemed to be "the fair market value" of such Product, where "fair market value" means the value that would have been derived had the Product been sold as a separate product to another customer in the applicable country on customary commercial terms.

"Sales and Marketing Expenses" means all reasonable direct costs and expenses (including labor) that are attributable to the distribution, sale, promotion and marketing of the Product in and for the Ocugen Territory (including all prelaunch activities), calculated on [\*\*\*]. For clarity, "Sales and Marketing Expenses" shall include [\*\*\*] in connection with the Commercialization of the Product in the Field in and for the Ocugen Territory.

2. <u>Operating Profit</u>. From and after the First Commercial Sale of the Product by Ocugen, its Affiliates or Sublicensees in and for the Ocugen Territory, "**Operating Profit**" shall be [\*\*\*].

## **SCHEDULE 1.5**

# **BBIL Patent Rights**

## **SCHEDULE 11.2**

## **Public Statements**

[\*\*\*]