

Confidential Treatment Requested by Achaogen, Inc.

COLLABORATIVE DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Collaborative Development and Commercialization Agreement (“Agreement”) is entered into as of April 26, 2016 (“Effective Date”) by and between **Microgenics Corporation** (hereinafter “Microgenics”), having its principal place of business at 46500 Kato Road, Fremont, California 94538, and **Achaogen Inc.** (hereinafter “Achaogen”), having a place of business at 7000 Shoreline Court, #371, South San Francisco, California 94080. Both Microgenics and Achaogen are referred to herein individually as a “Party” and collectively as the “Parties.”

WHEREAS, Achaogen possesses certain intellectual property rights and know-how relating to drug compound Plazomicin;

WHEREAS, Microgenics has certain expertise and know-how relating to the development, manufacture and sale of immunoassays for *in vitro* diagnostic use;

WHEREAS, the Parties are undertaking, as of the Effective Date, activities under that certain Antibody Development Agreement, dated [***] (the “Antibody Development Agreement”), for the purpose of identifying and developing antibodies against Plazomicin and this Agreement is the “Assay Commercialization Agreement” referred to in Section 2.6 of the Antibody Development Agreement; and

WHEREAS, the Parties desire to collaborate on the development and commercialization of a therapeutic drug monitoring assay for the measurement of concentrations of Plazomicin in biological fluids.

NOW THEREFORE, in consideration of the foregoing premises and the covenants and promises contained herein, the Parties intending to be bound, hereby agree as follows:

1. **Definitions**

For the purposes of this Agreement and the Exhibits hereto, the following words and phrases shall have the following meanings (words defined in the Agreement shall have the meaning ascribed to them in that Section):

1.1 “Achaogen Know-How” shall mean all proprietary, technical and clinical information, data and know-how relating to Plazomicin and haptens and polyclonal antibodies related directly to Plazomicin, whether or not patentable, which is Controlled as of the Effective Date or acquired during the Term by Achaogen.

1.2 “Achaogen Materials” shall mean the materials set forth in **Exhibit A**.

1.3 “Achaogen Patents” shall mean the Patents and Patent applications set forth in **Exhibit B** hereto.

1.4 “Affiliate” shall mean, with respect to a Party, any corporation, or other business entity which directly controls, is controlled by or is under common control with that Party. A person or entity shall be regarded as in control of another entity if it owns, directly or indirectly, fifty percent (50%) or more of the outstanding equity securities of the subject entity which is entitled to vote in the election of directors, or a fifty percent (50%) or greater interest in the net assets or profits of the subject entity if such entity is not a corporation.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential Treatment has been requested with respect to the omitted portions.

1.5 “Applicable Law” shall mean all applicable provisions of all statutes, laws, rules, regulations, administrative codes, ordinances, decrees, orders, decisions, injunctions, awards judgments, permits and licenses of or from governmental authorities, including those relating to or governing the use or regulation of the subject item and the listing standards or agreements of any national or international securities exchange.

1.6 “Assay” shall mean an antibody-based immunoassay or immunoassays used for the *in vitro* measurement of Plazomicin concentration in human blood and other body fluids, [***], that (a) uses or otherwise would infringe Immunoassay Technologies, (b) is developed by Microgenics and its Affiliates under this Agreement, and (c) [***].

1.7 “Commercially Reasonable Efforts” shall mean efforts and resources normally utilized by a Party for a product owned by it or to which it has rights, which is of similar market potential at a similar stage in its product life, taking into account the competitiveness of the marketplace, the proprietary position of the product, the regulatory structure involved, the profitability of the applicable products, the relative benefit that accrues to actual and potential patients and other relevant factors; provided, that, in any event, “Commercially Reasonable Efforts” under this Agreement require that a Party (a) [***], (b) [***], and (c) [***].

1.8 “Confidential Information” shall mean all proprietary and confidential business, technical, scientific, and/or regulatory information relating to the Assay, Plazomicin, and/or the purpose of, or activities under, this Agreement, that is provided by or on behalf of a Disclosing Party to a Receiving Party hereunder, whether disclosed in writing or orally.

1.9 “Control” shall mean with respect to any (a) item of information, including know-how, or (b) intellectual property right, the possession (whether by ownership or license) by a Party of the ability to grant to the other Party access and/or a license as provided herein under such item or right without violating the terms of any agreement or other arrangements with any Third Party existing before or after the Effective Date.

1.10 “Development and Manufacturing Phase” shall mean that phase of the Research Program set forth in the Project Plan relating to the optimization of the Assay and the manufacture and validation of [***] ([***)] production lots of the Assay that meet the Specifications [***].

1.11 “Feasibility Study Phase” shall mean that phase of the Research Program set forth in the Project Plan comprising all studies conducted by Microgenics to establish the feasibility for developing the Assay by demonstrating (a) [***], (b) [***], (c) [***], (d) [***], (e) [***], and (f) [***].

1.12 “First Commercial Sale” shall mean (a) with respect to the Assay, the initial sale by or on behalf of Microgenics (or its Affiliates) of the Assay and (b) with respect to Plazomicin, the initial sale by or on behalf of Achaogen (or its Affiliates) of Plazomicin, in each case, to a Third Party in exchange for cash or some equivalent to which value can be assigned; provided, that a sale of the Assay or Plazomicin, as applicable, in connection with [***] of the Assay or Plazomicin, as applicable, or for [***] therefor will not constitute First Commercial Sale.

1.13 “Good Clinical Practice” or “GCP” shall mean the then current standard for clinical trials for assays, as set forth in the United States Federal Food, Drug and Cosmetics Act and applicable regulations

promulgated thereunder, as amended from time to time and such standards of good clinical practice as are required by the European Union and other organizations and governmental agencies in countries where the Assay is intended to be sold, to extent such standards are no less stringent than United States GCP.

1.14 “Good Laboratory Practice” or “GLP” shall mean the then current standards for laboratory activities for assays, as set forth in the United States Federal Food, Drug and Cosmetics Act and applicable regulations promulgated thereunder, as amended from time to time and such standards of good laboratory practice as are required by the European Union and other organizations and governmental agencies in countries where the Assay is intended to be sold, to extent such standards are no less stringent than United States GLP.

1.15 “Good Manufacturing Practices” or “GMP” shall mean the then current standards for the manufacture of assays, as set forth in the United States Federal Food Drug and Cosmetics Act and applicable regulations promulgated thereunder, as may be amended from time to time and such standards of good manufacturing practice as are required by the European Union and other organizations and governmental agencies in countries where the Assay is intended to be sold, to extent such standards are no less stringent than United States GMP.

1.16 “Immunoassay Technologies” shall mean technologies, including any patentable or unpatentable intellectual property rights appurtenant thereto, Controlled by Microgenics or its Affiliates suitable for developing and manufacturing assays, calibrators and controls for application on [***], including [***] assay technology, [***] technology, [***] technology, [***] immunoassay, the Microgenics Cell Line, and Microgenics [***] Antibodies.

1.17 “Microgenics Cell Line” shall mean those certain cell lines (a) that were developed under the Antibody Development Agreement, or (b) that produce Microgenics [***] Antibodies and are Controlled by Microgenics and listed in **Exhibit C**, as such Exhibit may be amended from time to time upon the mutual written agreement of the Parties.

1.18 “Microgenics Know-How” shall mean all proprietary, technical information, data and know-how relating to the Assay or Immunoassay Technologies and reagents for use therewith which are Controlled as of the Effective Date or acquired or developed during the Term by Microgenics or its Affiliates.

1.19 “Microgenics [***] Antibodies” shall mean [***] antibodies developed by, or Controlled by, Microgenics or its Affiliates and directed to Plazomicin.

1.20 “Patent” shall mean any existing or future: (a) national, regional or international patent or patent application in any jurisdiction (including any provisional, divisional, continuation, continuation-in-part, non-provisional, converted provisional, or continued prosecution application, any utility model, petty patent, design patent and/or certificate of invention), (b) any extension, restoration, revalidation, reissue, re-examination and extension (including any supplementary protection certificate and the like) of any of the foregoing patents or patent applications, and (c) any ex-U.S. equivalents corresponding to any of the foregoing.

1.21 “Plazomicin” shall mean Achaogen’s aminoglycoside antibiotic that is in Phase 3 clinical development as of the Effective Date and having the chemical structure shown on **Exhibit D**, and [***] thereof, regardless of commercial name.

1.22 “Primary Countries” shall mean (a) the countries set forth on **Exhibit E** and (b) any other country in the Territory which the Parties mutually agree in writing shall be a Primary Country in accordance with Section 4.2.5, in each case, for which the Parties intend to pursue initial registration, commercialization and launch of the Assay.

1.23 “Project Plan” shall mean the plan of work to be conducted under the Research Program pursuant to Section 2.1 (Project Plan) hereof as attached as **Exhibit F**.

1.24 “Regulatory Approval” shall mean all authorizations, registrations or clearances with or by the appropriate Regulatory Authorities which are required for the marketing, promotion, pricing and sale of either the Assay or Plazomicin, as applicable, in any country or regulatory jurisdiction in the Territory.

1.25 “Regulatory Authority” shall mean any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity involved in the granting of Regulatory Approval, including the United States Food and Drug Administration.

1.26 “Research Program” shall mean the collaborative program of research relating to the development of the Assay to be carried out by the Parties pursuant to this Agreement.

1.27 “Secondary Countries” shall mean all countries in the Territory, other than the Primary Countries.

1.28 “Shortfall License” shall mean a temporary, fully-paid up, royalty-free, worldwide non-exclusive license granted by Microgenics (including on behalf of its Affiliates as appropriate), under Section 4.3.2.3, to (a) the Immunoassay Technologies and (b) all other intellectual property rights (including Patent applications, Patents, trade secrets, copyrights, and trademarks) (i) of Microgenics (or its Affiliates as appropriate) arising out of the performance of this Agreement or the Antibody Development Agreement, or (ii) Controlled by Microgenics (or its Affiliates as appropriate) that are necessary or desirable for or used in the manufacture and commercialization of the Assay, which license would be for the manufacture, use, sale, offer for sale and import of the Assay. Such license shall be fully sub-licensable to any Third Party for purposes of manufacturing and commercializing the Assay (including the components thereof) under Section 4.3.2.3.

1.29 “Specifications” shall mean the specifications applicable to the Assay, as set forth on **Exhibit G**.

1.30 “Territory” shall mean the world.

1.31 “Third Party(ies)” shall mean any person(s) or entity(ies) other than Achaogen, Microgenics or their respective Affiliates.

1.32 “Trademarks” shall mean all registered and unregistered trademarks (including all common law rights thereto), service marks, trade names, brand names, logos, taglines, slogans, certification marks, Internet domain names, trade dress, corporate names, business names and other indicia of origin, together with the goodwill associated with any of the foregoing and all applications, registrations, extensions and renewals thereof throughout the world, and all rights therein provided by international treaties and conventions.

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1.33 “Transfer License” shall mean a royalty-bearing, worldwide exclusive license granted by Microgenics (including on behalf of its Affiliates as appropriate), under Section 9.4.4.1, to (a) the Immunoassay Technologies and (b) all Patent applications, Patents, trade secrets and other know-how, (i) of Microgenics (or its Affiliates as appropriate) arising out of the performance of this Agreement or the Antibody Development Agreement, or (ii) Controlled by Microgenics (or its Affiliates as appropriate) as of the termination date of this Agreement that are necessary for or used in the development, manufacture, and commercialization of the Assay, which license would be solely for the development, manufacture, use, sale, offer for sale and import of the Assay in connection solely with the use of Plazomicin. Such license shall be fully sub-licensable to any Third Party for purposes of manufacturing and commercializing the Assay (including the components thereof) [***].

1.34 Additional Definitions. Each of the following definitions is set forth in the Section of the Agreement indicated below.

Definition	Section
AAA	13.8.2
Abandoned Commercialization	4.2.7.1
Abandoned Development	4.2.7.1
Achaogen	Preamble
Achaogen Indemnified Parties	11.2
Achaogen Inventions	8.1
Agreement	Preamble
Alliance Manager	5.1.1
Antibody Development Agreement	Recitals
Assay Commercialization Plan	4.2.4
Audit Outcome	4.4.2
Back-up Supplier	4.3.2.2
Binding Forecast	4.2.2
Commercial Leader	5.3.1
Convicted Entity or Convicted Individual	10.4.4
Debarred Entity	10.4.2
Debarred Individual	10.4.1
Development Leader	5.3.1
Disclosing Party	12.1
Dispute	13.8.1
Effective Date	Preamble
Excluded Entity or Excluded Individual	10.4.3
FDA	10.4.5
FDA Disqualified/Restricted List	10.4.5
Force Majeure Event	13.1
Functional Leaders	5.3.1
Joint Project Team or JPT	5.3.1
JSC	5.2
[***] Products	8.1
Joint Patent	8.2.2
Launch Plan	4.2.4
Losses	11.1

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential Treatment has been requested with respect to the omitted portions.

Definition	Section
Microgenics	Preamble
Microgenics Indemnified Parties	11.1
Microgenics Inventions	8.1
Minimum Threshold	4.2.3
Minimum Threshold Period	4.2.3
Party or Parties	Preamble
Plazomicin Commercialization Plan	4.2.1
Receiving Party	12.1
Regulatory Finding	3.3.1.2
Regulatory Leader	5.3.1
Responsible Party	8.3.1
Review Party	8.3.1
Supply Resumption Date	4.3.2.2
Term	9.1
Third Party Claims	11.1
VAT	7.3.2

2 **Research and Development Collaboration**

2.1 **Project Plan.** The Parties shall collaborate on the Research Program in accordance with the Project Plan, as set forth as **Exhibit F**. As may be necessary or reasonable from time-to-time, the JPT may suggest appropriate revisions to the Project Plan to the JSC for its review in accordance with Section 5.3.2 and, if approved by the JSC in accordance with Section 5.1, the Project Plan may be amended from time to time by the JSC.

2.2 **Party Responsibilities.**

2.2.1 **General.** Microgenics and Achaogen shall each perform their respective obligations under the Research Program, using Commercially Reasonable Efforts, in accordance with the Project Plan and in compliance with Applicable Law.

2.2.2 **Achaogen.** Achaogen shall supply to Microgenics, [***], (a) Achaogen Materials, including Plazomicin and Plazomicin clinical patient samples, in such quantities as are set forth in **Exhibit A** or otherwise mutually agreed by the Parties or set forth in the Project Plan; and (b) all necessary and in Achaogen's possession Plazomicin pharmacological and biochemical information, including [***] etc., to enable the JPT to correctly design the Assay and Microgenics to work with the appropriate Regulatory Authorities to secure Regulatory Approval for the Assay. Microgenics shall not transfer any portion of the Achaogen Materials to any Third Party or use the Achaogen Materials for any purpose other than the purposes of performing its obligations under, and in accordance with, this Agreement and the applicable Project Plan. Microgenics shall hold, store and transport all supplies of the Achaogen Materials in compliance with all Applicable Laws and [***]. Microgenics shall maintain complete and accurate records relating to the disposition of all Achaogen Materials.

2.2.3 **Microgenics.** Subject to the provisions of this Agreement (including Article 3 (Regulatory Submissions and Meetings)), Microgenics shall be responsible for the research, development, manufacture and sale of the Assay. Microgenics shall manufacture the Assay according to the Specifications

attached hereto as **Exhibit G** (which may be amended from time to time by the JSC in accordance with Section 5.1) and in accordance with the timelines set forth in the Project Plan. Without limiting the foregoing, Microgenics shall develop and commercialize the Assay such that it is capable of being run on no less than [***] ([***]) distinct [***] platforms, which [***] platforms shall be mutually agreed upon by the Parties in good faith.

2.3 Information Exchange, Records and Compliance.

2.3.1 Technology Transfer. Achaogen shall provide Microgenics with all Achaogen Know-How [***] reasonably necessary for Microgenics to carry out its responsibilities under the Research Program and to obtain Regulatory Approvals for the Assay. Microgenics shall provide Achaogen with all Microgenics Know-How [***] reasonably necessary for Achaogen to carry out its responsibilities under the Research Program and to conduct clinical trials of Plazomicin. All information exchanged shall be subject to the confidentiality requirements set forth in Article 12 (Confidentiality) hereof.

2.3.2 Record Keeping/Compliance. During the Term and for a period of [***] ([***]) years thereafter (or such longer period of time as required by Applicable Laws), each Party shall maintain records in sufficient detail and in good scientific manner appropriate for obtaining and maintaining Regulatory Approvals. Achaogen shall have the right (either by itself or through a Third Party reasonably acceptable to Microgenics), during normal business hours and upon reasonable notice, to inspect records pertinent to Microgenics' obligations under this Agreement. To the extent such records contain Confidential Information of Microgenics, Achaogen shall maintain such Confidential Information disclosed therein in confidence in accordance with Article 12. Achaogen shall have the right to arrange for its employee(s) and/or consultant(s) involved in the activities contemplated hereunder, during normal business hours and upon reasonable notice, to discuss the development activities and results contemplated under this Agreement in detail with the technical personnel and consultant(s) of Microgenics. Each Party shall comply with all applicable GLP, GCP, GMP, ISO 9001 and ISO 13485:2003 requirements and other Applicable Laws in the conduct of the Research Program and in the activities contemplated under this Agreement, including the development, manufacture and commercialization of the Assay.

2.4 Installation and Training. Upon Achaogen's request, Microgenics shall, [***], install any necessary equipment and train appropriate staff at clinical sites designated by Achaogen for the performance of clinical trials by Achaogen, in connection with obtaining Regulatory Approval for Plazomicin, and in order to enable such sites to use the Assay in connection with such use of Plazomicin and provide training for such sites' personnel on how to operate such equipment. For clarity, [***] shall be [***] responsible for the costs of (a) any clinical trials conducted for purposes of obtaining Regulatory Approval for the Assay (as opposed to Regulatory Approval for Plazomicin) and (b) any activities conducted in a given country in the Territory following the receipt of Regulatory Approval for the Assay for such country (e.g. commercial activities).

2.5 Quality Agreement. No later than [***] ([***]) days after the Effective Date (or such later date as may be otherwise agreed upon by the Parties in writing), the Parties shall enter into a quality agreement defining the commitments of both Parties to ensure that the Assay and related services developed and commercialized under this Agreement satisfy the quality and regulatory requirements required by this Agreement. Microgenics shall manage all Achaogen Materials (including clinical patient samples) according to customer property requirements described in such quality agreement.

2.6 BARDA Requirements. The Parties acknowledge and agree that Achaogen receives funding

from the United States government through the Biomedical Advanced Research and Development Authority within the office of the Assistance Secretary for Preparedness and Response in the United States Department of Health and Human Services (BARDA) in connection with Achaogen's development of new antibacterial treatment of MDR gram-negative bacterial infection. In connection with the foregoing, the terms and conditions of this Agreement shall be subject in their entirety to the terms and conditions set forth on Appendix A of **Exhibit H**. In the event of any conflict between the terms and conditions of the main body of this Agreement and Appendix A of **Exhibit H**, Appendix A of **Exhibit H** shall control.

3 **Regulatory Submissions and Meetings**

3.1 **Coordination.** Achaogen and Microgenics shall [***] coordinate the therapeutic and diagnostic regulatory filings and communications with Regulatory Authorities in the Territory. Achaogen will be responsible for all activities regarding the Regulatory Approval of Plazomicin (and, as between the Parties, Achaogen shall retain ownership of all regulatory filings and Regulatory Approvals for Plazomicin), and, subject to the terms and conditions of this Agreement, [***] will be responsible for all activities regarding the Regulatory Approval of [***] (and, as between the Parties, [***] shall retain ownership of all regulatory filings and Regulatory Approvals for [***]). For the avoidance of doubt, the Parties acknowledge and agree that, notwithstanding anything herein to the contrary, but subject to Section 3.2 and Section 4.2.7, (a) Achaogen shall have the sole discretion, at any time during the Term, to determine whether to conduct any clinical trial or make any regulatory filing, submission or correspondence with respect to Plazomicin; and (b) [***], subject to Section 4.2.7, at any time during the Term, to conduct any clinical trial (provided, that, in the event of a clinical trial that involves the use or administration of [***], [***]) or make any regulatory filing, submission or correspondence with respect to [***].

3.2 **Reporting and Consultation.** [***] shall keep [***] regularly informed in connection with the preparation of all regulatory filings, submissions or correspondence related to [***] and [***] shall have the right to review and comment on any regulatory filing, submission or correspondence related to [***] (including any [***]), to be submitted to any health authority by [***]. In connection therewith, [***] shall provide to [***] for review the text of any such regulatory filing, submission or correspondence for [***] prior to submission and [***] shall consider in good faith all comments provided by [***]; provided that any disputes with respect to comments provided by [***] shall be resolved by the JSC. In addition, [***] shall consult with [***] with respect to all material matters required for regulatory filings, submissions or correspondence, under this Agreement; provided, however, that, subject to Section 3.1, [***] shall have sole responsibility hereunder for all regulatory filings (including [***] or their ex-United States equivalent), submissions or correspondence, including preparing and analyzing all [***] information required pursuant to any and all Applicable Laws, and preparing and analyzing any additional data and information required by any applicable Regulatory Authority (other than any data or information regarding [***]). Upon written request from [***], [***] shall promptly provide to [***] copies of all submitted regulatory filings, submissions, and material correspondence to and from any Regulatory Authorities; provided, that [***] may redact from such copies information that does not relate to the Assay, Plazomicin or this Agreement and the activities hereunder.

3.3 **Correspondence from Regulatory Authority.**

3.3.1.1 If either Party receives any material communication from the Regulatory Authorities relating to [***] or has any meetings (telephonic or in person) with any Regulatory Authority for any material reason regarding [***], such Party shall promptly notify the other Party and, upon mutual agreement, decide whether it is necessary for the other Party to be present in any

discussions with the Regulatory Authorities regarding [***]; provided, however, that, notwithstanding the foregoing, Achaogen shall have the right to participate in (a) [***], (b) [***], or (c) [***] pertaining to Achaogen Materials or Achaogen Know-How. For clarity, as between the Parties, [***] shall be responsible for leading any meetings or other discussions with the [***]. [***] shall not make any representations or discuss the uses of [***] with any Regulatory Authority except to the extent it relates to [***]. Neither Party shall disclose, without the other Party's prior written consent, Confidential Information of such other Party in any regulatory filing, submission or correspondence or at a meeting with any Regulatory Authority, except to the extent required by Applicable Laws or otherwise under the Project Plan.

3.3.1.2 In addition, Microgenics shall notify Achaogen within [***] ([***) business days of any regulatory finding or violation identified by a Regulatory Authority that may potentially impact the activities contemplated under the Project Plan or the development, manufacture or commercialization of the Assay (a "Regulatory Finding"). With respect to each Regulatory Finding, if any, Microgenics shall provide (1) (a) [***], or (b) [***], or (c) [***] and (2) Microgenics' [***]; provided, that, in each case of clauses (a), (b), and (c), Microgenics' may redact from such copies or reports information that does not relate to the Assay, Plazomicin or this Agreement and the activities hereunder. Without limiting the next to last sentence of Section 3.5, Microgenics shall notify Achaogen promptly of any notification or information received from a Regulatory Authority, that: (i) would reasonably be expected to impair the integrity or reputation of Plazomicin or the Assay; (ii) raises any material concerns regarding the safety or efficacy of Plazomicin or the Assay; (iii) indicates or suggests a potential material liability of either Party to Third Parties in connection with Plazomicin or the Assay; (iv) is reasonably likely to lead to a recall or market withdrawal with respect to Plazomicin or the Assay; or (v) [***].

3.4 Package Insert Information. Notwithstanding anything to the contrary contained herein, but subject to any applicable review and comment rights of the other Party, and dispute resolution escalation procedures set forth in Section 13.8, [***] shall have final decision making authority on all package insert language directed [***], and [***] shall have final decision making authority on all Assay package insert language directed [***].

3.5 Filings. On a country-by-country basis, a Regulatory Approval from the applicable Regulatory Authority(ies) is required for the Assay prior to launch in such country. Upon Achaogen's request, Microgenics shall reasonably cooperate with Achaogen with respect to any regulatory filings, submissions, or correspondence made by Achaogen related to Plazomicin in any country in the Territory, including promptly providing data, information and advice regarding the Assay, including the manufacture (including any recall information) and use thereof. This Agreement generally assumes that there is a current 510(k) pathway for obtaining Regulatory Approval for the Assay; provided, that, if a PMA pathway is required, the Parties acknowledge and agree that [***] reviewed by the Parties and may need to be adjusted to the extent agreed upon between the Parties and subject to the proviso in the foregoing sentence. For the avoidance of doubt, Achaogen shall have sole right to control any such regulatory filings, submissions, correspondence or other matters related to Plazomicin including any joint submissions or filings, but not [***], and to communicate with Regulatory Authorities related thereto. No later than [***] (or such later date as otherwise agreed to by the Parties), the Parties shall enter into an agreement setting forth the Parties respective responsibilities for adverse event and complaint reporting, the exchange of safety data and, to the extent agreed by the Parties to be appropriate and relevant, recall matters.

3.6 Right of Reference. [***] hereby grants to [***] a non-exclusive, non-transferable (except

in connection with a permitted assignment, sublicense or subcontract) “right of reference” (as defined in 21 CFR 314.3(b)) with respect to clinical trial data and results related to [***], solely as necessary for [***] to prepare, submit and maintain regulatory submissions related to [***] and Regulatory Approvals for [***]. [***] hereby grants to [***] a non-exclusive, non-transferable (except in connection with a permitted assignment, sublicense or subcontract) “right of reference” (as defined in 21 CFR 314.3(b)) with respect to [***] clinical trial data (including [***]), information (including the [***], as applicable) and results related to [***], solely as necessary for [***] to prepare, submit and maintain regulatory submissions related to [***] and Regulatory Approvals for [***].

3.7 [***]. In connection with the [***] of [***] in any [***] in the Territory, [***] shall [***] of the [***] in [***] in [***] with such [***] of [***]. The Parties shall discuss in good faith (via the JPT) and mutually agree as to [***] shall [***] for [***], which discussion and decision shall occur no later than [***] ([***) year [***]. In the event that the Parties later agree to [***] for [***] in a [***], the Parties (through the JPT and JSC) shall amend the Project Plan to [***], subject to [***], and [***] shall [***].

4 **Manufacture and Commercialization of Assay**

4.1 **Manufacture.** Except as provided elsewhere in this Agreement, including Section 4.3 (Supply) and Section 9.4.4 (Effect of Termination), during the Term, Microgenics shall be solely and exclusively responsible for the worldwide manufacture of the Assay in accordance with GMP standards, the Specifications and Applicable Law. For clarity, from and after the expiration or termination of this Agreement, nothing in this Agreement shall restrict Microgenics from developing, manufacturing or commercializing the Assay as and to the same extent as any third party.

4.2 **Commercialization.** Upon successful completion of the Development and Manufacturing Phase and upon receipt of the applicable Regulatory Approval in a given country in the Territory required in order to sell the Assay in such country, Microgenics shall use Commercially Reasonable Efforts to exclusively commercialize and market the Assay, under the Thermo Scientific tradename and packaging and utilizing Microgenics’ and its Affiliate’s commercial infrastructure, in each country within the Territory in which Achaogen is commercializing Plazomicin for so long as Achaogen is commercializing Plazomicin in such country. Solely to the extent Achaogen elects to promote an assay which may be capable of measuring Plazomicin in a given Primary Country ([***) in the Territory, and subject to receipt and conditions of any applicable Regulatory Approvals, Achaogen shall prioritize the promotion of the Assay relative to any other assay which may be capable of measuring Plazomicin, in its marketing and sales efforts in such Primary Country; provided, however, that in the event (a) Microgenics [***] is unable to supply the Assay in quantities sufficient to meet each applicable Binding Forecast, including [***], or (b) [***], Achaogen may prioritize the promotion of assays capable of measuring Plazomicin in the affected country(ies). For clarity, and notwithstanding anything to the contrary in this Agreement, including this Section 4.2, Achaogen expressly reserves and retains the right to, directly or indirectly (including through contractors or collaborators), research, develop, manufacture, use or commercialize assays capable of measuring Plazomicin other than the Assay; provided, that, Achaogen may not, directly or indirectly (including through contractors or collaborators) commercialize any immunoassay [***], other than the Assay in accordance herewith, [***]; provided, further, that the restriction on Achaogen’s right to commercialize immunoassays [***], other than the Assay, shall be of no force or effect if Microgenics is unable to supply the Assay for [***] ([***) days at any time [***] or if the Parties mutually determine that Microgenics will not be able to supply the Assay. Additional commercialization and supply terms may be added to this Agreement in the form of an amendment. Without limiting the foregoing:

4.2.1 Plazomicin Commercialization Plan. As soon as commercially reasonable, but no later than [***] ([***) days after the Effective Date of this Agreement, Achaogen shall share its global commercialization plans for Plazomicin with Microgenics (“Plazomicin Commercialization Plan”). The Plazomicin Commercialization Plan shall include the list of countries consistent with the Primary Country list for commercialization of Plazomicin, anticipated launch timing, initial volume forecasts and such other information as may be determined by the JPT. Microgenics will develop timelines on a country basis to the extent it receives adequate Plazomicin Commercialization Plan details with respect to a given country. Achaogen agrees to keep such Plazomicin Commercialization Plan updated via regular communication with the JSC. For clarity, (a) the Plazomicin Commercialization Plan shall be Confidential Information of Achaogen hereunder, and (b) Achaogen [***] in preparing and conducting activities under the Plazomicin Commercialization Plan.

4.2.2 Volumes and Pricing.

4.2.2.1 On a regular basis, beginning at least [***] ([***) months prior to the anticipated date of the First Commercial Sale of Plazomicin in the Territory, Achaogen will share confidential, non-binding (except as described below) good faith volume forecasts in units for the Assay and updates thereof in the Plazomicin Commercialization Plan through the JSC in order for the Parties to develop a [***] market introduction including achieving Regulatory Approval [***] for the Assay in all relevant countries and regions. Thereafter, and on a [***] basis, Achaogen shall supply Microgenics with a confidential, good faith rolling [***] ([***) month forecast (in units, broken-down by country (or regions)) as to Achaogen’s estimated unit demand for worldwide commercial demand for the Assay (it being agreed and understood that such forecasts shall be Confidential Information of Achaogen hereunder); provided, however, only the first [***] ([***) months of each [***] ([***) month forecast shall be binding (a “Binding Forecast”) and the remaining [***] ([***) months of such forecast shall be non-binding (for clarity, when each [***] forecast update is provided, [***] of the previous forecast (i.e., [***] of the Binding Forecast previously submitted) shall not be changed as they become [***] of the current forecast and [***] of the current Binding Forecast). For clarity, except as otherwise provided in this Agreement with respect to the Binding Forecast, Achaogen shall have no liability whatsoever with respect to such forecasts, including no liability for any Assay manufactured or materials ordered by or on behalf of Microgenics based on such forecasts. Microgenics shall supply the quantities of the Assay set forth in the applicable Binding Forecasts and shall use Commercially Reasonable Efforts to ensure that [***], in each case, in accordance with Section 4.3; provided, however, [***].

4.2.2.2 The Parties acknowledge and agree that [***] shall have [***] with respect to the pricing of the Assay in any country in the Territory; provided, however, [***] shall [***] to price the Assay in a given country at an amount no greater than (i) (a) \$[***] in the United States or (b) \$[***] in any other country, or (ii) [***] percent ([***)%) of the applicable list price of any other [***] assay marketed in such country; provided, further, that [***] shall [***] to take into account [***]. In the event that (x) [***] to price the Assay at an amount greater than the foregoing subclauses (i) and (ii), then the JSC shall review the available data and discuss the Assay price in accordance with Section 5.2.1(h), and/or (y) the Assay pricing [***], the JSC will review the available data and discuss various alternative solutions.

4.2.3 Minimum Thresholds. In the event that, during the applicable Minimum Threshold Periods (as defined below), Microgenics does not receive the applicable Minimum Threshold Revenue (as defined below) during a given calendar year, Achaogen agrees to pay [***] Microgenics for such region during such calendar year (on a prorated basis, as applicable). For purposes of this Section 4.2.3,

4.2.3.1 The “First Minimum Threshold Period” shall begin on the [***] ([***]) anniversary of the date on which the First Commercial Sale of the Assay in [***] occurred and shall end on the [***] ([***]) anniversary of the date on which the First Commercial Sale of the Assay in [***] occurred. For example, if the First Commercial Sale of the Assay in [***] occurred on [***] then the First Minimum Threshold Period would begin on [***] and would end on [***];

4.2.3.2 The “Second Minimum Threshold Period” shall begin on the [***] ([***]) anniversary of the earlier of the date on which the First Commercial Sale of the Assay occurred in (i) [***] of the following countries - [***] (each an “[***] Country”); or (ii) an [***] Country and [***]; or (iii) [***] ([***]) of the Primary Country list ([***]) (subclause (i), (ii), or (iii), as applicable, the “Start Date”), and shall end on the earlier of (a) the [***] ([***]) anniversary of the Start Date or (b) the date this Agreement expires or terminates;

4.2.3.3 “Minimum Threshold Revenue” shall mean, with respect to each of the First Minimum Threshold Period and the Second Minimum Threshold Period, USD \$[***] of annual gross revenue received by Microgenics from sales of the Assay in the Territory (for clarity, during any overlap between the First Minimum Threshold Period and the Second Minimum Threshold Period, the total Minimum Threshold Revenue would be USD \$[***]); provided, however, that the Minimum Threshold Revenue (i) shall be determined by [***] for a given Assay, less [***] directly associated with such sale and Assay and permitted to be taken in accordance with generally accepted accounting principles in the United States, and (ii) that in the event the Minimum Threshold Period begins or ends during a given calendar year, the Minimum Threshold Revenue for such calendar year shall be prorated accordingly.

4.2.4 Market Introduction. The Parties will reasonably agree regarding details related to commercialization of the Assay once the [***] are clarified by Achaogen in the Plazomicin Commercialization Plan. Within [***] ([***]) months of receiving the initial Plazomicin Commercialization Plan, Microgenics will provide Achaogen with (a) a detailed market introduction plan for the Assay (the “Launch Plan”) and (b) a global commercialization plan for the Assay, in a form to be determined by the JSC (the “Assay Commercialization Plan”). During the Term, Microgenics shall provide Achaogen [***] with (i) an updated Launch Plan [***], and (ii) an updated Assay Commercialization Plan [***]. For clarity, (i) the Launch Plan and Assay Commercialization Plan shall be Confidential Information of Microgenics hereunder, and (ii) Microgenics is [***] in preparing and conducting activities under the Launch Plan and Assay Commercialization Plan.

4.2.5 Geographies. Other than the Primary Countries set forth on **Exhibit E**, the Parties shall mutually agree upon any Secondary Countries where Achaogen plans to introduce Plazomicin, which such Secondary Countries shall thereafter be deemed to be Primary Countries and included in the Plazomicin Commercialization Plan and the Assay Commercialization Plan, in all cases no later than [***] prior to the anticipated launch of Plazomicin in any such country; provided, however, the parties agree that actual product registration may take longer than [***] ([***]) months.

4.2.6 Selling, Marketing and Customer Support to Clinical Labs. Microgenics will establish and maintain a commercial infrastructure for the supply of the Assay, as well as adequate product support, customer support and regulatory support in each market where the Assay is introduced, including [***]. For clarity, Achaogen [***] the Assay to physicians and other prescribers and related individuals and organizations; provided, that, for clarity, Microgenics [***] of the Assay to any such physicians or other prescribers or related individuals and organizations.

4.2.7 Abandoned or Uninitiated Development or Commercialization of Assay.

4.2.7.1 If, during the Term, Achaogen determines in good faith that Microgenics has ceased to develop, commercialize and market the Assay in a specific country within the Territory in which Achaogen has obtained or is in the process of obtaining Regulatory Approval for Plazomicin for a period of at least [***] ([***)] months (“Abandoned Commercialization” or “Abandoned Development,” as applicable), then Achaogen may deliver to Microgenics written notice that Achaogen deems Microgenics to have Abandoned Commercialization. If Achaogen delivers such written notice to Microgenics, such notice shall set forth the basis for Achaogen’s good faith determination. If Microgenics disagrees with Achaogen’s determination that Microgenics has Abandoned Commercialization, then the Parties will meet within [***] ([***)] business days to discuss such disagreement. If the Parties cannot agree after such discussion, then the terms of Section 13.8 shall apply to resolve such Dispute.

4.2.7.2 If it is finally determined pursuant to the procedures set forth in Section 4.2.7.1 that Microgenics has Abandoned Commercialization, then, within [***] ([***)] business days of such determination, Microgenics will commercialize and market the Assay for [***] ([***)] months after the written determination is received. After the [***] ([***)] months period has expired, Microgenics will continue to supply the Assay to Achaogen or its distributor pursuant to the terms of a supply agreement that the Parties will negotiate during the first [***] ([***)] months of the [***] month period described in the prior sentence; provided, that such supply agreement shall include an initial (i.e., for a period of no less than [***] ([***)] months) supply price that is no greater than [***] ([***)] % of the lowest price at which Microgenics has made the Assay available to its distributors, or any Third Party if there is no distributor, in the affected country. Microgenics shall [***] promptly assist Achaogen (and/or its designee) in obtaining all necessary Regulatory Approvals and/or modifying and/or transferring existing Regulatory Approvals to enable Achaogen (and/or its designee) to develop, make, have made, use, market, distribute, import, sell and offer for sale the Assay ([***)] in any applicable country.

4.2.7.3 Solely in the event of Abandoned Development, the Parties acknowledge and agree that this Agreement does not supersede Section 5.3 of the Antibody Development Agreement and that Achaogen reserves all of its rights under Section 5.3 of the Antibody Development Agreement, including in the event of Abandoned Development.

4.3 Supply.

4.3.1 Clinical Supply. Microgenics shall supply to Achaogen the amount of Assay ordered by Achaogen, if any, for use in any clinical trials or other development of Plazomicin in accordance with the delivery and shipment terms set forth in the Project Plan to the extent applicable. Achaogen shall provide to Microgenics confidential, non-binding good faith clinical trial and other development supply forecasts for each [***] ([***)] month period starting on [***] and [***] of each calendar year and shall deliver each forecast in writing at least [***] ([***)] days prior to the commencement of the applicable [***] ([***)] month period. The Parties shall agree on the exact date for the delivery of such Assay. Achaogen shall reimburse Microgenics at (a) a price of USD \$[***] per patient result used to make diagnostic decisions for the applicable patient or (b) in the event the Assay is being commercialized at the time of supply, [***]; provided, however, in each case, if Microgenics utilizes any data from any clinical trial or other study conducted by Achaogen with Assay supplied under this Section 4.3.1, Achaogen shall have no obligation to reimburse Microgenics for such Assay.

4.3.2 Continued Supply.

4.3.2.1 Microgenics shall ensure the continued worldwide supply of the Assay in quantities at least sufficient to meet each applicable Binding Forecast. Without limiting the foregoing, Microgenics agrees to maintain a safety stock of rare reagents sufficient to meet each applicable Binding Forecast for the Assay. Microgenics shall provide Achaogen at least [***] ([***) months (or [***) prior written notice of any possible shortfall in meeting each applicable Binding Forecast or other commercial demand for the Assay, and the Parties shall promptly meet and discuss all reasonable commercial resolutions if Microgenics is unable to assure supply as needed to meet each applicable Binding Forecast pursuant to the terms set forth in Section 4.3.2.2.

4.3.2.2 In addition, in order to ensure security of supply of the Assay, within [***] of Microgenics' receipt of the first Regulatory Approval for the Assay in any country in the Territory, Microgenics shall designate [***] (the "Back-up Supplier") which such Back-up Supplier shall be and remain qualified as a manufacturer of the Assay for the supply of the Assay for sale in the Territory. Microgenics shall [***] ensure that the Back-up Supplier can supply the Assay for sale in the Territory within [***] days. Microgenics will develop a manufacturing transition plan that will highlight [***] needed to complete the transition to the back-up supplier. This plan will be presented to the JSC prior to first commercial launch of the Assay.

4.3.2.3 If, for any reason, [***], both Microgenics and the Back-up Supplier (as applicable) are unable to supply the Assay in quantities sufficient to meet the quantities of the Assay either (a) as set forth in each applicable Binding Forecast or (b) based on such other measure of commercial demand as agreed to by the Parties in writing, in either case, during any given [***] ([***) month period for a given country in the Territory, then Microgenics hereby grants Achaogen or its designee a Shortfall License, which license shall survive until [***] ([***) months following the date that either Microgenics or the Back-up Supplier (as applicable) is in a position again to fulfill such demand (as such positioning is demonstrated [***]) (the "Supply Resumption Date"). The Shortfall License shall expire automatically [***] ([***) months after the Supply Resumption Date; provided, however, that (a) Achaogen shall be entitled to use, sell, offer for sale, and import any assay that are in inventory prior to the expiration of the Shortfall License (even if such activity occurs after expiration of the Shortfall License). Additionally, [***], Microgenics shall (i) make its personnel available for a reasonable period of time (not to exceed [***] ([***) months) to effect a successful technology transfer with respect to the manufacture and commercialization of such Assay under the terms of this paragraph, (ii) provide Achaogen with copies of the physical embodiment of all processes, protocols, procedures, methods, tests and other intellectual property rights licensed to Achaogen under the Shortfall License, as applicable, related to Assay (including the manufacture thereof), (iii) supply [***] (including [***) reasonably required to perform [***] as may be required by the applicable Regulatory Authorities, and upon request by Achaogen, [***], provide Achaogen (and/or its designee) with [***] related to the Assay, and (iv) promptly assist Achaogen (and/or its designee) in obtaining all necessary Regulatory Approvals and/or modifying and/or transferring existing Regulatory Approvals to enable Achaogen (and/or its designee) to develop, make, have made, use, market, distribute, import, sell and offer for sale the Assay ([***)).

4.4 Audit Rights.

4.4.1 [***] during the Term, commencing on the [***] ([***) [***] of the Effective Date, Achaogen shall have the right to inspect and audit [***] per calendar year (either by itself or through a Third Party reasonably acceptable to Microgenics) the Assay manufacturing process, facilities, procedures,

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and records upon reasonable notice (which shall be no less than [***] ([***]) calendar days prior notice, unless a shorter period is mutually agreed to by the Parties), and during normal business hours. Notwithstanding the foregoing, Achaogen shall have the right to conduct “for cause” audits (either by itself or through a Third Party reasonably acceptable to Microgenics) [***] during normal business hours of the [***], including in the event of a failure to supply the Assay as specified under Section 4.3.2. Any information shared with Achaogen or a Third Party under this Section 4.4.1 shall be considered Confidential Information. In connection with any such inspection or audit, Microgenics shall have no obligation to provide Achaogen and/or a Third Party access to Microgenics’ Confidential Information related to any product other than the Assay.

4.4.2 Additionally, during the Term, Microgenics shall inform Achaogen within [***] ([***]) business days after receipt of any notice of an audit or inspection by any Regulatory Authority which directly or indirectly relates to the Assay or the Assay manufacturing or distribution operations and Microgenics shall promptly provide to Achaogen in writing the results of any such audit or inspection within [***] ([***]) business days of receipt, including (a) a copy of any inspection reports, Form 483s, warning letters or similar such reports or warnings (“Audit Outcome”), to the extent such Audit Outcome solely addresses the Assay, or (b) a summary of such Audit Outcome, including verbatim text copies of portions thereof pertaining to the Assay, to the extent such Audit Outcome addresses the Assay and other matters, or (c) a summary of such Audit Outcome, to the extent that the Assay is not mentioned in such Audit Outcome; provided, that, in each case of clauses (a), (b), and (c), Microgenics’ may redact from such copies or reports information that does not relate to the Assay, Plazomicin or this Agreement and the activities hereunder, and a summary of Microgenics proposed strategy for addressing any issues or violations noted during the course of such audit or inspection.

4.5 Labeling.

4.5.1 Assay Labeling. Microgenics shall be responsible for ensuring that all Assay packaging and labeling are in compliance with its Regulatory Approvals and Applicable Law.

4.5.2 Information for Labeling and Promotional Materials for Plazomicin. At the request of Achaogen, Microgenics shall provide to Achaogen such information related to the Assay which is in Microgenics’ possession, for Achaogen’s use and reference in the packaging and labeling (including package insert) and promotional materials for Plazomicin.

4.5.3 Changes to Labeling. Achaogen will promptly notify Microgenics of any changes to Plazomicin labeling relevant for the Assay, including [***]. [***], such changes will be implemented by Achaogen with [***] in order to allow Microgenics to change any labeling on the Assay as a result of such changes to Plazomicin labeling. Similarly, Microgenics will promptly notify Achaogen of any changes to the Assay labeling, and Microgenics will implement such changes with [***] in order to allow Achaogen to change any labeling on Plazomicin as a result of such changes to the Assay labeling; provided, however, that Microgenics shall not make any such changes directed to Plazomicin (including, [***]) or which would otherwise require a change to the labeling for Plazomicin, without Achaogen’s prior written approval.

5 Governance.

5.1 Alliance Managers.

5.1.1 No later than [***] ([***]) days after the Effective Date, each of the Parties shall

appoint one (1) representative as its alliance manager (“Alliance Manager”). The Alliance Managers shall have the right to attend all JSC and JPT meetings as non-voting participants and may bring to the attention of the JSC or JPT any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as set forth in Section 5.1.2 or as the Parties may mutually agree. Each Party may replace its Alliance Manager at any time or may designate different Alliance Managers by notice in writing to the other Party.

5.1.2 The Alliance Managers shall have responsibility for creating and maintaining a constructive work environment between the Parties. Without limiting the generality of the foregoing, each Alliance Manager shall:

5.1.2.1 identify and bring disputes and issues, including disputes that cannot be resolved by the JPT, that may result in disputes to the attention of the JSC in a timely manner, and function as the point of first referral in all matters of conflict resolution. In doing so, it is not intended that the Alliance Manager(s) act as a substitute for, or insert any delay in, the formal dispute resolution mechanisms set forth in Section 13.8, but rather that the Alliance Manager(s) shall endeavor to maintain a positive and constructive relationship between the Parties at the working level;

5.1.2.2 provide a single point of communication for seeking consensus both internally within the Parties’ respective organizations and between the Parties;

5.1.2.3 plan and coordinate cooperative efforts, internal communications and external communications between the Parties with respect to this Agreement; and

5.1.2.4 take responsibility for ensuring that meetings and the production of meeting agendas and minutes occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

5.2 Joint Steering Committee. The Parties agree that the Research Program shall be managed by a Joint Steering Committee (“JSC”) and that the JSC shall otherwise have responsibility for the general oversight of activities hereunder. No later than [***] ([***)] days after the Effective Date, each of the Parties shall appoint two (2) representatives to the JSC. The JSC shall be led by two (2) co-chairs, one (1) appointed by Microgenics and one (1) appointed by Achaogen. The JSC will make decisions by consensus, with Microgenics and Achaogen each having one vote. In the event of an impasse, the matter shall be resolved pursuant to Section 5.2.3 (Decision-Making). A Party may change any of its representatives at any time by giving [***] ([***)] days prior written notice to the other Party.

5.2.1 Responsibilities. In addition to its general responsibility to oversee and coordinate the development of the Assay according to the Project Plan and to assure the regular flow of information between the Parties, the JSC shall:

- (a) develop the Project Plan, monitor the progress of the Research Program, and review and approve all proposed changes to the Project Plan;
- (b) amend the Specifications for the Assay;
- (c) review and approve the [***] in accordance with Section [***] hereof;
- (d) oversee the activities of the JPT;
- (e) review and approve the most appropriate regulatory pathway for obtaining Regulatory

- Approval of the Assay;
- (f) review and approve the contents of all applications for Regulatory Approval and related and supporting submissions to Regulatory Authorities;
 - (g) develop and manage clinical samples supply;
 - (h) discuss pricing policy for the Assay in the Territory, including [***] and similar matters, to the extent permitted under Applicable Law; provided that, for clarity, [***];
 - (i) resolve disputes escalated by the Alliance Managers; provided that, if after [***], the JSC is unable to resolve any such dispute, such dispute shall be resolved in accordance with Section 5.2.3.2;
 - (j) confirm completion of each event described in Section 7.1 if the Joint Project Team has not agreed that a Milestone has been completed; and
 - (k) manage and coordinate the supply and commercialization of the Assay, including the initial commercial launch of the Assay and monitoring the progress of the Assay Commercialization Plan and Launch Plan.

5.2.2 Meetings. The JSC shall meet at least [***] during the Term at such place and time as is agreed upon by the Parties; provided, however, that in the event of an emergent situation, including a situation in which a decision by the JSC is required, a meeting shall be held within [***] ([***)] days after written request for such meeting by either Party. Meetings of the JSC may be conducted in person, by telephone or videoconference as agreed by the JSC or the Parties. When held in person, the location of the meetings shall alternate between Achaogen's facilities and Microgenics' facilities, unless otherwise mutually agreed by the Parties. The Alliance Managers shall be responsible for planning and scheduling the meetings and preparing the agenda. The Alliance Managers will record the minutes of each meeting (alternating between Achaogen and Microgenics). Minutes of each meeting of the JSC shall be exchanged for review, comment and approval by the members; provided that, if after [***] ([***)] days following the distribution of the minutes, neither Party has raised any objection, the minutes shall be deemed to have been approved by the Parties. Thereafter, the minutes shall be signed by the co-chairs and distributed to each of the Parties. Additionally, upon invitation by the JSC, the Functional Leaders (or other JPT members) may attend JSC meetings as non-voting members, and each JSC member may reasonably invite other guests to the meetings, in order to discuss special technical or commercial topics relevant to the applicable agenda; provided, that any guests are subject to the confidentiality provisions set forth in Article 12 (Confidentiality).

5.2.3 Decision-Making.

5.2.3.1 All decisions of the JSC shall be made in good faith in the interest of furthering the purposes of this Agreement and the JSC members shall use good faith efforts to make decisions unanimously.

5.2.3.2 If the JSC is unable to agree on any matter after good faith attempts to resolve such disagreement [***], then for matters that are [***], the JSC may refer the disagreement to a meeting between a senior executive (other than a JSC member) representing each Party (currently [***] for Achaogen and [***] for Microgenics) which meeting shall take place as soon as practicable, but in no event later than [***] ([***)] days after the date of the relevant referral. If the senior executives for Achaogen and Microgenics cannot resolve such disagreement over such [***] matter in a mutually acceptable manner within [***] ([***)] business days after such meeting then the matter shall be decided in accordance with Section 13.8.2. Notwithstanding the foregoing, except as otherwise provided in, and subject to the terms and conditions of, this Agreement: (a) [***], with appropriate consideration of the interests of [***], will have [***] that impact the development,

manufacture or marketing of [***] and (b) [***], with appropriate consideration of the interests of [***], will have [***] that [***] impact the development, manufacture or marketing of [***]; provided, that, [***] shall not have decision-making authority regarding (i) [***], or (ii) [***], which such decisions shall require the mutual agreement of the Parties, or (iii) [***] (which the Parties acknowledge will be ultimately dictated by [***]), or (iv) [***].

5.2.4 Expenses. Microgenics and Achaogen shall be responsible for all expenses incurred by its JSC members in connection with performing their duties hereunder, including all costs of travel, lodging and meals.

5.2.5 No Authority to Amend. For the avoidance of doubt, the JSC (and any Party exercising decision-making authority under Section 5.2.3.2) shall not have the authority to amend this Agreement, but the JSC shall have authority to amend the Project Plan and the Specifications as expressly set forth herein (and, for clarity, [***] shall not have decision-making authority with respect to any [***]).

5.3 Joint Project Team; Functional Leaders.

5.3.1 Formation. The Parties shall form a joint project team (the “Joint Project Team” or “JPT”). The JPT shall be comprised of a total of six (6) project team members from Microgenics and Achaogen, with Microgenics and Achaogen each designating a development leader, a regulatory leader, and a commercial leader (respectively, the “Development Leader”, the “Regulatory Leader” and the “Commercial Leader”, and collectively, the “Functional Leaders”) who shall be the principal point of contact for each Party for matters relating to its respective function, and shall be responsible for implementing and coordinating, on a day-to-day basis, all activities and facilitating the exchange of information between the Parties regarding the Project Plan for his or her function. Notwithstanding the foregoing, the Regulatory Leaders and Commercial Leaders may be appointed at such time as the Parties deem appropriate to facilitate the development of the Assay and a successful commercial launch of Plazomicin and the Assay.

5.3.2 Responsibilities. The JPT shall have responsibility for coordinating all development, regulatory, commercial and other business and technical activities under this Agreement. In addition to its general responsibility to deliver the development of the Assay according to the Project Plan and to assure the regular flow of information between the Parties, the JPT shall:

- (a) recommend changes to the Project Plan, Launch Plan and Assay Commercialization Plan to the JSC,
- (b) monitor the activities vs budget to the JSC,
- (c) recommend changes to the Specifications for the Assay to the JSC;
- (d) communicate progress to the JSC;
- (e) plan the regulatory pathway for obtaining Regulatory Approval of the Assay; and
- (f) prepare all applications for Regulatory Approval and related and supporting submissions to Regulatory Authorities.

5.3.3 Members. No later than [***] ([***)] days after the Effective Date, each Party shall provide the other with the names of its JPT members and Functional Leaders (other than the Regulatory Leaders and Commercial Leaders). Microgenics and Achaogen may replace its JPT members and Functional Leaders at any time and for any reason upon written notice to the other Party.

5.3.4 Sub-Teams. The JPT and Functional Leaders may delegate tasks and

responsibilities to sub-managers, working groups and other team members as they deem appropriate to efficiently and effectively perform their respective obligations hereunder.

5.3.5 Meetings. The JPT shall meet as soon as practicable after the Effective Date and thereafter during the performance of the Project Plan, at least [***], and at such additional times as the JPT or the Parties reasonably deem appropriate; provided, that, following the completion of the Project Plan, the JPT shall continue to meet no less frequently than [***]. Meetings of the JPT may be conducted in person, by telephone or videoconference as agreed by the JPT or the Parties. Additionally, the JPT and the Functional Leaders (or their designees) shall maintain close regular communications with each other as to the status of the ongoing and planned activities under the Project Plan, Launch Plan and Assay Commercialization Plan. Each JPT member may reasonably invite other guests to the meetings, in order to discuss special technical or commercial topics relevant to the applicable agenda; provided, that any guests are subject to the confidentiality provisions set forth in Article 12.

5.3.6 No Authority to Amend. Neither the JPT nor the Functional Leaders (or their designees) shall have authority to amend this Agreement or the Project Plan, but may make recommendations regarding such amendments to the JSC.

5.3.7 Dispute Resolution. The JPT and the Functional Leaders will cooperate with each other and work in good faith to resolve any disagreements between them or their respective teams. Any such disagreements that are not resolved by the JPT shall be raised to the Alliance Managers for internal escalation if needed.

5.3.8 Records. The JPT shall keep accurate and complete records of their activities and meetings and shall, from time to time as requested by the JSC, provide the JSC with appropriate updates and information to keep the JSC apprised of the progress of the Project Plan, Launch Plan and Assay Commercialization Plan. All records of the JPT that are disclosed to the other Party and which relate to the Project Plan shall be available at all times to the JSC and to each Party on a confidential basis solely for use with respect to such Party's activities conducted pursuant to this Agreement.

5.3.9 Expenses. Microgenics and Achaogen shall be responsible for all expenses incurred by its JPT members in connection with performing their duties hereunder, including all costs of travel, lodging and meals.

5.4 Reporting. The Parties shall keep each other promptly informed on an ongoing basis through the Joint Project Team and the JSC on the progress of the Project Plan, the Launch Plan and the Assay Commercialization Plan, including forecasts of expected performance and completion of activities. Without limiting the foregoing, within [***] ([***)] days following [***] of each calendar year during the Term, Microgenics shall provide to Achaogen a written progress report in English, in a form to be agreed upon by the JSC, which shall include any information required under the Project Plan and as otherwise reasonably determined by the JSC relating to the progress of the goals or performance of the development, commercialization and other activities under the Project Plan, the Launch Plan and the Assay Commercialization Plan.

6 Grant of License

6.1 Exclusive License by Achaogen. During the Term, and without limiting Section 4.2, Achaogen hereby grants to Microgenics a royalty-free, exclusive, worldwide license to use the Achaogen

Know-How, Achaogen Patents, and Achaogen Materials to research, develop, manufacture, use, market and sell the Assay in the Territory. [***].

6.2 License by Microgenics. During the Term, Microgenics hereby grants to Achaogen and its Affiliates a royalty-free, non-exclusive, sub-licenseable, worldwide license, under and with respect to the Immunoassay Technologies, Microgenics Know-How and any Patents or Patent applications Controlled by Microgenics or its Affiliates to the extent reasonably necessary for Achaogen to perform its obligations or exercise its rights under this Agreement or as is otherwise reasonably necessary to make, have made, use, sell, offer for sale, import and otherwise commercialize Plazomicin. For the avoidance of doubt, the foregoing license grant does not provide any license or right for Achaogen to make, have made, use, sell, offer for sale, import or otherwise commercialize the Assay, except in connection with Achaogen's exercise of the Shortfall License or Transfer License.

6.3 [***] Products and Joint Patents. Each Party shall be entitled to grant non-exclusive licenses to any Third Party under its interest in a [***] Products or Joint Patent [***]. [***], and if in certain countries the grant of a license, in order to be effective, requires declarations from the other Party, the other Party shall reasonably cooperate and provide the necessary declarations.

6.4 No Implied License. Achaogen retains all rights in and to the Achaogen Patents and Achaogen Know-How. Microgenics retains all rights in and to the Immunoassay Technologies and Microgenics Know-How. Only the licenses and other rights expressly granted by one Party to the other Party under terms of this Agreement are of any legal force or effect. No other licenses or other rights are granted, conveyed or created (whether by implication, estoppel or otherwise).

7 Consideration to Microgenics

7.1 Development Payments. In consideration of the development efforts of Microgenics under the Research Program, Achaogen shall pay to Microgenics the following one-time payments upon the occurrence of the corresponding events:

- (a) USD \$[***] upon the successful completion of Phase 0: [***] as determined in accordance with the Project Plan, including delivery by Microgenics of all deliverables required by the Project Plan for Phase 0;
- (b) USD \$[***] upon the successful completion of Phase 1: [***] as determined in accordance with the Project Plan, including delivery by Microgenics of all deliverables required by the Project Plan for Phase 1;
- (c) USD \$[***] upon the successful completion of Phase 2: [***] as determined in accordance with the Project Plan, including delivery by Microgenics of all deliverables required by the Project Plan for Phase 2;
- (d) USD \$[***] upon the successful completion of Phase 3: [***] as determined in accordance with the Project Plan, including delivery by Microgenics of all deliverables required by the Project Plan for Phase 3;
- (e) USD \$[***] upon the successful completion of the first milestone of Phase 4: [***] as determined in accordance with the Project Plan, including delivery by Microgenics of

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all deliverables required by the Project Plan for the first milestone of Phase 4;

- (f) USD \$[***] upon the successful completion of the second milestone of Phase 4: [***] as determined in accordance with the Project Plan, including delivery by Microgenics of all deliverables required by the Project Plan for the second milestone of Phase 4;
- (g) USD \$[***] upon the successful completion of the third milestone of Phase 4: [***] as determined in accordance with the Project Plan, including delivery by Microgenics of all deliverables required by the Project Plan for the third milestone of Phase 4;
- (h) [***], USD \$[***] upon the successful completion of the fourth milestone of Phase 4: [***] as determined in accordance with the Project Plan, including delivery by Microgenics of all deliverables required by the Project Plan for the fourth milestone of Phase 4;
- (i) USD \$[***] upon the successful completion of the first milestone of Phase 5: [***] as determined in accordance with the Project Plan, including delivery by Microgenics of all deliverables required by the Project Plan for the first milestone of Phase 5;
- (j) USD \$[***] upon the successful completion of the second milestone of Phase 5: [***] as determined in accordance with the Project Plan, including delivery by Microgenics of all deliverables required by the Project Plan for the second milestone of Phase 5;
- (k) [***]; and
- (l) [***] and assuming [***], USD \$[***] upon [***]; provided, however, this amount [***].

Thereafter, no additional payments shall be due and payable to Microgenics by Achaogen for any Assay [***].

7.2 Invoices; Mechanism of Payment. Upon the completion of each event as described in Section 7.1, Microgenics will invoice Achaogen within [***] ([***]) business days. Microgenics agrees to submit invoices to Achaogen (on a timely basis) for all payments due hereunder. Invoices shall reference Achaogen's contract number and the purchase order number. The invoices due under this Agreement shall be submitted to:

Achaogen Inc.
7000 Shoreline Court, #371
South San Francisco, CA 94080

Reference: Achaogen Contract No. _____, Attn.: _____
Email: _____

All payments due Microgenics under this Agreement shall be made by Achaogen in United States dollars within [***] ([***]) days after receipt of the applicable invoice by ACH transfer to the credit and account of Microgenics at the following account: [***].

7.3 Taxes.

7.3.1 Withholding. Microgenics shall be liable for all income and other taxes (including interest) imposed upon any payments made by Achaogen to Microgenics under this Agreement. In the event that any Applicable Law requires Achaogen to withhold taxes with respect to any payment to be made by Achaogen pursuant to this Agreement, Achaogen will notify Microgenics of such withholding requirement prior to making the payment to Microgenics and provide such assistance to Microgenics, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in Microgenics' efforts to claim an exemption from or reduction of such taxes. Achaogen will, in accordance with such Law withhold taxes from the amount due, remit such taxes to the appropriate tax authority, and furnish Microgenics with proof of payment of such taxes within [***] ([***)] days following the payment. If taxes are paid to a tax authority, Achaogen shall provide reasonable assistance to Microgenics to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid.

7.3.2 VAT. All payments due to Microgenics from Achaogen pursuant to this Agreement shall be paid exclusive of any value-added tax ("VAT") (which, if applicable, shall be [***]). If Microgenics is required to report any such tax, Achaogen shall promptly provide Microgenics with applicable receipts and other documentation necessary or appropriate for such report.

8 Intellectual Property Rights; Ownership

8.1 Ownership of Discoveries and Inventions. Achaogen shall own all discoveries and inventions made by one or both of the Parties as part of the Research Program, whether or not patentable, relating (i) solely to Plazomicin, the Achaogen Patents, the Achaogen Know-How, and Achaogen Materials or (ii) [***] (each of (i) and (ii), "Achaogen Inventions"). Microgenics shall own all inventions and discoveries made by one or both of the Parties as part of the Research Program, whether or not patentable, relating solely to Microgenics Cell Lines, Microgenics [***] Antibodies, the Assay, Immunoassay Technologies and Microgenics Know-How ("Microgenics Inventions"). For all other inventions and discoveries, whether or not patentable, made by the Parties as part of the Research Program, whether individually or jointly, inventorship shall be determined pursuant to the inventorship principles arising under the patent laws of the United States of America, [***] ("[***] Products"). Each Party shall ensure that each of its employees and other representatives performing activities hereunder has agreed to assign to it all discoveries and inventions made by such employee or other representative in the course of his or her employment.

8.2 Patent Procurement.

8.2.1 Achaogen and Microgenics shall each disclose to the other any inventions and discoveries made during the course of the Research Program. Achaogen shall be responsible for the prosecution and maintenance of any Patent applications and Patents claiming or covering any Achaogen Inventions, and Microgenics shall be responsible for the prosecution and maintenance of any Patent applications and Patents claiming or covering any Microgenics Inventions; provided, that [***] shall not, without first obtaining [***] prior written consent, file any Patent claiming or covering the [***]; provided, further, that, in the event that any such Patent applications covering or claiming any [***] are filed without first obtaining [***] prior written consent, then [***] hereby grants [***] a perpetual, irrevocable, fully paid-up, royalty-free, worldwide, sublicenseable, non-exclusive license under such Patent applications and any Patents issuing therefrom or related thereto for the purpose of developing, manufacturing, using or commercializing [***].

8.2.2 With respect to any Patent applications and Patents claiming or covering any [***] Products, the Parties shall meet to determine in what countries, if any, Patent applications claiming such [***] Products should be filed and the appropriate filing Party (a “Joint Patent”). The Parties shall [***] by the Party filing such patent applications in connection with any Joint Patents. If a Party elects [***] related to any Joint Patent, the other Party shall provide written notice upon the decision to [***] and the Party not giving such notice shall have the right to assume responsibility for any such prosecution or maintenance, [***].

8.3 Prosecution, Review, Cooperation.

8.3.1 The Party responsible for prosecuting and maintaining a given Patent pursuant to Section 8.2.1 or 8.2.2 (i.e., Microgenics with respect to Patents claiming or covering any Microgenics Inventions and the Assay Patent and the Party agreed to by the Parties with respect to Joint Patents) (the “Responsible Party”) shall keep the other Party (the “Review Party”) reasonably informed regarding the status of the filing, prosecution and maintenance of each applicable Patents, and shall provide the Review Party with copies of all documentation concerning each applicable Patent, including all correspondence to and from any Governmental Authority relating thereto. Prior to filing an applicable Patent application for, or material prosecution documents or other submissions relating to, an applicable Patent, the Responsible Party shall provide the Review Party with a reasonable opportunity to review and comment on the proposed application, document or submission, and the Responsible Party shall reasonably consider all such comments and incorporate such comments. In the event that the Responsible Party elects to abandon any applicable Patent, the Responsible Party shall notify the Review Party in writing (such notice, an “Abandonment Notice”) at least [***] ([***)] days prior to any filing or payment due date or any other due date that requires action to prevent loss of rights, and in the event that the Review Party provides the Responsible Party with written notice within [***] ([***)] days of receipt of the applicable Abandonment Notice, the Review Party shall thereafter have the right, [***], to conduct such filing, prosecution and maintenance for the applicable Patent.

8.3.2 Each of the Parties shall execute or have executed by its employees, representatives and agents such documents as may be reasonably necessary to obtain, perfect, or maintain any Patent rights which would be filed pursuant to this Agreement and to cooperate with the other Party, [***], as reasonably necessary with respect to the prosecution of such Patent rights.

8.4 Ownership. The Achaogen Patents, Achaogen Know-How and the Achaogen Materials shall at all times remain the sole property of Achaogen. Microgenics shall not use the Achaogen Know-How or the Achaogen Materials to develop or market, or have developed or marketed, any Assay for any Third Party. The Microgenics Cell Lines, Microgenics [***] Antibodies, Immunoassay Technologies and Microgenics Know-How shall remain the sole property of Microgenics. Except as may otherwise be expressly permitted pursuant to the terms and conditions of this Agreement, Achaogen shall not use the Microgenics Cell Lines, Microgenics Monoclonal Antibodies, Immunoassay Technologies and Microgenics Know-How to develop, manufacture, or market, or have developed, manufactured, or marketed, the Assay or any additional assay(s) for Plazomicin or any other compound/substance.

8.5 Enforcement. Each Party shall immediately notify the other if it becomes aware of any infringement, anywhere in the world, of any issued Patent within the Joint Patents. The Parties shall mutually determine whether to take action to obtain a discontinuance of infringement or bring suit against a Third Party infringer of any Joint Patents within [***] ([***)] days from the date of notice; provided that neither

Party shall be obligated to join any such action. In the event that either Party does not want to join as a Party plaintiff, then the Party not seeking to enforce such infringement claims shall have the right to assign the relevant Joint Patents to the other Party; provided that such assignment is solely and sufficient for purposes of commencing and maintaining the action. The Party seeking to enforce such infringement claims [***] of any suit brought by it claiming infringement of any Joint Patent. The Parties will reasonably cooperate, at the expense of the Party seeking to enforce such infringement claim, in any such suit and shall have the right to consult with the other Party and to participate in and be represented by independent counsel in such litigation [***]. Any recoveries obtained by Achaogen or Microgenics, as applicable, as a result of any proceeding against such a Third Party infringer shall be allocated as follows: (a) such recovery shall first be used to reimburse each Party for all reasonable attorney fees and other litigation costs actually incurred in connection with such litigation by that Party, and (b) any remainder shall be shared [***] by the Parties.

8.6 Patent Infringement. Each Party shall immediately notify the other if a claim or other proceeding is brought against either Party alleging infringement of Third Party Patent rights based upon the manufacture, use or sale of the Assay. The Parties shall immediately consult on how to proceed with respect to defending against any such claim of infringement.

8.7 Third Party Licenses. Microgenics shall be solely responsible, at its own expense, for obtaining rights under any Third Party intellectual property necessary for Microgenics to perform its obligations under this Agreement and Achaogen shall be under no obligation to provide support therefor, financial or otherwise.

8.8 Trademarks. As between the Parties, Microgenics shall own all right, title and interest in and to any Trademarks developed by or for Microgenics for use in connection with the Assay. Microgenics hereby grants to Achaogen a royalty-free non-exclusive right to use such Trademarks in connection with advertising, promoting and marketing Plazomicin, subject to Section 12.5 (Non-Use of Names). All use of Microgenics' Trademarks by Achaogen shall inure to the sole benefit of Microgenics. As between the Parties, Achaogen shall own all right, title and interest in and to all Trademarks developed by or for Achaogen for use in connection with Plazomicin.

9 Term and Termination

9.1 Term. This Agreement shall be effective as of the Effective Date and unless terminated earlier by mutual written agreement of the Parties or pursuant to Section 9.2 (Termination At Will) or Section 9.3 (Termination for Cause) below, the term of this Agreement shall continue in effect until Achaogen ceases development and commercialization of Plazomicin ("Term").

9.2 Termination At Will. Achaogen may terminate this Agreement in its entirety, for any reason, by providing at least sixty (60) days prior written notice to Microgenics.

9.3 Termination for Cause. This Agreement may be terminated in its entirety by written notice by either Party at any time:

9.3.1 For material breach by the other Party, which breach remains uncured for ninety (90) days from the date written notice of such breach is given to the breaching Party, or, if such breach is not susceptible of cure within such ninety (90) day period and the breaching Party uses diligent good faith efforts to cure such breach, for one hundred eighty (180) days after written notice to the breaching Party if such breach remains uncured; or

9.3.2 Upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party, or in the event a receiver or custodian is appointed for such Party's business, or if a substantial portion of such Party's business is subject to attachment or similar process; provided, however, that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the proceeding is not dismissed within sixty (60) days after the filing thereof.

9.4 Effect of Termination. Upon termination of this Agreement pursuant to Sections 9.1 (Term), Section 9.2 (Termination At Will) or 9.3 (Termination for Cause):

9.4.1 All rights and licenses granted under Section 6.1 (License by Achaogen) of this Agreement shall terminate and all rights to the Achaogen Patents and Achaogen Know-How shall revert to Achaogen.

9.4.2 All rights and licenses granted under Section 6.2 (License by Microgenics) of this Agreement shall terminate and, subject to Section 9.4.4, all rights to the Immunoassay Technologies and Microgenics Know-How shall revert to Microgenics.

9.4.3 Microgenics shall promptly return or destroy (as directed by Achaogen) to Achaogen all Achaogen Know-How and Achaogen Materials provided to Microgenics hereunder, and, subject to Section 9.4.4, Achaogen shall promptly return to Microgenics all Microgenics Know-How provided to Achaogen hereunder;

9.4.4 Solely in the case of termination of this Agreement by Achaogen under Section 9.3 (Termination for Cause):

9.4.4.1 Microgenics hereby grants Achaogen a Transfer License; provided, that, Achaogen covenants not to use the Transfer License beyond the scope set forth in Section 1.33. In the event that Microgenics reasonably believes that Achaogen has breached the foregoing covenant, Microgenics shall provide written notice thereof, including reasonable supporting evidence, and, in the event that Achaogen agrees with such written notice and does not indicate to Microgenics that it will conform its activities to the scope of the Transfer License within [***] ([***)] business days after receiving the written notice, then the Transfer License shall be void as of the end of [***] period described in this sentence. If Achaogen indicates that it will so conform its activities, then the Transfer License shall remain in full force and effect. In the event that Achaogen disagrees with such written notice and advises Microgenics of such disagreement, the Parties shall submit this matter to the Dispute resolution process in 13.8. For purposes of resolving any disputes regarding the Transfer License, the Parties agree to complete the Dispute resolution process in 13.8 within [***] from the date of Microgenics' first written notice of the breach of the covenant found in the proviso to the first sentence of this Section 9.4.4.1(i). If after concluding the Dispute resolution process in 13.8 it is determined that the covenant found in the proviso was breached, then the Transfer License shall terminate immediately. In the event that the Transfer License is granted, Achaogen shall owe no payments to Microgenics for the first [***] ([***)] months that any Assay commercialized under the Transfer License is commercialized and shall pay a [***] percent ([***)] percent royalty on its net sales (i.e., gross sales less all deductions, reductions and offsets reasonably taken in accordance with generally accepted accounting principles in the United States) of Assays commercialized under the Transfer License following the end of such [***] ([***)] month

period.

9.4.4.2 Microgenics shall (a) make its personnel available for a reasonable period of time (not to exceed [***] ([***]) months) to effect a successful technology transfer with respect to the manufacture and commercialization of the Assay, (b) provide Achaogen with copies of the physical embodiment of all processes, protocols, procedures, methods, tests and other intellectual property rights licensed to Achaogen under the Transfer License, as applicable, related to the Assay (including the manufacture thereof), (c) supply [***] (including [***]) reasonably required to perform [***] as may be required by the applicable Regulatory Authorities, and upon request by Achaogen, [***], provide Achaogen (and/or its designee) with [***] related to the Assay, and (d) promptly assist Achaogen (and/or its designee) in obtaining all necessary Regulatory Approvals and/or modifying and/or transferring existing Regulatory Approvals to enable Achaogen (and/or its designee) to develop, make, have made, use, market, distribute, import, sell and offer for sale the Assay ([***]).

9.4.4.3 If, at the date of the actual termination of this Agreement, Microgenics is commercializing the Assay, such termination shall be suspended, and Microgenics shall continue to supply the Assay to the market, until [***]; provided that (i) such period shall not extend beyond an additional [***] ([***]) months from the date of the actual termination of this Agreement, (ii) Achaogen, itself or through or in conjunction with a Third Party, may commercialize another assay for use in conjunction with Plazomicin (i.e., Microgenics shall lose its commercial exclusivity), and (iii) Section 4.2.3 shall be of no force or effect during any such suspended termination.

9.4.5 If this Agreement is terminated during the Term at any time by Achaogen under Section 9.2 (Termination At Will) or by Microgenics under Section 9.3 (Termination for Cause), the following terms shall apply:

9.4.5.1 Solely to the extent the expiration or termination of this Agreement occurs prior to the payment of all development payments described in Section 7.1, Achaogen shall pay to Microgenics an amount equal to the first applicable unpaid development payment as described in Section 7.1 (Development Payments) for the period in which the Agreement is terminated or expires (for illustrative purposes only, if Achaogen provides notice of termination under Section 9.1 (Term) prior to the completion of the Phase 3: [***], then Achaogen shall pay an amount equal to USD \$[***] to Microgenics pursuant to the terms of Section 7.2 (Invoices; Mechanism of Payment)); provided, that, notwithstanding the foregoing, no payment shall be due under this Section 9.4.5.1 in the event that this Agreement is terminated by Achaogen under Section 9.2 (Termination At Will) at any time in connection with the failure to obtain, or maintain, Regulatory Approval for Plazomicin; and

9.4.5.2 for a period of two (2) years after the expiration or termination date of this Agreement pursuant to Section 9.4.5, in the event Achaogen decides to continue to develop and commercialize Plazomicin, Achaogen shall provide written notice thereof to Microgenics and, upon Achaogen's receipt of a written proposal from Microgenics, the Parties shall use good faith efforts to negotiate a definitive agreement for the continued development, manufacture, supply and sale of the Assay by Microgenics on commercially reasonable terms; provided, however, that nothing in this Section 9.4.5.2 shall (a) obligate Achaogen to enter into any new agreement with Microgenics with respect to the development, manufacture, supply or sale of the Assay or (b) prohibit Achaogen from negotiating or entering into an agreement with any Third Party with respect to the development, manufacture, supply or sale of any assay.

9.4.6 The termination, expiration or non-renewal of this Agreement shall not relieve either Party from any obligation that accrues pursuant to this Agreement before the effective date of the termination or expiration nor shall it release the Parties from any obligation that may have been incurred as a result of operations conducted under this Agreement.

9.5 Survival. Termination of this Agreement for whatever reason in accordance with the provisions hereof or expiration of this Agreement shall not affect the accrued rights of the Parties, and shall not limit remedies that may be otherwise available in law or equity. Article 1 (Definitions), Section 4.1 (Manufacture), 8 (Intellectual Property Rights; Ownership) (except for Section 8.8 (Trademarks) (unless Achaogen intends to commercialize the Assay upon termination)), 11 (Indemnification), 12 (Confidentiality), and 13 (Miscellaneous) and Section 3.6 (Right of Reference) (but only in the event that Achaogen intends to commercialize the Assay upon termination), 9.4 (Effect of Termination) and 9.5 (Survival) shall survive expiration or termination of this Agreement for any reason. All other rights and obligations will terminate upon expiration of this Agreement.

10 Representations and Warranties

10.1 Representations and Warranties of Each Party. Each of Achaogen and Microgenics hereby represents, warrants and covenants to the other Party hereto as follows:

10.1.1 it is a corporation or other entity duly organized and validly existing under the laws of the state or other jurisdiction of incorporation or formation;

10.1.2 the execution, delivery, and performance of this Agreement by such Party has been duly authorized by all requisite corporate action and does not require any shareholder action or approval;

10.1.3 no consent, approval, order or authorization of, or registration, declaration or filing with, or exemption by, any Third Party or any governmental entity is required by or with respect to such Party in connection with the execution, delivery and performance of this Agreement;

10.1.4 this Agreement constitutes a valid and legally binding obligation of such Party, enforceable against such Party in accordance with its respective terms, except as may be limited by (a) applicable bankruptcy, insolvency, reorganization or other laws of general application relating to or affecting the enforcement of creditors' rights generally and (b) the effect of rules of law governing the availability of equitable remedies;

10.1.5 the execution, delivery and performance of this Agreement do not and will not conflict with, or result in any violation of, or default (with or without notice or lapse of time, or both) under, or give rise to a right of termination, cancellation or acceleration of any obligation that would result in the creation of any encumbrance upon any of the assets owned by such Party under, any material provision of Applicable Law, of such Party's organizational documents or of any agreement, judgment, injunction, order, decree, or other instrument binding on such Party or any assets owned by such Party; and

10.1.6 it shall comply with all material Applicable Laws relating to its activities under this Agreement.

10.2 Representations and Warranties of Microgenics. In addition to the representations and

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warranties made by Microgenics under Section 10.1 (Representations and Warranties of Each Party) above, Microgenics further represents and warrants to Achaogen that:

10.2.1 it has the capacity and resources (including [***]) to (i) develop, manufacture and supply the Assay in and for the Territory, and (ii) commercialize the Assay in the Primary Countries;

10.2.2 and further covenants that, the Assay shall be developed, manufactured, commercialized, and shall function, in accordance with applicable GMP, Specifications and Applicable Laws;

10.2.3 it has the capacity and resources to develop (including [***]), manufacture and commercialize the Assay in accordance with this Agreement, including in accordance with the Project Plan;

10.2.4 to the best of its knowledge, the development, manufacture, use and sale of the Assay will not infringe any issued Patents in the Territory owned or controlled by any Third Party; and

10.2.5 it owns or controls all rights to the Microgenics Cell Lines, Microgenics [***] Antibodies, and Immunoassay Technologies.

10.3 Representations and Warranties by Achaogen. In addition to the representations and warranties made by Achaogen under Section 10.1 (Representations and Warranties of Each Party) above, Achaogen further represents and warrants to Microgenics that:

10.3.1 it owns, controls or has the right and ability to grant Microgenics the licenses under its (and its Affiliates) rights in the Achaogen Patents (as listed in **Exhibit B** hereto) related to the use of Plazomicin, pursuant to this Agreement; and

10.3.2 it owns, controls or has the right and ability to provide to Microgenics the Achaogen Materials for development, manufacture, marketing, and sale of the Assay pursuant to this Agreement.

10.4 Debarment and Exclusion. Achaogen and Microgenics represent and warrant that neither it, nor any of its employees or agents working on the subject matter of this Agreement, has ever been, is currently, or is the subject of a proceeding that could lead to it becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, nor are they listed on the FDA's Disqualified/Restricted List for clinical investigators. Each Party further covenant, represent and warrant that if, during the Term, it, or any of its employees or agents working on their behalf, becomes or is the subject of a proceeding that could lead to that Party with respect to the subject matter hereof, becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, or added to FDA's Disqualified/Restricted List for clinical investigators, the Party shall immediately notify the other Party. This provision shall survive termination or expiration of this Agreement. For purposes of this provision, the following definitions shall apply:

10.4.1 A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application.

10.4.2 A "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of

any abbreviated drug application, or a subsidiary or Affiliate of a Debarred Entity.

10.4.3 An “Excluded Individual” or “Excluded Entity” is (a) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (b) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

10.4.4 A “Convicted Individual” or “Convicted Entity” is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

10.4.5 “FDA’s Disqualified/Restricted List” is the list of clinical investigators restricted from receiving investigational drugs, biologics or devices if the United State Food and Drug Administration (“FDA”) has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false information to the study sponsor.

10.5 Disclaimer. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS AGREEMENT, NEITHER MICROGENICS NOR ACHAAGEN MAKES, AND EACH HEREBY EXPRESSLY DISCLAIMS, ANY REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, WHETHER IN FACT OR IN LAW, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT.

10.6 No Representations Regarding Approval or Commercial Success. Neither Party makes any representations or warranties as to: (a) whether Plazomicin or the Assay will be approved for commercial sale by the applicable Regulatory Authorities; or (b) the commercial potential or success of Plazomicin or the Assay.

11 Indemnification

11.1 Indemnification by Achaogen. Achaogen shall indemnify, defend and hold harmless Microgenics and its Affiliates and each of its and their respective employees, officers, directors and agents (each a “Microgenics Indemnified Party”) from and against any and all liabilities, damages, penalties, expenses and/or losses (including reasonable legal expenses and attorneys’ fees) (collectively, “Losses”), resulting from any Third Party suits, claims, actions or demands (collectively, “Third Party Claims”), to the extent arising out of or relating to: (a) the breach by Achaogen of any representation, warranty or covenant contained in this Agreement; (b) the willful misconduct or negligent acts or omissions of Achaogen, its Affiliates or any of their respective employees, officers, directors or agents; (c) the manufacture, promotion, distribution, use, testing, marketing or sale of pharmaceutical products containing Plazomicin by Achaogen or its Affiliates; or (d) claims of infringement of Third Party Patents based upon the manufacture, use or sale of Plazomicin; except, in each case, to the extent such Losses result from clauses (a), (b), (c) or (d) of Section 11.2 (Indemnification by Microgenics).

11.2 Indemnification by Microgenics. Microgenics shall indemnify, defend and hold harmless Achaogen and its Affiliates and each of its and their respective employees, officers, directors and agents (each a “Achaogen Indemnified Party”) from and against any and all Losses, resulting from any Third Party

Claims, to the extent arising out of or relating to: (a) the breach by Microgenics of any representation, warranty or covenant contained in this Agreement; (b) the willful misconduct or negligent acts of Microgenics, its Affiliates or any of their respective employees, officers, directors, or agents; (c) the manufacture, promotion, distribution, use, testing, marketing or sale of the Assay; or (d) claims of infringement of Third Party Patents based upon the manufacture, use or sale of the Assay; except, in each case, to the extent such Losses result from clauses (a), (b) (c) or (d) of Section 11.1 (Indemnification by Achaogen).

11.3 Conditions to Indemnification The obligations of the indemnified Party under Sections 11.1 (Indemnification by Achaogen) and 11.2 (Indemnification by Microgenics) are conditioned upon the delivery of written notice to the indemnifying Party of any potential liability promptly after the indemnified Party become aware of such potential liability; provided, however, that the failure to give such notice promptly shall not impair a Party's right to indemnification under this Section 11.3 (Conditions to Indemnification) unless the delay in providing such notice has a material adverse effect on the ability of the indemnifying Party to defend against such liability. The indemnifying Party shall have the right to assume the defense of any suit or claim relating to the liability if it has assumed responsibility for the suit or claim in writing; however, if in the reasonable judgment of the indemnified Party, such suit or claim involves an issue or matter which could have a material adverse effect on the business operation or assets of the indemnified Party, the indemnified Party may waive its rights to indemnity under this Agreement and control the defense or settlement thereof, but in no event shall any such waiver be construed as a waiver of any rights such indemnified Party may have against any Third Party at law or in equity. If the indemnifying Party defends the suit or claim, the indemnified Party shall cooperate with the indemnifying Party in such defense and the indemnified Party or Parties may participate in (but not control) the defense thereof at its sole cost and expense.

11.4 Settlements. Neither of the Parties may settle a claim or action related to a Third Party Claim without the consent of the other Party, if such settlement would impose any monetary obligation on the other Party, or would require the other Party to submit to an injunction or otherwise limit the other Party's rights under this Agreement. Any payments made by a Party to settle any such claim or action shall be at its own costs and expense, except in the event such payment was made with the prior written consent of an indemnifying Party, in which case such payment shall be subject to the obligations of the Parties as set forth in Sections 11.1 (Indemnification by Achaogen), 11.2 (Indemnification by Microgenics), and 11.3 (Conditions to Indemnification).

11.5 Limitation of Liability. EXCEPT WITH RESPECT TO DAMAGES THAT ARISE DUE TO A PARTY'S BREACH OF CONFIDENTIALITY (ARTICLE 12) OR INDEMNIFICATION OBLIGATIONS (ARTICLE 11), IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR CONSEQUENTIAL, INDIRECT, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES FOR ANY CAUSE OF ACTION, WHETHER IN CONTRACT, TORT OR OTHERWISE, INCLUDING LOST REVENUES, PROFITS OR BUSINESS OPPORTUNITIES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, WHETHER OR NOT THE OTHER PARTY WAS OR SHOULD HAVE BEEN AWARE OF THE POSSIBILITY OF THESE DAMAGES. EXCEPT WITH RESPECT TO DAMAGES THAT ARISE DUE TO A PARTY'S BREACH OF CONFIDENTIALITY (ARTICLE 12) OR INDEMNIFICATION OBLIGATIONS (ARTICLE 11), THE LIABILITY OF EITHER PARTY UNDER THIS AGREEMENT (WHETHER BY REASON OF BREACH OF CONTRACT, TORT, OR OTHERWISE) WITH RESPECT TO A GIVEN CLAIM SHALL NOT EXCEED AN AMOUNT EQUAL TO [***].

11.6 Insurance. Each Party shall maintain, through self-insurance or commercially-placed insurance, adequate commercial general liability and products liability insurance, including contractual liability coverage, necessary to satisfy its obligations hereunder and consistent with pharmaceutical and

diagnostic industry practices.

12 **Confidentiality**

12.1 **Nondisclosure.** During the Term, and for a period of [***] ([***)] years thereafter, all Confidential Information disclosed to a Party hereto or its Affiliates (the “Receiving Party”) by the other Party or its Affiliates (the “Disclosing Party”) shall be deemed confidential and shall be treated as such by the Receiving Party (meaning that the Receiving Party shall take the same steps to protect such information as it does to protect its own confidential information, which in any event shall be no less than the reasonable protective measures for the industry) and shall only be used for the purposes of this Agreement. Notwithstanding the foregoing, Confidential Information shall not include information that is:

- (a) known by the Receiving Party at the time of its receipt and not through a prior disclosure by the Disclosing Party;
- (b) at the time of disclosure or thereafter, becomes published or otherwise part of the public domain through no breach of this Agreement by the Receiving Party;
- (c) subsequently disclosed to the Receiving Party by a Third Party having the right to make such a disclosure; or
- (d) developed by the Receiving Party, as evidenced by its records, independently of information received by it from the Disclosing Party hereunder.

12.2 **Permitted Disclosure.** Information provided under this Agreement may be disclosed to employees, agents or consultants of the Receiving Party, but only to the extent required to accomplish the purposes of this Agreement and only after the Receiving Party obtains the prior agreement of its employees, agents and consultants to whom disclosure is to be made to hold in confidence and not to make use of such information for any purpose other than that permitted by this Agreement. In addition to the foregoing exceptions, either Party may disclose Confidential Information to the extent it is required to be disclosed under Applicable Law, or in connection with any application by the Receiving Party for any Regulatory Approvals; provided, however, that the Receiving Party shall furnish the Disclosing Party with as much prior written notice of such disclosure requirement as reasonably practicable, so as to permit the Disclosing Party, in its sole discretion, and at its sole expense, to take appropriate action, including seeking a protective order, in order to prevent the Disclosing Party’s Confidential Information from passing into the public domain or becoming generally available to the public.

12.3 **Publicity.** The Parties agree to make a joint public release of the having entered into this Agreement upon the successful completion of Phase I as described in **Exhibit F**. The public release must however not contain any Confidential Information of any kind such as scientific, commercial or financial which both Parties have not agreed to include in writing. No public announcement concerning the existence, terms or subject matter of this Agreement shall be made, either directly or indirectly, by any Party, without first obtaining the prior written approval of the other Party and agreement upon the nature and text of such public announcement which such agreement and approval shall not be unreasonably withheld. Notwithstanding the foregoing, if, in the opinion of legal counsel for the Party desiring to make such public announcement, such disclosure is required under Applicable Law, subject to Section 12.2 (Permitted Disclosure) above, the Party required to make such public announcement shall inform the other Parties of the proposed announcement or disclosure in reasonably sufficient time prior to public release, which shall be not

less than [***] ([***) business days (or such shorter period as may be required under Applicable Law) prior to release of such proposed public announcement, and shall provide the other Parties with a written copy thereof in order to allow such other Parties to comment upon such public announcement. The Receiving Party shall reasonably cooperate with the Disclosing Party (at the Disclosing Party's expense) with respect to all disclosures regarding this Agreement required under Applicable Law, including requests for confidential treatment of proprietary information of the Disclosing Party included in any such disclosure.

12.4 Applicable Law. Nothing in this Agreement shall be construed as preventing or in any way inhibiting any Party from complying with Applicable Law governing activities and obligations undertaken pursuant to this Agreement, in any manner which it reasonably deems appropriate, including, for example, by disclosing to Regulatory Authorities confidential or other information received from the other Parties, subject to Sections 12.2 (Permitted Disclosure) and 12.3 (Publicity).

12.5 Non-Use of Names. Except as otherwise provided in this Agreement, neither Party (or its Affiliates) shall use, either directly or indirectly, the Trademarks of the other Party (or their Affiliates), or the names of any of their officers, employees or board members in any publicity, marketing advertising or other documents (or other disclosures) unless (a) such use is consistent with, and permitted under, the Project Plan or (b) a copy or transcript of the proposed disclosure is submitted to and approved in advance in writing by the other Party (each in its sole discretion), except in the case in which a governmental authority requires the use of the Trademark by a Party in the sale or distribution of the Assay or Plazomicin. Each Party will use good faith efforts to review and approve any proposed disclosure within [***] ([***) business days of its receipt from the other Party of a copy or transcript of the proposed disclosure. If a Party approves the other Party's usage of its Trademarks (or its Affiliates), or the names of any of their officers, employees or board members in accordance with this Section 12.5 (Non-Use of Names), the other Party shall comply with any usage guidelines or requirements imposed by the approving Party.

12.6 Publications. Publication in a journal, paper, magazine or any other such similar disclosure relating to the development, manufacture or commercialization of the Assay will not take place without the prior written agreement of both Achaogen and Microgenics, which shall not be unreasonably withheld. Any draft article intended to be submitted for publication by Microgenics or Achaogen (or a clinical trial site utilized by Achaogen) hereto shall first be sent to the other Party in order to allow such Party to preserve its intellectual property rights by delaying such publication (but not for more than [***] ([***) days) and/or removing its Confidential Information. Achaogen's and/or Microgenics' contribution shall be acknowledged in any publication by co-authorship or acknowledgment, whichever is appropriate. Republication of any article, in whole or in part, which has previously been approved by the Parties shall not require subsequent approval, provided that the content is substantially unchanged. These restrictions are not applicable to Plazomicin; provided, however, that, for clarity, Microgenics shall have no right to publish with respect to Plazomicin.

12.7 Prior CDAs. This Agreement supersedes that certain Confidential Disclosure Agreement between the Parties dated [***]; provided, however, that all Confidential Information disclosed or received by the Parties thereunder will be deemed Confidential Information hereunder and will be subject to the terms and conditions of this Agreement. For clarity, this Agreement does not supersede the Antibody Development Agreement.

13 Miscellaneous

13.1 Force Majeure. Neither Party shall be liable to the other for delay or failure in the

performance of the obligations on its part contained in this Agreement if and to the extent that such failure or delay is due to government action, war, terrorism, fire, explosion, flood, strike, lockout, embargo, shortage of materials or utilities, vendor failure to supply, act of God, or any other cause beyond the control and without the fault or negligence of the defaulting Party (a “Force Majeure Event”), provided that the Party claiming Force Majeure Event has exerted all Commercially Reasonable Efforts to avoid or remedy such force majeure. Such excuse shall continue as long as the condition preventing the performance continues. Upon cessation of such Force Majeure Event, the affected Party shall promptly resume performance hereunder. Each Party agrees to give the other Party prompt written notice of the occurrence of any such Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable to perform its obligations hereunder. Each Party further agrees to use all Commercially Reasonable Efforts to correct the Force Majeure Event [***] and to give the other Party prompt written notice when it is again fully able to perform its obligations hereunder.

13.2 Assignment. Neither Party may assign this Agreement to a Third Party unless both Parties have agreed to such assignment in a writing signed by an authorized representative of each Party hereto; provided, however, that upon providing written notice, (i) either Party may, without the other Party’s consent, assign this Agreement to an Affiliate or to any Third Party entity that acquires all or substantially all of its assets to which this Agreement relates and (ii) Achaogen may, without Microgenics’ consent, assign this Agreement (in whole or in part) to a Third Party licensee of Achaogen’s rights with respect to Plazomicin. This Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Section 13.2 (Assignment) shall be void.

13.3 No Waiver. The failure of either Party to require performance by the other Party of any of that other Party’s obligations hereunder shall in no manner affect the right of such Party to enforce the same at a later time. No waiver by any Party hereto of any condition, or the breach of any provision, term, representation or warranty contained in this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such condition or breach, or of any other condition or of the breach of any other provision, term, representation or warranty hereof.

13.4 Severability. If a court or other tribunal of competent jurisdiction should hold any term or provision of this Agreement to be excessive, or invalid, void or unenforceable, the offending term or provision shall be deleted, and, if possible, replaced by a term or provision which, so far as practicable, achieves the legitimate aims of the Parties. In the event that such provisions cannot be agreed upon, the invalidity, illegality or unenforceability of one or more provision of this Agreement shall not affect the validity of this Agreement as a whole.

13.5 Relationship Between the Parties. Both Parties are independent contractors under this Agreement. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

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13.6 Correspondence and Notices. Correspondence, reports, documentation and any other communication in writing between the Parties in the course of implementation of this Agreement shall be in writing and sent by internationally recognized overnight delivery service that maintains records of delivery, or by facsimile confirmed by prepaid registered or certified air mail letter, and shall be deemed to have been properly served to the addressee upon the date delivered by hand or transmitted by facsimile (with transmission confirmed) or on the second business day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. The proper address for communication and for all payments shall be:

To Microgenics: With a copy to:

Microgenics Corporation	Thermo Fisher Scientific
Attn: VP & General Manager	Attn: SDG General Counsel
46500 Kato Road	81 Wyman Street
Fremont, CA 94538	Waltham, MA 02451
Fax: (781) 622-1283	

To Achaogen: With a copy to:

Achaogen Inc.
7000 Shoreline Court, #371
South San Francisco, CA 94080
Fax:

13.7 Choice of Law. This Agreement is subject to and governed by the laws of the State of Delaware, U.S.A. (without regard to conflict of law principles).

13.8 Dispute Resolution.

13.8.1 Executive Resolution. In the event of a dispute with respect to (a) the validity, interpretation or construction of this Agreement, (b) compliance with this Agreement or (c) a breach of this Agreement (a “Dispute”), a Party may provide the other Party with written notice of the Dispute, and the Parties agree to exercise reasonable efforts to resolve the Dispute in good faith by promptly engaging in discussions with duly authorized representatives of the Parties. If the Dispute cannot be resolved by such authorized representatives of the Parties within [***] ([***)] business days, the authorized representatives shall refer the Dispute to a meeting between a senior executive representing each Party (currently the [***] for Achaogen, and the [***] for Microgenics), which such senior executives shall participate in at least one in person meeting as soon as practicable, but in no event later than [***] ([***)] days after the date of the relevant referral. If the senior executives for Achaogen and Microgenics cannot resolve such Dispute in a mutually acceptable manner within [***] ([***)] business days after such meeting, then the Dispute shall be resolved exclusively by final and binding arbitration in accordance with Section 13.8.2.

13.8.2 Arbitration. Arbitration will be conducted exclusively in the State of Delaware by arbitration administered by the American Arbitration Association (“AAA”) under its Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes, and judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. [***]. Notwithstanding anything in this Agreement to the contrary, each Party shall have the right, at its election, to seek injunctive or other equitable relief in any court of competent jurisdiction to enforce or obtain compliance with any provision of

this Agreement without first submitting such matter to arbitration. All rights and remedies hereunder shall be cumulative, may be exercised singularly or concurrently and, unless otherwise stated herein, shall not be deemed exclusive.

13.9 Entire Agreement; Amendment. Except as otherwise set forth in Section 12.7, this Agreement and the Antibody Development Agreement, including the Exhibits and Schedules hereto and thereto and all the covenants, promises, agreements, warranties, representations, conditions and understandings contained herein and therein sets forth the complete, final and exclusive agreement between the Parties and supersedes and terminates all prior and contemporaneous agreements and understandings between the Parties, whether oral or in writing. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement and the Antibody Development Agreement. No subsequent alteration, amendment, change, waiver or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. No understanding, agreement, representation or promise, not explicitly set forth herein, or in the Antibody Development Agreement, has been relied on by either Party in deciding to execute this Agreement. Notwithstanding anything to the contrary contained herein or in the Antibody Development Agreement, nothing in the Antibody Development Agreement shall be deemed to modify or diminish the representations, warranties, covenants and obligations of the Parties under this Agreement and in the event of any conflict between the terms and conditions of this Agreement and the terms and conditions of the Antibody Development Agreement, this Agreement shall govern except with respect to Section 4.2.7.3 of this Agreement which shall be subject to the Antibody Development Agreement.

13.10 Headings. The headings and captions used in this Agreement are solely for the convenience of reference and shall not affect its interpretation.

13.11 Counterpart. This Agreement may be executed in one or more counterparts, each of which shall be an original, and all of which shall constitute together the same document. Each Party acknowledges that an original signature or a copy thereof transmitted by facsimile (or .pdf file) shall constitute an original signature for purposes of this Agreement.

13.12 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement including any filings with any antitrust agency which may be required.

13.13 Affiliates. Both Parties shall have the right, in their sole discretion, to perform some or all of its obligations and exercise some or all of its rights under this Agreement through its Affiliates.

13.14 Joint Negotiation. This Agreement is the joint product of Microgenics and Achaogen, and each provision hereof has been subject to the mutual consultation, negotiation and agreement of the Parties and their respective legal counsel and advisers and any rule of construction that a document shall be interpreted or construed against the drafting Party shall not be applicable.

13.15 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). All references to a "business day" or "business days" in this Agreement means any day other than a day which is a Saturday, a Sunday or any day banks are authorized or required to be closed in the United States. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". The word "will" shall be construed to have the same

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meaning and effect as the word “shall.” The words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof. All currency herein shall refer to United States dollars, unless specifically provided otherwise. All exhibits to this Agreement are hereby made a part of this Agreement.

13.16 Use of Third Parties. All obligations under this Agreement shall be performed by the Party designated to perform such obligations under this Agreement and such obligations may not be performed by a Third Party on such Party’s behalf, unless (a) the other Party has consented in writing which shall not be unreasonably be withheld or delayed, (b) the Party engaging such Third Party performs appropriate qualification and oversight of such Third Party in accordance with the Applicable Law, including applicable GMP, GCP, and GLP requirements, and (c) the Party engaging such Third Party ensures that such Third Party complies with the terms and conditions of this Agreement, and provided that such performance of activities by a Third Party is consistent with the rights and obligations of the Parties under this Agreement. Notwithstanding any such consent, each Party shall remain at all times fully liable for its respective responsibilities under this Agreement. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against such subcontractor for an obligation or performance hereunder, prior to proceeding directly against the Party engaging such subcontractor.

[Signature Page to Follow]

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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential Treatment has been requested with respect to the omitted portions.

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

ACHAOGEN INC.

MICROGENICS CORPORATION

By: /s/ Blake Wise

By: /s/ Marc Tremblay

Name: Blake Wise

Name: Marc Tremblay

Title: COO

Title: President, Clinical Diagnostics

Date: 4/26/16

Date: 4/26/2016

DB2/ 26356633.19

Signature Page to Collaborative Development and Commercialization Agreement

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential Treatment has been requested with respect to the omitted portions.

Exhibit A
Achaogen Materials

Achaogen Materials	Estimated Amount	Estimated Development Phase Required
[***]		

(1) [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
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Exhibit B
Achaogen Patents
[***]

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Exhibit C
Microgenics' Cell Lines

[***]

Clone #	Clone ID
[***]	

[***]

Clone #	Clone ID
[***]	

[***]

Clone #	Clone ID
[***]	

[***]

Rabbit	Identity	Immunogen
[***]		

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential Treatment has been requested with respect to the omitted portions.

Exhibit D
Plazomicin Chemical Structure

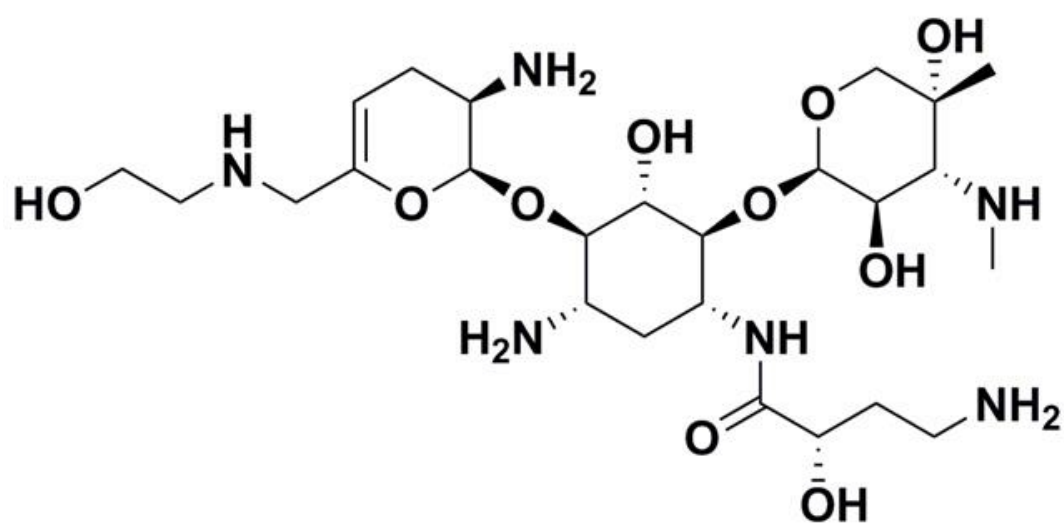


Exhibit E
Primary Countries

Achaogen Primary Country List	
Country	Country
[***]	

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential Treatment has been requested with respect to the omitted portions.

Exhibit F
Project Plan Timeline and Deliverables

Plazomicin TDM Immunoassay Development Project Plan Timeline and Deliverables				
Deliverables		Start	End	Duration (M)
Phase 0	***	***	***	***

Phase 1	***	***	***	***
•***				
•***				
Phase 2	***	***	***	***

Phase 3	***	***	***	***

Phase 4	***	***	***	***
Milestone 1:	***	***	***	***

Milestone 2:	***	***	***	***

Milestone 3:	***	***	***	***
Milestone 3A:	***	***	***	***

Milestone 3B:	***	***	***	***

***		***	***	***

Phase 5	***	***	***	***
Milestone 1:	***	***	***	***

Milestone 2:	***	***	***	***

Exhibit G
Specifications

[***]

Performance Attributes	Desired Value(s)	Acceptable Value(s)
[***]		

1 [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission.
Confidential Treatment has been requested with respect to the omitted portions.

Exhibit H - BARDA Requirements

1.0 Additional Terms and Conditions for this Agreement as a Federal Subcontract

1.1 Purpose. This Agreement is a subcontract under the following Achaogen Government Contract(s):

- Contract No. HHSO100201000046C (BARDA 0046C Contract) between Achaogen, Inc. and Department of Health and Human Services, Biomedical Advanced Research and Development Authority;

The purpose of this Section 1.0 is to incorporate by reference certain government (“Government”) contract clauses (flow downs) associated with the Achaogen Government Contract(s) specified above, that Achaogen, as a prime contractor, must include, and by which Microgenics, as a subcontractor, must abide.

1.2 Incorporated Government Contract Clauses

- (a) For BARDA Contract. **This Agreement incorporates by reference Appendix A, “Government Provisions for Commercial Item Subcontracts Under Contract No. HHSO100201000046C (BARDA 0046C Contract).” Microgenics agrees to abide by all of the provisions listed in Appendix A hereto as a condition of performance of services pursuant to any duly-executed Exhibit under this Agreement.**

1.3 Changes to Government Contracts Provisions

Microgenics agrees that upon the request of Achaogen it will negotiate in good faith with Achaogen amendments to this Agreement to incorporate additional provisions herein or to change provisions hereof, as Achaogen may reasonably deem necessary in order to comply with the provisions of the applicable Achaogen Government Contract or with the provisions of amendment(s) to such Achaogen Government Contract. If any such amendment to this Agreement causes [***], an equitable adjustment shall be made pursuant to the “Changes” clause of this Agreement.

1.4 RESERVED [Not applicable]

1.5 Government Right to Inspection of Research and Development (Reference: FAR 52.246-9)

- (a) Microgenics recognizes that the Government has the right to inspect and evaluate work performed or being performed under the Achaogen Government Contract, including any such work performed or being performed under this Agreement, to the extent practicable at all reasonable places and times and in a manner that will not unduly delay the work, including the period of performance, and in any event before its termination.
- (b) If the Government performs any inspection or test on Microgenics’ premises, Microgenics shall furnish all reasonable facilities and assistance for the safe and convenient performance of these duties.

1.6 Representations and Certifications

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential Treatment has been requested with respect to the omitted portions.

By executing this Agreement, Microgenics represents and certifies that:

- (a) neither it, nor any of its Principals (as defined hereinafter), is presently debarred, suspended, proposed for debarment or otherwise declared ineligible for participating in any federal or state procurement action by any federal, state, or local government or agency;
- (b) neither it, nor any of its Principals, has within the last three years, been convicted of, or had a civil judgment rendered against it, for any of the following: (i) the commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a federal, state or local government contract or agreement; (ii) a violation of federal or state antitrust statutes relating to the submission of offers; or (iii) the commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property;
- (c) it will comply with all applicable Federal laws and regulations regarding ethics in public acquisitions and procurement and performance of contracts;
- (d) RESERVED
- (e) it has not made or solicited and will not make or solicit kickbacks in violation of FAR 52.203-7 or the Anti-Kickback Act of 1986 (41 USC 51-58);
- (f) that (i) no federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with the awarding of this Agreement; (ii) if any funds other than federal appropriated funds (including profit or fee received under a covered federal transaction) have been paid, or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with this Agreement, Microgenics shall complete and submit, with its offer, OMB standard form LLL, Disclosure of Lobbying Activities, to the Contracting Officer; and (iii) it will include the language of this certification in all subcontract awards at any tier and require that all recipients of subcontract awards in excess of \$150,000 shall certify and disclose accordingly (the definitions and prohibitions contained in the clause at FAR 52.203-12, Limitation on Payments to Influence Certain Federal Transactions, included in this Subsection 12.7 (f) and will be included in all such certifications);
- (g) that (i) if Microgenics has participated in a previous contract or subcontract subject to the Equal Opportunity clause (FAR 52.222-26), Microgenics has filed all required compliance reports; and (ii) representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards; and
- (h) that to the best of the Microgenics's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR Subpart 9.5.

Microgenics agrees to provide immediate written notice to Achaogen if, at any time prior to termination, Microgenics learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances. For the purpose of paragraphs (a)

and (b) above, “Principal” means an officer; director, owner; partner; or a person having primary management or supervisory responsibilities within a business entity.

2.0 Government Interface

- 2.1 Microgenics employees may not communicate with any Government employee, including Achaogen’s contracting officer (“Contracting Officer”), Contracting Officer’s representative or their respective support staff, concerning any work performed pursuant to this Agreement or any associated Exhibit or appendix, without advance written consent from Achaogen.
- 2.2 Under no circumstances may Microgenics accept Government instruction on behalf of Achaogen. Microgenics is not authorized to make offers, commitments, or otherwise negotiate with the Government on Achaogen’s behalf or its own behalf in its capacity as a subcontractor to Achaogen. In case of occurrence of any such events, Microgenics shall:
- (a) suggest to the Government representative that Achaogen be involved in all such discussions, and
 - (b) immediately report to Achaogen any attempt by Government personnel to provide such instruction or conduct such negotiations.
- 2.3 If Microgenics communicates with the Government regarding a Project, Microgenics’s monthly contract management reports shall list all data exchanged and shall summarize each and every significant discussion with Government personnel during the reporting period.

3.0 Disputes

3.1 Disputes Involving the Prime Contract and/or the Government

- (a) Any dispute arising under or related to this Agreement which relates to a matter for which Achaogen has recourse against the Government under the Achaogen Government Contract (also hereinafter sometimes referred to as the “Prime Contract”) shall be resolved as follows unless the Parties otherwise agree in writing.
- (b) Microgenics shall give Achaogen a fully supported written request for equitable adjustment or claim concerning any such dispute within [***] years after the basis of the equitable adjustment arises or claim accrues, but in no event later than [***], or Microgenics shall be barred from any remedy for such claim.
- (c) Achaogen shall forward such request for equitable adjustment or claim to the Contracting Officer on Microgenics’s behalf for final decision, subject to the limitations and other conditions contained in this provision. Achaogen shall in good faith consult with Microgenics concerning the forwarding of such request for equitable adjustment or claim to the Contracting Officer.
- (d) Any final decision of the Contracting Officer under the Prime Contract as it relates to this Agreement, whether or not it results from a claim under Section 3.1(b) and (c) of this Agreement submitted on Microgenics’s behalf under the provision stated above, shall be binding upon Microgenics; provided however, that Achaogen shall notify Microgenics immediately of any such final decision of the Contracting Officer and if: (i) Achaogen elects not to appeal such decision pursuant to the

“Disputes” clause of the Prime Contract; (ii) Achaogen thereafter receives, no less than [***] ([***)] days before the expiration of the period of appeal under the “Disputes” clause of the Prime Contract, a written request by Microgenics to appeal such decision, and (iii) Achaogen has the right of such appeal under the Prime Contract, then Achaogen shall file an appeal from the final decision on Microgenics’s behalf.

- (e) If Achaogen appeals such a decision, whether at its election or at Microgenics’s request, any decision upon such appeal by the Board of Contract Appeals, the United States Court of Federal Claims, or any other board or agency having jurisdiction over the appeal shall be binding upon Microgenics insofar as it relates to a claim under this Section 3.1 of this Agreement, provided however, that if Microgenics timely (i.e., no less than [***] ([***)] days before the expiration of the relevant period of appeal) requests Achaogen to bring a further appeal to obtain judicial review of such final decision by a court of competent jurisdiction, Achaogen shall do so, subject to the terms below. A final judgment in any such further appeal, if binding on Achaogen under the Prime Contract, shall in turn be binding on Microgenics insofar as it relates to a claim under this Section 3.1 of this Agreement.
- (f) In any appeal brought by Achaogen on behalf of Microgenics, or at Microgenics’s request under the above provisions, [***] shall bear all costs and expenses incurred by Microgenics in prosecuting such appeal, including but not limited to, any legal fees or costs incurred. In any appeal taken or brought by Achaogen, whether at its election or at Microgenics request, Microgenics shall cooperate fully with Achaogen in its prosecution thereof in every reasonable manner and Microgenics shall be afforded reasonable opportunity to participate in the prosecution thereof to the extent Microgenics’s interest may be affected. To the extent requested by Achaogen, Microgenics shall prosecute for Achaogen any appeal taken or brought at Microgenics request and, in such event, Achaogen shall assist Microgenics in every reasonable manner.
- (g) If Achaogen is required to certify any claim of Microgenics, Achaogen shall not forward such claim unless it is reasonably satisfied the claim is in good faith, and Achaogen can certify such claim to the Contracting Officer to the extent and manner required by the Contract Disputes Act, as applicable. Microgenics agrees to provide Achaogen with such information as Achaogen reasonably may deem necessary to make this determination, including but not limited to, its own certification in the form prescribed by the Contract Disputes Act or its implementing regulations. Such certification shall be executed by a person duly authorized to bind Microgenics. Microgenics agrees that, with respect to any claim or dispute that arises under or relates to the Prime Contract which, if it were Achaogen’s claim, can properly be submitted for a decision of the Contracting Officer under the “Disputes” clause, its right of claim or appeal is limited to the procedures set forth in this provision.
- (h) Microgenics’s failure to comply with the terms of this provision shall entitle Achaogen to terminate any such appeal on Microgenics’s behalf. The rights and obligations described herein shall survive completion of and final payment under this Disputes section.

3.2 Other Disputes Any dispute arising under or related to this Agreement which relates to a matter for which Achaogen has recourse against the Government under the Prime Contract shall be resolved in accordance with Subsection 3.1. In the event of any dispute between the

Parties arising out of or in connection with this Agreement that does not relate to a matter for which Sponsor has recourse against the Government under the Prime Contract, such dispute shall be resolved pursuant to Section 13.8 of the Agreement.

- 3.3 Choice of Law: This Agreement is subject to and governed by the laws of the State of Delaware, U.S.A. without regard to conflict of law principles, as applicable except that any provision in this Agreement that is (i) incorporated in full text or by reference from the Federal Acquisition Regulation (FAR) or (ii) incorporated in full text or by reference from any agency regulation that implements or supplements the FAR or (iii) substantially based on any such FAR provision or agency regulation, shall be construed and interpreted according to the federal common law of government contracts as enunciated and applied by federal judicial bodies, boards of contract appeals, and quasi-judicial agencies of the federal government.

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APPENDIX A
Government Provisions for Commercial Item Subcontracts
Under Contract Number HHSO100201000046C (BARDA Prime Contract)

The following provisions, as they may be amended by the United States Government over time, are incorporated by reference with the same force and effect as if set forth in full text and shall be deemed to apply solely to such portions of work as are funded using Government funds. For the purposes of this Agreement, the term “contract” shall mean this Agreement; the terms “Contractor” and “Company” shall mean Microgenics; the term “prime contractor” shall mean Achaogen; and the terms “Government” and “Contracting Officer” may mean Achaogen or the United States Government as expressly indicated on this document. The dollar amount listed parenthetically in the titles of some referenced clauses in this Appendix A is the applicability threshold for the clause. If the total cumulative amount invoiced by Microgenics for all Government Sponsored Projects performed under the BARDA Prime Contract is expected to exceed this amount, the clause applies.

FEDERAL ACQUISITION REGULATION

<u>Clause</u>	<u>Date</u>	<u>Title</u>
FAR 52.202-1	Jul-04	Definitions (Over \$100,000)
FAR 52.203-3	Apr-84	Gratuities (Over \$100,000)
FAR 52.203-5	Apr-84	Covenant Against Contingent Fees (Over \$100,000). Substitute “Achaogen ” for “Government” or “United States” in paragraph (a) of this clause, provided however that Achaogen may annul the contract or deduct amounts only to the extent of a Government annulment or deduction due to conduct of Microgenics.
FAR 52.203-6	Sep-06	Restrictions on Subcontractor Sales to the Government (Over \$100,000)
FAR 52.203-7	Jul-95	Anti-Kickback Procedures (Over \$100,000)
FAR 52.203-8	Jan-97	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000). Substitute “Achaogen ” for “Government” or “United States” throughout this clause, provided however that Achaogen may rescind the contract and recover funds only to the extent of a Government rescission or recovery due to conduct of Microgenics.
FAR 52.203-10	Jan-97	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000) Substitute “Achaogen ” for “Government” or “United States” throughout this clause and “Achaogen” for “Contracting Officer” throughout this clause, provided however that Achaogen may make a reduction only to the extent that the Government makes a reduction due to conduct of Microgenics.
FAR 52.203-12	Sep-07	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
FAR 52.203-13	Apr-10	Contractor Code of Business Ethics and Conduct (applies if Agreement is over \$5,000,000 and has a performance period greater than 120 days). Disclosures made under this clause shall be made directly to the government entities listed in the clause.
FAR 52.203-14	Dec-07	Display of Hotline Poster(s). (d) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (d), in all subcontracts that exceed \$5,000,000, except when the subcontract-(1) Is for the acquisition of a commercial item; or (2) Is performed entirely outside the United States.

<u>Clause</u>	<u>Date</u>	<u>Title</u>
FAR 52.209-6	Sep-06	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$30,000)
FAR 52.215-2	Mar-09	Audit and Records- Negotiation (Over \$100,000) (Only Government receives access and audit rights under this clause)
FAR 52.215-21	Oct-97	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data-Modifications. Substitute "Achaogen" for "Contracting Officer" throughout this clause, provided however, that Achaogen may seek from Microgenics only such information as the Government has requested, and Microgenics shall deliver any such information directly and only to the Government. FAR 52.215-21 (as modified above) shall apply only with respect to modifications funded by the Government; FAR 52.215-21 shall not apply to modifications that are not funded by the Government.
FAR 52.219-8	May-04	Utilization of Small Business Concerns (Over \$100,000)
FAR 52.222-3	Jun-03	Convict Labor
FAR 52.222-21	Feb-99	Prohibition of Segregated Facilities
FAR 52.222-26	Mar-07	Equal Opportunity (Over \$10,000)
FAR 52.222-35	Sept-06	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Over \$100,000)
FAR 52.222-36	Jun-98	Affirmative Action for Workers with Disabilities (Over \$10,000)
FAR 52.222-37	Sep-06	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Over \$100,000)
FAR 52.222-39	Dec-04	Notification of Employee Rights Concerning Payment of Union Dues or Fees. Applicable if value of this Agreement equals or exceeds \$100,000.
FAR 52.222-50	Feb-09	Combating Trafficking in Persons
FAR 52.222-54	Jan-09	Employment Eligibility Verification. Applicable to services and construction subcontracts that: (1) exceed \$3,000; and (2) include work performed in the United States. This clause does not apply to subcontracts for commercial services that are (a) part of the purchase of a Commercially Available Off the Shelf (COTS) item (or an item that would be a COTS item, but for minor modifications) (b) performed by the COTS provider, and (c) are normally provided for that COTS item.
FAR 52.223-6	May-01	Drug-Free Workplace
FAR 52.224-1	Apr-84	Privacy Act Notification (If subcontract requires design, development, or operation of a system of records)
FAR 52.224-2	Apr-84	Privacy Act (If subcontract requires design, development, or operation of a system of records)
FAR 52.225-1	Feb-09	Buy American Act- Supplies
FAR 52.225-13	Jun-08	Restrictions on Certain Foreign Purchases
FAR 52.227-1	Dec-07	Authorization and Consent, Alternate I (Apr 1984) (Over \$100,000)
FAR 52.227-2	Dec-07	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000). Substitute "Achaogen" for "Contracting Officer" throughout this clause. Insert "or Achaogen" after "Government" throughout this clause.

<u>Clause</u>	<u>Date</u>	<u>Title</u>
FAR 52.227-11	Dec-07	Patent Rights -Ownership by the Contractor (Only Government receives license; Achaogen receives no license.) (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual. Microgenics shall provide to Achaogen a copy of any notice or election that Microgenics submits to the Contracting Officer pursuant to subparagraph (c)(1), (c)(2) and (e)(3).
FAR 52.227-16	Jun-87	Additional Data Requirements. Substitute "Achaogen" for "Contracting Officer" throughout this clause, provided however, that Achaogen may order from Microgenics only such data that the Government has ordered and provided further that the following data are hereby specifically identified for purposes of FAR 52.227-16(b), and are not subject to disclosure obligations under FAR 52.227-16, and shall not be disclosed: (i) Immunoassay Technologies (as defined in Section 1.16); (ii) Microgenics Know-How (as defined in Section 1.18) related to Immunoassay Technologies; and (iii) any and all limited rights data (<i>i.e.</i> , data that embody trade secrets or are commercial or financial and confidential or privileged, to the extent such data pertain to items, components, or processes developed at private expense, including minor modifications) not already included in (i) or (ii).
FAR 52.242-15	Aug-89	Stop Work Order (April 1984) (Achaogen may issue stop work order only to the extent the Government issues a stop work order) Substitute "Achaogen" for "Contracting Officer" throughout this clause.
FAR 52.244-5	Dec-96	Competition in Subcontracting
FAR 52.244-6	Jun-10	Subcontracts for Commercial Items
FAR 52.245-1	Aug-10	Government Property Applicable where government property involved in performance of subcontract; "Contracting Officer" means "Achaogen" except in the definition of Property Administrator and in paragraph h(1)(iii) and where it is unchanged, and in paragraphs (c) and (h)(4) where it includes Achaogen. "Government" is unchanged in the phrases "Government property" and "Government furnished property" and where elsewhere used except in paragraph (d)(1) where it means Achaogen and except in paragraphs (d)(2) and (g) where the term includes Achaogen.

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES SUPPLEMENTAL REGULATION PROVISIONS

<u>Clause</u>	<u>Date</u>	<u>Title</u>
HHSAR 352.203-70	Jan-06	Anti-lobbying
HHSAR 352.223-70	Jan-06	Safety and Health
HHSAR 352.224-70	Jan-06	Privacy Act (if subcontract requires design, development, or operation of a system of records)
HHSAR 325.242-73	Jan-06	Withholding of Contract Payments
HHSAR 352.270-4	Jan-06	Protection of Human Subjects
HHSAR 352.270-5	Jan-06	Care of Live Vertebrate Animals
HHSAR 352.270-6	Jan-06	Restriction on Use of Human Subjects

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BARDA REQUIRED PROVISIONS

Prime Contract Provision	Clause
H.2: Human Materials	<p>The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by Company in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.</p> <p>Company shall provide Achaogen with written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this Agreement were obtained with prior approval by the Office for Human Research Protections of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects.</p> <p>Provision by Company to Achaogen of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption," Form OMB No. 0990-0263 (formerly optional form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required.</p>
H.3: Research Involving Human Fetal Tissue	<p>All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 C.F.R. 46, Subpart B, and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.</p> <p>Company shall make available, for audit by Achaogen, the secretary, HHS, the physician statements and informed consents required by 42 U.S.C. 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.</p>
H.4: Needle Exchange	Company shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.
H.5: Press Releases	Company shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.
H.7: Animal Welfare	All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm .
H.8: Protection of Personnel who Work with Nonhuman Primates	All Company personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL: http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/

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Prime Contract Provision	Clause
H.9: Publications and Publicity	<p>No information related to data obtained under this contract shall be released or publicized without the prior written consent of Achaogen and the Contracting Officer Technical Representative.</p> <p>In addition to the requirements of HHSAR 352.227-70, Publications and Publicity incorporated by reference in section I of this contract shall acknowledge the support of the Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:</p> <p>“This project has been funded in whole or in part with Federal funds from the Biomedical Advanced Research and Development Authority, office of the Assistant Secretary for Preparedness and response, Office of the Secretary, Department of Health and Human Services, Under Contract No. HHSO100201000046C.”</p>
H.10: Reporting Matters Involving Fraud, Waste and Abuse	<p>Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs is encouraged to report such matters to the HHS Inspector General’s Office in writing or on the Inspector General’s Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:</p> <p>Office of Inspector General Department of Health and Human Services TIPS HOTLINE P.O. Box 23489 Washington, D.C. 20026.</p>
H.11 Prohibition on Contractor Involvement with Terrorist Activities	<p>Company acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of Company to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.</p>
H.15: Privacy Act Applicability	<p>Notification is hereby given that Company and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government.</p>
H.16: Laboratory license requirement	<p>Company shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as Amended). This requirement shall also be included in any subcontract for services under this contract.</p> <p>The parties anticipate that no part of the performance of this Agreement will be subject to the Clinical Laboratory Improvement Act As Amended.</p>
H.17: Dissemination of Information	<p>Except for any application to the FDA for approval of a diagnostic, any publication in connection with such FDA filing or approval, and any filing in connection with obtaining patent protection, no information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting officer, to be obtained through Achaogen.</p>
H.18: Identification and Disposition of Data	<p>Company will be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be directly related to and/or generated under this contract. Company shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time period specified by the FDA.</p>

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Prime Contract Provision	Clause
H.19: Information on Compliance With Animal Care Requirements	<p>Registration with the U.S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq), http://www.nal.usda.gov/awic/legislat/awa.htm</p> <p>The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) http://grants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS Policy, http://grants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U.S. Public Health Service.</p> <p>The PHS Policy requires that Assured institutions base their programs of animal care and use on the <i>Guide for the Care and Use of Laboratory Animals</i> http://www.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 C.F.R., subchapter A) http://www.nal.usda.gov/awic/legislat/usdaleg1.htm issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with USDA regulations is an absolute requirement of this Policy.</p> <p>The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates programs of animal care institutions at their request. Those that meet the high standards are given accredited status. As of the 2002 revision of the PHS policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the <i>Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching</i>. It is published by the American Science Societies. http://www.fass.org.</p>

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Prime Contract Provision	Clause
H.20: Requirements for Adequate Assurance of Protection of Vertebrate Animal Subjects	<p>The PHYS Policy on Humane Care and Use of Laboratory Animals requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS Policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. Also the PHS policy defines “animal” as “any live, vertebrate animal used, or intended for use, in research, research training, experimentation, biological testing or for related purposes.” This policy implements and supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires that institutions use the Guide for the Care and Use of Laboratory Animals as a basis for developing and implementing an institutional animal care use program. This Policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act, as amended and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163. http://grants.nih.gov/grants/olaw/olaw.htm.</p> <p>No PHYS supported work or research involving vertebrate animals will be conducted by an organization, unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the institution for further review in the case of an apparent or potential violations of the PHS policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. Foreign applicant organizations are not required to submit IACUC approval, but should provide information that is satisfactory to the Government to provide assurances for the humane care of such animals.</p>
H.21: Approval of Required Assurance by OLAW	<p>Under governing regulations, federal funds which are administered by DHHS, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by Company under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance, with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e., are clearly severable and independent from those activities) may be conducted by the contractor or individual performance sites pending OLAW approval of their respective assurance of compliance.</p>

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Prime Contract Provision	Clause
H.22: Registration with the Select Agent Program for Work involving the possession, use, and/or transfer of select biological agents or toxins	<p>Company shall not conduct work involving select agents or toxins under this contract until it and any associated subcontractor(s) comply with the following:</p> <p>For prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, the institution must comply with the provisions of 42 C.F.R. part 73, 7 C.F.R. part 331, and/or 9 C.F.R. part 121 (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) as required, before using NIH funds for work involving a <i>Select Agent or Toxin</i>. No government funds can be used for research involving a <i>Select Agent or Toxin</i> at a domestic institution without a valid registration certificate.</p> <p>For prime or subcontract awards to foreign institutions that possess, use, and/or transfer a <i>Select Agent or Toxin</i>, before using NIH funds for any work directly involving a <i>Select Agent or Toxin</i>, the foreign institution must provide information satisfactory to the government that safety, security, and training standards equivalent to those described in 42 C.F.R. part 73, 7 C.F.R. part 331, and/or 9 C.F.R. part 121 are in place and will be administered on behalf of all <i>Select Agent or Toxin</i> work supported by these funds. The process for making this determination includes inspection of the foreign laboratory facility by a government representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. No funds can be used for work involving a <i>Select Agent or Toxin</i> at a foreign institution without written approval from Achaogen.</p> <p>Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http://www.cdc.gov/od/sap/ and http://www.cdc.gov/od/sap/docs/salist.pdf.</p> <p>Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at: http://www.aphis.usda.gov/programs/ag_selectagent/index.html and: http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html</p> <p>For foreign institutions, see the NIAID Select Agent Award information: http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm.</p>
H.23: EPA Energy Star Requirements	All microcomputers, including personal computers, monitors, and printers purchased with government funds in the performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always satisfies Energy Star efficiency levels.

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Prime Contract Provision	Clause
H.24: Acknowledgement of Federal Funding	<p>(a)Section 507 of P.L. 104-208 mandates that contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state (1) the percentage and dollar amounts of the total program or project costs financed with federal money, and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources. This requirement is in addition to the continuing requirement to provide an acknowledgement of support and disclaimer on any publication reporting the results of a contract funded activity.</p> <p>(b)Publication and Publicity. The contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows: "This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract no. HHSO100201000046C.</p> <p>(c)Press Releases. Pursuant to Section 508 of Public Law 105-78, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with federal money that: (1) the percentage of the total costs of the program or project which will be financed with federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.</p>
H.25: Manufacturing Standards	<p>The Current Good Manufacturing Practice Regulations ("cGMP") (21 C.F.R. Parts 210-211) and regulations pertaining to biological products (21 C.F.R. Part 600) will be the standard to be applied for manufacturing, processing, packing, storage, and delivery of this product.</p> <p>If at any time during the life of the contract, Company fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, purity or potency of this product (a material failure), the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Contractor fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated for default.</p>
H.26: Export Control Notification	Company is responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies.

***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential Treatment has been requested with respect to the omitted portions.

Prime Contract Provision	Clause
H.27: Institutional responsibility Regarding Conflicting Interests of Investigators	<p>Company shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principle investigator and any other person who is responsible for design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest. For the purposes of this part relating to financial interest, “investigator” includes the investigator’s spouse and dependent children.</p> <p>Company shall at a minimum:</p> <ul style="list-style-type: none"> (a) Maintain a written, enforceable policy on conflict of interest and inform each investigator of the policy, the investigator’s reporting responsibilities, and the applicable regulations. The contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations. (b) Designate and official to review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such a conflict. (c) Require updating of financial disclosure statements during the period of award. (d) Maintain records taken under this provision for three years after final payment. (e) Establish adequate enforcement mechanisms. <p>If a conflict of interest is identified, the Institution shall report to Achaogen the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within thirty (30) days of that identification.</p>

ORDER OF PRECEDENCE

In the event of a conflict between the terms of this Appendix and any term of the Agreement or an Exhibit or other appendix issued there under, the terms of this Appendix shall govern.

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