

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

FORM 10-K/A
(Amendment No. 1)

(Mark One)

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

For the fiscal year ended December 31, 2017

or

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

For the transition period from _____ to _____

Commission File Number 001-36193

Trevena, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

26-1469215
(I.R.S. Employer
Identification No.)

955 Chesterbrook Blvd., Suite 200, Chesterbrook, PA
(Address of Principal Executive Offices)

19087
(Zip Code)

Registrant's telephone number, including area code: **(610) 354-8840**

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

| <u>Title of each class</u> | <u>Name of each exchange on which registered</u> |
|---|--|
| Common Stock, par value \$0.001 per share | NASDAQ Global Select Market |

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

Emerging growth company

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2017, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$94.0 million. Such aggregate market value was computed by reference to the closing price

of the Common Stock as reported on the NASDAQ Global Select Market on June 30, 2017. For purposes of making this calculation only, the registrant has defined affiliates as including only directors and executive officers and shareholders holding greater than 10% of the voting stock of the registrant as of June 30, 2017.

The number of shares of the registrant's Common Stock outstanding as of March 2, 2018 was 64,785,659.

EXPLANATORY NOTE

Trevena, Inc. (the “Company”) is filing this Amendment No. 1 to its Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (the “Form 10-K”) only to re-file Exhibits 10.45 and 10.46 in response to comments the Company received from the Securities and Exchange Commission on a confidential treatment request submitted by the Company for certain portions of such Exhibits in the Form 10-K.

This Amendment No. 1 to the Form 10-K does not reflect events occurring after the filing of the Form 10-K. No other modifications or changes have been made to the Form 10-K as originally filed or the Exhibits filed therewith.

EXHIBIT INDEX

| Exhibit Number | Description |
|---------------------------|--|
| 10.45* | <u>Master Commercial Supply Agreement dated October 20, 2017 by and between Alcami Corporation and Trevena, Inc.</u> |
| 10.46* | <u>Development and Supply Agreement by and between Pfizer, Inc. and Trevena, Inc. dated as of December 15, 2016.</u> |
| 31.1 | <u>Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.</u> |
| 31.2 | <u>Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934</u> |
| 32.1 | <u>Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u> |
| 32.2 | <u>Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u> |

* Portions of this exhibit, indicated by asterisks, have been omitted and separately filed with the Securities and Exchange Commission pursuant to a request for confidential treatment that has been granted by the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: June 14, 2018

TREVENA, INC.

By: _____ /s/ John M. Limongelli

John M. Limongelli
*Senior Vice President, General Counsel and Chief Administrative
Officer*



[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

MASTER COMMERCIAL SUPPLY AGREEMENT

THIS MASTER COMMERCIAL SUPPLY AGREEMENT (the “Agreement”) is made and entered into this 20th day of October, 2017 (the “Effective Date”), by and between **Alcami Corporation**, having a place of business at 2320 Scientific Park Drive, Wilmington, NC 28405 (including its wholly-owned subsidiaries, collectively, “Company”), and **Trevena, Inc.**, having a place of business at 955 Chesterbrook Blvd, Suite 200, Chesterbrook, PA 19087 (“Client”). Company and Client, as used herein, may be referred to, collectively, as “Parties” and individually as a “Party”.

Recitals

WHEREAS, the Parties entered into a certain Master Services Agreement dated on or about July 2, 2014, as amended on March 1, 2015, and August 10, 2016, and as may be amended from time-to-time in the future (the “MSA”).

WHEREAS, the MSA governs the pre-commercial supply of Drug Product and API (both as defined below) for Client’s clinical trial programs.

WHEREAS, subject to the terms and conditions contained in this Agreement, Client desires to engage Company to perform Services (as defined below) to address some of Client’s commercial Drug Product and API supply needs.

WHEREAS, Company is willing to perform such Services for Client according to the terms and conditions provided for in this Agreement.

NOW, THEREFORE, for and in consideration of the foregoing premises and of the mutual covenants of the Parties hereinafter set forth, the Parties hereto agree as follows:

ARTICLE 1 DEFINITIONS

The following words, terms and phrases, when used herein, shall have the following respective meanings:

- 1.1 “**Act**” shall mean the United States Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), as amended from time to time, and the regulations promulgated thereunder.
- 1.2 “**Affiliate**” shall mean, with respect to a Party, a company, whether a corporation or other business entity, that is Controlling, Controlled by or under common Control with such Party.
- 1.3 “**API**” shall mean the active pharmaceutical ingredient with respect to the Drug Product.
- 1.4 “**API Firm Commitment**” shall have the meaning set forth in Section 4.2(b).
- 1.5 “**API Firm Order**” shall have the meaning set forth in Section 4.2(d).
- 1.6 “**API Long-Term Forecast**” shall have the meaning set forth in Section 4.1.

- 1.7 “**API Minimum Order Requirement**” shall have the meaning set forth in Section 4.2(a).
- 1.8 “**API Yield**” shall have the meaning set forth in Section 4.4.
- 1.9 “**Applicable Law(s)**” shall mean applicable federal, state, provincial and local laws applicable to the activities of a Party and all rules and regulations promulgated thereunder, including, without limitation, regulations promulgated by the FDA, DEA and/or other regulatory authorities.
- 1.10 “**Arising Intellectual Property**” means rights in all intellectual property which are made, developed or generated through the performance of the Services.
- 1.11 “**Batch**” shall mean a specific quantity of material produced in a contiguous process or series of processes that is expected to be homogeneous within specified limits.
- 1.12 “**Cancellation Fee**” shall have the meaning set forth in Section 4.3 for API and Section 5.3 for Drug Product.
- 1.13 “**cGMP**” or “**GMP**” shall mean the recognized pharmaceutical regulations and requirements of regulatory authorities such as those defined by the FDA’s regulations at 21CFR Parts 210 and 211, those defined by Eudralex, “The Rules Governing Medicinal Products in the European Union,” and specifically Volume 4, “Guidelines for Good Manufacturing Practices for Medicinal Products for Human and Veterinary Use” and applicable Annexes (Directives 2001/83/EC and amendments including Directives 2003/94/EC dated October 2003 and 2004/27/EC dated March 2004 and/or others that may be appropriate for the particular project) and as may be amended from time to time.
- 1.14 “**Client**” shall have the meaning set forth in the preamble.
- 1.15 “**Client Arising Intellectual Property**” shall have the meaning set forth in Section 15.2.
- 1.16 “**Client Indemnified Parties**” shall have the meaning set forth in Section 11.1.
- 1.17 “**Client Information**” shall have the meaning set forth in Section 14.1.
- 1.18 [*]
- 1.19 “**CML-474 Yield**” shall have the meaning set forth in Section 4.4.
- 1.20 “**Commercial Year**” means each period of twelve (12) consecutive calendar months during the Term of this Agreement beginning on January 1st and ending December 31st, except for the first Commercial Year, which shall commence upon [*] The first Commercial Year is expected to commence [*].
- 1.21 “**Commercialize**” or “**Commercialization**” shall mean, with respect to the Drug Product, the marketing, promotion, sale and distribution of such Drug Product.
- 1.22 “**Company**” shall have the meaning set forth in the preamble.
- 1.23 “**Company Arising Intellectual Property**” shall have the meaning set forth in Section 15.3.
- 1.24 “**Company Indemnified Parties**” shall have the meaning set forth in Section 11.2.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

- 1.25 “**Company Information**” shall have the meaning set forth in Section 14.2.
- 1.26 “**Confidential Information**” shall have the meaning set forth in Section 14.3.
- 1.27 “**Control**” shall mean the direct or indirect ownership of more than fifty percent (50%) of the equity interest in such corporation or business entity, or the ability in fact to control the management decisions of a corporation or other business entity.
- 1.28 “**DEA**” means the United States Drug Enforcement Agency and any successor agency thereto.
- 1.29 “**Deliverables**” shall have the meaning set forth in Section 2.3.
- 1.30 “**Dispute**” shall have the meaning set forth in Section 16.14(a).
- 1.31 “**DMF**” shall have the meaning set forth in Section 8.8.
- 1.32 “**Documentation**” shall have the meaning set forth in Section 8.4.
- 1.33 “**Drug Product**” shall mean Oliceridine, a finished dosage form of human pharmaceutical product containing API.
- 1.33.1 “**Drug Product — Bulk**” shall mean Oliceridine in filled, unlabeled vials, packaged in appropriate bulk packaging suitable for shipment to a third party for further processing/packaging.
- 1.33.2 “**Drug Product — Finished**” shall mean Oliceridine fully packaged for commercial distribution.
- 1.34 “**Drug Product Firm Commitment**” shall have the meaning set forth in Section 5.2(b).
- 1.35 “**Drug Product Firm Order**” shall have the meaning set forth in Section 5.2(c).
- 1.36 “**Drug Product Long-Term Forecast**” shall have the meaning set forth in Section 5.1.
- 1.37 “**Drug Product Minimum Order Requirement**” shall have the meaning set forth in Section 5.2(a).
- 1.38 “**ERP**” or “**Tail Coverage**” shall mean Extended Reporting Period.
- 1.39 “**Facility**” shall mean Company’s facility(ies) where the Services are performed, as reflected in more detail on Appendix C hereto.
- 1.40 “**FDA**” shall mean the U.S. Food and Drug Administration and any successor agency thereto.
- 1.41 “**Force Majeure**” is an event described in Section 16.12.
- 1.42 “**Indemnification Claim**” shall have the meaning set forth in Section 11.3(a).
- 1.43 “**Initial Term**” shall have the meaning set forth in Section 13.1.

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- 1.44 “**Inspection Period**” shall have the meaning set forth in Section 6.2(a).
- 1.45 “**Intellectual Property**” means collectively, patents, patent applications, trademarks, copyright, trade secrets, inventions, know-how and any other intellectual property whether statutory or non-statutory.
- 1.46 “**Latent Defect**” shall have the meaning set forth in Section 6.2(a).
- 1.47 “**Losses**” shall have the meaning set forth in Section 11.1.
- 1.48 “**Manufacture**” or “**Manufacturing**” shall mean the manufacture, processing, packaging and labeling if such packaging and labeling is performed by Company, quality control and testing of CML-474, API and/or Drug Product performed prior to their Release To The Client by Company in accordance with the terms of this Agreement and the Quality Agreement.
- 1.49 “**Marketing Authorizations**” shall mean the United States new drug application or abbreviated new drug application, as applicable, for the Drug Product(s).
- 1.50 “**Material Change**” shall have the meaning set forth in Section 3.2.
- 1.51 “**Nonconforming Product**” shall have the meaning set forth in Section 6.2(a)(ii).
- 1.52 “**Other Changes**” shall have the meaning set forth in Section 3.4.
- 1.53 “**Out of Specification**” shall mean a result that is not within the Specifications, whether these are qualitative or quantitative.
- 1.54 “**Pre-Existing Intellectual Property**” means all Intellectual Property owned, conceived, developed, first reduced to practice or otherwise made or acquired by a Party prior to the Effective Date hereof *or* outside of the Services performed under this Agreement or any Work Order, including all modifications, adjustments or improvements thereto.
- 1.55 “**Program Manager**” shall have the meaning set forth in Section 3.14(b).
- 1.56 “**Project Team**” shall have the meaning set forth in Section 3.14(b).
- 1.57 “**Purchase Prices**” shall have the meaning set forth in Section 7.1.
- 1.58 “**Quality Agreement**” shall have the meaning set forth in Section 8.3.
- 1.59 “**Raw Material Costs**” shall have the meaning set forth in Section 7.2(a).
- 1.60 “**Raw Materials**” shall mean any starting and reagent materials used to Manufacture the API or Drug Product.
- 1.61 “**Recall**” shall have the meaning set forth in Section 12.1(b).
- 1.62 “**Release To The Client**” shall mean [*]
- 1.63 “**Renewal Period**” shall have the meaning set forth in Section 13.1.
- 1.64 “**Replacement Product**” shall have the meaning set forth in Section 6.2(d).

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1.65 “Rolling Forecast” shall have the meaning set forth in Section 4.1 for API and Section 5.1 for Drug Product.

1.66 “Services” shall mean the Manufacturing services described herein.

1.67 “SMF” shall have the meaning set forth in Section 8.8.

1.68 “Specifications” means the release specifications for the Manufacture, processing, bulk packaging, testing and testing procedures, shipping, storage and supply of the API, CML-474 intermediate and/or Drug Product, any Raw Materials requirements, analytical procedures and standards of quality control and quality assurance, agreed upon and maintained in Company’s controlled documents for the API, CML-474 intermediate, and/or Drug Product. The API, CML-474 intermediate and Drug Product release Specifications as of the Effective Date shall be attached hereto as Appendix D-1, D-2 and D-3 below and updated from time to time. Current API, CML-474 intermediate and Drug Product Release Specifications shall be maintained in Company’s controlled document system.

1.69 “Steering Committee” shall have the meaning set forth in section 3.14(a).

1.70 “Technology Transfer” shall have the meaning set forth in Section 13.4(d).

1.71 “Term” shall have the meaning set forth in Section 13.1.

1.72 “Territory” shall mean the United States, its territories and possessions, or other jurisdictions agreed upon in writing by the Parties.

1.73 “Third Party Claims” shall have the meaning set forth in Section 11.1.

1.74 “Work Order” shall have the meaning set forth in Section 2.3.

ARTICLE 2 SCOPE OF AGREEMENT

2.1 **Agreement.** As a master form of contract, this Agreement together with all Appendices (all of which are incorporated herein by reference) and any written amendments to any of the foregoing executed by the Parties allows the Parties to set forth the terms, conditions and administrative procedures generally applicable to Services provided by Company or any of its wholly-owned subsidiaries to Client or any of its Affiliates.

2.2 **Appendices.** The attached Appendices are incorporated herein by reference and form part of this Agreement:

| | |
|---------------|---|
| APPENDIX A: | Sample Work Order Template |
| APPENDIX B-1: | API Batch Sizes and Cost |
| APPENDIX B-2: | Drug Product - Finished, Batch Sizes and Cost |
| APPENDIX B-3: | Drug Product - Bulk, Batch Sizes and Cost |
| APPENDIX C: | Facilities |
| APPENDIX D-1: | Initial API Release Specifications (for reference) |
| APPENDIX D-2: | Initial Drug Product Release Specifications (for reference) |
| APPENDIX D-3: | Initial CML-474 Release Specifications (for reference) |

2.3 **Work Orders.** This Agreement may provide for the issuance of multiple work orders or a work order may be issued hereunder for non-Manufacturing Services, or other Services more fully described in the work order, substantially in the form of Appendix A to this Agreement (each, a “Work Order”). The Work Order shall set forth the scope of Services to be provided, the deliverables

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(“Deliverables”) and budget and payment schedule. Client’s execution of each Work Order will be deemed its authorization for Company to proceed with the Services. All Work Orders and Deliverables hereunder shall be governed by the terms of this Agreement. Additions to or modifications of a Work Order must be made in writing and signed by both Parties.

2.4 Grant. Client hereby grants to Company during the Term of this Agreement, on a product-by-product basis, a nonexclusive, royalty-free right to Manufacture the API, Drug Product and CML-474 in the Territory and to use, if reasonable and necessary, any and all of Client’s licenses, trademarks, regulatory data and/or technical information, know-how and Confidential Information of Client related to the API and Drug Product for the purpose of Company carrying out its obligations hereunder, subject to the conditions of this Agreement. Upon termination of this Agreement, the grant provided in this Section 2.4 shall immediately terminate.

2.5 Engagement.

(a) During the Term of this Agreement and subject to the terms and conditions set forth herein, Client agrees to purchase from Company, and Company agrees to Manufacture and supply, the number of Batches of API, Drug Product — Finished (if any), Drug Product — Bulk and CML-474 per calendar year specified in the applicable purchase order in accordance with Sections 4.2 and 5.2 at the effective Purchase Price (initial prices outlined in Appendices B-1, B-2 and B-3). Notwithstanding the foregoing, Client shall be entitled, at its sole cost and expense, to qualify other manufacturer(s) to manufacture CML-474, Drug Product and API at any time to supply quantities of CML-474, Drug Product and API that Company is unable or unwilling to supply in accordance with this Agreement. In the event Company is unable to accommodate Client’s Drug Product or API requirements as set forth herein and in accordance with Article 3, Client, at its discretion, may have a third party manufacture such quantities of CML-474, Drug Product or API that Company is unable or unwilling to supply.

(b) Notwithstanding the foregoing, to the extent Client intends to Commercialize API or Drug Product in a jurisdiction outside the Territory and desires, in its sole discretion, to engage Company to Manufacture such API or Drug Product the Parties shall, upon written notice from Client to Company, use reasonable efforts to negotiate in good faith an agreement, or amendment to this Agreement, as necessary.

2.6 Marketing Authorizations. Client shall use commercially reasonable efforts to maintain the Marketing Authorizations in full force and effect at all times. Upon request by Client, Company shall use commercially reasonable efforts to assist Client in connection therewith as may be outlined in a separate statement of work or other related agreement, the terms of which shall be governed by this Agreement.

2.7 Additional API or Drug Product. The Parties covenant and agree that additional products may be added to this Agreement upon Client’s written request and such additional products shall be governed by the general conditions hereof with any special terms (including, without limitation, price) governed by an addendum hereto signed by both Parties.

ARTICLE 3
MANUFACTURING SERVICES

3.1 Manufacture of API and Drug Product. Subject to the terms and conditions contained herein, Company shall Manufacture, handle and prepare for shipment all API and Drug Product Manufactured pursuant to this Agreement (a) in accordance with this Agreement and the Quality Agreement, and (b) in material compliance with cGMP applicable to the Manufacturing of the API and Drug Product.

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3.2 Company Changes to Manufacturing Process. Except as required by Applicable Law(s), or cGMP, Company shall not Materially Change the Manufacturing process of API or Drug Product or change the Facility where the API or Drug Product is Manufactured without the prior written consent of Client, which consent shall not be unreasonably withheld, conditioned, or delayed. Company shall notify Client of all Material Changes, including Material Changes required by Applicable Law(s), as soon as practicable after Company learns of such change. A “Material Change” is one that requires a submission to the applicable regulatory authority(ies) for the Territory or is a change to the Manufacturing process, as set forth in the Manufacturing Batch record.

3.3 Client Requested Changes. Client shall inform Company in writing of any proposed modifications to the Specifications or the Manufacturing process. Unless required by Applicable Law(s), cGMP and/or the Marketing Authorizations, any proposed change that will materially impact Company’s Manufacturing process shall require Company’s prior written consent, which consent shall not be unreasonably withheld, conditioned, or delayed. Company shall make changes required by Applicable Law(s), as well as those to which it consents, which consent shall not be unreasonably withheld, conditioned or delayed, as promptly as practicable; provided, however, that such changes comply with Applicable Law(s), cGMP and the Marketing Authorizations.

3.4 Costs of Changes. Unless otherwise agreed by the Parties, any and all direct costs associated with changes requested by Company and/or changes required by Applicable Law(s) that apply generally to Company’s Facility where the applicable Manufacturing occurs shall be borne by Company; provided, however, in the event Applicable Law(s) imposes a registration fee (such as GDUFA or PDUFA) or similar user fee, and the fee relates to Company’s Services hereunder, the Parties shall determine in good faith an equitable portion of such fee to be paid by Client. The Parties understand and agree that Company shall Manufacture the Drug Product in accordance with Applicable Law(s) and regulations, as the same may be amended from time to time. Each Party shall keep the other promptly and fully advised of any new instructions or specifications required by regulatory authority or Applicable Law(s) and shall discuss the cost of implementing such requirements, including by way of example, implementation of serialization.

Unless otherwise agreed by the Parties, or otherwise necessitated by Company’s gross negligence and/or intentional acts or omissions, any and all direct costs associated with other changes, including, without limitation, changes requested by Client, changes required by Applicable Law(s) that apply specifically to API or Drug Product, and changes required by a change to a Marketing Authorization, shall be borne by Client (collectively, the “Other Changes”). If the change is an Other Change, (i) the Purchase Prices shall be adjusted by the change in Company’s cost of Manufacture of the API or Drug Product caused by such Other Change, and (ii) Client shall reimburse Company for costs, expenses or losses associated with write-offs, obsolescence and/or destruction of any work in process or finished inventory resulting from any such Other Change. If permitted by Applicable Law(s) and cGMP, any work in process and/or finished inventory resulting from any Other Change may be made available for delivery or pickup by Client, at Client’s sole cost and expense. The Parties agree to use good faith efforts to discuss changes to the Purchase Prices due to any Other Change, or otherwise, prior to any Purchase Price increase taking effect.

Client may be required to make changes to the proposed API or Drug Product presentations based on clinical data and/or FDA feedback. In such instances, both Parties will work in good faith to identify and implement these changes expeditiously and agree on any adjustments in pricing or cost as appropriate.

Both Parties shall use reasonable efforts to identify and evaluate process improvements for quality and cost improvement opportunities. Such changes may include, but are not limited to, larger Batch sizes, alternative components, or otherwise. The cost savings and reductions to unit pricing achieved by such process improvements and/or cost improvements will be shared in the same proportion as which the cost-savings activities were funded by each of the Parties.

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3.5 Notification and Approval of Changes. Client shall have sole responsibility for obtaining any and all necessary regulatory approvals from the relevant regulatory agencies in the Territory for changes to the Specifications and the Marketing Authorizations and for reporting any changes to such Specifications and the Marketing Authorizations to the relevant regulatory agencies in the Territory as appropriate. Upon request by Client, Company shall use commercially reasonable efforts to assist Client in obtaining any such approvals; provided that Client will pay Company in accordance with the terms of a separate statement of work or similar agreement which is governed by the terms of this Agreement. Client will provide to Company for its files a final copy of the CMC section related to Company activities of any such applications and/or submissions for regulatory approval unless otherwise prohibited by Applicable Law(s).

3.6 Retesting of Materials. In the event an analytical test results in Out of Specification or aberrant data, the Parties agree that appropriate re-testing may be performed to confirm the initial test result. [*], unless such re-testing demonstrates that the Out of Specification or aberrant data was due to Company's failure to perform the Services in accordance with the Work Order or related to an assignable laboratory error or otherwise attributable to Company's gross negligence or intentional acts or omissions.

3.7 Labeling. Client shall be responsible for the labeling to be used on each Drug Product and the packaging thereof, including any changes to such labels, and Client shall ensure that all such labeling complies with Applicable Law(s). Company shall use the specified labeling (and only such labeling) on the Drug Product, and shall not use such labeling on any other product unless approved by Client and permitted by Applicable Law(s). Any Client-directed change to a Drug Product label shall be implemented by Company as soon as reasonably practicable following Company's receipt of written notification of such label changes. [*] any materials acquired from a third-party that are required for Company to perform the Services.

3.8 Finished Drug Product Release. Company will provide Client with Manufacturing documents as are necessary for Client to release each lot of Drug Product for human use. Client shall be responsible for the final release of Drug Product for human use and other approved commercial purposes.

3.9 Raw Materials and Client Supplied Materials. Company shall purchase at its own expense and for its own account all Raw Materials and packaging components not supplied by Client that Company may use to Manufacture the API and Drug Product. Except as otherwise agreed to between the Parties, all right, title, and interest in and to these items shall remain the sole property of Company until API and/or Drug Product incorporating such items are Manufactured and prepared for shipment to Company's alternate Manufacturing Facility or Released To The Client, as applicable. However, [*]. Company shall obtain Client's written consent prior to changing the source/and or type of Raw Material if such change will impact the Client's Marketing Authorizations. Client may supply to Company at its own expense and for its own account Raw Materials to be used in the Manufacture of API and Drug Product hereunder, and such Raw Materials shall remain the sole property of Client. Company shall have no liability for lost or damaged Raw Materials [*].

3.10 Delivery Schedule; Project Delay. The scheduled dates for the performance of the Services as defined by the Parties represent the Parties' best estimates of the timing for the various activities to be performed; however, both Parties agree that unforeseen delays may occur. If such delays occur, both Parties will use good faith efforts to minimize the timing disruption to the scope of work and shall agree upon an appropriate adjustment in the lead times or delivery schedules, as needed, for the API and/or Drug Product(s). Except in the event of a Force Majeure event, delay in Raw Material delivery not due to Company error, or delay in delivery of Client supplied Raw Materials, Company shall not be entitled to invoke this Section 3.10 to excuse any delay in performance of obligations under this Agreement. If a Party believes the performance of any obligations under this Agreement will be delayed it shall immediately notify the other Party of the delay and cause and shall provide a good faith estimate of when performance will resume. When the affected Party is able to recommence the performance of

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obligations hereunder, it shall notify the other Party, and unless otherwise agreed, shall immediately resume performing its obligations. In the event Company anticipates delivery of API or Drug Product will not meet the scheduled delivery date [*], Company shall provide notice to Client and propose a remedy plan to the Steering Committee within [*] thereafter. The Steering Committee shall discuss and mutually agree upon a timeline for execution of the remedy plan.

For API orders [*].

For Drug Product orders [*].

Subject to Client's rights under Section 6.2(a), no delay in the shipment or delivery of any API or Drug Product shall relieve Client of its obligations under this Agreement, including arranging for shipment and accepting delivery of API and Drug Product.

3.11 Client Delays/Rescheduling. Client or its designee must provide on time, in the right quantity and within Specification, any Raw Materials (including starting materials) agreed to be supplied by Client. In a timely manner after execution of this Agreement, the Steering Committee shall agree to a supply strategy for Client supplied Raw Materials, to include lead time required for receipt by Company and minimum stock levels to be maintained. If required Raw Materials are not supplied by Client to Company as and when needed, all dates quoted by Company for delivery and completion of any stage of the Services may be extended if necessary. Client shall propose a remedy plan to the Steering Committee within [*] from the date Client recognizes the delay. The Steering Committee shall discuss and mutually agree upon a revised timeline for delivery of a delayed Client order. In the event of a Force Majeure event, Client shall not be liable for any delay fees or expenses that Company may incur. If the delivery of any Client-supplied Raw Materials (including RM1023) is delayed, other than due to a Force Majeure event, Company may charge Client for the reasonable and necessary cost and expenses directly resulting from such Client delay, which are not otherwise avoidable, including idle capacity cost which cannot be filled with new, unplanned work for another client, [*]. Company shall not be held liable for any delay, supply deficiency or supply failure caused solely by Client.

[*] Client shall also be responsible for the cost of any Raw Materials that may expire as a result of the request to delay. Notwithstanding anything to the contrary contained herein, Client shall have no liability for a delay caused by Company's gross negligence or intentional acts or omissions or caused by a Force Majeure event. Client shall not be charged [*] if Company can avoid idle capacity costs by successfully re-allocating the designated resource with new, unplanned work for another client.

3.12 Changes to Firm Orders. Any Firm Order may be amended only by mutual agreement of the Parties and such amendments shall not affect the Minimum Order Requirement. Client may submit purchase orders for volumes of API or Drug Product in excess of any Firm Order subject to the limitations herein. Company shall exercise commercially reasonable efforts to comply with any proposed amendments to accepted Firm Orders or accommodate additional purchase orders, but shall not be liable for its inability to do so. Client acknowledges that Company will rely on the Rolling Forecast and Firm Orders submitted pursuant to Articles 4 and 5 herein in ordering or producing the Raw Materials required for production, including the Manufacture of intermediate CML-474. To accommodate changes in orders, Company shall order or produce Raw Materials sufficient to meet Client's excess order requirements. If Raw Materials ordered or produced to support Client's excess order requirements are not included in API or Drug Product Manufactured [*], or if such Raw Materials have expired (subject to a cGMP compliant inventory rotation such as "First-in First-Out"), [*].

API: [*], provided the purchase order is issued no later than six (6) months prior to the scheduled Manufacture start date. Any request is subject to DEA quota and Raw Materials availability. [*].

Drug Product: [*], provided the purchase order is issued no later than three (3) months prior to the scheduled Manufacture start date. Any request is subject to available capacity, DEA quota, and Raw Materials availability. [*]

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3.13 Stability Study Cancellation. [*], as defined in the approved stability protocol, [*], as defined in the approved stability protocol, [*], as defined in the approved stability protocol, [*]. Upon cancellation, Client shall pay any fees associated with the removal and disposition of samples from the stability chambers, if any, and all Services completed through the effective date of cancellation.

3.14 Steering Committee; Project Management.

(a) **Steering Committee.** Company and Client will jointly constitute a team (“Steering Committee”) including at a minimum, senior representatives from Operations, Commercial and Quality from each Party (or such representatives as the Parties mutually agree) to oversee the work under each Work Order as well as commercial Manufacturing with one (1) representative from each of Client and Company having the authority to make decisions on behalf of such Party. The Steering Committee representatives may invite other employees, consultants or advisors of the Parties or their Affiliates to the Steering Committee meetings, to serve in an advisory capacity as relevant to the matters at hand. The Steering Committee will be considered as a working committee that will have as its goal the prompt and mutually agreeable resolution of any financial, technical or quality issues that may arise in order to advance and preserve a harmonious relationship established by and between Company and Client. Either Party may change its representatives on the Steering Committee at any time by written notice to the other Party.

The Steering Committee shall meet at least quarterly or as otherwise as may be necessary or agreed by the Steering Committee, which meetings shall occur by teleconference, videoconference or in person and may address any relevant issue a Party wishes to call to the attention of the Steering Committee, to review past performance on mutually agreed upon metrics, discuss future partnership objectives, and to oversee the relationship between Client and Company. The Steering Committee shall be responsible for performing the following functions:

- (i) reviewing business strategy;
- (ii) ensuring goal alignment by establishing and reviewing agreed upon KPI’s;
- (iii) assessing and developing risk mitigations and/or redundancies;
- (iv) discussing market dynamics and impact to supply/demand;
- (v) reviewing Client’s Long-Term Forecast and Company’s anticipated capacity at least annually; and
- (vi) implementing procedures for project governance and the resolution of questions or disputes that may arise under this Agreement or a Work Order.

(b) **Project Management.** Promptly upon execution of this Agreement, Company and Client shall each designate such of their respective employees to sufficiently represent process development, quality assurance, analytical services, manufacturing, and project management to form a team (“Project Team”). The project team has the responsibility to direct and oversee the activities to be carried out per this Agreement. Each Party shall also designate one of its employees to act as its project manager (each, a “Program Manager”), who will be primarily responsible for communicating all instructions and information concerning the project to the members of the Project Team. The Project Team and/or the Program Managers shall consult periodically during the performance of the Services, through face-to-face meetings, telephone conferences and/or videoconferences, at times to be mutually agreed upon by the Program Managers. Each Party may appoint a substitute or replacement Program Manager or a member(s) of the Project Team in the absence of its original Program Manager or original member(s) of the Project Team by notifying the other Party in writing of such substitution or replacement. Neither the

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Program Managers nor the Project Team shall have the right to modify, amend or waive any provision of this Agreement.

ARTICLE 4
SPECIFIC API MANUFACTURING TERMS

In addition to the foregoing, the following provisions will apply to API Manufacturing Services. For clarification, "API Manufacturing Services" shall mean services performed in Company's GMP manufacturing suites and in-process testing directly supporting those activities. The terms contained in this Article 4 shall not apply to Drug Product Manufacturing Services (as defined in Article 5 below).

4.1 Forecasting. [*], unless otherwise agreed by the Parties, Client shall provide to Company a written non-binding delivery forecast estimating Client's annual requirements [*] (each such forecast, the "API Long-Term Forecast").

Concurrent with the placing of its first API order with Company and during the first month of each calendar quarter thereafter, [*], specifying the requested delivery dates by calendar quarter (each, a "Rolling Forecast"). Notwithstanding anything contained in this Section 4.1, Client shall provide the first API order under this Agreement at least [*] prior to the expected delivery date.

In response to each Rolling Forecast, Company shall provide Client with an estimated schedule of Manufacturing start and delivery dates, including a schedule for Manufacture of CML-474, if required to meet Client's Rolling Forecast requirements. The first [*] shall show specific dates and the [*] shall be shown by quarter.

4.2 Firm Commitments.

(a) Provided Company is not in default of this Agreement, [*].

(b) Except as provided in Section 2.5(a) above, [*], as determined by the Manufacturing start dates, shall be [*] for Company to produce such quantities on the delivery dates described therein and for Client to purchase the quantities of API specified therein (the "API Firm Commitment"); [*] shall be [*] upon the Parties.

(c) Client understands that to ensure a timely supply of API and Drug Product, it is necessary for Company to Manufacture CML-474 in sufficient volumes to meet the forecasted production requirements for API in Client's Rolling Forecast. Client understands and agrees that Company shall rely upon the Rolling Forecast to produce such quantities of CML-474 as required to meet the forecasted quantities of API in Client's Firm Commitment. Client will review plans for CML-474 Manufacturing and the Parties shall agree to the plan to support API supply.

(d) With respect to each API Firm Commitment, Client shall submit to Company binding written purchase orders (an "API Firm Order") confirming the quantity of API ordered and CML-474 as required by Company (which shall be in full Batch quantities), the requested delivery dates, and such other information as Company may find reasonably necessary to Manufacture the API and CML-474, if applicable. Company will confirm acceptance of any API Firm Order (consistent with this Agreement) within [*] of receipt and respond with a schedule of estimated Manufacture start dates and estimated delivery dates. Except as provided in Section 3.10 of this Agreement, the Parties expressly agree that any requested delivery dates shall not be binding on Company and that any timelines represent the Parties' best estimates of the timing for the various activities or Services to be performed.

(e) All purchase orders shall be placed in accordance with this Section 4.2 and no later than nine (9) months prior to the planned Manufacturing start date. Company shall Manufacture and prepare for shipment the quantity of API specified in the API Firm Order and related purchase orders. If

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requested by Client, Company shall use its commercially reasonable and good faith efforts to deliver quantities in excess of [*] of the applicable API Firm Order subject to available capacity. The API Firm Order shall be made available for shipment in accordance with Section 6.1 (Delivery/Shipment).

(f) Company's acceptance of any API Firm Commitment or purchase order is contingent upon Company's ability to obtain a DEA quota. Further, Company's ability to Manufacture designated quantities of API for Client shall be contingent upon Company obtaining a DEA quota sufficient to meet Client's commercial API demand. Company reserves the right to modify any API Firm Order, as needed, to comply with regulatory requirements, including DEA quota. At the time Company is required by DEA to submit request for controlled substance quota (currently in the month of May of the current year for the following year) Company shall use commercially reasonable efforts to obtain necessary DEA quotas using the most current Rolling Forecast. Additional requests will be made as required based on increases to the API Firm Order.

4.3 Cancellation. Company, at its sole discretion, [*] (or Batch Manufacture start date if Company is not manufacturing a series of Batches in a campaign) (a "Cancellation Fee"). Such Cancellation Fee will be [*]. Client is responsible for [*].

4.4 API and CML-474 Process Yield Company shall use commercially reasonable efforts to maximize the API process yield (the "API Yield") and the [*] for each commercial Batch. The [*] the respective commercial Manufacturing process, or as may be agreed to by the Steering Committee. [*]. Manufacturing line losses for RM1023 will be calculated based on [*] during the Commercial Year, after reconciling all Batches produced during the calendar year. Within [*] the previous Commercial Year, [*]. Client shall provide documentation of the RM1023 acquisition cost on an annual basis.

ARTICLE 5 **SPECIFIC DRUG PRODUCT MANUFACTURING TERMS**

In addition to the foregoing, the following provisions will apply to Drug Product Manufacturing Services. For clarification, "Drug Product Manufacturing Services" shall mean services performed in Company's GMP manufacturing, inspection or packaging suites and in-process testing directly supporting those activities. All other services are defined as non-Manufacturing. The terms contained in this Article 5 shall not apply to API Manufacturing Services.

5.1 Forecasting. [*], unless otherwise agreed by the Parties, [*].

[*] (each, a "Rolling Forecast") specifying by quarter the requested delivery dates. Notwithstanding anything contained in this Section 5.1, [*]

In response to each Rolling Forecast, Company shall provide Client with an estimated schedule of Manufacture start and corresponding delivery dates, the first [*] of which shall be displayed by week, and the remainder shall be shown by quarter.

5.2 Firm Commitments.

(a) [*]

(b) [*] Company to produce and deliver such quantities on the delivery dates described therein, and for Client to accept such Batches delivered per the terms of this Agreement (the "Drug Product Firm Commitment"). [*].

(c) With respect to each Drug Product Firm Commitment, Client shall submit to Company binding written purchase orders (a "Drug Product Firm Order") confirming the quantity of each Drug Product ordered (which shall be in full Batch quantities), the requested delivery dates, and such other

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information as Company may find reasonably necessary to Manufacture the ordered Drug Product. Company will confirm acceptance of any Drug Product Firm Order (consistent with this Agreement) within [*] of receipt and respond with a schedule of estimated Manufacture start dates and estimated delivery dates. Except as provided in Section 3.10 of this Agreement, the Parties expressly agree that any requested delivery dates shall not be binding on Company and that any timelines represent the Parties' best estimates of the timing for the various activities or Services to be performed.

(d) [*]

(e) [*] Company shall Manufacture and prepare for shipment the quantity of a Drug Product specified in the Drug Product Firm Order and related purchase orders. Notwithstanding the foregoing, with respect to a Drug Product, in no event shall Company be required in any calendar quarter to deliver more than [*] of the quantities in the applicable Drug Product Firm Order applicable to that quarter but Company shall use its commercially reasonable and good faith efforts to deliver quantities in excess of [*] of the applicable Drug Product Firm Order, subject to available capacity. The Drug Product Firm Order shall be made available for shipment in accordance with Section 6.1 (Delivery/Shipment).

(f) Company's acceptance of any Drug Product Firm Commitment or purchase order is contingent upon Company's ability to obtain a DEA quota. Further, Company's ability to Manufacture designated quantities of Drug Product for Client shall be contingent upon Company obtaining a DEA quota sufficient to meet Client's commercial Drug Product demand. Company reserves the right to modify any Drug Product Firm Order, as needed, to comply with regulatory requirements, including DEA quota. At the time Company is required to submit the necessary request for controlled substance quota to DEA (currently, due in the month of April, for quota for the following year) Company shall use commercially reasonable efforts to obtain necessary DEA quotas using the current Rolling Forecast. Company shall make additional requests as required, based on increases to the Drug Product Firm Order.

5.3 Cancellation. Company, at its sole discretion, reserves the right to charge [*] for any Batch or campaign that is [*] Manufacture start date (or Batch Manufacture start date if Company is not Manufacturing a series of Batches), [*]. Such Cancellation Fee will be [*]. Client is responsible for [*].

5.4 API Consumption Factor. Company shall use commercially reasonable efforts to maximize the API Yield for each commercial Batch of Drug Product. A maximum API consumption target, or Drug Product per API ratio, shall be [*] using the commercial Manufacturing process or as may be agreed to by the Steering Committee. Within [*] following the end of each Commercial Year, Company shall prepare an annual reconciliation of Drug Product Batches to calculate the annual Drug Product yield. For any API consumption above the API consumption target [*].

ARTICLE 6 DELIVERY; ACCEPTANCE AND REJECTION

6.1 Delivery/Shipment. Company shall use commercially reasonable efforts to make API and Drug Product available for shipment by the delivery date requested in the applicable Firm Order. All API and Drug Product(s) shall be delivered [*] (Incoterms 2010) Company's Manufacturing Facility. Client shall pay all crating, skidding, rigging, customs, freight, shipping, insurance and common carrier charges on all shipments in connection with Client's chosen method of shipment. Unless otherwise agreed or due to Company's gross negligence or intentional acts or omissions, Company shall have no liability for loss or damage to API or Drug Product(s) that occurs during shipment.

In the case of scheduled Drug Product, prior to pick-up by the carrier Client must provide Company with reasonable evidence (e.g. a copy of the current DEA registration for the destination, when applicable) that the destination for the Drug Product is authorized to receive the Drug Product. Notwithstanding anything to the contrary in this Agreement or any Work Order, Client acknowledges and agrees that Company shall have no obligation to release Drug Product for shipment to any destination for

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which Client has not provided adequate evidence of authorization as required in this Section 6.1. [*] Release to The Client [*]. [*] Release to The Client and [*] following API Release to The Client.

Should Client not take delivery of API or Drug Product(s) within [*] Release to The Client [*]. Company shall store API or Drug Product for up to [*] after Release to The Client [*], after which time, Company shall invoice Client [*] for storage fees at Company's then-current rates. Company shall store all API and Drug Product at proper temperatures, in proper conditions and in accordance with applicable Specifications, cGMP and as may be required by Applicable Law(s). [*]. Notwithstanding anything to the contrary in this Section 6.1, the time periods noted above shall automatically extend and Client shall not be charged for storage fees if Client either requests additional information as part of its inspection of API and/or Drug Product, or rejects API and/or Drug Product that was Released To The Client as noted in Section 6.2 below.

Notwithstanding the foregoing, where Company Manufactures API to be used in production of the Drug Product at a Facility, [*] until the API shelf life expires or such API is used in the Manufacture of Drug Product. Company shall arrange for shipment on behalf of the Client upon Release To The Client of Batch documentation. Title to API used in production of the Drug Product shall remain with Client at all times while in Company's possession or stored on Client's behalf. [*] all required insurance in amounts necessary to insure all API and Drug Product while maintained at any Facility or shipped between Company's Facilities.

6.2 Inspection, Acceptance and Rejection of Delivered API or Drug Product.

(a) Upon Release to The Client, Client shall have the right, but not the obligation, to inspect and test the API and Drug Product. Client may, within [*] after Release to The Client (the "Inspection Period"), reject any API and Drug Product that:

- i. was not in compliance with the applicable API and Drug Product Specifications or such API and Drug Product's Certificate of Analysis at the time of Release to The Client; or
- ii. is recalled by any regulatory authority or by Company due to Company's negligence, intentional acts or omissions or breach of this Agreement (collectively, "Nonconforming Product").

In the event that any API or Drug Product is rejected or if additional information regarding Batch release documentation was requested by Client, by written notice to Company within [*] of Release to The Client, then such API or Drug Product shall be deemed accepted. This shall not include API or Drug Product that later is found to have had Latent Defect(s) which were not reasonably discoverable within [*] of Release to The Client. As used herein, "Latent Defect" shall mean any defect in any Batch of API or Drug Product that subsequently becomes evident, provided that the defect is attributable to Company and was not reasonably discernible during the Inspection Period. Following confirmation or substantiation by a mutually agreeable independent expert, Company will only be responsible for Latent Defects to the extent such defect is directly attributable to Company's breach of warranties set forth in Section 10.1 herein or breach of any of its obligations in Manufacturing API and/or Drug Product as provided in this Agreement. Notwithstanding any other provision contained herein, Company shall not be responsible for any Latent Defect discovered more than [*] from Release to The Client in the case of [*] and [*] from Release to The Client in the case of [*].

(b) Company will only be responsible for Batch(es) of API or Drug Product rejected after the Inspection Period to the extent that Company is responsible for said non-conformity. Notwithstanding anything to the contrary herein, in no event shall Company be responsible for noncompliance with Specifications for API or Drug Product that met Specifications at time of Release To The Client or from non-conformities that result from a deficiency or change in the Client supplied materials utilized in such Batch(es) of API or Drug Product(s) or a defect in the Specifications for the API or Drug Product(s).

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(c) In the event that Client rejects API or Drug Product(s) as provided in this Agreement, Company shall use commercially reasonable efforts to replace the Nonconforming Product(s) or give notice that it disagrees with the rejection. If Client and Company do not agree whether the API or Drug Product met Specifications at the time of Release To The Client, such API or Drug Product(s) shall be submitted for testing to an independent laboratory acceptable to both Parties for the purpose of determining the results. Any determination by such authority with respect to compliance to Specification shall be final and binding upon the Parties. If it is determined that such API or Drug Product(s) failed to meet applicable Specifications at the time of Release to The Client due to Company's breach of its warranties contained in Section 10.1 herein, or if due to Company's gross negligence and/or intentional acts or omissions, Company shall pay the expenses associated with such analyses; otherwise, Client shall pay such expenses and purchase the API or Drug Product in accordance with this Agreement.

(d) If it is determined that Company is directly responsible for the nonconformance, Company shall as soon as it is commercially practicable to do so, replace such Nonconforming Product with conforming API or Drug Product (the "Replacement Product") at its sole cost and expense, not including the price for any Client supplied materials in excess of insurance limits. All Replacement Product shall be subject to Client's testing and approval as provided in this Section 6.2 and the Quality Agreement. If Client previously paid the Purchase Price for the Nonconforming Product(s), then, Company shall Manufacture the Replacement Product and prepare Replacement Product for shipment in accordance with Section 6.1 (Delivery/Shipment).

ARTICLE 7 **PRICE, TERMS OF PAYMENT**

7.1 Purchase of API and Drug Product(s). The Batch size and the initial prices to be paid for the API, CML-474, and Drug Product — Finished, if any, and Drug Product — Bulk by Client to Company shall be set forth in Appendix B-1, B-2, and B-3 respectively, attached hereto and incorporated herein by reference (the "Purchase Prices"). The Purchase Prices are in United States Dollars, and are exclusive of applicable taxes. Client shall be responsible for the payment of any and all taxes applicable to the API, CML-474, Drug Product(s) and Services described herein.

7.2 Price Change; Notice.

(a) [*], subject to Section 7.2 (b) below, [*] such increased prices pertain ("Raw Material Costs"), and (ii) [*], for API or Drug Product to be delivered after January 1st for each year during the Term. Upon Client's request, Company shall provide reasonable documentation that reflects the increase in cost of Raw Material Costs. Company may also increase the Purchase Price to reflect any material change in an environmental, safety or regulatory standard that impacts Company's costs or its ability to perform the Services. Upon request, Company shall provide written evidence of this material change prior to any change in the Purchase Price. Company shall provide written notification, and written, supporting evidence upon request, of any annual increase in the Purchase Prices prior to the January 1st effective date of the increase in Purchase Prices, or as increases in the cost of Raw Materials occur, as applicable.

(b) In the event the first Commercial Year does not commence on or before the Commercial Year Outside Date, then Purchase Price increases permitted by Section 7.2(a) shall apply beginning on January 1st of the year immediately following the Commercial Year Outside Date. In such event, until [*]

7.3 Invoices.

(a) **Intermediate.** Company shall provide invoices to Client for CML-474 upon each Release To The Client of Batch Documentation.

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(b) **API.** Company shall provide invoices to Client for API upon each Release to The Client. Where Company Manufactures API to be used in production of Drug Product at another Facility, Company shall arrange for shipment and provide invoices to Client upon Release to The Client of the API.

(c) **Drug Product.** Company shall provide invoices to Client for Drug Product upon each Release to The Client (e.g. finished bulk, finished packaged, or finished packaged and labeled, including serialization).

(d) Client shall pay each such invoice [*], regardless of when or whether Client has arranged for shipment of the API or Drug Product(s) to its final destination. Client shall pay each undisputed invoice, in United States Dollars by business check, Client wired funds or Client ACH transfers (unless otherwise agreed upon in writing by the Parties), [*]. Invoice receipt shall be defined as date of electronic verification of invoice communication via fax or email to a Client contact designee. Company reserves the right to charge administrative fees when Client's payment preferences deviate from Company's standard practices. Client shall make no setoff or deduction of any kind from any payments due to Company unless Client receives written authorization from Company authorizing such setoff or deduction. Undisputed invoice balances not remitted [*]. Should any part of the invoice be in dispute, Client shall pay the balance of the undisputed amount according to the terms and conditions described herein while said dispute is being resolved. Should payment of undisputed amounts not be received within [*] of Client's receipt of an invoice, after [*] notice to Client the payment shall be deemed in default and Company reserves the right to cease all work and pursue collection activities. In such event, Client shall be responsible for all collection fees and expenses incurred by Company, including reasonable attorney's fees.

7.4 Taxes and Duties. Client shall be responsible for all taxes imposed on the sale of API, Drug Product or Services by operation of law and Purchase Prices are exclusive of applicable taxes. The consideration stated under any Work Order or otherwise is net of any taxes imposed on the amounts payable to Company hereunder.

ARTICLE 8 **REGULATORY MATTERS; RECORDS**

8.1 Access to Company's Facilities by Client Representatives. During regular business hours and mutually agreed upon times, Client may review the records of Company relating to the Services performed and expenses incurred to assure compliance with all provisions of this Agreement. Such review [*], unless otherwise agreed, and shall be offered to Client by Company not more than [*]. Subsequent reviews during the same calendar year or such reviews that cannot be completed in [*] will be at Client's sole cost and expense, at Company's then current rates [*]. Client shall also be provided an invoice for any incidental expenses Company incurs resulting from such review. While Services are being performed for Client, [*], or more if agreed upon by the Parties in writing, shall be permitted to be on-site at Company's Facility as reasonably required to monitor such Services. Client's rights in this Section 8.1 shall be subject to compliance with Company's reasonable measures for purposes of confidentiality, safety, and security, and will be further subject to Client's compliance with Company's premises rules that are generally applicable to all persons at Company's Facilities. Company reserves the right to require an independent third party to audit on behalf of any client deemed by Company in its reasonable discretion to be a direct competitor of Company. Should Client utilize one or more third party(ies) in exercising its rights in this paragraph, Client certifies that such party(ies) shall be subject to an obligation of confidentiality consistent with the obligations of confidentiality required of Client hereunder and such third party(ies) shall be subject to any and all conditions upon Client's rights that are set forth in this Section.

At all times, Company shall be solely responsible for obtaining, maintaining and paying for all necessary approvals, licenses and permits to perform the Services provided in this Agreement at each of its Facilities.

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Any 'for cause' audits shall be conducted in accordance with the Quality Agreement (defined below).

8.2 Inspections by Governmental or Regulatory Authority. Company shall be responsible for handling and responding to any FDA or other governmental body inspections or inquiries received by Client or Company regarding the Services during the Term of this Agreement. Company shall prepare for preapproval inspection at its own cost (not including out-of-pocket expenses incurred) and allow audits and inspections by the Pharmaceuticals and Medical Devices Agency (PMDA), European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA), and the FDA. All out-of-pocket costs incurred by Company for regulatory agency inspections directly related to the API and/or Drug Product being Manufactured at the Facility shall be charged to Client. In cases where Company is required to provide significant Client or Drug Product specific support to such inspections or inquiries, or allow audits or inspections by regulatory agencies other than those listed above, Client agrees to pay Company for the time required, at Company's then current regulatory support rate.

Each Party shall notify the other regarding any such inquiries and provide the other Party copies of any pertinent correspondence from such authorities related to the API, Drug Product or Services covered in this Agreement. Company shall provide to Client and any governmental body any information reasonably requested by Client and/or such governmental body concerning any governmental inspection related to any API or Drug Product (with all information provided to Client being subject to the confidentiality provisions in Article 14 herein and with Company being able to redact any information provided to Client to remove third party confidential information that does not relate to the Client's API or Drug Product). Client agrees to fully cooperate with and assist Company in fulfilling its obligations pursuant to this Section 8.2. Client shall have the right to review and comment on any communication to any regulatory authority which is related to or involves API or Drug Product

8.3 Quality Agreement. The Parties have entered into a quality agreement, effective November 4, 2016 (the "Quality Agreement") which shall be maintained in the controlled documents of the Parties. The Quality Agreement details the quality and regulatory responsibilities of the Parties with respect to the API and Drug Product; provided, however, that in the event of conflict between the terms of this Agreement and the Quality Agreement, (i) the provisions of the Quality Agreement will prevail with respect to all matters pertaining to, or governed by, GMP and (ii) in all other respects, the provisions of this Agreement will prevail.

8.4 Retention of Documentation. Raw data, documentation, Batch records, source documents and reports (collectively, "Documentation") shall be retained by Company for the period of time set forth in the Quality Agreement, with the exception of Documentation that supports validations, which will be maintained for the duration of the utilization of the method or process validated. If specifically requested by Client, longer term storage may be arranged at Client's expense. Otherwise, Documentation may be destroyed following the retention period.

During the above-described retention periods, Documentation shall be available for inspection by Client, its authorized agents and authorized government agencies.

8.5 Retention of Materials. Samples retained by Company shall be held according to the Quality Agreement.

Analytical test samples are retained for [*] and then destroyed. Prior arrangements must be made to retain samples [*].

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Upon request, Client may arrange longer term storage at its expense. Documentation, Drug Product retains or other materials shall be held by Company for longer periods of time if required by Applicable Law(s).

8.6 Safety Information. Client shall provide all necessary safety information concerning chemical entities it supplies to Company to ensure safe handling, storage, usage, shipment and disposal. Company may refuse, without liability, substances that Company cannot handle safely or which lack, in Company's assessment, sufficient information such that Company can determine that such substances do not pose a risk to health or safety while in Company's possession.

8.7 Waste. Company will be responsible for the removal and disposal of all waste resulting from Company's Manufacturing of the API and/or Drug Product, consistent with the Material Safety Data Sheet and DEA guidelines.

8.8 Access to Drug Master Files. Where applicable, Company will grant Client reference rights to all Drug Master Files (the "DMF") and Site Master Files (the "SMF") necessary to support Client's regulatory filings for the API and/or Drug Product. To affect this, Company will execute certain letters of authorization, which will be delivered to the appropriate regulatory authorities to permit them to consult Company's DMF and SMF in their review of Client's API and/or Drug Product regulatory submissions. Company will send copies of such authorization letters to Client. Company will update its DMF and SMF annually and will inform Client prior to making any modifications thereto in order to permit Client to amend or supplement any affected regulatory submissions and filings for API and/or Drug Product.

8.9 Ownership of Regulatory Approvals. The Parties agree that Client will be the sole and exclusive owner of all right, title and interest in and to all regulatory approvals related to the API and Drug Product and any submissions for such regulatory approvals. Company will reasonably assist Client in the preparation of all documents necessary to affect Client's rights in such regulatory approval applications and submissions, at the expense of Client.

ARTICLE 9 INSURANCE

9.1 Client Insurance. At all times while this Agreement is in effect Client shall maintain the following insurance:

- a. Products Liability Insurance (including coverage for Clinical Trials) in an amount of not less than [*]; or, if outside the US at compulsory limits (whichever is greater).
- b. General Liability (Premises Operations) in the amount of not less than [*] per occurrence and in the annual aggregate.
- c. Automobile Liability in the amount of not less than [*] combined single limit;
- d. Workers' Compensation (or equivalent outside the U.S) — Statutory limits;
- e. Employer's Liability in an amount not less than:
 - (i) [*] — Each Accident
 - (ii) [*] — Disease Each Employee
 - (iii) [*] — Disease Policy Limit.

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Client may utilize its Umbrella Liability policy to satisfy the above insurance requirements. To the extent that any of the above coverages are underwritten on a claims-made basis, Client shall agree to maintain coverage, or procure an Extended Reporting Period (“ERP” or “Tail Coverage”) for a period of [*].

Coverage should be placed with an insurance carrier with an A.M. Best rating of not less than A-VII. Evidence of the above coverage shall be provided prior to the Effective Date of this Agreement and annually thereafter during the Term.

Client shall cause its insurers to name Company as additional insured for the following lines of coverage:

- x. Products Liability/Clinical Trials; and
- y. Commercial General Liability; and
- z. Umbrella Liability.

9.2 Company Insurance. At all times while this Agreement is in effect Company shall maintain the following insurance:

- a. Products and Professional Liability Insurance (including coverage for Clinical Trials) in an amount of not less than [*].

Such Professional Liability Insurance shall include third-party insurance coverage and shall be at Client’s expense, with a limit of [*], to cover loss or damage to Client supplied Raw Materials, API or Drug Product arising from Company’s negligence in the Manufacturing or handling of any API, CML-474, Client supplied Raw Materials or Drug Product as further provided in Sections 6.2(d), 11.4 and 12.1(b). In the event of an actual loss, Company shall reimburse Client for the premium and pay any applicable deductible attributable to the policy and such policy shall pay covered amounts in excess of the deductible. At Client’s option and expense, Company shall renew the third-party insurance policy annually.

- b. General Liability (Premises Operations) in the amount of not less than [*] and in the annual aggregate.
- c. Automobile Liability in the amount of [*];
- d. Workers’ Compensation (or equivalent outside the U.S) — Statutory limits;
- e. Employer’s Liability in an amount not less than:
 - (i) [*]— Each Accident
 - (ii) [*]— Disease Each Employee
 - (iii) [*]— Disease Policy Limit.

To the extent that any of the above coverages are underwritten on a claims-made basis, Company shall agree to maintain coverage, or procure an ERP or Tail Coverage for a period of [*].

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Coverage should be placed with an insurance carrier with an A.M. Best rating of not less than A-VII. Evidence of the above coverage shall be provided prior to the Effective Date of this Agreement and annually thereafter during the Term.

Company shall cause its insurers to name Client as additional insured for the following lines of coverage:

- x. Products Liability/Clinical Trials; and
- y. Commercial General Liability; and
- z. Umbrella Liability.

Company and Client shall each cause its respective insurers to waive all right of subrogation and shall cause insurers to agree that they shall act as primary and not require contribution from any valid and collectible insurance which may be available to Company for liability arising from Client's negligence or to Client for liability arising from Company's negligence.

ARTICLE 10 **REPRESENTATIONS, WARRANTIES AND COVENANTS**

10.1 Representations, Warranties and Covenants of Company. Company hereby represents and warrants as follows:

(a) The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby are within Company's powers and have been duly authorized by all necessary action on the part of Company. This Agreement has been duly executed and delivered by Company and constitutes legal, valid and binding obligations of Company, enforceable against Company in accordance with its terms.

(b) The execution, delivery and performance by Company of this Agreement does not and will not (i) contravene or conflict with the organizational documents of Company, (ii) contravene or conflict with or constitute a violation of any Applicable Law(s), or (iii) breach or constitute a default under the provisions of any material contract, agreement or instrument to which it is a party or by which it is bound.

(c) Company shall perform its obligations hereunder in conformance with Applicable Law(s) (and cGMP if applicable).

(d) Company is not debarred and has not and shall not knowingly and intentionally use in any capacity the services of any employee or third party debarred under subsections 306(a) or (b) of the Generic Drug Enforcement Act of 1992.

(e) As of Release To The Client, all API and Drug Product(s) delivered to Client during the Term of this Agreement: (i) shall have been Manufactured by Company in material compliance with this Agreement, the Quality Agreement, and cGMP, in each case, as in effect at the time of Manufacture, (ii) assuming compliance by Client with Section 3.7 (Labeling), shall not be adulterated or misbranded within the meaning of the Act, and (iii) shall not have been Manufactured by Company in violation of any Applicable Law(s) in any material respect.

(f) Upon Release to The Client, Company shall convey good title to all API and Drug Product(s) so delivered to Client or its designee.

(g) Company has all necessary and proper licenses, permits, approvals and expertise to perform its Manufacturing and related duties under this Agreement and any Work Order, and all Facilities

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have all necessary licenses, permits, and approvals necessary to perform the Manufacturing and related duties provided in this Agreement.

(h) Under no circumstances shall Company transfer any API and/ or Drug Product to any third parties, including any generic drug manufacturers, without first obtaining Client's prior written approval, which approval may be withheld in Client's sole discretion.

(i) There are no suits, claims, or proceedings pending, or to its best knowledge and belief, after due inquiry, threatened against it or any of its Affiliates in any court or by or before any governmental body or agency which would affect its ability to perform its obligations under this Agreement.

(j) Company represents and warrants to Client that, to the best of Company's knowledge, Company's Intellectual Property, that Company may license to Client under this Agreement or use in performing Services under this Agreement, does not infringe any patents of a third party. In performance of its obligations under this Agreement, Company will not knowingly incorporate into the Manufacturing process any third party Intellectual Property except with Client's consent.

EXCEPT AS SET FORTH IN THIS SECTION 10.1, COMPANY MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, AND SPECIFICALLY DISCLAIMS ALL SUCH REPRESENTATIONS AND WARRANTIES, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, INFRINGEMENT, TITLE OR FITNESS FOR A PARTICULAR PURPOSE OR USE.

10.2 Representations, Warranties and Covenants of Client. Client hereby represents and warrants as follows:

(a) The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby are within Client's powers and have been duly authorized by all necessary action on the part of Client. This Agreement has been duly executed and delivered by Client and constitutes legal, valid and binding obligations of Client, enforceable against Client in accordance with its terms.

(b) The execution, delivery and performance by Client of this Agreement does not and will not (i) contravene or conflict with the organizational documents of Client, (ii) contravene or conflict with or constitute a violation of any Applicable Law(s), or (iii) breach or constitute a default under the provisions of any material contract, agreement or instrument to which it is a party or by which it is bound.

(c) Client shall comply in all material respects with all Applicable Law(s) relating to its Commercialization of the Drug Product(s).

(d) To the extent that Client supplies any Raw Materials or other information to Company (including packaging and labeling requirements) or engages in manufacturing with respect to any of the API or Drug Product (either directly or indirectly through a third party), all such Raw Materials or other information and formulas will comply with the Specifications and Applicable Law(s), including GMP.

(e) Client represents that to the best of its knowledge, the manufacture or the sale of the API or Drug Product(s) does not and will not infringe any third party intellectual property rights or other rights and that it is not aware of any patents existing in the Territory in which Client markets or distributes such Drug Product relating in any manner to the Drug Product or any use, method, activity or application relating thereto which could adversely impact upon or prevent Company from Manufacturing the API or Drug Product as contemplated by the terms hereof.

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ARTICLE 11
INDEMNIFICATION

11.1 By Company. Company hereby indemnifies Client and its directors, officers, employees, Affiliates, stockholders, agents, attorneys, representatives, successors and permitted assigns (collectively, the “Client Indemnified Parties”) against and agrees to hold each of them harmless from any and all claims relating to (i) product liability associated with the Client’s API or Drug Product, (ii) losses, liabilities, obligations, damages, costs and expenses (“Losses”) incurred by any Client Indemnified Party as a result of third party claims, actions or proceedings (collectively, “Third Party Claims”) to the extent based upon, attributable to or resulting from the gross negligence, willful misconduct or intentional acts or omissions by a Company Indemnified Party in connection with this Agreement, (iii) intentional or willful infringement or alleged infringement of any Intellectual Property (except in either case if such Third Party Claims are directed at Client Intellectual Property), (iv) breach of any representations, warranties or covenants of Company under this Agreement, (v) personal injury or property damage to the extent that the injury or damage is the result of a material breach of any representations, warranties or covenants of Company under this Agreement; except in each case, to the extent such Losses are attributable to Client’s material breach of this Agreement or arising from the gross negligence or willful misconduct of a Client Indemnified Party.

11.2 By Client. Client hereby indemnifies Company and its directors, officers, employees, wholly-owned subsidiaries, stockholders, agents, attorneys, representatives, successors and assigns (collectively, the “Company Indemnified Parties”) against and agrees to hold each of them harmless from any and all Third Party Claims, including Losses incurred by any Company Indemnified Party to the extent based upon, attributable to or resulting from (i) intentional or willful infringement or alleged infringement of any third party Intellectual Property in the API or Drug Product (except in the case if such Third Party Claims are directed at Company Intellectual Property), (ii) any claim of personal injury or property damage to the extent that the injury or damage arises from the safety or efficacy of the Drug Product or is the result of a breach of this Agreement by Client, including, without limitation, any representation or warranty contained herein, (iii) any products liability claims related to Client API or Drug Product or claims arising directly or indirectly from the manufacture (but only to the extent caused by Client supplied Raw Materials), promotion, marketing, distribution or sale of, or use of or exposure to, the API or Drug Product, or Client supplied Raw Materials; except in each case, to the extent such Losses are attributable to Company’s material breach of this Agreement, or arising from the gross negligence or willful misconduct of a Company Indemnified Party.

11.3 Indemnification Procedures.

(a) The indemnified Party shall give the indemnifying Party prompt notice of any such claim or lawsuit (“Indemnification Claim”) (including a copy thereof) served upon it and shall fully cooperate with the indemnifying Party and its legal representatives in the investigation of any matter the subject of indemnification. The indemnifying Party may enter into a settlement agreement with a claimant but shall not admit liability to a claimant, purport to impose any obligation on the indemnified Party or fail to obtain a complete release of the indemnified Party without the prior written permission of the Party or Parties seeking indemnification, which permission shall not be unreasonably withheld. The indemnifying Party shall be responsible for all actual losses in the form of reimbursement for any Indemnification Claim.

(b) The failure of the indemnified Party to give reasonably prompt notice of any Indemnification Claim shall not release, waive or otherwise affect the indemnifying Party’s obligations with respect thereto except to the extent that the indemnifying Party can demonstrate actual loss and prejudice as a result of such failure.

(c) The indemnified Party shall have no liability for any settlement entered into by an indemnified Party without the indemnifying Party’s prior written consent.

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11.4 Limitation on Liability. Except where arising from breach of Article 14 or gross negligence or willful misconduct, neither Party shall be liable, whether in contract, tort (including negligence) or otherwise, for any punitive, special, indirect, incidental, consequential or exemplary damages (including lost profit or business interruption even if notified in advance of such possibility) arising out of or pertaining to the subject matter of this Agreement, or performance of the Services.

In the event of a failed Manufacturing Batch due to Company's sole negligence, [*] Company will be liable for the cost of the insurance premium and deductible as set forth in Section 9.1 of this Agreement as well as re-working, re-processing or Manufacturing a replacement Batch of Drug Product and/or API and/or CML-474 (as applicable), at no additional charge to Client, including components, manufacturing supplies and testing.

11.5 Aggregate Cap. Except where arising from breach of Article 14 or gross negligence or willful misconduct, the total aggregate liability of either Party to this Agreement arising out of the Services performed hereunder shall be [*]. Except as specifically stated in this Agreement, Company shall not be liable for Client-supplied materials. Such liability cap amount does not alter each Party's insurance obligations under Article 9 (Insurance).

ARTICLE 12 **COMPLAINTS; RECALL PROCEDURES**

12.1 Complaints and Recalls.

(a) **Complaints.** Drug Product complaints received by Client with respect to Drug Product Manufactured by Company hereunder shall be sent to Company within the time period set forth in the Quality Agreement, after receipt to:

Alcami Corporation
Attention: Corporate Quality
2320 Scientific Park Drive
Wilmington, NC 28405
Facsimile No.: (910) 815-2387
Email: product.complaints@alcaminow.com

As more fully described in the Quality Agreement, Company shall investigate all complaints directly associated with the Manufacture of Drug Product(s) and shall provide an update every [*] and a report to Client regarding its investigation and any conclusions. Client shall investigate all other complaints associated with the Drug Product(s).

(b) **Recall Procedures.** As further set forth in the Quality Agreement, in the event that a recall, withdrawal or field correction of any Drug Product (a "Recall") is initiated, whether by a statutory or regulatory authority in any jurisdiction or by Client, Client shall notify Company promptly and in any event within [*] of receipt of written notice. Company shall reasonably cooperate with Client in connection with any Recall. Client shall (i) bear the cost of and be responsible for conducting all Recalls or market withdrawals of Drug Product, and (ii) purchase the Drug Product that was Recalled or incorporated into any final product that was Recalled, and (iii) reimburse Company for any out-of-pocket expenses related to the Recall. Notwithstanding the foregoing, to the extent such Recall or market withdrawal is directly attributable to Company's breach of warranties set forth in Section 10.1 herein, or Company's gross negligence or intentional acts or omissions, upon confirmation or substantiation by a mutually agreeable independent expert, Company shall Manufacture Replacement Product to replace any Nonconforming Product, including API (but not including any Client supplied materials in excess of insurance limits). Subject to Section 11.5, Company also shall be responsible to pay for the administrative expenses of such Recall, limited to reasonable expenses of notification of customers, the return and destruction of the recalled Nonconforming Product and any costs associated with delivery of Replacement API and/or Drug Product, but will not include any exceptional testing or investigations not required by Applicable Law(s).

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The foregoing constitutes Client's sole remedy and shall be Company's sole liability with respect to Recalls under this Agreement.

ARTICLE 13
TERM AND TERMINATION

13.1 Term of the Agreement. Unless earlier terminated in accordance with this Article 13, this Agreement shall take effect and commence on the Effective Date and continue in effect for eight (8) years (the "Initial Term"). In addition, after the expiration of the Initial Term, this Agreement will automatically renew for consecutive two (2) year terms (each, a "Renewal Period") unless either of the Parties terminates this Agreement at the end of the Initial Term or any applicable Renewal Period by providing the other Party with written notice, at least twelve (12) months prior to the end of the Initial Term or Renewal Period. The Initial Term and all Renewal Periods shall be collectively referred to herein as the "Term".

Notwithstanding the foregoing, unless the Parties agree or otherwise terminate the Services under Article 4 or Article 5 and all Work Orders in process, the provisions of this Agreement will continue to be effective for so long as Services are being performed under this Agreement, an API Firm Order, Drug Product Firm Order or any purchase order executed prior to expiration or termination of this Agreement. Termination of any Services or Drug Product under this Agreement shall not terminate this Agreement in its entirety unless so directed by the terminating Party and permitted under the terms of this Agreement.

13.2 Termination of the Agreement. Notwithstanding Section 13.1 herein, this Agreement may be terminated as follows:

(a) immediately upon the delivery of written notice by one Party, if the other Party is in material breach of any of the provisions of this Agreement and such breach is capable of being cured and is not cured within [*] after receipt of written notice identifying such breach (or if the breach is not capable of being remedied in such time period, if such cure has been commenced but is not diligently pursued and prosecuted to completion within a commercially reasonable time); or

(b) immediately upon the delivery of written notice by one Party, if the other Party has been unable to perform its obligations hereunder for [*] by reason of Force Majeure; or

(c) either Party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other Party in the event that (i) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other Party; (iii) the other Party ceases or threatens to cease to carry on business; (iv) this Agreement is assigned by such other Party for the benefit of creditors; (v) there is a complete market withdrawal of a Drug Product; or (vi) in the event Client does not obtain appropriate regulatory authorization or approval to manufacture, market, sell and/or otherwise Commercialize a Drug Product in the Territory (including, but not limited to, failure to obtain FDA and/or DEA approvals); or

(d) either Party may terminate this Agreement as to any Drug Product upon [*] written notice in the event that any governmental agency takes any action that prevents Client from importing, exporting, purchasing or selling such Drug Product; or

(e) either Party at its sole option may terminate this Agreement by providing not less than [*] advance written notice of request to terminate this Agreement in its entirety.

13.3 Termination of Services, Products, or a Work Order. Unless otherwise agreed upon by the Parties, either Party may terminate the API Manufacturing Services under Article 4, or the Drug

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Product Manufacturing Services under Article 5, in whole or in part, as follows:

- (a) on [*] written notice; or
- (b) immediately upon the delivery of written notice by one Party, if the other Party is in material breach of any of the provisions of this Agreement and such breach is not cured within [*] after receipt of written notice identifying such breach (or if the breach is not capable of being remedied in such time period, if such cure has been commenced but is not diligently pursued and prosecuted to completion within a commercially reasonable time); or
- (c) immediately upon the delivery of written notice by one Party, if the other Party has been unable to perform its obligations under this Agreement, or any Work Order for [*] by reason of Force Majeure; or
- (d) either Party at its sole option may immediately terminate this Agreement or Services performed under Article 4 or Article 5 herein, upon written notice, but without prior advance notice to the other Party, in the event that (i) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other Party; (iii) the other Party ceases or threatens to cease to carry on business; or (iv) this Agreement is assigned by such other Party for the benefit of creditors; or
- (e) either Party may terminate this Agreement as to any Drug Product upon [*] written notice in the event that any governmental agency takes any action that prevents Client from importing, exporting, purchasing or selling such Drug Product; or
- (f) either Party may terminate the Services performed under Article 4 or Article 5 of this Agreement if: (i) an individual Drug Product is withdrawn from the market; or (ii) an individual Drug Product is found to infringe a third party's intellectual property. Termination of a Service under this Section 13.3(f) shall result in the termination of only API Manufacturing under Article 4 or only Drug Product Manufacturing under Article 5 and shall not affect or terminate the remaining Manufacturing Services of this Agreement.
- (g) Client may terminate any Work Order, if activities or Services have not yet commenced, on [*] written notice.
- (h) In the event Client, in its sole discretion, changes the final packaging presentation of Finished Drug Product and Company is unable or unwilling (without costs or charges to Client) to accommodate changes, and/or if Client consolidates packaging services under a single vendor, Client may terminate Drug Product packaging services upon [*] notice. Termination will take effect upon completion of all binding Firm Orders outstanding at the time notification is provided. Changes in packaging shall not be deemed or considered Other Changes as contemplated in Section 3.4 above.

Termination pursuant to Section 13.3(b) may be effected only with respect to the API or Drug Product and related Article of this Agreement to which the material breach relates and shall be effected by delivering written notice of such termination to the other Party. Termination shall be effective upon the date of such written notice unless a later date is specified in such written notice.

13.4 Effect of Termination. Upon termination or expiration of this Agreement in its entirety or with respect to any particular Services or Drug Product(s):

- (a) Cessation of Activities. Upon termination or expiration of this Agreement, or any Services or Drug Product(s), Company shall stop performing Services and each Party shall return to the other any Confidential Information of such other Party subject to such termination or expiration. Client shall pay for

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the cost of work, materials used for the project and Services performed through the effective date of the termination, reasonable project shut down costs, and Company's cost of all materials and Services irrevocably incurred which cannot be reallocated and any applicable Cancellation Fees. Any unconsumed materials may be returned to Client at Client's sole cost and expense, or credited toward future Services, where permissible.

(b) **Payment of Minimum Order Requirement: Client to Take API or Drug Product.** In the event of termination of this Agreement or any Services or Drug Product(s) pursuant to Section 13.3(a) or 13.3(h) above by Client, Client shall pay Company any balance remaining of any Minimum Order Requirement (as set forth in Section 4 for API and Section 5 for Drug Product) in the same manner as set forth herein. Further, Client shall, at its option and with respect to any API or Drug Product that are subject to termination, be permitted to take delivery for any Raw Materials with applicable cost and handling, work-in-process or finished API or Drug Product (at prices then in effect under Appendix B-1, B-2 or B-3).

(c) **Firm Orders.** In the event of termination of this Agreement or any Services, pursuant to the terms set forth herein, Firm Orders (as set forth in Section 4.2(d) for API and Section 5.2(c) for Drug Product) with respect to API and/or Drug Product(s) not yet started, may be cancelled at Client's option. Provided, if requested by Client in writing, Company will complete the Manufacture of any work-in-process or scheduled work that is subject to a valid and effective Firm Order on the date on which the termination is effective. Once such work-in-process or scheduled work is completed, the resulting API and/or Drug Product(s) shall be delivered in accordance with Client's Firm Orders and paid for by Client in accordance with the Purchase Prices initially set forth in Appendix B-1, B-2 or B-3.

(d) **Technical Transfer.** In the event of expiration or earlier termination of this Agreement, Client may, at its sole expense and by written notice to Company, seek reasonable assistance from Company with respect to the transfer to another manufacturer or third party of the then-current process for Manufacturing API and/or Drug Product ("Technology Transfer"). Following Company's receipt of this notice, the Parties will establish, in good faith, a schedule and plan to effect the Technology Transfer and Company will thereafter reasonably cooperate with Client in implementing the plan. Upon written approval of the project plan by the Parties and agreed payment schedule to Company by Client, Company shall perform the related activities reasonably necessary to effect such Technology Transfer in a timely manner. As part of the Technology Transfer, Company will make available for collection one (1) copy of all Documentation (to the extent not previously delivered to Client) generated pursuant to the Manufacturing Services up to the date of termination or expiration of this Agreement including Batch records, development reports and production process documentation.

13.5 Survival. Notwithstanding anything else contained herein, the Parties agree that the provisions which by their nature should survive termination or expiration of this Agreement, including any Work Order entered hereunder, shall survive expiration or earlier termination of this Agreement and specifically agree that the following provisions shall survive the termination of this Agreement: the definitions of Article 1 to the extent such definitions pertain to terms in surviving provisions, Articles 6, 7, 8, 9, 11, 12, 13, 14, 15 in their entirety, and Sections 2.3, 3.4 through 3.13, 4.2, 4.3, 5.2, 5.3, 10.1(f), 10.1(j), 16.9, 16.14, 16.15, and 16.16.

ARTICLE 14 **CONFIDENTIALITY AND PUBLIC DISCLOSURE**

14.1 Company will hold in strict confidence, and shall not disclose to any third party without Client's prior written consent, all proprietary or confidential information concerning all materials and information provided by Client (collectively, "Client Information"). Company further agrees that it shall not use Client Information for any purpose other than providing Services for Client under this Agreement and any Work Order issued hereunder.

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14.2 Client will hold in strict confidence, and shall not disclose to any third party without Company's prior written consent, all proprietary or confidential information and materials belonging to Company ("Company Information").

14.3 "Confidential Information" shall mean Client Information and Company Information. Confidential Information also shall include all of a Party's written or oral information, disclosed by, or made available to the other Party (whether or not it has been identified as confidential) that by the nature of the information or the circumstances surrounding disclosure ought reasonably to be treated as confidential and/or proprietary, including, but not limited to, any oral, written, graphic or machine-readable information including any software code, trade secret, patent application, drawing, or claim, information, data, and data results, price, technique, protocol, invention, idea, process, formula, sample, compound, extract, media, vector and/or cell line and procedures and formulations for producing any such sample, compound, extract, media, vector and/or cell line, any process, formula or data relating to any research project, work in process, future development, engineering, manufacturing, marketing, servicing, financing or personnel matter relating to a Party, its present or future products, sales, suppliers, clients, customers, employees, investors, or business. Without limiting the generality of the foregoing, any non-public information regarding or related to a Party's business, products, drugs, compounds or chemical structures shall be deemed such Party's Confidential Information. Each Party may disclose Confidential Information only to its, and its subsidiaries' and Affiliates', directors, officers and employees who have need to know Confidential Information for the purposes of this Agreement, and each Party will be responsible for ensuring that all its, and its subsidiaries' and Affiliates', directors, officers, and employees to whom Confidential Information is disclosed will also observe such obligations of confidentiality and non-use as provided herein.

14.4 The above confidentiality obligation shall not apply or shall cease to apply to any information which the receiving Party can demonstrate by documentary proof:

- (a) is already in the possession of the receiving Party at the time it is disclosed by the disclosing Party and not subject to a prior confidentiality agreement, or confidentiality protection contained in a separate, pre-existing agreement;
- (b) is in the public domain at the time it is disclosed by the disclosing Party;
- (c) enters the public domain through sources independent of the receiving Party and through no fault of the receiving Party;
- (d) is lawfully obtained by the receiving Party without any confidentiality restrictions from a third party who has a right to disclose such information to the receiving Party;
- (e) has been at any time developed by the receiving Party independently of disclosure from the disclosing Party; or
- (f) to the limited extent necessary in order to comply with Applicable Law(s) or the order or requirement of a court, administrative agency, or other governmental body; provided, however, that the receiving Party shall provide prompt notice of such court order or requirement to the disclosing Party to enable the disclosing Party to seek a protective order or otherwise prevent or restrict such disclosure.

14.5 Neither Party (nor any of their respective subsidiaries and Affiliates) shall issue any press release or make any public announcement with respect to this Agreement and the transactions contemplated hereby without obtaining the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed), except as may be required by Applicable Law(s) upon the advice of counsel and only if the disclosing Party provides the non-disclosing Party with a reasonable opportunity to first review the release or other public announcement, to the extent practicable.

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14.6 These confidentiality obligations shall survive termination or expiration of this Agreement for a period of [*]. Any trade secrets shall remain protected by the confidentiality obligations contained in this Article 14 in perpetuity.

ARTICLE 15
INTELLECTUAL PROPERTY

15.1 Company acknowledges that Client Information, Client's Pre-Existing Intellectual Property, and Client-supplied materials provided to Company pursuant to this Agreement shall be and remain the sole and exclusive property of Client. Likewise, Client acknowledges that Company's Pre-Existing Intellectual Property utilized pursuant to this Agreement shall be and remain the sole and exclusive property of Company.

15.2 All rights, title, and interest to any Arising Intellectual Property shall be the exclusive property of Client to the extent such Arising Intellectual Property is directly related to the Client API or Drug Product(s) or in any way incorporates or relies upon Client Information, Client Confidential Information or Client's Pre-Existing Intellectual property ("Client Arising Intellectual Property"). Company hereby assigns to Client all rights, title and interest in and to Client Arising Intellectual Property. Company will, at Client's request and expense, do all reasonable acts and things and execute all documents as Client may reasonably request, to transfer and vest in Client the ownership and registration of Client Arising Intellectual Property rights, and thereafter Client shall be responsible for and shall control, at its sole expense, the preparation, prosecution, maintenance and enforcement of all patent applications, resulting patents, and any other forms of Client Arising Intellectual Property.

15.3 Client agrees that, as between Company and Client, Company shall own all Arising Intellectual Property that (i) is not derived from, reliant upon, based upon or otherwise incorporate any Client Information, Client's Confidential Information, Client's Pre-Existing Intellectual Property, Client Arising Intellectual Property, or Client-supplied materials, and (ii) is not directly related to the API or Drug Product(s) ("Company Arising Intellectual Property"). The Parties acknowledge and agree that Company may develop Company Arising Intellectual Property, in the course of fulfilling its obligations under this Agreement, which improvements are a result of Company's expertise and are of general applicability to Company's business of providing services for a variety of organizations other than Client. Company shall not incorporate any Company Pre-Existing Intellectual Property or Company Arising Intellectual Property into the Drug Product without (a) Client's written consent and (b) the grant of a license on commercially reasonable terms, with the right to grant and authorize sublicenses, by Company to Client under any and all such Company Pre-Existing Intellectual Property or Company Arising Intellectual Property incorporated into or used in the Manufacturing of the API and/or Drug Product, to manufacture, market, develop, sell, and otherwise Commercialize the Drug Product, which such license shall be fully-paid, perpetual and royalty free during the period Company Manufactures API and/or Drug Product on behalf of Client. To the extent that any Company Pre-Existing Intellectual Property or Company Arising Intellectual Property is incorporated into the API and/or Drug Product, Company hereby grants Client a fully-paid, perpetual and royalty free license to market, develop, sell, and otherwise Commercialize the API and/or Drug Product.

ARTICLE 16
MISCELLANEOUS

16.1 Successors and Assigns. This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors and permitted assigns. No assignment by either Party of this Agreement or any of its rights or obligations hereunder shall be permitted, nor shall it be effective as between the Parties, unless and until the assignee shall have executed and delivered to the other Party an instrument in writing reasonably satisfactory to the other Party pursuant to which the assignee covenants in writing to be bound by all the obligations of the assigning Party hereunder. No assignment shall relieve the assignor of any of its obligations hereunder. Client shall not be prevented from or otherwise required to obtain Company consent or provide any other covenants to Company to the

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extent that Client provides written notice to Company prior to any assignment of this Agreement to a parent, subsidiary or Controlled Affiliate.

Except in the case of the sale of all of Client's outstanding shares of stock and/or assets or a Client merger with another entity, in the event any Drug Product is sold, Client shall require as a condition of the sale that the purchaser honor all of Client's outstanding purchase orders, any pending Client Minimum Order Requirements and the termination notice requirements in this Agreement.

16.2 Notices. Any notice required or permitted under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be sent by hand, recognized overnight courier, confirmed facsimile transmission, or registered or certified mail service, postage prepaid, return receipt requested, to the following addresses or facsimile numbers of the Parties:

Client:

Trevena, Inc.
955 Chesterbrook Blvd.
Suite 200
Chesterbrook, PA 19087
Attn: Michael Lark
Fax: (610) 354-8850

With a copy to: General Counsel, located at the above address and fax number

Company:

Alcami Corporation
2320 Scientific Park Drive
Wilmington, NC 28405
Attn: Legal Department
Fax: (910) 815-2340

With a copy to: Chief Commercial Officer, located at the above address and fax number

All notices shall be deemed received (a) upon receipt when hand-delivered, (b) two (2) business days after deposit with a recognized overnight courier, (c) upon confirmation of delivery when sent by facsimile, and (d) five (5) business days after deposit in registered or certified mail service. A Party may change its contact information immediately upon written notice to the other Party in the manner provided in this Section.

16.3 Waiver. No delay on the part of Company or Client in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any waiver on the part of either Party of any right, power or privilege hereunder operate as a waiver of any other right, power or privilege hereunder, nor shall any single or partial exercise of any right, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder. Any provision of this Agreement may be waived if, and only if, such waiver is in writing and signed by the Party against whom the waiver is to be effective.

16.4 Entire Agreement. This Agreement, the Quality Agreement, and Work Orders constitute the entire agreement between the Parties with respect to the Manufacture of API and Drug Product(s) by Company for Client from the Effective Date and supersede all prior agreements, understanding and negotiations, both written and oral, between the Parties with respect to the subject matter of this Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

16.5 Amendment. This Agreement, the Quality Agreement and any Work Order may be modified or amended only by written agreement of the Parties hereto.

16.6 Cooperation. Each Party will execute and deliver all such instruments and perform all such other acts as the other Party may reasonably request to carry out the transactions contemplated by this Agreement.

16.7 Headings. All headings herein are for convenience only and shall not be construed as a limitation of the scope of the particular sections to which they refer.

16.8 Counterparts. This Agreement may be executed by facsimile or email and in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute a single instrument.

16.9 Governing Law; Jurisdiction. This Agreement shall be governed and construed in accordance with the laws of the State of Delaware excluding any choice of law rules which may direct the application of the law of another state.

16.10 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of any Party hereto under this Agreement will not be materially and adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement will be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar to the terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties herein.

16.11 No Third Party Rights. Except as otherwise expressly set forth herein, no provision of this Agreement shall be deemed or construed in any way to result in the creation of any rights or obligations in any person not a Party to this Agreement.

16.12 Force Majeure. If either Party is prevented from complying, either totally or in part, with any of the terms or provisions set forth herein by reason of force majeure, including, by way of example and not of limitation, fire, flood, explosion, storm, hurricane, riot, war, rebellion, accidents, equipment failure, acts of God, or acts of governmental agencies or instrumentalities, in each case to the extent beyond its control despite its commercially reasonable efforts to avoid, minimize, and resolve such cause as promptly as possible, said Party shall (a) provide written notice of same to the other Party, and (b) subject to the obligations set forth above with respect to said Party's efforts to remove the disability, its obligations that are prevented from compliance by such force majeure are suspended, without liability, during such period of force majeure. Said notice shall be provided within ten (10) business days of the occurrence of such event and shall identify the requirements of this Agreement or such of its obligations as may be affected. The Party so affected shall give to the other Party a good faith estimate of the continuing effect of the force majeure condition and the duration of the affected Party's nonperformance.

16.13 No Other Relationship. It is expressly agreed that Company, on the one hand, and Client, on the other hand, shall be independent contractors and that nothing contained herein shall be deemed to create any joint venture or partnership between the Parties hereto, and, except as is expressly set forth herein, neither Party shall have any right by virtue of this Agreement to bind the other Party in any manner whatsoever.

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16.14 Dispute Resolution.

(a) **Negotiated Settlement.** In the event of a dispute regarding payment or the performance of Services pursuant to this Agreement (each, a "Dispute"), the Parties shall endeavor to negotiate in good faith an agreeable solution. If after [*] following receipt of a Party's written notification of a Dispute such Dispute has not been resolved, the Dispute shall be brought to the attention of the senior management of each Party and such senior manager or his/her designee will negotiate in good faith to define and implement a final resolution. The intent of this Section 16.14(a) is to encourage the Parties to work together to resolve any Dispute without having to rely on arbitration or any other legal proceeding. However, nothing in this Section 16.14(a) shall prevent or inhibit either Party to institute any other action to resolve such Dispute(s).

(b) **Binding Arbitration.** If not resolved in accordance with the preceding paragraph (a), then any controversy or claim arising out of or relating to this Agreement, or the breach thereof, shall be settled by arbitration administered by the American Arbitration Association in accordance with its Commercial Arbitration Rules, and judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof.

16.15 Destruction of API or Drug Product. Subject to the provisions of Section 6.2, notwithstanding any other provisions of this Agreement, the Quality Agreement or any Work Order, Client agrees to dispose of any API or Drug Product(s) at Company's direction that are nonconforming, fail to meet Specifications, are determined by the Parties or any third party not to meet quality standards, and otherwise are not usable due to a potential risk to health or safety. If such API and/or Drug Product is usable then return or destruction shall be at Client's discretion, provided that Client agrees to provide a statement or other reasonable documentation requested by Company regarding Client's intended use for the API and/or Drug Products. Any API or Drug Product(s) subject to a dispute shall not be disposed of, or otherwise used or distributed prior to resolution by the Parties. Each Party shall act in good faith and shall cooperate with the other Party and with any qualified independent expert in connection with an investigation or resolution of a dispute. At Client's direction, Company shall dispose of any Nonconforming Product(s) returned by Client in accordance with Applicable Law(s) at Company's cost if the nonconformity is directly attributable to Company's gross negligence or willful misconduct or Company's breach of this Agreement, otherwise at Client's cost.

16.16 No Solicitation of Employees. Company and Client agree that neither Party will directly nor indirectly recruit a current or former employee of the other Party who has performed any work in connection with this Agreement provided that newspaper, internet or other advertisements to fill job openings shall be deemed not to be "solicitation" hereunder. This provision shall remain in effect during the Initial Term and any Renewal Period of this Agreement and for [*] thereafter. Any exceptions to this provision must be in writing and signed by an authorized representative of each Party.

16.17 English Language. The Parties to this Agreement have agreed that this Agreement and all related documents shall be drafted in the English language only.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the Effective Date.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Trevena, Inc.

Alcami Corporation

Name: _____
Title: _____
Date: _____

Name: Syed T. Husain
Title: Chief Commercial Officer
Date: _____

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Appendix A
Sample Work Order Template

WORK ORDER #
Dated

The services described herein will be provided in accordance with the terms and conditions of the Master Commercial Supply Agreement dated October 20, 2017 (the "Agreement") between Trevena, Inc. (hereinafter referred to as "Client") and Alcami Corporation ("Company").

The following documents are attached to this Work Order and shall be incorporated herein:

| | |
|---------------|------------------------------------|
| ATTACHMENT I | DESCRIPTION OF SERVICES AND BUDGET |
| ATTACHMENT II | PAYMENT SCHEDULE AND TERMS |

The Agreement and this Work Order together constitute the entire agreement with respect to the Services to be provided hereunder. In the event a Client purchase order or Company quotation or invoice contains any terms or conditions which are different from those contained in the Agreement and this Work Order, the terms of the Agreement and this Work Order shall control. In the event of a conflict between any provision of the Agreement and any provision of this Work Order, this Work Order shall control with respect to any inconsistencies over pricing, payments, budgets, pass-through expenses (and any sourcing or handling fees), shipping terms or the description of Services, and the Agreement shall control in all other respects.

All terms and conditions provided in the Agreement executed by the parties referenced above remain unmodified and in full force and effect.

ACKNOWLEDGED, ACCEPTED AND AGREED TO:

Trevena, Inc.

Alcami Corporation

Name: _____
Title: _____
Date: _____

Name: _____
Title: _____
Date: _____

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Appendix B-1
API Batch Sizes and Cost

[*] (1 page omitted)

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

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Appendix B-2
Drug Product - Finished
Batch Sizes and Cost

[*] (2 pages omitted)

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

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Appendix B-3
Drug Product - Bulk
Batch Sizes and Cost

[*] (2 pages omitted)

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

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Appendix C
Facilities

[*] (1 page omitted)

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

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Appendix D-1
Initial API Release Specifications (for reference)*

**Parties agree to negotiate in good faith an Amendment to replace this Appendix D-1 with final Specifications upon approval of Client's Marketing Authorization.*

[*] (1 page omitted)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Appendix D-2
Initial Drug Product Release Specifications (for reference)*

**Parties agree to negotiate in good faith an Amendment to replace this Appendix D-2 with final Specifications upon approval of Client's Marketing Authorization*

[*] (1 page omitted)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Appendix D-3
Initial CML-474 Release Specifications (for reference)*

**Parties agree to negotiate in good faith an Amendment to replace this Appendix D-3 with final Specifications upon approval of Client's Marketing Authorization*

[*] (1 page omitted)

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

DEVELOPMENT AND SUPPLY AGREEMENT

by and between

PFIZER, INC.

and

TREVENA, INC.

Dated as of December 15, 2016

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DEVELOPMENT AND SUPPLY AGREEMENT

THIS DEVELOPMENT AND SUPPLY AGREEMENT (“*Agreement*”) is made as of this 15th day of December, 2016 (the “*Effective Date*”) by and between Trevena, Inc., a company formed under the laws of Delaware and having its principal offices at 1018 West 8th Avenue, Suite A, King of Prussia, Pennsylvania 19406 (“*Trevena*”) and the Pfizer CentreOne group of Pfizer, Inc., a corporation formed under the laws of Delaware and doing business at 275 North Field Drive, Lake Forest, Illinois 60045, on behalf of itself and any one or more of its Affiliates (collectively, “*Pfizer*”). Pfizer and Trevena collectively shall be referred to as the “Parties” and each as a “Party.”

RECITALS

WHEREAS, Trevena owns rights to the pharmaceutical compound known as Oliceridine (TRV130) in development for the treatment of moderate to severe acute pain, and, upon receiving Regulatory Approval (as defined below), wishes to develop and market the Oliceridine (TRV130) product in standard glass vials with flip-off caps or as may otherwise be directed by Trevena;

WHEREAS, Trevena and Pfizer desire that Pfizer assist Trevena in the development of the Oliceridine (TRV130) product for commercial distribution;

WHEREAS, to govern the initial development of Oliceridine (TRV 130), on or about May 26, 2016, Trevena and Pfizer executed a certain Letter of Engagement for the Development and Manufacture of Trevena’s Proprietary Pharmaceutical Compound, Oliceridine (TRV 130) (the “*LOE*”) a copy of which is attached hereto and incorporated herein as Annex 1; and

WHEREAS, after Trevena has received all necessary Regulatory Approval (as defined herein) for Oliceridine (TRV130) product, the Parties desire that Pfizer manufacture and sell to Trevena certain of its commercial requirements for the Oliceridine (TRV130) product as set forth herein.

AGREEMENT

NOW THEREFORE, in consideration of the mutual covenants and representations contained in this Agreement and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1 DEFINITIONS

Certain Defined Terms

As used in this Agreement:

1.1 “*Active Pharmaceutical Ingredient*” or “*API*” means the active pharmaceutical ingredient of the Drug in bulk form that Trevena will provide to Pfizer for incorporation into the Products, as specified in the Statement of Work.

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- 1.2 **“Active Pharmaceutical Ingredient Specifications”** means the detailed description and parameters of the API, as set forth on Schedule 1.2.
- 1.3 **“Adverse Drug Experience(s)”** has the meaning as set forth in 21 CFR 310.305 or the substantial equivalent provisions of other Applicable Laws.
- 1.4 **“Affiliate”** means any corporation, firm, partnership or other legal entity, which directly or indirectly controls, is controlled by or is under common control with a Party to this Agreement. A Party will be deemed to “control” another entity if it (a) owns at least fifty percent (50%) of the equity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of such other entity, or (b) has the power by contract or otherwise to direct the management and policies of the entity.
- 1.5 **“Applicable Law”** means all laws applicable to the manufacture, processing, distribution, sale and use of the Product as may be amended and in effect from time to time, including the FD&C Act and all applicable federal, state and local laws and regulations, all applicable cGMP and all other applicable laws and regulations, of any other applicable jurisdiction.
- 1.6 **“Business Day”** means any day of the week which is not a Saturday, Sunday or legal holiday observed by the United States Federal Government or the State governments of Illinois, Kansas, New York and Pennsylvania.
- 1.7 **“Certificate of Analysis”** means a document, signed by an authorized representative of Pfizer, describing the Product Specifications of and testing methods applied to the Product, and the results thereof.
- 1.8 **“Certificate of Compliance”** means a document signed by an authorized representative of Pfizer attesting that a particular lot, batch or run was manufactured in accordance with cGMP, Applicable Law, and the Product Specifications. The Certificate of Compliance may be included within the Certificate of Analysis, or separately, if required by Trevena for regulatory purposes or Applicable Law.
- 1.9 **“cGMP”** means those principles and guidelines of good manufacturing practices as current Good Manufacturing Practices is defined in the FDA rules and regulations, including the United States regulations set forth at 21 CFR Parts 210-211, as appropriate and as the same may be amended from time to time, and the corresponding requirements of any other applicable jurisdiction.
- 1.10 **“Commercial Year”** means each period of twelve (12) consecutive calendar months during this Agreement beginning on January 1st and ending December 31st, except for the first Commercial Year, which shall commence on the first day of the month after the month in which Trevena makes its first *bona fide* commercial sale of a Product to a non-Affiliate customer and ends on December 31st of the following year.
- 1.11 **“Components”** means the excipients, the vials and the component parts of the vials into which the Drug will be filled, and the labeling, packaging, ancillary goods, shipping materials

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and other items to be procured by Pfizer from various components supplier(s) to manufacture the Products in accordance with the Product Specifications.

1.12 **“Confidential Information”** has the meaning set forth in Section 11.1.

1.13 **“Controlled Substance”** means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of 21 U.S.C., §802(6).

1.14 **“Drug”** means Trevena’s proprietary human pharmaceutical compound known as TRV130 (Oliceridine), an intravenous G Protein-biased ligand of the μ -opioid receptor used in the treatment of moderate to severe acute pain.

1.15 **“Drug Master File”** or **“DMF”** as used in Section 4.3, means the drug master file (as such term is defined in 21 C.F.R. Part 314.420) that may be used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of drug products intended for human use.

1.16 **“DEA”** means the United States Drug Enforcement Agency.

1.17 **“Facility”** means Pfizer’s pharmaceutical manufacturing plant at McPherson, Kansas, or such other manufacturing facility mutually agreed to by the Parties in writing.

1.18 **“FDA”** means the United States Food and Drug Administration or any successor entity thereto.

1.19 **“FD&C Act”** means the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), as amended from time to time.

1.20 **“Intellectual Property”** or **“IP”** means all inventions, formulations, processes, works of authorship, and any and all rights under U.S. and/or foreign patents, trade secrets, know-how, copyrights, trademarks and other industrial or intangible property rights of a similar nature and moral rights; all rights pursuant to grants and/or registrations worldwide in connection with the foregoing and all other rights with respect thereto; all rights under applications for any such grant or registration, all rights of priority under international conventions to make such applications and the right to control their prosecution, and all rights under amendments, continuations, divisions and continuations-in-part of such application; and all rights under corrections, reissues, patents of addition, extensions and renewals of any such grant, registration and/or right.

1.21 **“Manufacturing Process”** means any and all processes (or any step in any process) that is provided to Pfizer by Trevena and that will be used to manufacture the Product, as evidenced in the batch documentation and/or development reports.

1.22 **“Master Batch Record”** shall mean the document that defines the manufacturing methods, materials, and other procedures, directions and controls associated with the manufacture and testing of the Product, which may be amended in writing from time to time by mutual agreement of the Parties.

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1.23 “*MSDS*” means the Material Safety Data Sheet for the Product or the API containing such information as may be required by applicable government agencies.

1.24 “*Product*” means the Drug in final dosage form, filled, finished and packaged in standard glass vials with flip-top seals, or as otherwise mutually agreed by the Parties.

1.25 “*Product Specifications*” means those product, labeling and performance specifications for the Product filed with and approved by the relevant Regulatory Authority, including Product formulae, labeling, and materials required for the manufacture of the Product that is to be purchased and supplied under this Agreement, as such are set forth on Schedule 1.25, which specifications may be amended by the Parties from time to time in accordance with this Agreement.

1.26 “*Quality & Technical Agreement*” means the quality agreement that will be negotiated and signed by authorized representatives of the Parties and which will govern the essential quality obligations of them in the manufacture, testing and release of the Products hereunder. The Quality & Technical Agreement may be amended or revised from time to time by the mutual written agreement of the Parties. A copy of the Quality & Technical Agreement is attached hereto and incorporated herein as Schedule 7.2.

1.27 “*Regulatory Approval*” means the pre- and post-approval, licenses, registrations or authorizations of any relevant Regulatory Authority, including the FDA and DEA, necessary for the manufacture, distribution, sale or use of the Product in any relevant jurisdiction in accordance with Applicable Law.

1.28 “*Regulatory Authority*” means any federal, state or local or other regulatory agency, department, bureau or other governmental entity (including the FDA and DEA), which is responsible for issuing approvals, licenses, registrations or authorizations necessary for the manufacture, import, sale and use of the Product in any relevant jurisdiction.

1.29 “*Term*” means, individually the Initial Term of this Agreement, or collectively the Initial Term and any Renewal Term, as those defined terms are used herein.

1.30 “*Territory*” means the United States of America, including the District of Columbia, the Commonwealth of Puerto Rico, all territories and possessions of the United States of America, United States military bases, and any other location over which the FDA has jurisdiction to regulate medicinal products intended for human use.

1.31 “*Third Party*” means any party other than Pfizer or Trevena and their respective Affiliates.

1.32 “*Waste*” means all rejects, improper goods, garbage, refuse, remainder, residue, waste water or other discarded material, including solid, liquid, semisolid, or contained gaseous material that arises from the manufacture of the Product, including rejected, excess or unsuitable materials, API and Products.

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**ARTICLE 2
PROJECT OVERVIEW**

2.1 General Principles

The Parties shall undertake a product development project ("**Project**") consisting of the development activities and applicable timelines set forth on Schedule 2.1 ("**Statement of Work**"). Under the Project, Pfizer shall assist Trevena to develop the Product and to obtain any required Regulatory Approval(s) in the Territory. Subject to the successful completion of the Project in accordance with the Statement of Work, and following receipt by Trevena of all necessary Regulatory Approvals, Pfizer then shall manufacture and deliver Product to Trevena for sale by Trevena as a human pharmaceutical product.

2.2 Commercially Reasonable Efforts

Each Party shall use all commercially reasonable efforts successfully to complete the Project. However, the Parties acknowledge and agree that neither of them can guarantee that the Project will be successful, nor warrants that a marketable product will result from the Project.

**ARTICLE 3
SERVICE FEES; SCOPE CHANGES; PROJECT MANAGEMENT**

3.1 Development Fees

Trevena shall pay Pfizer a non-refundable development fee (the "**Development Fee**") for its work under the Project in accordance with the payment schedule set forth in the tables on Schedule 3.1.

3.2 Stability Studies

In accordance with requirements of the Statement of Work, Pfizer will prepare pre-market, and if requested by Trevena, market-life stability batches of Products and perform stability studies ("**Stability Work**"). The essential obligations of the Parties regarding Stability Work and the charges therefor are set forth on Schedule 3.2.

3.3 Changes in Project Scope

(a) **Changes; Proposal** In the event (i) Trevena requests that changes be made to any material aspect of the Project or the Product Specifications, or (ii) technical difficulties require that Pfizer perform either additional work or repeat work, and such additional work is required not because of Pfizer's fault or negligence, or (iii) the Parties mutually agree to conduct additional work related to the subject matter of this Agreement, Pfizer shall provide Trevena with terms and conditions of any such additional, repeat or new work, including the scope of work, pricing, timeframes and responsibilities in a proposal to be mutually agreed upon in writing and signed by both Parties (each, a "**Proposal**"). Pfizer's pricing will include professional and other employees service fees quoted at its customary per/hour, per/person rates then in effect, relative to the work to be performed, consistent with its charges to other similarly-situated customers. Each Proposal shall reference this Agreement, shall be

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implemented as a change order when signed by the Parties, and the terms and conditions of this Agreement shall govern and control any and all such additional, repeat or new work; *provided, however*, that if any provision of any Proposal conflicts with this Agreement, the terms of this Agreement shall prevail with respect to all terms except pricing terms. Pfizer shall bear the costs and expenses of any changes to the Proposal or delays to the Project which are caused by Pfizer's requirement for Regulatory Authority approval or other authorizations (specifically, Drug Enforcement Agency ("**DEA**") quotas) which are not requirements of Applicable Law or occur as a result of Pfizer-specific policies that are not otherwise required by Applicable Law.

(b) **Expansion of Territory.** Trevena shall give Pfizer reasonable prior notice in the event that it desires to pursue marketing and sales activities for the Product in countries or geographic regions outside of the Territory. The Parties will then determine the preparatory work that may be required (if any) and upon agreement, Pfizer shall provide Trevena with all necessary additional technical/developmental and regulatory support, including, for example, regulatory support for Trevena's supplemental regulatory filings, packaging and product development, labeling, and relevant Regulatory Authority inspections. Any additional technical/developmental and regulatory support for such other countries or geographic regions shall be considered a change in Project scope and the Parties will agree to the reasonable incremental costs of such additional support in accordance with [Section 3.3\(a\)](#). Any additional pre-approval inspections of the Facility that may be required by relevant Regulatory Authorities as a result shall be reimbursed in accordance with [Section 7.5\(b\)](#). If Trevena chooses to engage Pfizer to manufacture the Product for marketing and sale outside of the Territory, such batches which are produced shall be applied to any and all of Trevena's Minimum Purchase Requirement as defined in [Section 6.8](#). Except as provided herein, nothing contained in this [Section 3.3\(b\)](#) shall grant any right to Pfizer, or obligate Trevena in any way to engage Pfizer to manufacture the Product for sale outside of the Territory.

(c) **Assignment Fee.** In the event that Trevena assigns or otherwise transfers substantially all of its rights and obligations under this Agreement to a Third Party pursuant to [Section 12.5](#), either to a commercial licensing partner or an acquirer of Trevena's business, [*] If a technology transfer is associated with the assignment, the specific technology transfer scope, activities and associated costs will be defined in a project plan.

3.4 Steering Committee; Project Manager

(a) **Steering Committee.** Pfizer and Trevena will jointly constitute a team ("**Steering Committee**") comprised of not less than [*] members from each Party (or such number as the Parties mutually agree) to oversee the work under the Statement of Work as well as commercial manufacturing with [*] representative from each of Trevena and Pfizer having the authority to make decisions on behalf of such Party. The Steering Committee representatives may invite other employees of the Parties or their Affiliates to the Steering Committee meetings, to serve in an advisory capacity as relevant to the matters at hand. The Steering Committee will be considered as a working committee that will have as its goal the prompt and mutually agreeable resolution of any financial, technical or quality issues that may arise in order to advance and preserve a harmonious relationship established by and between Pfizer and Trevena. Either Party may change its representatives on the Steering Committee at any time by written notice to the other Party.

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The Steering Committee shall meet at least quarterly or as otherwise may be necessary or agreed by the Steering Committee, which meetings shall occur by teleconference, videoconference or in person and may address any relevant issue a party wishes to call to the attention of the Steering Committee, to review past performance on mutually agreed upon metrics, discuss future partnership objectives, and to oversee the relationship between Trevena and Pfizer. The Steering Committee shall be responsible for performing the following functions:

- (i) reviewing business strategy;
- (ii) ensuring goal alignment;
- (iii) assessing and developing risk mitigations and/or redundancies;
- (iv) discussing market dynamics and impact to supply/demand; and
- (v) implementing procedures for project governance and the resolution of questions or disputes that may arise under this Agreement or the Project Statement of Work

(b) **Project Team; Project Manager.** Promptly upon execution of this Agreement, Pfizer and Trevena shall each designate such of their respective employees from product development, quality assurance, manufacturing, and project management to form a team ("**Project Team**") to direct the activities to be carried out under the Statement of Work. Each Party shall also designate one of its employees to act as its project manager (each, a "**Project Manager**"), who will be primarily responsible for communicating all instructions and information concerning the Project to the members of the Project Team. The Project Team and/or the Project Managers shall consult periodically during the performance of the Services, through face-to-face meetings, telephone conferences and/or videoconferences, at times to be mutually agreed upon by the Project Managers. Each Party may appoint a substitute or replacement Project Manager or a member(s) of the Project Team in the absence of its original Project Manager or original member(s) of the Project Team by notifying the other Party in writing of such substitution or replacement. Neither the Project Managers nor the Project Team shall have the right to modify, amend or waive any provision of this Agreement.

3.5 Development Supplies

Based on Trevena's final Product formulations, concentration and fill volume and the Parties' agreement to the final Product Specifications, Pfizer will manufacture the Products as engineering batches, validation batches and stability batches (collectively, the "**Development Supplies**") at the prices set forth in the Statement of Work. The Parties acknowledge that Development Supplies may include products utilized for development purposes only (e.g., in media fills, engineering runs, or as stability testing materials), which are not intended for commercial sale in the market; *provided, however*, that Pfizer will manufacture all validation batches of Product in accordance with cGMP, which, if permitted by Applicable Law, would allow Trevena to use such validation batches as part of its commercial supply. In accordance with a schedule to be mutually agreed by the Parties, Trevena shall issue its purchase order(s) for such Development Supplies at least [*] days before any requested delivery date. For the sake of clarity, all relevant provisions of Articles 5, 7, 8 and 9 also shall apply to the manufacture and delivery of the Development Supplies.

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ARTICLE 4
REGULATORY SUBMISSIONS; APPROVALS

4.1 Regulatory Assistance

Except as otherwise provided herein, Trevena will be solely responsible for obtaining and maintaining any Regulatory Approvals, licences, registrations or authorizations of any relevant Regulatory Authority required for the manufacture, distribution, sale and use of the Product in the Territory.

(a) **General Review.** In consideration of the Development Fees that Trevena will pay under the Statement of Work, upon Trevena's request, Pfizer will review those portions of Trevena's proposed regulatory submissions as relate to Pfizer's manufacturing, packaging and quality control, quality assurance, facilities, personnel, procedures and organization before the submissions are filed with relevant Regulatory Authorities. Pfizer will use its commercially reasonable efforts to complete its review of Trevena's submissions within [*] calendar days (but in any event, no later than [*] calendar days) after receipt and will promptly inform Trevena of any anticipated delays.

(b) **Responses to Regulatory Authorities.** At Trevena's request, Pfizer shall consult with and advise Trevena in responding to questions from a Regulatory Authority regarding Trevena's regulatory submission for the Product, *provided, however*, that Trevena shall have the final control over such submissions. Pfizer shall provide Trevena with cost estimates based on Pfizer's customary per/hour, per/person rates for professional and other employees then in effect, relative to the work to be performed, consistent with its charges to other similarly-situated customers for any additional review and consultation as may be required by the Regulatory Authority (for example, for technical responses to an FDA finding of deficiency, should one arise). If Trevena approves such costs in writing, Trevena shall reimburse Pfizer for such approved costs upon completion of the work and within [*] days of receipt of Pfizer's invoice.

4.2 Facility Approvals

Pfizer will secure and maintain in good order, at its sole cost and expense, such current governmental registrations, licences, permits and approvals as are required by Regulatory Authorities in order for Pfizer to perform all of its obligations under this Agreement and to manufacture the Products at the Facility.

4.3 Access to Drug Master Files

Where applicable, Pfizer will grant Trevena reference rights to all Drug Master Files and Site Master Files necessary to support Trevena's regulatory filings for the Product. To affect this, Pfizer will execute certain letters of authorization, which will be delivered to the appropriate Regulatory Authorities to permit them to consult Pfizer's DMFs and SMFs in their review of Trevena's Product regulatory submissions. Pfizer will send copies of such authorization letters to Trevena. Pfizer will update its DMFs and SMFs annually and will inform Trevena prior to making any modifications thereto in order to permit Trevena to amend or supplement any affected regulatory submissions and filings for Product.

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4.4 User Fees

Trevena will pay any Regulatory Authority user fees, if any, which may become payable for the Product.

4.5 Ownership of Regulatory Approvals

The Parties agree that Trevena will be the sole and exclusive owner of all right, title and interest in and to all Regulatory Approvals related to the API and Product and any submissions for such Regulatory Approvals. Pfizer will reasonably assist Trevena in the preparation of all documents necessary to affect Trevena's rights in such Regulatory Approval applications and submissions, at the expense of Trevena. Trevena will provide to Pfizer for its files a final copy of the CMC section related to Pfizer activities of any such applications and/or submissions for Regulatory Approval unless otherwise prohibited by Applicable Law.

ARTICLE 5 PRODUCT MANUFACTURING

5.1 Purchase and Sale of Products

Upon Trevena's receipt of all necessary Regulatory Approvals pursuant to the terms and conditions of this Agreement and for the term of this Agreement, Pfizer shall manufacture, sell and deliver to Trevena and Trevena will purchase from Pfizer certain of its requirements for the Product for sale in the Territory at the prices set forth herein. Trevena agrees that [*] to be marketed, distributed and sold in the Territory. Beginning with [*], and thereafter, throughout remainder of the Term, provided that Pfizer is not in material default of its obligations under this Agreement, Trevena agrees that [*].

5.2 Manufacturing Standards; Changes

(a) **Product Specifications.** The Product Specifications are set forth on Schedule 1.25. Pfizer will manufacture the Product in accordance with the Specifications, cGMP and all Applicable Laws, as then in effect. The Product Specifications may be modified from time to time in accordance with the provisions of Section 5.2(b) and Section 7.7.

(b) **Changes.** The Parties agree that if Trevena wishes to amend any aspect of its Manufacturing Process or the Product Specifications ("**Discretionary Changes**"), Trevena will provide written notice thereof to Pfizer for Pfizer's review and approval, which approval Pfizer will not unreasonably withhold, except where such change would have a material adverse impact on Pfizer's manufacturing operations in the area of the Facility where the Product is to be manufactured. Furthermore, each Party will promptly notify the other of any new instructions or changes to the Product Specifications that are required by any Regulatory Authority, change in Applicable Laws or other regulatory requirements, or by medical concerns related to the toxicity, safety and/or efficacy of the Products ("**Required Changes**"). The Parties will confer with respect to the best means to comply with such instructions or change requirements; *provided, however*, that Pfizer will comply with any reasonable instructions issued by Trevena with respect to implementing any Required Changes. An analytical

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improvement will be considered to be a Discretionary Change unless requested or required by a Regulatory Authority, in which case such improvement will be considered a Required Change.

(c) **Costs of Changes.** Except as may otherwise be agreed in the Statement of Work, [*] any and all costs with respect to Required Changes that are required to bring its manufacturing operations into compliance with Applicable Laws, and [*] any and all other costs related to Required Changes affecting the Product, which are unrelated to bringing Pfizer's manufacturing operations into compliance with Applicable Laws. Any Discretionary Changes to the Product Specifications or the Manufacturing Process initiated by either Party will be agreed to by the Parties, including which Party or Parties will be responsible for the funding of such Discretionary Changes. All Discretionary or Required Changes will be implemented in accordance with the change control provisions of the Quality & Technical Agreement.

(d) **Cost Reduction Changes Prior to Commercialization.** The Steering Committee and the Project team shall undertake good faith discussions to consider measures to reduce the cost/pricing of the Product resulting from business, manufacturing and/or other changes which may be necessitated due to phase III clinical data and/or regulatory feedback. These changes could include, among other things:

- (i) Different fill volume and vial size combinations [*];
- (ii) [*]; and
- (iii) [*]

Any such measures to be undertaken must be first approved by the Steering Committee and will be implemented in accordance with the scope change provisions of [Section 3.3\(a\)](#).

5.3 Pre-Approval Manufacture

Pfizer agrees to manufacture and supply those quantities of Product requested in firm Purchase Orders by Trevena that are necessary to validate Pfizer's manufacturing Facilities, obtain the necessary Regulatory Approval for Pfizer's production of the Product and build Trevena's pre-Regulatory Approval inventory as may be requested by Trevena. Trevena will pay for such Products in accordance with the terms and conditions of this Agreement, irrespective of whether the Products ultimately receive Regulatory Approval.

5.4 Active Pharmaceutical Ingredient

(a) **API Supply.** Unless otherwise provided in the Project Statement of Work or this Agreement, the following provisions will apply to supplies of API by Trevena to Pfizer.

(i) **Trevena API Supply.** Pfizer will manufacture the Product for Trevena from API that Trevena shall supply to Pfizer [*]. Trevena will supply API to Pfizer in quantities sufficient to satisfy Pfizer's gross manufacturing requirements of the Product, as specified in [*] purchase orders submitted by Pfizer and on lead times discussed and agreed by the Project Managers, but in no event later than [*] days prior to the scheduled start of manufacture. Pfizer will use the API received from Trevena only for the development activities contemplated by this

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Agreement and the manufacture of Product for Trevena and for no other purpose. Pfizer agrees that it will not acquire any right, title or interest in or to the API and will not distribute, sell or otherwise transfer the API to any Third Party or generic manufacturer or otherwise use the API for the manufacture of any generic version of the Product unless otherwise directed by Trevena in writing. Trevena will deliver the API, [*], the Facility pursuant to [*] purchase orders that Pfizer issues to Trevena. Pfizer shall be solely responsible, at its own cost and expense, for the proper storage and handling of all API once it has been accepted into the Facility, including separate storage as a Controlled Substance if and as required by the DEA. In accordance with DEA regulations, Pfizer will produce and maintain complete and accurate records regarding the receipt, storage and use of the API under this Agreement and will provide to Trevena a copy of its year-end Controlled Substance reconciliation report pertaining to the API. Any API, which is not used as provided in this Agreement shall be returned to Trevena or otherwise disposed as directed by Trevena in writing in accordance with Section 10.6(b).

(ii) **API Documentation; Samples.** With each delivery of API, Trevena will include a certificate of analysis, signed by an authorized individual of Trevena (or its designated API supplier) containing basic information regarding the API, including (A) the manufacturing date of the batch/lot delivered, (B) the batch/lot number, and (C) the quantity of API in such batch/lot as shipped to Pfizer (will be provided on the certificate of analysis or an equivalent document such as a bill of lading or packing slip).

(iii) **Incoming Testing.** Within [*] days of Pfizer's receipt of any API supplied by Trevena, Pfizer will (A) perform an identification test on the API and confirm the shipment quantity and (B) notify Trevena in writing of any inaccuracies with respect to quantity or certificate of analysis or of any claim that any portion of the shipment fails the identification test. Subject to the provisions of Section 5.4(a)(iv), in the event Pfizer notifies Trevena of any deficiency in the quantity or quality of API received, Trevena will promptly ship to Pfizer, [*], the quantity of API necessary to complete the API shipment. In the event Pfizer notifies Trevena that the API shipment does not conform to the Active Pharmaceutical Ingredient Specifications, Trevena will have the right to confirm such findings at the Facility.

(iv) **API Dispute Resolution.** If Trevena contends that such shipment of API conforms to the API Specifications and Pfizer does not concur, the Parties will submit samples of such shipment to a mutually acceptable independent laboratory for testing. If such independent laboratory determines that the shipment conforms to the API Specifications, Pfizer will bear all expenses of shipping and testing such shipment samples. If such independent laboratory confirms that such shipment does not meet the API Specifications, Trevena will replace, at no cost to Pfizer, the portion of the API shipment which does not conform to the API Specifications and reimburse Pfizer for all expenses of shipping and testing the shipment samples. Pfizer will dispose of any nonconforming portion of any API shipment as directed by Trevena, at Trevena's expense.

(b) **Title.** Notwithstanding [*] Trevena will retain title to the API while it is in the Facility. [*] and accepted by Pfizer, subject to the limitation in Section 5.4(c). Pfizer will mark the API as the property of Trevena and not permit any lien to be placed upon the API arising out of any act or omission of Pfizer.

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(c) **Loss and Replacement of API.** In the event of loss or damage of any API delivered hereunder or the failure of Product to meet Product Specifications, Trevena will supply to Pfizer replacement API according to the terms set forth in Section 5.4(a), except as otherwise provided herein. If the need for replacement of such API results from a material breach of any obligation of Pfizer under this Agreement or any negligent or intentional act or willful omission by Pfizer in the manufacture, handling or storage of Product or API, Trevena will supply to Pfizer replacement API and Pfizer will be responsible for the cost of the replacement API equal to Trevena's purchase cost/kg (as evidenced by Trevena's invoices) plus all related shipping and handling charges.

(d) **Maximum Liability.** In no event shall Pfizer's liability for API replacement costs exceed [*] This Section 5.4(d) states Trevena's sole remedy, and Pfizer's sole liability, with respect to any claim arising under Sections 5.4(c), 5.4(e), 5.8(h) and 7.10(b). For purposes of this Section 5.4(d), the term "Occurrence" shall mean any incident involving (A) the handling and storage of Trevena's API prior to the start of compounding operations, (B) storage of the Product after completion of filling, testing and release operations, but (C) explicitly excludes any and all aspects of compounding, filling, finishing, testing and releasing the API and/or Product. Pfizer shall not be responsible for replacement of the API beyond the limitations of liability stated herein. However, this limitation of liability shall not apply if any API losses are caused by Pfizer's gross negligence or willful misconduct or if Pfizer knowingly supplies any of the API to a Third Party (except as for testing purposes under Section 5.4(a)(iv)) under this Agreement, including a Third Party competitor of Trevena or a generic drug product manufacturer.

(e) **API Consumption Factor.** After Pfizer has completed its initial validation runs and during the initial stages of Pfizer's commercial manufacture of the Product, the Parties shall consult with a view to develop a strategy for maximizing the yield of the API supplied by Trevena. Based upon such consultations, the Parties shall establish a maximum API consumption factor target for the Product to be manufactured in accordance with Trevena's Purchase Orders. When Pfizer has achieved manufacturing of consistent batch quantities [*] of the Product in accordance with the maximum consumption factor target, the Parties shall set out in writing binding terms and conditions for manufacturing criteria, such as an API yield minimum, permitted variances of API usage and consequences of out-of-variance performance. Once the maximum consumption factor has been established, if, during any Commercial Year period, Pfizer's consumption of API exceeds the maximum agreed upon consumption factor Pfizer shall reimburse Trevena for any excess consumption at Trevena's cost/kg, subject to the limitation of Section 5.4(d).

5.5 Facility: Dedicated Equipment

(a) **Facilities and Equipment.** Except as provided below, Pfizer will provide, at its own cost and expense, all facilities, equipment, machinery, and materials to manufacture the Product in accordance with the Product Specifications, and the professional and other labor necessary for the successful performance of its obligations hereunder.

(b) **Dedicated Equipment.** The Parties have agreed that certain specialized or dedicated equipment ("**Dedicated Equipment**") is required to manufacture Product for Trevena as set forth on Schedule 5.5. The Parties have further agreed that Pfizer shall advise Trevena of

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the Dedicated Equipment required and the estimated costs associated with the purchase, installation and validation of the Dedicated Equipment. [*], subject to Trevena's prior written approval of such costs, which approval will not be unreasonably withheld or conditioned. Upon such approval, Pfizer will then purchase, install and validate the equipment and bill Trevena for the associated costs in accordance with the terms agreed in the Statement of Work. [*] Title to the Dedicated Equipment shall be and remain in Trevena's name. Pfizer shall (and shall cause its Affiliates to) (i) label the Dedicated Equipment as the property of Trevena, (ii) use the Dedicated Equipment solely for the manufacture of the Product for and on behalf of Trevena, (iii) keep the Dedicated Equipment free of liens, claims and encumbrances, (iv) operate the Dedicated Equipment in accordance with the manufacturer's instructions, (v) maintain the Dedicated Equipment in good working condition and in compliance with cGMP and Applicable Laws, *provided that*, for any repairs covered by a manufacturer's warranty, Trevena shall authorize such repairs under such warranty solely to the extent Pfizer grants access to the Facility for the performance of such repairs, and (vi) ensure the Dedicated Equipment is insured at all times in the amounts adequate to replace the Dedicated Equipment. Upon the expiry or earlier termination of this Agreement, Pfizer will return or otherwise dispose of Dedicated Equipment at Trevena's direction in accordance with Section 10.6(b).

5.6 Components; Materials

Unless otherwise agreed, Pfizer will be responsible for the procurement and qualification of the Components and other raw materials required for the manufacture of the Product. Pfizer will procure all of the Components from suppliers that have been approved and qualified by Pfizer in accordance with Pfizer's internal vendor qualification and approval processes. The Parties understand and agree that Trevena has reviewed and approved the Components and Component suppliers listed in the Product Specifications. Under no circumstances will Pfizer have any liability to Trevena, nor will Pfizer be deemed to be in breach of this Agreement, if Pfizer is unable to supply the Product to Trevena due to a failure of such suppliers to provide such Components to Pfizer, *provided, however*, that Pfizer has used all commercially reasonable efforts to obtain the relevant Components from approved Component suppliers in accordance with Trevena's forecasts. [*] The cost of the Components is included in the price of the Product.

5.7 Product Labeling

(a) **Labeling.** Pfizer shall label the Product in accordance with the Product Specifications using content provided by Trevena. Trevena shall control the content and type of all labeling and packaging (and any changes or supplements thereto) for the Product and shall have the responsibility, at Trevena's expense, for (i) ensuring such content is compliant with the Regulatory Approval and all Applicable Law, and (ii) any changes or supplements to such content, including the expense of securing any approvals required by any applicable Regulatory Authority for any such changes or supplements. Pfizer shall be responsible for obtaining such labels, packaging and packaging Components (and any changes or supplements thereto) in accordance with content specified by Trevena.

(b) **Labeling Changes.** Should Trevena request or be required to make any modifications to Product labeling and packaging, it shall submit a written change order to Pfizer containing the requested or required modifications, together with any documentation specifying

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the content of the new labeling and packaging, including all necessary photo-ready art (or its substantial equivalent). Pfizer shall promptly provide Trevena with a statement of estimated charges for the work to be performed based on its per/person, per/hour rates then in effect, and its estimated timeline for implementing the changes. Upon written approval by Trevena, which approval shall not be unreasonably withheld, Pfizer will perform all requested or required labeling and packaging work. Trevena shall pay Pfizer for the work performed, in addition to reimbursing Pfizer for the cost of any existing labeling and packaging that has become obsolete as a result of such changes; *provided, however*, that such labeling and packaging shall not exceed the quantity of labeling and packaging required for the Product forecasted by Trevena for manufacture in the relevant Firm Order Period.

5.8 Product Testing and Release

(a) **Test Methods.** Upon completion of manufacture, Pfizer will test each batch of Products for conformance with the Product Specifications and cGMP in accordance with agreed-upon quality control test methods set forth on Schedule 7.1, the Quality & Technical Agreement or as otherwise requested by Trevena.

(b) **Documentation.** After Pfizer has carried out and reviewed all testing in accordance with its quality control processes, procedures and other agreed test methods, Pfizer will provide Trevena with a Certificate of Analysis (and a Certificate of Compliance, if so required) confirming that the batch was manufactured in conformity with the Manufacturing Process and Applicable Law (including cGMP) and complies with the Product Specifications. Pfizer will also provide copies of batch records and all other documents and records as required by the Quality & Technical Agreement, as well as such samples of the batch as Trevena may reasonably request. Trevena will review all of the documentation and discuss its observations, if any, with Pfizer. Once all observations are resolved, and Trevena has reviewed and approved all of the documentation provided by Pfizer, Trevena will approve the batch by providing to Pfizer its authorization to release the batch for delivery ("**Release Authorization**"). Pfizer will then make the batch available to Trevena at the Facility.

(c) **Inspection; Rejection.** Trevena shall inspect, perform its quality assurance tests, and accept or reject, the corresponding batch as conforming or non-conforming with the Product Specifications [*], the timely resolution of all error and deviation records and if, applicable, batch samples. If Trevena rejects the batch as being non-conforming, it shall promptly notify Pfizer. If, as a result of further review and testing, Pfizer determines that the batch does conform to the Product Specifications or is otherwise not defective, the Parties shall mutually confer to find the root cause of the disagreement regarding batch non-conformity. If the Parties do not agree that a non-conformity exists, the Parties shall then submit samples of such batch to an independent laboratory acceptable to both Parties as further provided in Section 5.8(f).

(d) **Deemed Acceptance.** If Trevena does not notify Pfizer in writing of Trevena's rejection [*], Trevena shall be deemed to have accepted the Product, except that Trevena shall retain the right to revoke acceptance of Product for a Latent Defect pursuant to Section 5.8(h).

(e) **Product Quantity.** If the quantity of Products produced in any batch manufactured and proffered for delivery to Trevena is materially less than the quantity specified in the applicable Purchase Order, then the parties will meet to discuss in good faith and agree to

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one or more remedies to resolve the shortage in a fair and equitable manner. For purposes of clarity, “materially less” shall mean a batch of Products with an abnormally high number of units either rejected or set aside at Pfizer’s determination for sampling, stability or for other reasons outside of the ordinary course of manufacturing and based on historic experience at the Facility.

(f) **Disputes Regarding Non-Conformity; Independent Testing.** In the event of an unresolved dispute as to whether a batch does or does not comply with Product Specifications, Pfizer and Trevena will appoint a mutually agreeable independent laboratory to perform comparative tests and/or analyses on samples of the Product claimed to not comply with the Product Specifications. The independent laboratory’s results will be in writing and will be final and binding, save for manifest error on the face of its report; *provided, however*, that the independent laboratory may also determine that additional sample testing by an independent laboratory is necessary. Unless otherwise agreed to by Pfizer and Trevena in writing, the costs associated with such testing and review will be borne by the Party against whom the independent laboratory rules. Pfizer will furnish the independent laboratory such instructions regarding the storage, handling and potential hazards of any Product as are provided to or developed by Pfizer by or on behalf of Trevena. Notwithstanding the foregoing, the Parties agree that the independent testing and review processes are only relevant to determine whether a batch complies with Product Specifications and shall not apply to disputes concerning whether a batch was manufactured in accordance with the Manufacturing Process and Applicable Law (including, cGMP).

(g) **Replacement; Disposition of Rejected Product.** Pfizer shall use all reasonable efforts to replace, at no cost to Trevena, that portion of the batch which does not conform to the Product Specifications or was not manufactured in accordance with the Manufacturing Process and Applicable Law (including cGMP) as soon as possible, given manufacturing capacities and scheduling at the Facility [*]; *provided, however*, that [*]. Pfizer shall dispose of any rejected Products at its own cost and expense and in accordance with Applicable Law. Pfizer shall make all documentation relating to such disposition available to Trevena upon Trevena’s request

(h) **Latent Defects.** Notwithstanding the acceptance provisions of [Section 5.8\(c\)](#) and [\(d\)](#), Trevena will have the right to reject any batch of Products that are subsequently found to be non-conforming due to latent defects. For purposes of this [Section 5.8\(h\)](#), “latent defects” are any defects in the Product which are not discoverable using ordinary diligence and reasonable care in applying the quality control and test methods specified in the Quality & Technical Agreement, render the Product not conforming to Product Specifications and are caused by Pfizer. The Parties will consult to confirm the cause of the latent defects. If the Parties do not agree as to whether the Product is non-conforming, they will submit samples of such Product for independent testing in accordance with [Section 5.8\(f\)](#). If it is confirmed that the cause of the latent defect is attributable to Pfizer, then Pfizer will replace at no cost to Trevena all such latently defective Products with Products that meet the Product Specifications, subject to the provisions of [Section 5.4\(c\)](#) and the limitations of [Section 5.4\(d\)](#). All other relevant provisions of this [Section 5.8](#) will apply to the inspection, testing and release of such replacement Products.

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5.9 Waste

Pfizer will be responsible for the removal and disposal of all Waste resulting from Pfizer's manufacturing of the Product, consistent with the Product's Material Safety Data Sheet.

5.10 Miscellaneous

(a) **Process Rework.** Pfizer will not rework or reprocess a Product unless authorized in advance by Trevena in writing and there is a validated process for such rework or reprocessing of Product. Re-inspection does not constitute rework or reprocessing. Process rework that may become necessary as a result of Trevena's changes will be billed separately at a reasonable fee to be mutually agreed between the Parties in writing.

(b) **Sub-Lots.** Should Trevena desire Pfizer to split a manufacturing lot of Product into two (2) or more sub-lots during packaging, [*].

ARTICLE 6 FORECASTS; ORDERS; DELIVERY; INVOICING

6.1 [*] Product Supply Forecast

For capacity planning purposes, upon its submission for Regulatory Approval for the McPherson Facility, Trevena will provide Pfizer with a non-binding, written forecast of its estimated annual requirements of the Product during each of the first [*] Commercial Years of this Agreement ("**Annual Forecast**"). Thereafter, by [*] of each Commercial Year, Trevena will update the Annual Forecast for the period commencing on January 1st of the next Commercial Year. The Parties acknowledge that Trevena may adjust its Annual Forecast based on the controlled substance quota that the DEA issues for the Facility in any given year. For such purpose, Pfizer will promptly notify Trevena of any DEA quota that may be inconsistent with Trevena's Annual Forecast.

6.2 First Purchase Order

The Parties will cooperate in estimating and scheduling production for Trevena's first commercial order of Product from Pfizer, which in any case Trevena will place no later than [*] months in advance of Trevena's desired Product availability date.

6.3 Rolling Forecast

(a) **Forecasting.** Concurrent with the placing of its first order of Product with Pfizer, and thereafter, during the first month of each calendar quarter thereafter, Trevena will provide to Pfizer a good faith, estimated rolling forecast of the quantity of Products that Trevena expects to order for the coming [*] period of time (each, a "**Rolling Forecast**"). The first [*] of each Rolling Forecast shall be considered a binding commitment upon Trevena to purchase quantities described therein and a binding commitment upon Pfizer to produce and deliver such quantities on the delivery dates described therein ("**Firm Order Period**"). The last [*] of each Rolling Forecast shall be non-binding upon the Parties. Based upon each Rolling Forecast, Pfizer will place adequate quota requests to the DEA in a timely fashion to ensure compliance with all Applicable Laws, regulations and timing requests (including applicable reporting requirement).

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(b) **Adjustments.** Pfizer shall review Trevena's Rolling Forecasts at the time they are submitted and if any such Rolling Forecast is not consistent with the requirements of this Agreement (e.g., a change to a DEA quota), the Parties shall meet to discuss any necessary adjustments to the Rolling Forecasts. Notwithstanding the foregoing, in the event that circumstances beyond the control of both Parties cause a delay in commercialization of Product in the Territory, Trevena may cancel Products ordered within the Firm Order Period without penalty or liability to Pfizer, *provided that* [*] but (iii) if Trevena cancels any Purchase Order within [*] days of the scheduled start of manufacture, Trevena will be liable for the full price of the cancelled Purchase Order, as set forth in Section 6.9(b).

6.4 Purchase Orders

Trevena shall submit purchase orders for Product (each, a "**Purchase Order**") to Pfizer at the time it submits its Rolling Forecasts per Section 6.3(a), which in all cases shall be least [*] days prior to Trevena's requested delivery date as specified in the Purchase Order. Pfizer shall use its commercially reasonable efforts to meet the delivery dates set forth in each Purchase Order, *provided, however*, that, absent any investigations, testing or other issues raised by Trevena in its inspection of the Product in accordance with Section 5.8(c), [*] after Trevena's Purchase Order submission. All Purchase Orders shall reference this Agreement and shall be governed exclusively by the terms contained herein. Trevena shall set forth in each Purchase Order (a) the quantity of Product ordered, (b) the amount of API required to fill the Purchase Order, (c) the specified delivery date and delivery instructions, and (d) the purchase price to be paid for the batch of Product.

6.5 Purchase Order Acceptance

Pfizer will confirm each Purchase Order issued by Trevena within [*] Business Days after receipt and shall confirm in writing to Trevena its acceptance of the Purchase Order, the delivery date(s), the quantity of Products ordered and the purchase price to be paid by Trevena. Provided that Trevena has placed its Purchase Orders in compliance with Section 6.4, Pfizer may not reject any Purchase Order that complies with this Agreement.

6.6 Excess Quantities

[*] Pfizer will not be obligated to supply quantities of Product over and above [*] ("**Non-Binding Excess**") but will use commercially reasonable efforts to manufacture and deliver to Trevena all or part of the Non-Binding Excess as soon as reasonably practicable.

6.7 Format of Forecasts and Purchase Orders

Trevena will submit each Rolling Forecast electronically in spreadsheet form and will specify the quantities of Products in units and the Pfizer product number (list number/inventory number). Trevena will submit its Purchase Orders on its standard purchase order forms.

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6.8 Minimum Purchase Requirement

Trevena further agrees to purchase from Pfizer in each Commercial Year not less than the minimum quantity of Products from Pfizer in accordance with the provisions of this Section 6.8 (“**Minimum Purchase Requirement**”). The Minimum Purchase Requirement shall be calculated on the basis of a percentage of the number of units/batches of Product forecasted by Trevena in the most recent twelve-month period in the Rolling Forecast that Trevena provides to Pfizer pursuant to Section 6.3(a). Provided that Pfizer is not in breach of, and materially performs all of its obligations set forth in this Agreement, [*] and waive Pfizer’s manufacture and delivery obligations for the Product. In the latter event, Pfizer shall invoice Trevena for the amount payable, and Trevena shall pay Pfizer such amount [*]. Notwithstanding anything of the foregoing [*] all Product paid for by Trevena in lieu of delivery shall count towards the Minimum Purchase Requirement.

6.9 Purchase Order Changes; Cancellations

(a) **Changes.** If Trevena requests that changes be made to any of its Purchase Orders within the Firm Order period, Pfizer will use all commercially reasonable efforts to accommodate such changes within reasonable manufacturing capabilities and efficiencies. If Pfizer can accommodate such changes, Pfizer will advise Trevena of any costs associated therewith. If Trevena indicates in writing to Pfizer that it should proceed to make the changes, Trevena will be deemed to have accepted the obligation to pay Pfizer for such costs. [*]

(b) **Cancellations.** Except as provided in Section 6.3(b), if Trevena cancels any Purchase Order within the Firm Order Period, Pfizer shall be relieved of its manufacturing obligations relating to such order. Pfizer shall use commercially reasonable efforts to minimize its expenses and to fill any idle or unused manufacturing capacity as a result of such cancellation and Trevena shall be liable only to the extent of the time and costs actually incurred that result from Pfizer’s inability to fill such idle or unused capacity; *provided, however*, [*], Trevena shall be liable for the full cost of the batch of Product to have been manufactured and supplied. Furthermore, if Trevena does not supply sufficient API (without providing appropriate notification to Pfizer and allowing for a period for both companies to evaluate the impact of such delay in API delivery) to allow Pfizer to fulfill any Purchase Order or acts improperly in any other manner to effectively prevent Pfizer’s ability to perform, such action shall be deemed a cancellation and Trevena shall reimburse Pfizer for costs actually incurred as a result of such cancellation.

6.10 Shortage of Supply; Risk Mitigation; Redundancies

(a) **Shortage of Supply.** In the event that Pfizer is unable to manufacture the Product in accordance with Trevena’s Purchase Orders, Pfizer shall notify Trevena promptly. If the inability is not: (i) caused by an event of *force majeure*; (ii) attributable in whole or in part to Trevena’s acts or omissions or breach of its obligations under this Agreement; or (iii) attributable in whole or in part to Pfizer’s Component suppliers’ acts or omissions and which are not otherwise due to Pfizer’s failure timely to submit orders for Components and maintain an adequate safety stock as per Section 5.6, then Pfizer shall be solely responsible, at its sole cost and expense, for undertaking all commercially reasonable measures to minimize any possible shortage of Product to Trevena as a result of its manufacturing issues. If Pfizer cannot undertake such measures promptly, and [*], (“**Inability to Supply**”) then Trevena will be

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relieved of its obligations under [Section 5.1](#), and its Minimum Purchase Requirements for the applicable Commercial Year in accordance with [Section 6.8](#). Trevena shall have the right to procure Product from its existing Third Party contract manufacturer for so long as Pfizer's Inability to Supply continues. Thereafter, if Pfizer manufactures and delivers Product to Trevena in compliance with all Purchase Orders issued by Trevena [*], the applicable exclusivity and Minimum Purchase Requirement obligations under [Section 5.1](#) and [Section 6.8](#) shall be reinstated.

(b) **Risk Mitigation; Redundancies.** If requested by Trevena, the Steering Committee will discuss measures for risk mitigation, including planning and implementing manufacturing redundancies at the Facility or one or more of Pfizer's other manufacturing facilities. Such redundancies may include the qualification of additional filling lines or other equipment to support a possible expanded validation strategy for the manufacture and additional site approval of the Product. The Parties shall mutually determine the procedures, methods, means and timing for carrying out all of the necessary qualification and validation activities to be set forth by an amendment to be made to the Project Statement of Work in accordance with the procedures of [Section 3.3](#).

6.11 Delivery

Pfizer will deliver the Product to Trevena FCA (Incoterms 2010), the Facility. Title to and risk of loss over the Product will pass to Trevena at the time the Product is placed aboard the vehicle of Trevena's designated carrier at the loading dock of the Facility. Pfizer will not deliver any Product to Trevena until (a) Pfizer has released such Product pursuant to the Specifications and the terms of the Quality & Technical Agreement, and (b) Trevena has issued to Pfizer its Release Authorization. All freight, handling, insurance, duties and other shipping expenses will be borne by Trevena. For any shipments outside of the United States as agreed by the Parties in writing and permitted by Applicable Law, Trevena will be the exporter of record; *provided, however*, that Pfizer will assist Trevena, at no additional expense, in the preparation of any required export documentation. Trevena will be responsible for all shipping validation and transportation quality control. Should Trevena request or require Pfizer to include electronic temperature monitoring devices ("**Loggers**") with any shipping cartons of the Product, it will comply with Pfizer's policies on the use of and responsibilities for Loggers set forth on [Schedule 6.11](#).

6.12 Storage Fee

Trevena will use its commercially reasonable efforts to take delivery of all Products from the Facility no later than [*] days after the date of issuance of its Release Authorization. If Trevena anticipates that it will not be able to meet the delivery date, it will notify Pfizer promptly that Pfizer should store the Products at the Facility on an interim basis and indicate a date certain on which it will take delivery. [*] If Trevena has not taken delivery of the Product more than [*] days after issuing its Release Authorization, then title to and risk of loss over the Products shall be deemed to have passed to Trevena and Pfizer shall be entitled to invoice Trevena for the Products deemed to have been delivered at the prices set forth on [Schedule 6.13](#). Pfizer shall not be liable for any loss or damage occurring to the Products kept in storage for more than [*] days

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after the Release Authorization or any deemed acceptance date per Section 5.8(d) for any reason, except for Pfizer's gross negligence, willful omissions or intentional acts of misconduct.

6.13 Prices

Pfizer shall invoice Trevena for the Products it delivers to Trevena at applicable [*] pricing set forth on Schedule 6.13. For the start of each Commercial Year, Pfizer will apply an assumed [*] price ("**Assumed Price**") based on the number of units of Product set by Trevena in the most recent year of the Annual Forecast that Trevena provides to Pfizer pursuant to Section 6.1, which Assumed Price shall remain in effect for the entire Commercial Year, subject to a year-end reconciliation with the number of units actually purchased. Each of Pfizer's invoices shall reference the Assumed Price.

6.14 Invoices; Payment

Pfizer will invoice Trevena upon delivery of the Products. Trevena will make payment of all amounts in Pfizer's invoices net [*] days from the date of receipt of Pfizer's invoice. In the event of a good faith dispute between the Parties as to the amount due, Trevena will pay the undisputed amount and the Parties will attempt to resolve the disputed payment within [*] days.

6.15 Pricing Reconciliation

Within [*] days after the close of each Commercial Year, the Parties will conduct a reconciliation process to determine the actual pricing for Product manufactured and delivered to Trevena during that Commercial Year, which process shall be as follows:

- (a) The Parties will jointly confirm the actual quantity of Products that Pfizer has delivered to Trevena, which shall include retained samples and stability samples but will exclude any Product rejected by or recalled by Trevena and has not yet been replaced by Pfizer under the terms of this Agreement ("**Actual Quantity**");
- (b) The Parties will then determine the corresponding actual [*] prices ("**Actual Price**") set forth on Schedule 6.13 and will calculate a total dollar amount resulting from the Actual Quantity multiplied by the Actual Prices ("**Actual Total Amount**");
- (c) The Parties will then calculate a total dollar amount resulting from the Actual Quantity multiplied by the Assumed Price ("**Assumed Total Amount**"); and
- (d) If the Actual Total Amount equals or is greater than the Assumed Total Amount, then Pfizer will issue a credit memorandum to Trevena in an amount equal to the positive difference that Trevena may use to offset any future amounts due under this Agreement. If the Actual Total Amount is less than the Assumed Total Amount, then Pfizer will issue to Trevena a debit memorandum equal to the negative difference, which Trevena will pay within [*] days after Trevena's receipt of such debit memorandum.

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6.16 Price Increases

All pricing is firm through the first Commercial Year. Effective on [*] Pfizer will have the right to increase the price of the Product once annually. Price increases will be effective for deliveries of Products [*] Pfizer shall use all reasonable efforts to provide written notice to Trevena of any anticipated price increase no later than October 31st of any Commercial Year. No price increase shall be effective [*].

6.17 Taxes

Trevena shall pay all federal, state, county or municipal sales or use tax, excise, customs charges, duties or similar charge, or any other tax assessment (other than that assessed against income), licence, fee or other charge lawfully assessed or charged on the manufacture, sale or transportation of the Product that Pfizer manufactures, sells and delivers pursuant to this Agreement. In particular, Trevena will be responsible for and pay all applicable annual establishment fees specified in the Prescription Drug User Fee Amendments to the FD&C Act, with respect to the Product. For the avoidance of doubt, Trevena shall not be required to pay any such annual fees as relate to the Pfizer Facility, which shall be Pfizer's sole and exclusive obligation. Trevena shall provide Pfizer with copies of any state tax exemption form(s) if it intends to claim exemption for sales or use taxes in any state(s) where the Product is to be shipped. Under no circumstances shall Trevena be responsible for payment of any Pfizer employment related taxes or withholdings.

6.18 Continuous Improvements

Pfizer shall use reasonable commercial efforts to identify any opportunity to reduce the cost of manufacturing the Product and shall notify Trevena of such cost reduction opportunities ("**Cost Reduction Program**"). Any such measures to be undertaken must be first approved by the Steering Committee and will be implemented in accordance with the scope change provisions of Section 3.3(a). Any cost savings realized from the Cost Reduction Program shall first be used to reimburse each Party's financial contribution to such program's development and implementation costs, thereafter, such cost savings shall be shared equally between the Parties.

ARTICLE 7 QUALITY ASSURANCE

7.1 Quality Control

Pfizer will apply its quality control procedures and in-plant quality control checks on the manufacture of Product for Trevena in the same manner as Pfizer applies such procedures and checks to products of similar nature manufactured for sale by Pfizer. Pfizer will also test and release all batches of Product in accordance with the test methods described in Schedule 7.1 to ensure that the Products meet the requirements of the Product Specifications and are manufactured in accordance with cGMP.

7.2 Quality & Technical Agreement

The Parties will use all commercially reasonable efforts to negotiate and conclude a Quality & Technical Agreement which will be attached hereto as Schedule 7.2 no later than [*] days after the Effective Date, but in any case prior to any cGMP manufacture of the Product.

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7.3 **Documentation; Batch Records; Retention Samples**

(a) **Quality Assurance Documentation.** Pfizer will prepare such records documenting the development work as foreseen in the Project Statement of Work or as are otherwise reasonably requested by Trevena. Pfizer will prepare batch manufacturing records, which include the information relating to the manufacturing, packaging and quality operations for each lot of Product at the time such operations occur. Pfizer will prepare all development work and batch records in accordance with Applicable Laws, the Quality & Technical Agreement, cGMP and any similar regulations of applicable Regulatory Authorities and Pfizer's standard operating procedures. Upon Trevena's request, Pfizer will provide Trevena with copies of such development records and batch production records, including manufacturing and analytical records.

(b) **Document Retention.** Unless otherwise specified in the Quality & Technical Agreement, Pfizer will retain all records documenting the development work and all records relating to the manufacture of each batch of Products for [*] or for such other period as required by Applicable Law. Thereafter, Pfizer will not destroy such records without giving Trevena prior written notice and the opportunity further to store such records or to have such records shipped to Trevena, [*].

(c) **Retention Samples.** Pfizer will be responsible for storing and maintaining retention samples of each batch of Product delivered to Trevena and associated API and other raw materials in accordance with cGMP and the Quality & Technical Agreement.

7.4 **Trevena Audits Rights**

(a) **General Audit.** [*], Trevena shall have the right to have representatives visit the Facility during normal business hours to review Pfizer's manufacturing operations relating to the Product and assess its compliance with cGMP and quality assurance standards and to discuss any related issues with Pfizer's manufacturing and management personnel. Pfizer shall provide Trevena with copies of Pfizer's manufacturing records (including the Master Batch Record) and other relevant documentation relating to the Products for the purposes of assuring Product quality and compliance with agreed-upon manufacturing procedures. Such general audits shall (i) be limited to not more than [*] auditors [*] designated by or representing Trevena, (ii) last for not more than [*] days, and (iii) may be conducted not more than [*] per calendar year.

(b) **For Cause Audits.** Trevena shall also have the right to conduct "for-cause" audits to address significant product or safety concerns as discovered through Product failures related to Pfizer's manufacture of the Product. Product failures would include issues related to stability out of specification, sterility, labeling or container integrity. Trevena shall notify Pfizer in writing in advance of the audit and thereafter, Trevena and Pfizer shall mutually determine the timing of the audit, which shall be as soon as possible, and in any event within [*]. Each for-cause audit shall be [*], except if the parties mutually agree that a longer for-cause audit period is necessary.

(c) **Confidential Information in Audits.** Audits by Trevena or its designees may involve the transfer of Confidential Information, and any such Confidential Information shall be

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subject to the terms of Article 11 hereof. The results of such audits and inspections shall be considered Confidential Information under Article 11 and shall not be disclosed to Third Parties, including the FDA and any other relevant Regulatory Authority, unless required by law and only then upon prior written notice to Pfizer.

7.5 Regulatory Authority Inspections

(a) **Inspections.** Pfizer shall allow the FDA and any other relevant Regulatory Authority to conduct any Pre-Approval Inspection (“*PAI*”) or other inspection of the area in the Facility where the Product is to be manufactured and Pfizer agrees to cooperate with the FDA and any other relevant Regulatory Authority in connection with such inspection. Pfizer will provide Trevena with notice of any PAI as specified in the Quality & Technical Agreement. The Parties shall consult regarding the nature, extent, duration of such inspection to determine whether Trevena may have an interest to send its personnel or representatives to the Facility. Upon agreement, Pfizer shall allow, but not require, such representatives to be present at the Facility during the FDA inspection to the extent permitted by the FDA inspectors and/or Applicable Law.

(b) **Additional PAIs.** In the event that Trevena determines to expand its sales and marketing of the Product in countries or geographic regions outside of the Territory as described in Section 3.3(b) a Regulatory Authority other than the FDA requests or requires a PAI audit of the Facility in connection therewith, Pfizer will be entitled to charge a supplementary audit fee of [*] per each such PAI.

7.6 [*]

7.7 Change in Product Specifications: Manufacturing Process

Except as otherwise provided in Section 5.2, each of Trevena and Pfizer agrees that it will not change the Product Specifications or any aspect of the Manufacturing Process (including change of the Components, equipment, processes or procedures used to manufacture Product) without the prior written approval of the other Party, which approval will not be unreasonably withheld, delayed, or conditioned. Upon agreement, the Parties will implement all such changes in accordance with the change control provisions of the Quality & Technical Agreement.

7.8 Failed Batch

In accordance with the Quality & Technical Agreement and Section 5.8 hereof, Pfizer will investigate, and cooperate fully with Trevena in investigating, any batch of Product that fails to comply with the Manufacturing Process or Applicable Law (including, but not limited to, cGMP) or fails to meet the Product Specifications or any Regulatory Authority requirements. Pfizer will keep Trevena informed of the status of any investigation and, upon completion of the investigation, will provide Trevena with a final written report describing the cause of the failure and summarizing the results of the investigation.

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7.9 **Complaints and Adverse Drug Experiences**

Consistent with the terms of the Quality & Technical Agreement, each Party will promptly advise the other of any complaints, notices of Adverse Drug Experience(s) or event reports, safety issues or toxicity issues relating to the Products of which it becomes aware, and which may be the result of, or have an effect on, the Product manufacturing operations performed by Pfizer but in no event later than [*] Business Days from the date of so becoming aware. Trevena will be responsible for all reporting of such information to Regulatory Authorities. Pfizer will promptly evaluate any complaint or notice of Adverse Drug Experience(s) and reasonably assist Trevena in responding to the same.

7.10 **Product Recalls**

(a) ***Recalls.*** In the event (i) any Regulatory Authority or other national government authority issues a request, directive or order that the Product be recalled, (ii) a court of competent jurisdiction orders such a recall, or (iii) Trevena or Pfizer reasonably determines that Product should be recalled or subject to other corrective action, the Parties will take all appropriate actions, and will cooperate in any governmental investigations surrounding the recall. Pfizer will provide to Trevena all relevant information in support of its recommendation for a recall or other corrective action; *provided, however*, that Trevena shall have the final and sole decision making authority on the action to be taken, except if Pfizer has definitive evidence that any Product on market is either misbranded or adulterated, as defined in the FD&C Act.

(b) ***Product Replacement; Expenses.*** In the event that such recall results from a breach of Pfizer's express warranties under Sections 8.3(a) and 8.3(b), Pfizer will be responsible for replacing the quantity of Products that were recalled at no cost to Trevena. Pfizer will use all commercially reasonable efforts to replace such Product as soon as practicable, given scheduling at the Facility. In addition, Pfizer agrees that it will be responsible for the administrative expenses of any recall. For purposes of this Section 7.10(b), the "administrative expenses" of recall will include the reasonable expenses of notification of customers, the return, storage and destruction of the recalled Product and any costs associated with the delivery of replacement Products, [*]. In the event that the recall does not result from the breach of Pfizer's express warranties under this Agreement, [*].

ARTICLE 8 WARRANTIES; COVENANTS; INDEMNIFICATION

8.1 **Mutual Representations and Warranties**

Each Party represents, warrants and covenants to the other Party that:

(a) ***Good Standing.*** It is duly incorporated, validly existing and in good standing under the laws of the state in which it is incorporated;

(b) ***Power and Authority.*** It has the corporate power and authority to enter into this Agreement and perform its obligations hereunder and the execution, delivery and performance of this Agreement and the performance of its obligations hereunder have been duly authorized and approved by all necessary action and no other action on the part of it is necessary to authorize the execution, delivery and performance of this Agreement;

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(c) **Existence of Claims.** There are no suits, claims, or proceedings pending, or to its best knowledge and belief, after due inquiry, threatened against it or any of its Affiliates in any court or by or before any governmental body or agency which would affect its ability to perform its obligations under this Agreement; and

(d) **No Conflicts.** The performance of its obligations under this Agreement will not result in a material violation or breach of any agreement, contract, commitment or obligation to which Trevena is a party or by which it is bound and will not conflict with or constitute a default under its corporate charter or bylaws.

8.2 Trevena's Representations, Warranties and Covenants

Trevena covenants to Pfizer that:

(a) all API that Trevena provides to Pfizer will, at the time of delivery, not be adulterated or misbranded within the meaning of the FD&C Act or within the meaning of any other Applicable Law in which the definitions of adulteration and misbranding are substantially the same as those contained in the FD&C Act, as the FD&C Act and such laws are constituted and effective at the time of delivery, and will not be an article which, under the provisions of Sections 404 and 505 of the Act, may not be introduced into interstate commerce;

(b) all API that Trevena provides to Pfizer will have been manufactured in accordance with all applicable cGMP (including ICH Q7A) and meets the API Specifications;

(c) all specifications, including API Specifications and Product Specifications that Trevena provides to Pfizer will conform to the post-NDA submission that Trevena files with the FDA or other relevant Regulatory Authorities;

(d) it will not sell any Product into any regulatory jurisdiction unless and until it receives the necessary Regulatory Approval(s); and

Trevena represents and warrants to Pfizer that, to the best of Trevena's knowledge, and after having performed a reasonably diligent search of the record, Trevena's Intellectual Property, proprietary technology, Manufacturing Processes or other proprietary rights that Trevena licenses to Pfizer under this Agreement does not infringe any patents or know-how of a Third Party.

8.3 Pfizer's Representations, Warranties and Covenants

Pfizer covenants to Trevena that:

(a) all Product that Pfizer delivers to Trevena hereunder will, at the time of delivery, not be adulterated or misbranded within the meaning of the FD&C Act or within the meaning of all Applicable Laws in which the definitions of adulteration and misbranding are substantially the same as those contained in the FD&C Act, as the FD&C Act and such laws are constituted and effective at the time of delivery and will not be an article which may not under the provisions of Sections 404 and 505 of the FD&C Act be introduced into interstate commerce;

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(b) all Product Pfizer delivers to Trevena hereunder will, at the time of delivery, be free from defects in material and workmanship and will be (i) in conformity with the Product Specifications, and (ii) manufactured in compliance with all Applicable Laws, including those relating to the environment, food or drugs and occupational health and safety, including those enforced or promulgated by the FDA (including compliance with cGMP);

(c) Pfizer will perform all of its services under this Agreement using personnel who have been properly qualified and trained in accordance with its internal SOP's and qualification programs and Applicable Laws;

Pfizer represents and warrants to Trevena that, to the best of Pfizer's knowledge, Pfizer's Intellectual Property, proprietary technology, manufacturing processes or other proprietary rights that Pfizer licenses to Trevena under this Agreement, does not infringe any patents or know-how of a Third Party and in its performance of its obligations under this Agreement, Pfizer will not knowingly incorporate into the Manufacturing Process any patents or know-how of a Third Party for which it does not have a licence that permits it to do so and/or to be able to grant to Trevena the licences and other rights otherwise required to be granted to Trevena hereunder.

The foregoing warranties will not extend to any nonconformity or defect which relates to or is caused by API supplied by Trevena to Pfizer. Subject to Pfizer's indemnity obligations in [Section 8.5](#), the replacement provisions of [Sections 5.4\(c\), 5.4\(d\), 5.8\(g\), 5.8\(h\)](#) and [7.10\(b\)](#) will be Trevena's sole and exclusive remedies for nonconforming or defective Products.

PFIZER MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCTS. PFIZER HEREBY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

8.4 Indemnification by Trevena

Trevena hereby agrees to save, defend, indemnify and hold harmless Pfizer and its Affiliates and their respective officers, directors, employees and representatives (each, a "**Pfizer Indemnitee**") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees ("**Losses**"), to which any Pfizer Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (a "**Claim**") against a Pfizer Indemnitee arising or resulting directly or indirectly from (a) Trevena's breach of any representation or warranty set forth in [Section 8.1](#) or [Sections 8.2\(a\)](#) through [8.2\(d\)](#), (b) infringement of any Intellectual Property right of any Third Party relating to the API Specifications, Product Specifications, API, Drug, Product or the Manufacturing Process, other than Pfizer's processes used in the manufacture of the Product pursuant to this Agreement, (c) the use of or lack of safety or efficacy of the Product, or (d) any negligent or wrongful act or omission on the part of Trevena, its employees, agents or representatives and which relate to Trevena's performance hereunder except, in each case, to the extent such Losses result from the negligence or willful misconduct of any Pfizer Indemnitee or the breach by Pfizer of any express warranty or representation made by Pfizer in this Agreement.

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8.5 Indemnification by Pfizer

Pfizer will indemnify and hold harmless Trevena and its Affiliates and their respective officers, directors, employees and representatives (each, a “*Trevena Indemnitee*”) from and against any and all Losses to which any Trevena Indemnitee may become subject as a result of any Claim against a Trevena Indemnitee arising or resulting, directly or indirectly, from (a) Pfizer’s breach of any representation or warranty set forth in Section 8.1 or Sections 8.3(a) through Section 8.3(c), (b) infringement of any Intellectual Property right of any Third Party relating to Pfizer’s manufacturing processes used in the manufacture of Product pursuant to this Agreement (excluding the API Specifications, Product Specifications, API, Drug, Product or the Manufacturing Process), or (c) any negligent or wrongful act or omission on the part of Pfizer or any Pfizer Indemnitee and which relate to Pfizer’s performance hereunder except, in each case, to the extent such Losses result from the negligence or willful misconduct of any Trevena Indemnitee or the breach by Trevena of any express warranty or representation made by Trevena in this Agreement.

8.6 Conditions of Indemnification

A Party (an “*Indemnified Party*”) which intends to claim indemnification under this Article 8 shall notify the other Party (an “*Indemnifying Party*”) within a reasonable time in writing [*] of any Claim, in respect of which the Indemnified Party believes it is entitled to claim indemnification; *provided, however,* that the failure to give timely notice to the Indemnifying Party shall not release the Indemnifying Party from any liability to the Indemnified Party to the extent the Indemnifying Party is not prejudiced thereby. The Indemnifying Party shall have the right, by notice to the Indemnified Party, to assume the defense of any such action or claim within [*] of any Claim with counsel of the Indemnifying Party’s choice and at the sole cost of the Indemnifying Party. If the Indemnifying Party does not so assume the defense of such Claim, the Indemnified Party may assume such defense with counsel of its choice and at the sole cost of the Indemnifying Party. If the Indemnifying Party so assumes such defense, the Indemnified Party may participate therein through counsel of its choice, but at the sole cost of the Indemnified Party. The Party not assuming the defense of any such claim shall render all reasonable assistance to the Party assuming such defense, and all reasonable out-of-pocket costs of such assistance shall be for the account of the Indemnifying Party. No such Claim shall be settled other than by the Party defending the same, and then only with the consent of the other Party which shall not be unreasonably withheld; *provided, however,* that the Indemnified Party shall have no obligation to consent to any settlement of any such Claim which imposes on the Indemnified Party any liability or obligation which cannot be assumed and performed in full by the Indemnifying Party, and the Indemnified Party shall have no right to withhold its consent to any settlement of any such Claim if the settlement involves only the payment of money by the Indemnifying Party or its insurer.

8.7 No Consequential Damages

EXCEPT FOR A PARTY’S INDEMNIFICATION OBLIGATIONS OR BREACH OF ARTICLE 11, NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES, LOST PROFITS, BUSINESS OR USE RESULTING FROM ANY BREACH OF THIS AGREEMENT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY

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THEREOF, AND REGARDLESS OF THE LEGAL OR EQUITABLE THEORY (CONTRACT, TORT, OR OTHERWISE).

ARTICLE 9 INTELLECTUAL PROPERTY RIGHTS

9.1 Background Intellectual Property

(a) **Pfizer IP.** The Parties acknowledge that all rights to and interest in Intellectual Property developed or obtained by or on behalf of Pfizer (i) prior to the Effective Date and or (ii) independent of this Agreement, and (iii) without the use of or reliance upon the Confidential Information of Trevena or any Trevena Background IP (as defined below) (collectively the "**Pfizer Background IP**") will remain the exclusive property of Pfizer. Pfizer hereby represents and warrants that Pfizer owns, or holds sufficient rights to use for the purposes of manufacturing Product, all Pfizer Background IP used by Pfizer in the manufacture of Product(s) pursuant to this Agreement.

(b) **Trevena IP.** The Parties acknowledge that all rights to and interest in Intellectual Property, including, collectively (i) the Drug and the API, (ii) the Product, (iii) API Specifications, (iv) the Intellectual Property of Trevena developed or obtained by or on behalf of Trevena (A) prior to the Effective Date, or (B) independent of this Agreement and without the use of the Confidential Information of Pfizer, and (v) the Manufacturing Process, and any intermediates or derivatives thereof as contained in b(i)-(v) hereof are referred to herein as "**Trevena Background IP**" will remain the exclusive property of Trevena. Trevena hereby grants to Pfizer a non-exclusive, royalty-free, non-transferable license (with no rights to sublicense), under the Trevena Background IP, solely for purposes of performing its obligations under this Agreement, during the Term hereof. Pfizer agrees that its rights to Trevena Background IP are for the limited purpose of performing Pfizer's obligations under this Agreement and for no other purpose, express or implied, and shall not be shared with any Third Party, competitor or generic drug manufacturer.

9.2 Development IP

All Intellectual Property developed by Pfizer in performance of its obligations under this Agreement including (a) improvements to Trevena's Manufacturing Processes; and/or (b) improvements to the API or Product or the processing of the API used in the manufacturing of the Product shall be owned by Trevena ("**Trevena Development IP**"). Pfizer shall assign, and does hereby assign, to Trevena all right title and interest in and to such Trevena Development IP. Pfizer will promptly notify Trevena of any such Trevena Development IP, and will provide as much information about such Trevena Development IP as may be reasonably requested by Trevena. For the sake of clarity, improvements to Pfizer Background IP by Pfizer in performance of the development activities and any other developments or discoveries that Pfizer may make in the performance of its obligations hereunder that relate to general technology for fill-finish operations of injectable drugs, for example, aseptic filling, terminal sterilization, lyophilization and the like and that do not use any Trevena Background IP or Trevena Development IP or Trevena Confidential Information shall be owned by Pfizer ("**Pfizer Development IP**"). In the event that Pfizer incorporates any Pfizer Background IP, Pfizer Development IP or Pfizer Confidential Information into the processing, filling, and/or finishing of the Product in the

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performance of its obligations hereunder, Pfizer will grant, and does hereby grant to Trevena a non-exclusive, perpetual, worldwide, fully paid-up, transferrable (with rights to sub-license) and royalty-free license solely to develop, have developed, make, have made, use, import, export, commercialize, register, modify, enhance, improve, offer for sale and sell the Product.

9.3 No Implied Licenses

No right or license is granted under this Agreement by either Party to the other, either expressly or by implication, except those specifically set forth herein.

ARTICLE 10 TERM AND TERMINATION

10.1 Term

This Agreement will commence on the Effective Date and, unless earlier terminated as provided in this Article 10, will expire at the end of the fifth (5th) Commercial Year ("**Initial Term**"). This Agreement will be automatically extended for additional and successive renewal terms of two (2) years each ("**Renewal Term**"), unless either Party gives notice of non-renewal at least twenty-four (24) months prior to the expiry date of the Initial Term or any Renewal Term.

10.2 Termination of Project

Either Party shall have the right to terminate the Project in accordance with the provisions herein. The Party wishing to terminate the Project shall request in writing a pre-termination consultation with the other Party to review potential concerns and to make reasonable efforts to continue with this Agreement. [*] days following said consultation, either Party may terminate the Project upon a further [*] days' prior written notice to the other Party if the terminating Party determines in good faith that the development of the Product is not clinically, commercially or technically feasible using commercially reasonable efforts. If the Project or this Agreement is terminated in accordance with this Section 10.2, Pfizer will advise Trevena of the costs it has incurred under the Project up to the date of such termination Trevena will pay to Pfizer that portion of the Development Fees that represents (a) the work that Pfizer has completed and for which payment has not yet been received, and (b) on a *pro rata* basis, all work that Pfizer has undertaken but not yet completed as of the date of notice of termination. In addition, Trevena will reimburse Pfizer for all of its out-of-pocket costs related to any non-cancelable commitments for raw materials, Components and other services that Pfizer has undertaken as part the Project in accordance with the Statement of Work. Trevena shall pay Pfizer any amount [*].

10.3 General Termination Rights

Either Party may terminate this Agreement:

(a) **Failure to Obtain Regulatory Approval.** Upon [*] days written notice if the FDA or other relevant Regulatory Authority does not grant Regulatory Approval for the Product by December 31, 2019; or

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(b) **Bankruptcy.** Immediately by providing written notice to the other Party: (i) if proceedings in voluntary or involuntary bankruptcy are initiated by, on behalf of or against the other Party (and, in the case of any such involuntary proceeding, not dismissed within [*] days); or (ii) if the other Party is adjudicated bankrupt, files a petition under applicable insolvency laws, is dissolved or has a receiver appointed for substantially all of its property; or

(c) **Material Breach.** By giving to the other Party [*] days' prior written notice upon the breach of any warranty or any other material provision of this Agreement by the other Party if the breach is not cured within [*] days after written notice thereof to the Party in default;

(d) **Force Majeure.** Upon simple notice to the other Party should the other Party continue to be unable to perform its obligations under this Agreement for a period in excess of [*] days by reason of *force majeure*, in accordance with Section 12.1(a).

10.4 Pfizer Specific Termination Rights

Pfizer shall have the right to terminate this Agreement:

(a) **Failure to Purchase Minimums.** upon ninety (90) days prior written notice to Trevena if, in any two (2) consecutive Commercial Years, Trevena fails to meet its Minimum Purchase Requirements and waives Pfizer's manufacturing and delivery obligations pursuant to Section 6.8.

10.5 Termination Without Cause

Either Party may terminate this Agreement at any time and for any reason or for no reason upon providing [*] notice to the other Party; *provided, however*, that neither Party shall issue such notice until after the third Commercial Year.

10.6 Consequences of Termination

Upon expiry or termination of this Agreement for whatever reason the Parties will wind-up this Agreement and settle all outstanding issues in accordance with the principles described below.

(a) **Cessation of Manufacturing.** Pfizer will cease all manufacturing-in-progress and other ongoing activities in an orderly manner, unless Pfizer reasonably determines that manufacturing-in-progress or other ongoing activities must be completed in order to comply with applicable laws and regulations.

(b) **Disposition of Inventory, API, Dedicated Equipment.** At a time to be mutually agreed between the Parties, Pfizer will return to Trevena, at Trevena's option and election (i) any quantities of work-in-progress at price(s) to be mutually agreed, (ii) any inventory of API remaining in Pfizer's possession, and (iii) all items of Dedicated Equipment. All expenses associated with the preparation, packing and delivery of the work-in-progress, API, and Dedicated Equipment shall be borne by Trevena, unless termination shall have been as a result of a material breach by Pfizer, in which case Pfizer will be responsible for such expenses. If Trevena does not elect to take back the work-in-progress, API, or Dedicated Equipment,

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Trevena may direct Pfizer to destroy such work-in-progress, API or Dedicated Equipment. If Trevena does not elect either option, Pfizer may dispose of such items as it deems appropriate. In no instance may Pfizer share any such items with a competitor or generic drug manufacturer.

(c) **Reimbursement for Components and Materials.** In addition, Trevena will reimburse Pfizer for Pfizer's cost of all Components and other raw materials purchased and on hand or on order, if such Components and materials were ordered by Pfizer based on Trevena's Product forecasts, and Pfizer cannot reasonably use such Components and materials for other purposes. Pfizer will invoice Trevena for all amounts due hereunder and Trevena will pay such invoice on the terms set forth in Section 6.14.

(d) **Return of Confidential Information.** Upon expiry or earlier termination of this Agreement for any reason, each Party shall promptly return [*] to the other all of the other Party's Confidential Information, in any form or medium disclosed by the disclosing Party. In lieu of returning all Confidential Information, each Party shall have the option to destroy any Confidential Information in place and/or purge it from its respective electronic information systems; *provided, however*, that neither Party shall be required to destroy any computer files stored securely by a Party that are created during automatic system back-up, all of which shall remain bound by the confidentiality provisions of in Article 11 of this Agreement and any prior confidentiality agreement between the Parties notwithstanding the expiration or termination of such agreements. Notwithstanding the foregoing, each Party shall be allowed to retain one (1) copy of the other's Confidential Information to ensure continuing compliance with Article 11. *provided, however*, that all Confidential Information shall be returned no more than [*] years following expiration or termination of this Agreement or such longer period as may be required by Applicable Law.

10.7 Accrued Obligations

Termination of this Agreement will not relieve either Party of any liability which has accrued prior to the effective date of such termination, nor will prejudice either Party's right to obtain performance of any obligation provided for in this Agreement, which by its express terms or context survive termination.

10.8 Nonexclusive Rights and Remedies

Termination is not an election of remedies. Except as otherwise provided herein, all rights and remedies of the Parties provided under this Agreement are not exclusive and are in addition to any other rights and remedies provided by law or under this Agreement.

10.9 Survival

The terms, provisions, representations, and warranties contained in this Agreement that by their sense and context are intended to survive the performance hereof by either or both Parties will so survive the completion of performance and termination of this Agreement, including, confidentiality obligations and the making of any and all payments due hereunder.

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ARTICLE 11
CONFIDENTIAL INFORMATION

11.1 Confidential Information

As used in this Agreement, “**Confidential Information**” means, collectively, all of Party’s written or oral information, whether or not it has been identified as confidential or that by the nature of the information or the circumstances surrounding disclosure ought reasonably to be treated as confidential and/or proprietary, including, but not limited to, any oral, written, graphic or machine-readable information relating to a Party’s and its Affiliates’ businesses, protocols, projects or products, whether patentable or not, including but not limited to, know-how, scientific information, chemical structures, compounds, devices, data, documents, methods, trade secrets, patent applications, work product, intellectual property, technology, financial or business information and transactions already entered into or contemplated that have been disclosed or will be disclosed in the future by such Party or its designee (“disclosed” shall include any information learned or witnessed by the other Party), or information exchanged for the purpose of exploring a potential business transaction between the Parties and/or their Affiliates or any information which already is subject to an existing confidentiality agreement. For the avoidance of doubt, the definition of Confidential Information shall include Confidential Information of each Party’s Affiliates. The Party disclosing Confidential Information shall be referred to as the “**Discloser**” and the Party receiving Confidential Information shall be referred to as the “**Recipient**”. The Parties agree that any Confidential Information disclosed between them under the pre-existing Mutual Nondisclosure Agreement, dated as of March 3, 2015 (as amended and extended), shall be subsumed under the terms of this Article 11. Confidential Information does not include information that (a) is in possession of the receiving Party at the time of disclosure, as reasonably demonstrated by written records and without obligation of confidentiality and not subject to a prior confidentiality agreement, (b) is or later becomes part of the public domain through no fault of the receiving Party, (c) is received by the receiving Party from a Third Party without obligation of confidentiality, or (d) is developed independently by the Recipient without use of, reference to, or reliance upon the Discloser’s Confidential Information by individuals who did not have access to Confidential Information. The Discloser shall, to the extent practical, use reasonable efforts to label or identify as confidential, at the time of disclosure all such Confidential Information that is disclosed in writing or other tangible form. Confidential Information of Pfizer includes all of Pfizer’s manufacturing processes, technology and know-how, whether or not labeled confidential. Confidential Information of Trevena includes among other things, Trevena’s processes, technology, know-how, API and materials, whether or not labeled confidential.

11.2 Duty of Nondisclosure and Non-Use; Exceptions

Each Party agrees (a) to keep confidential the Confidential Information of the other Party, (b) not to disclose the other Party’s Confidential Information to any Third Party, including, any generic drug manufacturers or companies without the prior written consent of such other Party, and (c) to use such Confidential Information only as necessary to fulfill its obligations or in the reasonable exercise of rights and obligations granted to it hereunder. Notwithstanding the foregoing, a Party may disclose (i) Confidential Information of the other Party to its Affiliates, and to its and their directors, employees, consultants, and authorized agents in each case who

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have a specific need to know such Confidential Information and who are bound by a either and effective written agreement or professional obligation of confidentiality and restrictions on use at least no less restrictive as contained herein, (ii) its respective Development IP, to the extent required to exploit its rights under Article 9 of this Agreement, and (iii) Confidential Information of the other Party to the extent such disclosure is required to comply with Applicable Law or to defend or prosecute litigation; *provided, however*, that the Recipient provides prior written notice of such disclosure to the Discloser and takes reasonable and lawful actions to avoid or minimize the degree of such disclosure. Furthermore, Trevena may disclose Confidential Information of Pfizer relating to the Project and/or the manufacture of Product to Regulatory Authorities and entities with whom Trevena has (or may have) a marketing and/or development collaboration and who have a specific need to know such Confidential Information and who is or are around Party to an effective agreement protecting the Confidential Information on terms no less restrictive than those contained herein.

11.3 Public Announcements

Neither Party will make any public announcement concerning the transactions contemplated herein, or make any public statement or filing which includes the name of the other Party or any of its Affiliates, or otherwise use the name of the other Party or any of its Affiliates in any public statement or document, except as may be required by law, the rules of a stock exchange or judicial order, without the written consent of the other Party, which consent will not be unreasonably withheld. Subject to any legal or judicial disclosure obligation, any such public announcement or filing proposed by a Party that names the other Party will first be provided in draft to the other Party.

11.4 Injunctive Relief

The Parties acknowledge that either Party's breach of this Article 11 may cause the other Party irreparable injury for which it would not have an adequate remedy at law. In the event of a breach, the non-breaching Party may be entitled to injunctive relief in addition to any other remedies it may have at law or in equity.

ARTICLE 12 MISCELLANEOUS

12.1 Force Majeure and Failure of Suppliers.

(a) ***Force Majeure.*** Neither Party will be considered to be in breach of this Agreement if a delay in the performance of any of its duties or obligations hereunder (except the payment of money) has been caused by or is the result of an act of God, acts of a public enemy, acts of terrorism, insurrections, riots, embargoes, labor disputes, including strikes, lockouts, job actions, boycotts, fires, explosions, floods, shortages of material or energy, or other unforeseeable causes beyond the control and without the fault or negligence of the Party so affected (each an event of "***force majeure***"). The performance of the affected Party will be extended for a period equal to the period of such delay; *provided, however*, that affected Party will give prompt notice to the other Party of such cause, and will promptly take whatever reasonable steps are necessary to relieve the effect of such *force majeure* and resume compliance with this Agreement as soon as possible. Should the event of *force majeure* continue for a period

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longer than [*] days, then the Party not so affected may terminate this Agreement in accordance with Section 10.3(d).

(b) **Transfer of Production.** If Pfizer becomes subject to an event of *force majeure* which interferes with production of Product at the Facility, the Parties will mutually agree on implementation of an agreed-upon action plan to transfer production of Product to another Pfizer manufacturing facility. The Parties will, after the execution of this Agreement and at the request of either Party, meet to discuss and define such an action plan.

12.2 Notices

All notices, requests, claims, demands and other communications between the Parties will be in writing. All notices will be given (a) by delivery in person, (b) by a nationally recognized next day courier service, (c) by first class, registered or certified mail, postage prepaid, (d) by facsimile, or (e) by PDF scanned copy sent by electronic mail to the following addresses of the respective Parties:

If to Trevena:

Trevena, Inc.
1018 W. 8th Avenue, Suite A
King of Prussia, PA 19406

Attention: Michael Lark
Facsimile: (610) 354-8850
Email: mlark@trevenainc.com

If to Pfizer:

Pfizer CentreOne
Pfizer, Inc.
275 North Field Drive
Lake Forest, Illinois 60045

Attention: V.P. Contract Manufacturing
Facsimile: (224) 212-3210
Email: kevin.orfan@pfizer.com

With a copy to: Trevena Legal Department

Trevena, Inc.
1018 W. 8th Avenue, Suite A
King of Prussia, PA 19406

Attention: General Counsel
Facsimile: (610) 354-8850
Email: jlimongelli@trevena.com

With copy to:

Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Attention: General Counsel
Facsimile: (212) 309 0874
Email: generalcounsel@pfizer.com

Notices will be effective (w) upon receipt, if personally delivered, (x) is sent by courier, [*] Business Day after the delivery time promised by the nationally recognized next day courier service, (y) if delivered by facsimile or electronic mail, on the [*] Business Day after the date of receipt by the transmitting person of written confirmation of successful transmission (which confirmation may be produced by the transmitting person's facsimile or electronic mail equipment), or (z) [*] Business Days after being deposited in the United States mail, with proper postage and documentation, for first-class registered or certified mail, prepaid. A Party may change its address listed above by written notice to the other Party.

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12.3 Governing Law

This Agreement will be construed, interpreted and governed by the laws of the State of Delaware, excluding its choice of law provisions. The United Nations Convention on the International Sale of Goods is hereby expressly excluded.

12.4 Alternative Dispute Resolution

The Parties recognize that bona fide disputes may arise which relate to the Parties' rights and obligations under this Agreement. The Parties agree that except as provided in Section 11.4, any such dispute will be resolved by alternative dispute resolution in accordance with the procedures set forth in Schedule 12.4.

12.5 Assignment

Neither Party will assign this Agreement nor any part thereof without the prior written consent of the other Party; *provided, however*, that either Party may, without such consent, assign the rights and obligations of this Agreement (a) to one of its Affiliates, subsidiaries or parent corporation, and (b) in connection with the transfer, sale or divestiture of substantially all of its business to which this Agreement pertains or in the event of its spin-off, merger or consolidation with another company. Any permitted assignee will assume all obligations of its assignor under this Agreement. No assignment will relieve either Party of responsibility for the performance of any accrued obligation which such Party then has hereunder.

12.6 Severability

This Agreement is subject to the restrictions, limitations, terms and conditions of all applicable governmental regulations, approvals and clearances. If any term or provision of this Agreement will for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other term or provision hereof, and this Agreement will be interpreted and construed as if such term or provision, to the extent the same will have been held to be invalid, illegal or unenforceable, had never been contained herein.

12.7 Modification of Agreement; Waiver

No waiver or modification of any of the terms of this Agreement will be valid unless in writing and signed by authorized representatives of both Parties. Failure by either Party to enforce any such rights under this Agreement will not be construed as a waiver of such rights, nor will a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

12.8 Relationship of the Parties

The relationship of the Parties under this Agreement is that of independent contractors. Nothing contained in this Agreement or the performance of any obligations under this Agreement will create an association, partnership, joint venture, or relationship of principal and agent, master and servant, or employer and employee between the Parties hereto. Neither Party has any express or implied right or authority under this Agreement to assume or create any

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obligations or make any representations or warranties on behalf of or in the name of the other Party or its Affiliates.

12.9 Insurance

Each party will procure and maintain, at its own expense, for the duration of the Agreement, and for five (5) years thereafter if written on a claim made or occurrence reported form, the types of insurance specified below with carriers rated A- VII or better with A. M. Best or like rating agencies:

- (a) Workers' Compensation in accordance with applicable statutory requirements and [*] Employers Liability and each party shall provide a waiver of subrogation in favor of the other party and its affiliate;
- (b) Commercial General Liability including premises operations, products & completed operations, blanket contractual liability, personal injury and advertising injury including fire legal liability for bodily injury and property damage in an amount [*] per occurrence and [*] in the aggregate;
- (c) Commercial Automobile Liability for owned, hired and non-owned motor vehicles with a combined single limit in an amount [*];
- (d) Marine Insurance covering all shipments from warehouse to warehouse as described on the bill of lading at full replacement cost, except as otherwise provided herein.

Each party will include the other party and its Affiliates, directors, officers, employees and agents as additional insureds with respect to Commercial General Liability (via CG20101185 or its equivalent), Commercial Automobile Liability and Excess Liability but only as required by written contract. Prior to commencement of the development services, and annually thereafter, each party will furnish to the other party certificates of insurance evidencing the insurance coverages stated above. At least [*] days written notice to the other party shall be provided prior to any cancellation, non-renewal or material change in said coverage. In the case of cancellation, non-renewal or material change in said coverage, each party will promptly provide to the other party a new certificate of insurance evidencing that the coverage meets the requirements in this Section 12.9. Each party, to the extent of its negligence, agrees that its insurance will act as primary and noncontributory from any other valid and collectible insurance maintained by the other party. Pfizer may, at its option, satisfy, in whole or in part, its obligation under this Section 12.9 through its self-insurance program. Each party may satisfy its insurance requirements by any combination of primary and excess coverage. Each party shall provide a waiver of subrogation in favor of the other party and its affiliates on all required coverages, above. All deductibles/retentions are the sole responsibility of the named insured.

12.10 Schedules

All Schedules referred to herein are hereby incorporated by reference.

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12.11 Binding Effect

This Agreement will be binding upon and inure to the benefit of each of the Parties and such Party's successors and permitted assigns.

12.12 Debarment Warranty

Pfizer and Trevena represent and warrant that neither Party uses nor will use in the future use in any capacity the services of any person debarred under Section (a) or (b) of 21 U.S.C. Section 335a.

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12.13 Compliance with Laws

Each Party will comply with all Applicable Laws, statutes, rules and regulations governing its performance of the terms of this Agreement.

12.14 Entire Agreement

This Agreement and the Quality & Technical Agreement, together with the Schedules referenced and incorporated herein, constitute the entire agreement between the Parties concerning the subject matter hereof and supersede all written or oral prior agreements or understandings with respect thereto. If there is any conflict, discrepancy, or inconsistency between the terms of the Quality & Technical Agreement, this Agreement or other form used by the Parties, the Quality & Technical Agreement will control as regards all issues related to quality assurance; in all other cases, the Agreement will control.

12.15 Condition Precedent

This Agreement will enter into force as of the Effective Date, but will remain conditional upon the Parties negotiating and delivering a Quality & Technical Agreement, signed by all required authorized quality officers and representatives of both Parties.

12.16 Construction

In construing this Agreement, unless expressly specified otherwise (a) references to Articles, Sections and Schedules are to articles, sections of, and Schedules to, this Agreement, (b) except where the context otherwise requires, use of either gender includes the other gender, and use of the singular includes the plural and vice versa, (c) headings and titles are for convenience only and do not affect the interpretation of this Agreement, (d) any list or examples following the word “including” will be interpreted without limitation to the generality of the preceding words, (e) except where the context otherwise requires, the word “or” is used in the inclusive sense, (f) all references to “dollars” or “\$” herein will mean United States Dollars, and (g) each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions. Any terms or conditions contained in an invoice that are inconsistent or in conflict with this Agreement will be deemed not to be a part of such invoice.

12.17 Counterparts

This Agreement may be executed in any number of counterparts, each of which will be deemed an original, and all of which together will constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail will be deemed to be original signatures. Any Party delivering an executed counterpart of this Agreement by facsimile or electronic mail will also deliver an original executed counterpart, but the failure to do so will not affect the validity, enforceability or binding effect of this Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

IN WITNESS WHEREOF, the Parties intending to be bound by the terms and conditions hereof have caused this Agreement to be signed by their duly authorized representatives as of the date first above written.

**PFIZER CENTREONE
PFIZER, INC.**

TREVENA, INC.

By: _____ By: _____
(Signature) (Signature)

| | | | |
|--------|---|--------|--|
| Name: | Kevin Orfan | Name: | Michael W. Lark, Ph.D. |
| Title: | Vice President Pfizer CentreOne Contract Manufacturing Services | Title: | Senior Vice President, Research and Chief Scientific Officer |

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SCHEDULE 1.2

API Specifications

[*](1 page omitted)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule Page I

SCHEDULE 1.25

Product Specifications

[*](1 page omitted)

[*]= Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule Page II

SCHEDULE 2.1

Project Statement of Work

[*]

(10 pages omitted)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule Page III

SCHEDULE 3.1

Estimated Payment Schedule

[*](1 page omitted)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule Page IV

SCHEDULE 3.2

Stability Studies

[*]

(2 pages omitted)

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SCHEDULE 5.5

Dedicated Equipment

[*] (1 page omitted)

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Schedule Page VI

SCHEDULE 6.11

Pfizer Logger Policies

[*] (1 page omitted)

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Schedule Page VII

SCHEDULE 6.13

Product Price Estimates

[*] (1 page omitted)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule Page VIII

SCHEDULE 7.1

Product Test Methods

[*] (1 page omitted)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule Page IX

SCHEDULE 7.2

Quality & Technical Agreement

[*] (1 page omitted)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule Page X

SCHEDULE 12.4

Alternative Dispute Resolution

[*] (3 pages omitted)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

ANNEX 1

Letter of Engagement

(LOE attached following this Annex 1 cover page)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**Certification of Principal Executive Officer of Trevena, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Maxine Gowen, certify that:

1. I have reviewed this Amendment No. 1 to the Annual Report on Form 10-K of Trevena, Inc.; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: June 14, 2018

/s/ Maxine Gowen

Maxine Gowen
President and Chief Executive Officer
(Principal Executive Officer)

**Certification of Principal Financial Officer of Trevena, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, John P. Hamill, certify that:

1. I have reviewed this Amendment No. 1 to the Annual Report on Form 10-K of Trevena, Inc.; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: June 14, 2018

/s/ John P. Hamill

John P. Hamill
Interim Principal Financial Officer

**Certification Of
Principal Executive Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 Of The Sarbanes-Oxley Act Of 2002**

In connection with Amendment No. 1 to the Annual Report of Trevena, Inc. (the "Company") on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Maxine Gowen, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: June 14, 2018

/s/ Maxine Gowen

President and Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Report and shall not be deemed "filed" by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

**Certification Of
Principal Financial Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 Of The Sarbanes-Oxley Act Of 2002**

In connection with Amendment No. 1 to the Annual Report of Trevena, Inc. (the "Company") on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John P. Hamill, Interim Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: June 14, 2018

/s/ John P. Hamill

Interim Principal Financial Officer

This certification accompanies the Report and shall not be deemed "filed" by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.
