Exhibit 10.39  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 MANUFACTURING AGREEMENT  
 THIS AGREEMENT is made and entered into effective as of the 30th day of September, 2014, by and between Anacor Pharmaceuticals, Inc, a company with its principal place of business at 0000 Xxxx Xxxxxx Xxxxxx, Xxxx Xxxx, Xxxxxxxxxx 00000-0000, XXX (“COMPANY”), and Hovione FarmaCiencia SA, a company with its principal place of business at Sete Xxxxx, 2674-506 Loures, Portugal (“HOVIONE”).  
 WHEREAS, HOVIONE has expertise, facilities and experience related to the development, synthesis, formulation, testing and production of active pharmaceutical ingredients, has both pilot plant and commercial scale facilities to provide such manufacturing services and has been interested in providing such manufacturing services to COMPANY.  
 WHEREAS, COMPANY has been desirous of utilizing the services of HOVIONE to manufacture COMPANY’s active pharmaceutical ingredient “Tavaborole” using the validated technology on a commercial scale in HOVIONE’s facility.  
 NOW, THEREFORE, in consideration of the acknowledgements, confirmations, representations, warranties and covenants contained herein, COMPANY and HOVIONE (which shall each hereinafter be referred to as a “Party” or together as the “Parties”) hereby agree as follows:  
 ARTICLE 1  
DEFINITIONS  
 The following terms (in addition to such other terms as are specifically defined within the Agreement), whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement:  
 1.1 “Affiliate” shall mean, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.  
 1.2 “Agreement” shall mean this Manufacturing Agreement dated as of the date first set forth above, as the same may be amended from time to time.  
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 1.3 “API” shall mean the active pharmaceutical ingredient Tavaborole.  
 1.4 “Applicable Laws” shall mean all applicable ordinances, rules, regulations, laws, guidelines, guidance, statutes, requirements and court orders of any kind whatsoever, as amended from time to time, including the bodies of law, regulations (including without limitation, cGMP or its equivalent) for each country of the Territory, including but not limited to, in the US, the FD&C Act.  
 1.5 “[\*\*\*\*\*] SOW” shall have the meaning set forth in Section 2.2 hereof.  
 1.6 “Batch” shall mean a specific quantity of API, as further described in Exhibit 1 hereto, that is intended to be of uniform character and quality, within specified limits, and is produced during the same cycle of Manufacture as defined by the Batch record.  
 1.7 “Calendar Year” shall mean the twelve (12) month period commencing on January 1, and each separate successive twelve (12) month period thereafter during the Term, with the exception of the period commencing on the Effective Date of this Agreement and ending on the immediately succeeding December 31st, which will be considered Contract Year 0.  
 1.8 “cGMP’s” shall mean current good manufacturing practices established by the FDA or any equivalent regulatory agency in the Territory applicable to the manufacture and testing of active pharmaceutical ingredients.  
 1.9 “Certificate of Analysis” shall have the meaning set forth in Section 10.1 hereof.  
 1.10 “Confidential Information” shall mean all information, data, know-how and all other business, technical and financial data disclosed hereunder by one Party or any of its Affiliates to the other Party or any of its Affiliates, except any portion thereof which:  
 1.10.1 at the time of disclosure, is in the public knowledge; or  
 1.10.2 after disclosure, becomes part of the public knowledge, by publication or otherwise, except by breach of this Agreement by the recipient; or  
 1.10.3 the recipient can demonstrate by its written records was in the recipient’s possession at the time of such disclosure, and which was not acquired, directly or indirectly, from the disclosing Party; or  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
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 1.10.4 is lawfully disclosed to the recipient on a non-confidential basis by a third party who is not obligated, directly or indirectly, to the disclosing Party to retain such information in confidence.  
 This Agreement and its terms and conditions shall be deemed Confidential Information of each Party. Confidential Information disclosed orally, visually and/or in another intangible form shall be identified by the disclosing Party to the receiving Party as confidential at the time of such disclosure.  
 1.11 “Delivery Date” shall mean a date on which delivery of API or other services is designated in a purchase order placed by COMPANY under this Agreement.  
 1.12 “Drug Master File” or “DMF” shall mean a drug master file providing detailed information about the facility, the equipment and Manufacturing processes relating to API and such other information as required by Applicable Laws, including 21 C.F.R. Section 314.420 and to the extent applicable, any equivalent requirement under Applicable Laws.  
 1.13 “Effective Date” shall mean the date first appearing at the beginning of this Agreement.  
 1.14 “Facility” shall have the meaning set forth in Section 2.5.  
 1.15 “FD&C Act” shall mean the United States Federal Food, Drug and Cosmetic Act, including all regulations, guidelines and guidances arising thereunder, as any of the same may be amended from time to time.  
 1.16 “FDA” shall mean the United States Food and Drug Administration or any successor entity.  
 1.17 “Initial Term” shall have the meaning set forth in Section 9.1 hereof.  
 1.18 “Licensee(s)” shall mean any third party licensee of the Product.  
 1.19 “Manufacture”, “Manufactured” or “Manufacturing” shall mean all operations of HOVIONE in the scheduling, production, Process, packaging, labeling, warehousing, quality control testing (including as requested all in-process, release and stability testing), release and storage of API.  
 1.20 “Process” shall mean the series of operations needed to convert the Starting Materials to API, including the testing thereof.  
 1.21 “Product” shall mean the finished product form of the pharmaceutical product Kerydin™ (tavaborole) topical solution, 5%.  
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 1.22 “Quality Agreement” shall have the meaning set forth in Section 7.1 hereof and be attached as Exhibit 2 hereof.  
 1.23 “Regulatory Application” shall mean the new drug application or other submission made by COMPANY to the FDA or any equivalent regulatory agency in the Territory seeking allowance to market, distribute and sell the Product in the United States and/or elsewhere in the Territory, as such application may be amended or supplemented.  
 1.24 “Regulatory Authority(ies)” shall mean the regulatory entities in the Territory with regulatory authority over the manufacture, storage, testing, use or sale of pharmaceutical products (including API), as well as any successor entity thereto. In the United States “Regulatory Authority” includes the FDA.  
 1.25 “Specifications” shall mean the specifications for the API as set forth in Exhibit 1 (as may be amended from time to time by written agreement of the Parties).  
 1.26 “Starting Materials” shall mean those materials identified on Exhibit 4. Such Starting Materials shall meet the Specifications.  
 1.27 “Term” shall have the meaning set forth in Section 9.1 hereof.  
 1.28 “Territory” shall mean the United States of America, including all possessions, territories and commonwealths thereof and all United States military bases, and such other markets as the Parties may, from time to time, designate in writing.  
 ARTICLE 2  
COMMERCIAL MANUFACTURE AND SUPPLY OF API  
 2.1 Manufacture and Supply. Subject to the terms of this Agreement, (i) during (A) the period from the Effective Date until [\*\*\*\*\*], COMPANY shall purchase from HOVIONE [\*\*\*\*\*] of COMPANY’s and its Affiliates’ requirements of API for Product intended for distribution in the Territory, and (B) [\*\*\*\*\*], COMPANY shall purchase from HOVIONE [\*\*\*\*\*] of COMPANY’s and its Affiliates’ requirements of API for Product intended for distribution in the Territory, and (ii) HOVIONE shall Manufacture and supply such API ordered by COMPANY in accordance with this Agreement. Notwithstanding the foregoing, COMPANY may (x) qualify a third party manufacturer as an alternate supplier of API for COMPANY (such third party manufacturer being referred to herein as the “Alternate Supplier”), (y) require that HOVIONE provide the Alternate Supplier [\*\*\*\*\*] all Manufacturing information, including, without limitation, documentation, technical assistance, materials and reasonable cooperation by appropriate employees of HOVIONE necessary to qualify such Alternate Supplier, and (z) purchase,  
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 subject to the below proviso, quantities of API for use in the Territory from such Alternate Supplier as necessary to maintain such Alternate Supplier as an alternate supplier; provided, however, that, unless otherwise permitted under Section 4.3, [\*\*\*\*\*]. For the avoidance of doubt, during any period during the Term that any Licensee is obligated to purchase from COMPANY Product for sale, distribution and promotion in the Territory, COMPANY agrees to purchase API used in the manufacture of such Product in accordance with its obligations under this Agreement.  
 2.2 Forecasts; Orders. Commencing on the [\*\*\*\*\*] following the execution of this Agreement, COMPANY shall provide HOVIONE with a rolling [\*\*\*\*\*] forecast of COMPANY’s and its Affiliates’ anticipated orders of API for sales of the Product in the Territory, which forecast shall be updated no less than [\*\*\*\*\*] during the Term (each, a “Forecast”). Each Forecast after the first Forecast shall be provided to HOVIONE no later than [\*\*\*\*\*] after the start of [\*\*\*\*\*] to assist HOVIONE in planning its production. The [\*\*\*\*\*] of each Forecast shall be binding and the remaining [\*\*\*\*\*] shall be non-binding. COMPANY shall place firm orders for the API using its standard purchase orders (which shall be subject to the terms of this Agreement), setting forth the quantity of API required [\*\*\*\*\*], as well as its required Delivery Dates, which shall be in no event earlier than [\*\*\*\*\*] from the date of the purchase order (any such purchase order, a “COMPANY Purchase Order”). HOVIONE will notify COMPANY of its receipt of each COMPANY Purchase Order within [\*\*\*\*\*] thereafter. Such notice will include confirmation of the Delivery Date, which shall be not less than [\*\*\*\*\*] from the date of the COMPANY Purchase Order issue date. If HOVIONE fails to notify COMPANY of its receipt of such COMPANY Purchase Order within such [\*\*\*\*\*] period, the COMPANY Purchase Order will be deemed to have been received and accepted; provided, however, that if requested by COMPANY in writing, HOVIONE may agree, in its sole discretion, to deliver a shipment of API prior to the date that is [\*\*\*\*\*] after the date of the applicable COMPANY Purchase Order. Within [\*\*\*\*\*] after a COMPANY Purchase Order issue date, COMPANY may request that additional quantity of API be Manufactured under such COMPANY Purchase Order, such additional quantity to be delivered not less than [\*\*\*\*\*] after the COMPANY Purchase Order to which such additional quantity request relates; provided, that only such additional quantity of API, which shall not be greater than [\*\*\*\*\*] of the applicable COMPANY Purchase Order [\*\*\*\*\*], may be requested unless otherwise agreed to in writing by HOVIONE. HOVIONE shall use commercially reasonable efforts to Manufacture any such additional quantity, subject to HOVIONE’s other supply commitments and capacity. In the event of any conflict between the provisions of this Agreement and any COMPANY Purchase Order, acknowledgement, invoice, xxxx of lading, acceptance or other preprinted form provided by either Party, the provisions of this Agreement shall control. No additional provision in any other document shall apply unless both Parties explicitly agree in writing that such additional provision shall apply to the Parties rights and obligations under this Agreement. Notwithstanding the above, HOVIONE has agreed to use commercially reasonable efforts to manufacture [\*\*\*\*\*]  
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 Batches of API for Company no later than [\*\*\*\*\*] pursuant to that certain Statement of Work (the “[\*\*\*\*\*] SOW”) dated [\*\*\*\*\*] executed by COMPANY and HOVIONE.  
 2.3 Supply of Starting and Raw Materials. HOVIONE shall, based upon the maximum shelf life (or such longer period as equals the retest period) of all Starting Materials and the Forecast provided under Section 2.2, order Starting Materials required to Manufacture API from vendors that have been mutually agreed to and approved by the Parties. HOVIONE shall have sufficient Starting Materials as of the date hereof to Manufacture API for the [\*\*\*\*\*] batches of API deliverable under the [\*\*\*\*\*] SOW.  
 2.4 Quantities. HOVIONE shall Manufacture, supply and deliver to COMPANY such quantities of API as COMPANY orders and HOVIONE receives (or is deemed to receive), including any additional quantities requested by COMPANY in accordance with the terms and conditions of Section 2.2.  
 2.5 Facility; No Subcontracting. HOVIONE shall perform all work contemplated under this Agreement, including but not limited to all Manufacturing of the API, at its facilities at Hovione Loures (the “Facility”). HOVIONE shall not subcontract to any third party any part of the work contemplated under this Agreement without the prior written approval of COMPANY, which shall not be unreasonably withheld. If, to HOVIONE’s knowledge, any HOVIONE subcontractor approved by COMPANY is placed on ‘Official Action Indicated’ status by FDA or a substantially similar status by FDA or another Regulatory Authority, then HOVIONE shall promptly notify COMPANY and, at COMPANY’s request, HOVIONE shall use an alternate subcontractor approved by COMPANY.  
 ARTICLE 3  
OWNERSHIP OF MATERIALS  
 3.1 Ownership of Tangible Materials. COMPANY shall retain ownership of all information, documents, and materials which COMPANY has provided or provides to HOVIONE in connection with the Manufacture of API hereunder. Further, and without limitation, COMPANY shall solely own all reports, results, records (including batch records), documents and other tangible materials (collectively, the “Materials”) which HOVIONE generates or has generated in connection with this Agreement and such Materials shall be deemed COMPANY’s Confidential Information. For the avoidance of doubt, while the content of such reports will be solely owned by COMPANY, HOVIONE retains ownership of all report formats and templates. Upon COMPANY’s written request, HOVIONE shall take all commercially reasonable steps to transfer such Materials to COMPANY; provided, however, that HOVIONE shall be entitled to retain one copy of any such Materials solely for archival purposes. For the avoidance of doubt, and notwithstanding anything to the contrary in this Agreement, report formats and templates provided by HOVIONE hereunder shall, together with any other Confidential  
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 Information of HOVIONE, remain Confidential Information of HOVIONE in accordance with the terms and conditions of this Agreement.  
 3.2 Ownership of Intangible Materials. Subject to Section 3.3, as between COMPANY and HOVIONE, COMPANY shall solely own all patents, methods, techniques, trade secrets, copyrights, know-how, data, documentation, hardware, software, information, and other intangible material and intellectual property rights relating to the Process, Manufacture, Specifications, Starting Material, analytical methods, testing, use and sale of API. COMPANY hereby grants to HOVIONE the non-exclusive right to utilize the same solely in the Manufacture of API under this Agreement solely for the Term and purposes hereof. All inventions, know-how, technology, information, and other intangible material and intellectual property rights, whether patentable or not, including without limitation the Process, API, Manufacture, Specifications, Starting Materials, compositions, or product-by-process, and any improvements thereto, which are discovered, conceived, reduced to practice or created by HOVIONE and/or its agents or contractors in connection with all activities of HOVIONE pursuant to this Agreement (“Refinements”) shall be solely owned by COMPANY, subject only to HOVIONE’s non-exclusive right to utilize such Refinements in the Manufacture of API under this Agreement, and such Refinements shall be deemed COMPANY’s Confidential Information hereunder. HOVIONE hereby irrevocably assigns to COMPANY all of its right, title and interest in and to all Refinements. HOVIONE agrees to cooperate with COMPANY in seeking any patent protection for Refinements and to execute and deliver all documents and take such actions as may be considered necessary by COMPANY to obtain and defend intellectual property rights in the Refinements [\*\*\*\*\*]. Nothing in this Agreement shall be construed as granting to HOVIONE any right or license to any patent, trade secret, copyright or other proprietary right of COMPANY except as expressly provided herein.  
 3.3 HOVIONE Technology. Notwithstanding anything herein to the contrary, all methods, techniques, trade secrets, copyrights, know-how, data, documentation, hardware, software and other intellectual property of any kind, whether or not protectable under patent, trademark, copyright or similar law developed or obtained by or on behalf of HOVIONE (i) prior to the Effective Date without the use of the Confidential Information of COMPANY, or (ii) independent of this Agreement and without the use of the Confidential Information of COMPANY (such intellectual property, the “HOVIONE Technology”) and any improvements to the HOVIONE Technology that do not require the use of the Confidential Information of COMPANY (the “HOVIONE Improvements”) are and shall remain the exclusive property of HOVIONE. HOVIONE covenants that it shall neither incorporate any HOVIONE Technology or HOVIONE Improvements thereto into the API, nor shall it perform the services contemplated hereunder in a manner that would cause the Manufacture of the API to require a license to any HOVIONE Technology or HOVIONE Improvements without, in either case, first obtaining COMPANY’s prior written consent.  
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 ARTICLE 4  
EXCLUSIVITY BY HOVIONE  
 4.1 Exclusivity. Other than to fulfill its obligations hereunder and subject to Section 4.4, HOVIONE shall not, during the Term and for a period of [\*\*\*\*\*] thereafter: (i) [\*\*\*\*\*]; or (ii) [\*\*\*\*\*], in each case, without COMPANY’s prior written authorization.  
 4.2 [\*\*\*\*\*] Purchase Amount; Reporting. Subject to the terms of Sections 2.1 and 4.3 hereof, COMPANY shall, during (i) the period from the Effective Date until [\*\*\*\*\*], purchase from HOVIONE [\*\*\*\*\*] of COMPANY’s and its Affiliates requirements of API for Product intended for distribution in the Territory, and (ii) [\*\*\*\*\*], purchase from HOVIONE [\*\*\*\*\*] of COMPANY’s and its Affiliates’ requirements of API for Product intended for distribution in the Territory. No later than [\*\*\*\*\*], the COMPANY shall provide to HOVIONE a report certified by an officer of COMPANY setting forth (i) the total kilograms of API for Product intended for distribution in the Territory purchased by COMPANY and its Affiliates from all suppliers during the immediately preceding [\*\*\*\*\*] (the “Total Kilograms”), (ii) the total kilograms of API for Product intended for distribution in the Territory purchased by COMPANY and its Affiliates from HOVIONE during the immediately preceding [\*\*\*\*\*] (the “HOVIONE Kilograms”), and (iii) the difference between (i) and (ii) above. If, based on such report, [\*\*\*\*\*], COMPANY fails to purchase [\*\*\*\*\*] of COMPANY’s and its Affiliates’ API requirements, on a kilogram basis, for Product intended for distribution in the Territory from HOVIONE, COMPANY shall, within [\*\*\*\*\*] days after receiving HOVIONE’s written notice of such shortfall, pay to HOVIONE an amount equal to [\*\*\*\*\*]; provided, however, that no amount shall be payable by COMPANY to HOVIONE pursuant to this Section 4.2 to the extent such amount arises from HOVIONE’s inability to supply API to COMPANY ordered by COMPANY in accordance with this Agreement.  
 4.3 Insufficient Supply. During the Term, HOVIONE shall use commercially reasonable efforts to allocate its inventory and Manufacturing output of API to ensure that HOVIONE has sufficient supply of API to satisfy COMPANY’s orders. Notwithstanding the prior sentence, if at any time during the Term, HOVIONE is, or expects that it will be, unable, in full or in part, to satisfy COMPANY’s orders for API for any reason, including a Force Majeure Event (as defined in Section 14.1), HOVIONE shall so notify COMPANY as soon as possible, detailing the extent to which it will not meet such orders. In the event that at any time HOVIONE is unable to meet COMPANY’s requirements for API for more than [\*\*\*\*\*] for reasons other than COMPANY’s breach of the terms of this Agreement, then COMPANY will have the right, in its sole discretion, to cancel any and all outstanding COMPANY Purchase Orders subject to such supply interruption without penalty and purchase any and all of its requirements of API from the Alternate Supplier until such time as HOVIONE notifies COMPANY that HOVIONE is able to resume supplying COMPANY’s requirements of API (provided, however, that HOVIONE’s right to resume supply of such requirements  
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 does not include amounts of API that COMPANY is already committed to purchase from such Alternate Supplier).  
 4.4 Supply to Third Parties. COMPANY acknowledges that, notwithstanding anything to the contrary in this Agreement, HOVIONE shall have the right to (i) supply API to any Licensee or other third party, in each case, to the extent designated in writing by COMPANY, for use in products for sale outside the Territory and (ii) consent to COMPANY’s or any Licensee’s reference to the DMF for API supplied by HOVIONE outside the Territory.  
 ARTICLE 5  
WARRANTIES; SPECIFICATIONS  
 5.1 Warranties. HOVIONE represents, warrants and covenants that:  
 5.1.1 Upon delivery to COMPANY, all API shall be Manufactured in accordance with cGMP and all Applicable Laws, the DMF (in the event HOVIONE is requested to file a DMF by Company), the Quality Agreement, and the Manufacturing and Process requirements set forth in the Specifications. All API shall have a shelf life no less than [\*\*\*\*\*]; provided, however, that COMPANY provides HOVIONE with no less than [\*\*\*\*\*] prior written notice of any change in [\*\*\*\*\*]. HOVIONE and COMPANY agree that, as of the Effective Date, [\*\*\*\*\*]. HOVIONE shall use commercially reasonable efforts to comply with (i) any request by COMPANY [\*\*\*\*\*] for feasible changes in the Specifications, Manufacturing, Process and materials, and (ii) any change in analytical testing methods requested by COMPANY, the FDA or any other applicable Regulatory Authority.  
 5.1.2 All API, and HOVIONE’s Manufacture of API shall be performed in accordance with and conform in all respects to the Applicable Laws governing the Manufacture and supply of API in the place where manufactured and the Territory.  
 5.1.3 If requested by COMPANY, HOVIONE, [\*\*\*\*\*] subject to COMPANY providing HOVIONE with the necessary or required information in connection therewith, shall file and maintain a DMF for API with Regulatory Authorities within the Territory, shall provide COMPANY with a copy of the same, and shall give and authorize COMPANY and its Affiliates, and its and their respective Licensees and distributors, rights to reference said DMF in any Regulatory Application COMPANY, any of its Affiliates or its and their respective Licensees files for the Product containing API (providing such letters of access as may be required by the Regulatory Authorities).  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
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 5.1.4 HOVIONE shall: (i) retain the minimum number of samples of API as are required and specified to comply with the retention requirements as set forth in the cGMPs, DMFs, Regulatory Applications and the Quality Agreement; (ii) report to COMPANY any confirmed out-of-specification test results with respect to delivered API within [\*\*\*\*\*]; and (iii) make stability reports and findings available for reasonable inspection by COMPANY and/or COMPANY’s designees at reasonable times and with prior notice. HOVIONE shall retain all production records of the Process and Manufacture of API in accordance with Applicable Laws, including without limitation cGMP’s. [\*\*\*\*\*] HOVIONE shall perform stability testing in accordance with the API stability protocol agreed by the Parties.  
 5.1.5 HOVIONE shall: (i) promptly report to COMPANY and investigate all out of specification events in Manufacturing and/or complaints by COMPANY regarding non-conformance in accordance with the Quality Agreement; (ii) promptly report to COMPANY and investigate all Manufacturing deviations, (iii) keep COMPANY regularly apprised of the status of such investigations; and (iv) promptly share all investigative reports upon the conclusion of the investigation with COMPANY (except those portions of such reports that contain third party confidential information).  
 5.1.6 HOVIONE shall inform COMPANY of any FDA or other Regulatory Authority inspection of the Facility [\*\*\*\*\*] after such inspection is initiated, and shall allow COMPANY and its designated employees and consultants (provided that, any such consultants are (1) subject to written obligations of confidentiality and non-use protecting HOVIONE’s Confidential Information that are at least as restrictive as those in this Agreement, and (2) not a competitor of HOVIONE) to be present during such audits [\*\*\*\*\*]. HOVIONE shall, within [\*\*\*\*\*] after receipt by HOVIONE, provide copies to COMPANY of all FDA Form 483s, inspection observation reports, establishment inspection reports and other regulatory communications [\*\*\*\*\*]. HOVIONE shall also provide copies of HOVIONE’s proposed responses to such regulatory communications within [\*\*\*\*\*] of their preparation (the regulatory communications, HOVIONE’s proposed and actual responses and other regulatory correspondence are referred to collectively as “Regulatory Audit Materials”). COMPANY will be allowed to review and comment on those Regulatory Audit Materials [\*\*\*\*\*], provided that COMPANY shall use its reasonable best efforts to provide HOVIONE with timely comments on such Regulatory Audit Materials. HOVIONE shall promptly notify COMPANY as to what corrective measure HOVIONE is taking [\*\*\*\*\*], whether in response to a notice of a regulatory inspection or audit or following any regulatory inspection or audit, and keep COMPANY informed on a regular, ongoing and periodic basis of related developments.  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
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 5.1.7 Within [\*\*\*\*\*] of HOVIONE’s receipt of COMPANY’s written request [\*\*\*\*\*], HOVIONE shall provide COMPANY with any and all documentation, records and any and all information (whatever the format) related to the Manufacture of API by HOVIONE to allow COMPANY or its Affiliates to prepare and file on a timely basis supplements or amendments to Regulatory Applications or other government licenses for API and any annual reports to the FDA or other Regulatory Authority, subject, in each case to the confidentiality provisions of this Agreement and the redaction of any third party confidential information.  
 5.1.8 Neither HOVIONE nor any of its officers or employees, nor any other person used by HOVIONE to perform services under this Agreement is to the best of HOVIONE’s knowledge: (i) an individual who has been debarred by the FDA pursuant to section 306 of the FDCA, 21 U.S.C. § 335a (“Debarred Individual”): or (ii) a corporation, partnership or association that has been debarred by FDA pursuant to section 306 of the FDCA, 21 U.S.C. § 335a (“Debarred Entity”). HOVIONE has no knowledge of any circumstances which may affect the accuracy of the foregoing representation, including, without limitation, any FDA investigations of, or debarment proceedings against, HOVIONE or any person or entity performing services or rendering assistance which is in any way related to activities taken pursuant to this Agreement. HOVIONE shall notify COMPANY in writing as soon as possible, and, in any case, no later than [\*\*\*\*\*], if HOVIONE, at any time during the Term, becomes aware of any such circumstances.  
 5.2 Specifications and Other Changes. COMPANY represents and warrants that the Specifications shall be in conformance with the Regulatory Applications. In the event COMPANY or any of its Affiliates changes the Specifications, COMPANY shall promptly advise HOVIONE in writing of such changes, and HOVIONE shall promptly inform COMPANY as to any scheduling and/or price adjustments which may reasonably result from such changes. In the event that HOVIONE wishes to propose any change to the Manufacturing (including without limitation components, equipment, Facility or process), the DMF or the Specifications, it shall provide all relevant details related to such proposed change for review by COMPANY, but shall not implement any such change prior to COMPANY’s written approval (unless such change is required by Applicable Law) and any necessary approval by the applicable Regulatory Authority.  
 5.3 Additional COMPANY Warranties. COMPANY represents and warrants that neither the Manufacture, supply, sale or use of API as contemplated in this Agreement will infringe any patents or any other proprietary rights of third parties, and, as of the Effective Date, neither COMPANY, nor any of its Affiliates, nor any of their respective Licensees, has received any notice of any claimed infringement (including, without limitation, patent infringement) in  
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 11  
  
 connection with API. COMPANY will promptly notify HOVIONE in writing should it become aware of any such claims asserting such infringement.  
 5.4 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT.  
 ARTICLE 6  
PRICE AND TERMS FOR COMMERCIAL API  
 6.1 Price. With the exception of the [\*\*\*\*\*] Batches of API to be delivered pursuant to the [\*\*\*\*\*] SOW (the price of which was agreed in the [\*\*\*\*\*] SOW), the price for commercial API supplied by HOVIONE to COMPANY during the Term of this Agreement is set forth in Exhibit 5. Notwithstanding anything to the contrary herein, the price per kilogram payable by COMPANY for commercial API applicable to any COMPANY Purchase Order shall be determined in accordance with Exhibit 5.  
 6.2 Delivery Terms. HOVIONE shall prepare all API for shipment to COMPANY or to COMPANY’s designated consignee. All shipments shall be delivered [\*\*\*\*\*], by a common carrier designated by COMPANY. [\*\*\*\*\*] shall procure, at its cost, insurance covering damage or loss of API during shipping. All shipping instructions of COMPANY shall be accompanied by the name and address of the recipient and the shipping date and any costs associated therewith shall be borne by [\*\*\*\*\*]. Should COMPANY require HOVIONE to provide special handling, packaging or services, then the cost of such special handling, packaging or services will be borne [\*\*\*\*\*].  
 6.3 Method of Payment. All undisputed invoices shall be due and payable [\*\*\*\*\*] from receipt by COMPANY. In the event any payment is not made when due, HOVIONE shall notify COMPANY of such nonpayment and, regardless of such notification, shall be entitled, in addition to its other rights and remedies, to charge interest on the unpaid amount at the rate of [\*\*\*\*\*]. In the case where disputed invoices are found in favor of HOVIONE, this interest charge will apply from the date that the invoice payment was originally due. All payments hereunder shall be made in United States Dollars. COMPANY shall make all payments pursuant to this Agreement by wire transfer to a bank account as designated in writing by HOVIONE.  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 12  
  
 6.4 Taxes. Any use, sales, excise or value added tax, duty, custom, inspection or testing fee, or any other tax, fee or charge of any nature whatsoever imposed by any governmental authority on or measured by the transaction between HOVIONE and COMPANY (other than taxes on HOVIONE’s income), shall be paid by COMPANY in addition to the prices quoted or invoiced by HOVIONE. In the event HOVIONE is required to pay any such tax, fee, or charge, COMPANY shall reimburse HOVIONE for such payment, or in lieu of such payment, COMPANY shall provide HOVIONE at the time the order is submitted an exemption certificate or other document acceptable to the authority imposing the tax, fee or charge.  
 ARTICLE 7  
QUALITY AGREEMENT  
 7.1 The Parties hereby incorporate into this Agreement the terms and conditions of that certain Quality Agreement effective between HOVIONE and COMPANY as of [\*\*\*\*\*], which is attached hereto as Exhibit 2 (“Quality Agreement”). In the event the Quality Agreement contains provisions which are not inconsistent with, but in addition to, the terms set forth herein, the Quality Agreement shall be supplemental to the terms and conditions set forth in this Agreement. Notwithstanding the foregoing or anything in this Agreement or the Quality Agreement to the contrary, however, in the event of any conflict or inconsistency between the provisions of this Agreement and the provisions of the Quality Agreement, the provisions of this Agreement shall govern.  
 ARTICLE 8  
MANUFACTURING AUDITS  
 8.1 Periodic MA. Once every [\*\*\*\*\*] during the Term of this Agreement, COMPANY shall have the right to conduct one (1) Manufacturing Audit (as defined below) according to the terms specified in Section 8.3 hereof (such Manufacturing Audit to be hereinafter referred to as a “Periodic MA”). [\*\*\*\*\*] shall bear [\*\*\*\*\*] costs and expenses incurred in connection with the conduct of such Manufacturing Audit.  
 8.2 Event MA. In addition to the Periodic MA referred to in Section 8.1 hereof, in the event that: (i) the Regulatory Authorities schedule a regulatory inspection of the Facility in which API is Manufactured; (ii) HOVIONE receives a “Warning Letter” or Form 483 Observations from the FDA relating to the Manufacture of API by HOVIONE or compliance with cGMP’s at any facility where Manufacturing or other activities related to the API occurs; (iii) COMPANY has rejected a shipment of API for failure to meet Specifications; or (iv) COMPANY otherwise has reasonable concern regarding the quality or Manufacturing of API supplied by HOVIONE (individually or collectively, an “Event”), COMPANY shall have the right to conduct additional Manufacturing Audits in  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 13  
  
 respect of the API according to the terms specified in Section 8.3 hereof (such Event Manufacturing Audit to be hereinafter referred to as an “Event MA”). [\*\*\*\*\*] shall bear [\*\*\*\*\*] costs and expenses incurred in connection with the conduct of such Event MA.  
 8.3 Audit. For purposes of this Agreement, the term “Manufacturing Audit” shall mean an audit of the Facility to be conducted by COMPANY’s employees or consultants (provided that, any such consultants are (1) subject to written obligations of confidentiality and non-use protecting HOVIONE’s Confidential Information that are at least as restrictive as those in this Agreement, and (2) not a competitor of HOVIONE). Each Manufacturing Audit shall be conducted during HOVIONE’s normal business hours and upon reasonable prior written notice to HOVIONE (“reasonable”, for purposes of this provision, shall be [\*\*\*\*\*] for the Periodic MA and [\*\*\*\*\*] for the Event MA) and shall last no longer than [\*\*\*\*\*]. During a Manufacturing Audit, upon COMPANY’s reasonable request, HOVIONE shall make available for review and photocopying such documents as COMPANY and its auditors may reasonably request provided they relate to the API and its Manufacture by HOVIONE.  
 ARTICLE 9  
TERM; TERMINATION  
 9.1 Term. The term of this Agreement shall commence on the Effective Date and shall expire on December 31, 2020 (the “Initial Term”) unless terminated earlier pursuant to the terms hereof. This Agreement shall be automatically renewed for additional eighteen (18) month terms (each such additional term a “Renewal Term” and, together with the Initial Term, the “Term”) after the end of the Initial Term and any subsequent Renewal Term, unless either Party provides written notice to the other at least eighteen (18) months prior to the end of the Initial Term or any such Renewal Term, as the case may be, that this Agreement shall expire at the end of the Initial Term or such Renewal Term. Notwithstanding the above, the Parties agree that unless this Agreement is terminated earlier pursuant to the terms hereof, the Parties will meet between [\*\*\*\*\*] and [\*\*\*\*\*] to review the cumulative actual and anticipated purchases of API pursuant to this Agreement by COMPANY between [\*\*\*\*\*] and [\*\*\*\*\*] (the “Measurement Period”). In the event that the aggregate purchase price of all API delivered, or expected to be delivered, by HOVIONE to COMPANY during the Measurement Period is [\*\*\*\*\*], HOVIONE may, in its sole discretion, no later than January 31, 2018, deliver written notice to COMPANY of its intention to terminate this Agreement effective December 31, 2018 (the “Early Termination Notice”). If HOVIONE does not deliver the Early Termination Notice to COMPANY on or prior to January 31, 2018, this Agreement shall expire on December 31, 2020 (subject to the automatic renewal provisions set forth above), unless terminated earlier pursuant to the terms hereof.  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 14  
  
 9.2 Termination by COMPANY. This Agreement may be terminated by COMPANY, at any time during the Term, in the event (i) the Regulatory Application for the Product as submitted for approval by the FDA is withdrawn, either by COMPANY or any of its Affiliates or the applicable Regulatory Authorities, or (ii) HOVIONE is unable to satisfy, in full or in part, any COMPANY Purchase Order for API for any reason, including any Force Majeure Event (as that term is defined in Section 14.1), for [\*\*\*\*\*] or more. Termination under this Section 9.2 shall be effective immediately upon COMPANY’s delivery of written notice to HOVIONE, provided that COMPANY shall remain responsible for any amounts owed to HOVIONE under Section 9.5.  
 9.3 Termination for Breach. This Agreement may be terminated by either Party in the event of the material breach by the other Party of the terms and conditions hereof; provided, however, the non-breaching Party shall first give to the breaching Party written notice of the proposed termination or cancellation of this Agreement, specifying the grounds therefor. Upon receipt of such notice, the breaching Party shall have [\*\*\*\*\*] to (i) respond by curing such breach, or (ii) confirm to the non-breaching Party in writing that such breach is not capable of being cured within such [\*\*\*\*\*] period and that the breaching Party is working diligently to cure such breach and request an additional [\*\*\*\*\*] period to cure such breach. The non-breaching Party may, in its sole discretion, accept such request for an extension of the cure period or deny such request and terminate the Agreement effective immediately. Termination of this Agreement pursuant to this Section 9.3 shall not affect any other rights or remedies which may be available to the non-breaching Party. For the avoidance of doubt, in the event of a termination of this Agreement by HOVIONE pursuant to Section 9.3 or 9.4, HOVIONE’s exclusivity obligations under Section 4.1 shall terminate. Further, for the avoidance of doubt, in the event of a termination of this Agreement by COMPANY pursuant to Section 9.3 or 9.4, COMPANY’s [\*\*\*\*\*] purchase commitment obligations under Section 4.2 shall terminate.  
 9.4 Bankruptcy; Insolvency. Either Party may terminate this Agreement upon: (i) the entry of a decree or order for relief by a court having jurisdiction in the premises in respect of such Party in an involuntary case under the Federal Bankruptcy Code, as now constituted or hereafter amended, or any other applicable federal or state insolvency or other similar law and the continuance of any such decree or order unstayed and in effect for a period of [\*\*\*\*\*]; or (ii) filing by such Party of a petition for relief under the Federal Bankruptcy Code, as now constituted or hereafter amended, or any other applicable federal or state insolvency or similar law.  
 9.5 COMPANY’s Obligations Upon Termination. Upon termination of this Agreement by COMPANY under clause (ii) of Section 9.2, Section 9.3 or Section 9.4 above, COMPANY shall promptly pay HOVIONE for (i) any outstanding, unpaid invoices issued by HOVIONE pursuant to this Agreement prior to the time of termination for services actually performed in accordance with the terms of this Agreement prior to the time of termination, (ii) any purchasing obligations of COMPANY under  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 15  
  
 COMPANY Purchase Orders placed under Section 2.2 prior to the time of termination for API actually supplied by HOVIONE to COMPANY in accordance with the terms of this Agreement prior to the time of termination, and (iii) the following expenses related to the termination of the Agreement: (A) reasonable and documented costs and expenses related to the disposal or transfer of API, samples, and raw materials directly related to HOVIONE’s obligations hereunder, and (B) reasonable and documented staff time and related costs necessary to transfer to COMPANY or its designee any API-related Manufacturing information (including, without limitation, any documentation, technical information and materials). Upon the expiration of this Agreement, any termination of this Agreement by COMPANY under clause (i) of Section 9.2, or any termination of this Agreement by HOVIONE pursuant to an Early Termination Notice delivered in accordance with the penultimate sentence of Section 9.1 or under Section 9.3 or 9.4 above, COMPANY shall promptly pay HOVIONE for (i) any outstanding, unpaid invoices issued by HOVIONE pursuant to this Agreement prior to the time of termination for services actually performed in accordance with the terms of this Agreement prior to the time of termination, (ii) any binding purchasing obligations of COMPANY under Section 2.2 including, but not limited to, monies due and owing HOVIONE at the time of termination for services actually performed in accordance with the terms of this Agreement prior to the time of termination and for COMPANY’s obligations under the binding portion of the then current Forecast (whether or not COMPANY Purchase Orders for such amounts were placed prior to such termination), (iii) all authorized expenses actually incurred by HOVIONE prior to the time of termination and any uncancellable commitments made by HOVIONE in accordance with the terms of this Agreement prior to the time of termination in connection with the services provided hereunder, (iv) any shortfall based on a report certified by an officer of the COMPANY delivered to HOVIONE within [\*\*\*\*\*] of such termination and calculated pursuant to the last sentence of Section 4.2 for the [\*\*\*\*\*] (or, in the event this Agreement is terminated [\*\*\*\*\*], the pro rata portion of [\*\*\*\*\*]) [\*\*\*\*\*], and (v) any reasonable and documented costs and expenses related to the termination of the Agreement, including, but not limited to: (A) the disposal or transfer of API, samples, and raw materials directly related to HOVIONE’s obligations hereunder, and (B) staff time and related costs necessary to transfer to COMPANY or its designee any API-related Manufacturing information (including, without limitation, any documentation, technical information and materials). All transfers of API-related Manufacturing information and the associated timelines for such transfers pursuant to this Section 9.5 shall be covered in a Statement of Work to be entered into between the Parties within [\*\*\*\*\*] of the termination of this Agreement. In addition, COMPANY shall, upon written request from HOVIONE, at HOVIONE’s discretion, promptly either return or destroy all Confidential Information of HOVIONE that COMPANY received pursuant to this Agreement; provided that, COMPANY may retain one (1) copy of all such Confidential Information of HOVIONE for the sole purpose of monitoring its ongoing obligations of confidentiality and non-use under this Agreement.  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 16  
  
 9.6 HOVIONE’s Obligations Upon Termination. Upon termination or expiration of this Agreement, HOVIONE shall promptly suspend work and take all reasonable steps to mitigate out-of-pocket expenses incurred in connection therewith. In particular, HOVIONE shall: (i) perform only those services and activities mutually agreed upon by COMPANY and HOVIONE as being necessary or advisable in connection with the close-out of the relevant services; (ii) use commercially reasonable efforts to cancel any third party obligations; (iii) promptly deliver to COMPANY all materials ordered by HOVIONE for COMPANY and all API (including any work in process) after receipt of payment in full for such materials and API by COMPANY; (iv) transfer to COMPANY or its designee [\*\*\*\*\*] any API-related Manufacturing information (including, without limitation, any documentation, technical information and materials); and (v) promptly return all Confidential Information of COMPANY that it has received pursuant to this Agreement; provided that, HOVIONE may retain one (1) copy of all such Confidential Information of COMPANY for the sole purpose of monitoring its ongoing obligations of confidentiality and non-use under this Agreement. All transfers of API-related Manufacturing information and the associated timelines for such transfers pursuant to this Section 9.6 shall be covered in a Statement of Work to be entered into between the Parties within 15 days of the termination of this Agreement.  
 ARTICLE 10  
CONTROL SAMPLE; CLAIMS OF NON-CONFORMANCE  
 10.1 Certificate of Analysis and Control Sample. Each Batch of API shipped to COMPANY shall be accompanied by a certificate of analysis substantially in the form of Exhibit 3, approved by a responsible representative of the quality assurance function at HOVIONE (“Certificate of Analysis”). If requested by COMPANY, each Batch shipped shall also include a control sample of each Batch shipped for analysis in a container provided or otherwise pre-approved by COMPANY or its designee to conduct quality control release testing. Such control sample must be from, and representative of, the lot of the API actually shipped.  
 10.2 Inspection. Every Batch of API supplied by HOVIONE shall be delivered in accordance with Section 6.2, subject to COMPANY’s or its designee’s inspection, and may be rejected if any such API fails to conform at the time of delivery in accordance with Section 6.2 with any representation or warranty of HOVIONE (including, without limitation, all representations and warranties of HOVIONE made in Article 5 hereof), the Specifications or the other requirements set forth herein. Such a rejection shall be communicated in writing to HOVIONE within [\*\*\*\*\*] of delivery of such API and will provide sufficient detail for the reasons for such rejection to permit HOVIONE to investigate the alleged non-conformity. COMPANY shall be deemed to have accepted each Batch in a shipment of API if HOVIONE does not receive written notice to the contrary within such [\*\*\*\*\*] period as set forth in this Section 10.2. COMPANY shall have the right to reject a Batch or part thereof by notifying HOVIONE in writing within  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 17  
  
 such [\*\*\*\*\*] period after delivery to COMPANY of any non-conforming Batch or part of a Batch of API containing obvious defects discoverable without affecting the integrity of the API. In addition, COMPANY will have the right to reject a Batch or part thereof by notifying HOVIONE within [\*\*\*\*\*] from its discovery of any latent defects in a Batch or part thereof; provided that HOVIONE will not be responsible for any latent defects that COMPANY discovers in any API that has been further processed in any way (except to the extent any such defect is shown to have been present in such API at the time of delivery in accordance with Section 6.2) or that cannot be shown to have been present at the time of delivery in accordance with Section 6.2. If there is a disagreement between the Parties as to whether any API conforms to the requirements of this Agreement, then samples, Batch records and other information, as appropriate, from the Batch in dispute will be submitted for testing and evaluation to an independent cGMP testing laboratory agreed to in writing by both Parties. The determination of such laboratory as to conformance will be binding upon the Parties. If it is determined by such laboratory that the API [\*\*\*\*\*] to the requirements herein at the time of delivery in accordance with Section 6.2, the cost of any testing, evaluation by the testing laboratory and the total invoice value of the API in question will be borne [\*\*\*\*\*]. If the API is determined to [\*\*\*\*\*] at the time of delivery in accordance with Section 6.2, the cost of any testing and evaluation by the testing laboratory will be borne [\*\*\*\*\*], and HOVIONE shall [\*\*\*\*\*]. COMPANY shall [\*\*\*\*\*] promptly (i) return any such rejected API to HOVIONE, or (ii) at HOVIONE’s direction dispose of such API. The remedies set forth in this Section 10.2 are COMPANY’s sole remedies under this Agreement with respect to non-conforming API. Notwithstanding the above, nothing in this Section 10.2 shall in any way limit the indemnification obligations of either Party set forth in this Agreement. In addition, nothing in this Section 10.2 shall limit COMPANY’s rights under Section 4.3, Section 9.2, Section 9.3 or Section 11.1.  
 ARTICLE 11  
RECALLS; CMC DOCUMENTATION; REGULATORY FILINGS  
 11.1 Recalls and Returned API. In the event: (a) COMPANY or any of its Affiliates reasonably determines that API should be recalled for any reason; (b) any Regulatory Authority issues a request, directive, or order that the Product containing API be recalled or otherwise withdrawn from any country in the Territory; or (c) a court of competent jurisdiction orders such a recall or withdrawal (either (b) or (c) together, an “Order”), each Party shall take all appropriate corrective actions reasonably requested by the other Party or any Regulatory Authority. To the extent such recall or withdrawal results from HOVIONE’s: (i) failure to perform any covenant, agreement or undertaking on the part of HOVIONE contained in this Agreement, including but not limited to supply of API that conforms to Specifications; (ii) the gross negligence or willful misconduct of HOVIONE or its Affiliates (including, for the avoidance of doubt, their respective directors, officers, employees, agents, contractors, successors and assigns); or (iii) failure to comply with Applicable Laws, then, in each case, HOVIONE shall be responsible for:  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 18  
  
 (w) its own out-of-pocket costs for such recall or withdrawal; (x) COMPANY’s documented out-of-pocket costs for such recall or withdrawal, [\*\*\*\*\*] (subject to the terms of this Section 11.1); (y) unless otherwise prohibited, promptly replacing, at the COMPANY’s option and at no cost or expense to COMPANY, the API recalled or withdrawn with API which conforms to the Specifications. If COMPANY believes that the recall results from any reason defined in (i), (ii), and/or (iii) above, then COMPANY and its Affiliates may proceed with such recall at their own risk and expense (subject to the following sentence) and will hold a dialogue with HOVIONE between the respective chief executive officers of the Parties or their designees to ensure the facts that led to such a decision are shared. If HOVIONE agrees, or a final determination is made in an arbitration or court, that the recall results from any reason defined in (i), (ii), and/or (iii) above, then HOVIONE shall be responsible for its and COMPANY’s expenses as set forth above; provided that HOVIONE’s aggregate liability to COMPANY under this Section 11.1 for any recall or withdrawal shall be [\*\*\*\*\*]. If the recall or withdrawal results from any reason other than as defined in (i), (ii) or (iii) above, COMPANY shall be responsible for its own and HOVIONE’s documented out-of-pocket costs of such recall or withdrawal. For purposes of this Agreement, out-of-pocket costs of such recall or withdrawal shall be all direct expenses incurred by either Party relative to notification, shipping, disposal and return of the recalled or withdrawn API or Product containing API, but shall not include lost profits or legal fees of either Party. The Parties have the right to audit such recall costs. COMPANY shall be responsible for coordinating any and all such recall or withdrawal activities with the Regulatory Authorities, its customers or otherwise.  
 11.2 CMC Documentation. Upon COMPANY’s written request, HOVIONE shall supply [\*\*\*\*\*] all information required by COMPANY in support of the Chemistry, Manufacturing & Control (“CMC”) section of any NDA or other filings to be filed by COMPANY, its Affiliates, its Licensees or other designee in the Territory with the Regulatory Authorities for the Product containing API Manufactured by HOVIONE under this Agreement. HOVIONE shall co-operate with, and provide support and assistance to [\*\*\*\*\*] any consultant that COMPANY, its Affiliates or its Licensees selects to write the documentation in the CMC section; provided that, any such consultant is (i) subject to written obligations of confidentiality and non-use protecting HOVIONE’s Confidential Information that are at least as restrictive as those in this Agreement, and (ii) not a competitor of HOVIONE.  
 11.3 Regulatory Matters. As between HOVIONE and COMPANY, COMPANY shall be responsible for obtaining [\*\*\*\*\*] all regulatory and governmental approvals and permits necessary for COMPANY, its Affiliates and its and its Affiliates’ Licensees to Manufacture and sell the Product, including, without limitation, all submissions filed with the FDA or other Regulatory Authorities.  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 19  
  
 ARTICLE 12  
INDEMNIFICATION; INSURANCE  
 12.1 Indemnification by COMPANY. COMPANY shall indemnify, defend and hold HOVIONE, its Affiliates and its and their respective directors, officers, employees, contractors, agents, successors and assigns (“HOVIONE Indemnitees”) harmless from and against any damages, judgments, liabilities, costs and expenses (including, but not limited to, reasonable attorneys’ fees) resulting from any third party claim, suit or action, to the extent arising out of: (i) any breach by COMPANY Indemnitees of any representation, warranty, covenant, agreement or undertaking made by COMPANY in this Agreement; (ii) the gross negligence or willful misconduct of COMPANY Indemnitees or (iii) the marketing, distribution, import, use or sale by COMPANY or its Affiliates of the Product (including without limitation any claim of infringement of any patent or trademark or the unauthorized use of a trade secret and any product liability claims, in each case related to API) except, in each case, to the extent that such claim, suit or action results from or arises out of any act or omission described in clause (i), (ii) or (iii) of Section 12.2.  
 12.2 Indemnification by HOVIONE. HOVIONE shall indemnify, defend and hold COMPANY, its Affiliates their respective Licensees, and its and their respective directors, officers, employees, contractors, agents, successors and assigns (“COMPANY Indemnitees”) harmless from and against any damages, judgments, liabilities, costs and expenses (including, but not limited to, reasonable attorneys’ fees) resulting from any third party claim, suit or action, to the extent arising out of: (i) any breach by HOVIONE Indemnitees of any representation, warranty, covenant, agreement or undertaking made by HOVIONE in this Agreement; (ii) the gross negligence or willful misconduct of HOVIONE Indemnitees; or (iii) the use of the HOVIONE Technology or HOVIONE Improvements in the provision of services under this Agreement except, in each case, to the extent that such claim, suit or action results from or arises out of any act or omission described in clause (i) or (ii) of Section 12.1.  
 12.3 Indemnification Procedures. A Party who intends to claim indemnification under Section 12.1 or 12.2 hereof (the “Indemnitee”) shall promptly notify the other Party (the “Indemnitor”) in writing of any claim for which the Indemnitee intends to seek indemnification hereunder. The Indemnitor shall have the exclusive right and authority to conduct the defense or settlement of any such claim at the Indemnitor’s sole expense and the Indemnitee shall cooperate with the Indemnitor therewith; provided, however, that (i) the Indemnitee shall be entitled to provide consultation in the defense of such matter and to employ counsel at its expense to assist Indemnitee in providing such consultation (but, for the avoidance of doubt, the Indemnitor shall have final decision-making authority regarding all aspects of such defense) and (ii) in the defense or settlement of any claim, the Indemnitor shall not (x) admit to any wrongdoing by the Indemnitee, or (y) consent to the entry of any judgment or enter into any settlement with respect to any claim to the extent such judgment or settlement provides for equitable  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 20  
  
 relief against the Indemnitee or if such judgment or such settlement does not expressly unconditionally release the Indemnitee from all liabilities, in each case, without the prior written consent of the Indemnitee (which consent shall not be unreasonably withheld or delayed). The Indemnitee shall provide the Indemnitor with such information and assistance as the Indemnitor may reasonably request, at the expense of the Indemnitor.  
 12.4 Insurance.  
 12.4.1 COMPANY’s Insurance. COMPANY will, throughout the Term of this Agreement and until the date of the [\*\*\*\*\*] of the expiration of this Agreement, obtain and maintain at its own cost and expense, commercial general liability insurance and product liability insurance. Such policies will provide protection against commercially reasonable types of claims, demands and causes of action that could arise against the COMPANY under this Agreement. The minimum amount of (i) product liability coverage required by this Agreement will be [\*\*\*\*\*] per occurrence and [\*\*\*\*\*] in the annual aggregate for bodily injury and/or for property damage; (ii) workers’ compensation insurance will be the amount required under applicable statutory requirements; and (iii) commercial general liability insurance will be [\*\*\*\*\*] per occurrence and [\*\*\*\*\*] annual aggregate. COMPANY agrees to furnish within [\*\*\*\*\*] after execution of this Agreement, and upon written request of HOVIONE thereafter, a certificate of insurance or self-insurance evidencing that such insurance is in effect. COMPANY shall use its commercially reasonable efforts to provide HOVIONE [\*\*\*\*\*] prior written notice of cancellation, non-renewal or material reduction in the insurance required by this Agreement.  
 12.4.2 HOVIONE’s Insurance. HOVIONE agrees to maintain, during the Term and for [\*\*\*\*\*] thereafter, at its own expense API product liability insurance and contract liability insurance with a minimum limitation of [\*\*\*\*\*] per occurrence and [\*\*\*\*\*] annual aggregate. HOVIONE shall submit to COMPANY within [\*\*\*\*\*] after execution of this Agreement, and upon written request of COMPANY thereafter, from a reputable Insurance company, a certificate of insurance evidencing that the required insurance is in force and effect. Such certificate shall provide that not less than [\*\*\*\*\*] advance notice, in writing, shall be given to COMPANY of any cancellation, termination or material alteration or reduction of such insurance coverages.  
 12.5 Disclaimer of Consequential Damages. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY. THIS LIMITATION SHALL APPLY EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE; PROVIDED, HOWEVER, THAT THIS LIMITATION SHALL NOT APPLY TO DAMAGES RESULTING FROM BREACHES BY A PARTY OF ITS DUTY OF CONFIDENTIALITY AND NON-USE IMPOSED UNDER ARTICLE 13 OR TO ITS  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 21  
  
 INDEMNIFICATION OBLIGATIONS UNDER THIS ARTICLE 12. Notwithstanding anything to the contrary in this Section 12.5, the total liability of HOVIONE to COMPANY for losses under this Agreement (other than in respect of indemnification obligations under Section 12.2) shall be limited to [\*\*\*\*\*].  
 ARTICLE 13  
CONFIDENTIALITY  
 13.1 Treatment of Confidential Information. Each Party shall retain in confidence and use only for purposes of this Agreement any Confidential Information disclosed or owned by the other Party.  
 13.2 Limited Right to Disclose. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement or any rights which survive termination or expiration hereof, each Party may disclose the other Party’s Confidential Information to its Affiliates and its and its Affiliates’ respective licensors, licensees, consultants, agents, representatives, contractors and clinical investigators or other third parties on condition that such entities or persons agree in writing to: (i) keep such Confidential Information confidential for the same time periods and to the same extent as each Party is required to keep such Confidential Information confidential under this Agreement; and (ii) use the Confidential Information only for such purposes as such Party is entitled to use the Confidential Information. Each Party or its Affiliates may disclose the other Party’s Confidential Information to government or other Regulatory Authorities to the extent that such disclosure is necessary to engage in activities contemplated under this Agreement. Notwithstanding the foregoing, COMPANY and its Affiliates may disclose that HOVIONE is the manufacturer/supplier of API hereunder and HOVIONE’s address, and HOVIONE may disclose, under obligation of confidentiality, COMPANY Confidential Information as necessary to carry out HOVIONE’s rights and obligations existing on the date hereof, subject to the limitations contained in Sections 4.4 and 11.2.  
 13.3 Notice of Disclosure. Each Party agrees to notify the other Party as soon as reasonably possible prior to its disclosure of the other Party’s Confidential Information under Section 13.2, except as permitted in accordance with Section 4.4. Such notice shall include: (i) the names and addresses of the intended recipients of the Confidential Information; (ii) copies of the Confidential Information to be disclosed; and (iii) the dates when the disclosure(s) are intended to be made.  
 13.4 Legal and Regulatory Process. Each Party may disclose the other Party’s Confidential Information to the extent such disclosure is required by law, regulation, court order or request of Regulatory Authority; provided, however, that the Party being compelled to disclose shall give the other Party prompt prior notice of such required disclosure and cooperate with such other Party in order that such other Party may seek a protective order or relief to prevent or limit the Confidential Information required to be  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 22  
  
 disclosed; and provided, further, that the compelled Party shall only disclose that portion of the Confidential Information that such Party is advised by its legal counsel is required to be disclosed by law and shall seek assurances that such Confidential Information will be maintained in confidentiality by the third party who is to receive such Confidential Information. The Parties acknowledge that COMPANY may be obligated to describe in a periodic report filed with the U.S. Securities and Exchange Commission (“SEC”) the material terms of the Agreement and file a copy of the Agreement with the SEC, which is subject to HOVIONE’s review and approval. COMPANY shall be entitled to describe such material terms and to make such a required filing, provided that it (i) requests confidential treatment of at least the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to COMPANY, and (ii) provides HOVIONE with at least [\*\*\*\*\*] to review any such confidential treatment request prior to filing with the SEC and considers in good faith any comments timely received from HOVIONE thereon.  
 ARTICLE 14  
FORCE MAJEURE  
 14.1 Effects of Force Majeure. Except for the obligation to pay any amounts due under this Agreement, neither Party shall be held liable or responsible for failure or delay in fulfilling or performing any of its obligations under this Agreement to the extent such failure or delay is due to any condition beyond the reasonable control of the affected Party including, without limitation, acts of God, acts of war or terrorism, fire, flood, earthquake, embargoes, shortages, epidemics, quarantines, civil commotion, strikes, or acts, omissions, or delays in acting, by any governmental authority (which acts, omissions, or delays do not arise from such Party’s breach of this Agreement or failure to comply with Applicable Laws) and labor disputes (a “Force Majeure Event”). Subject to COMPANY’s rights in the event of a supply interruption under Section 4.3 and COMPANY’s right to terminate this Agreement under Section 9.2, such excuse shall continue as long as the Force Majeure Event continues. Upon cessation of such Force Majeure Event, such Party shall promptly resume performance hereunder.  
 14.2 Notice of Force Majeure Event. Each Party agrees to give the other Party written notice, promptly following its first knowledge of any Force Majeure Event, as to the nature thereof, and the extent to which the affected Party expects to be unable fully to perform its obligations hereunder. The Party experiencing any such event further agrees to use commercially reasonable efforts to promptly correct the Force Majeure Event and to give the other Party periodic updates including notice when it expects to be fully able to perform such obligations. The Parties acknowledge and agree that in the event of a Force Majeure Event, if COMPANY determines, based upon a convincing demonstration by HOVIONE, that HOVIONE can fulfill its obligations hereunder through the use of an alternate facility owned by HOVIONE at no additional cost to COMPANY or delay relative to COMPANY’s or its Affiliates’ market inventory needs, then HOVIONE may  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 23  
  
 use such facility until such Force Majeure Event has been resolved, provided that HOVIONE provides COMPANY prior written notification of the use of such facility and COMPANY consents in writing (such consent not to be unreasonably withheld).  
 ARTICLE 15  
MUTUAL REPRESENTATIONS  
 15.1 Each Party hereby represents, warrants and covenants to the other Party as follows:  
 15.1.1 Organization. It is duly organized, validly existing and in good standing under the laws of the jurisdiction of incorporation or organization. Such Party has the requisite legal and corporate power and authority to conduct its business as presently being conducted and as proposed to be conducted by it and is duly qualified to do business in those jurisdictions where its ownership of property or the conduct of its business requires.  
 15.1.2 Authority. It has all requisite legal and corporate power and authority to enter into this Agreement and to perform the services contemplated hereunder. All corporate actions on the part of such Party, the boards of director or managers, or similar governing body of such Party and the equity holders of such Party necessary for: (i) the authorization, execution, delivery and performance by such Party of this Agreement; and (ii) the consummation of the transactions contemplated hereby, have been duly taken.  
 15.1.3 Binding Obligation. This Agreement is a legally valid and binding obligation of such Party, enforceable against such Party in accordance with its terms.  
 15.1.4 No Conflicts. None of the execution and delivery of this Agreement, the consummation of the transactions provided for herein or contemplated hereby, or the fulfillment by such Party of the terms hereof or thereof, will (with or without notice or passage of time or both): (i) conflict with or result in a breach of any provision of the certificate or articles of incorporation or formation, by-laws, statutes, operating agreement or other governing documents of such Party; (ii) result in a breach, constitute a breach under, give rise to any right of termination, cancellation or acceleration, or require any consent or approval (other than approvals that have heretofore been obtained) of any governmental authority or under any of the terms, conditions or provisions of any material note, bond, mortgage, indenture, loan, arrangement, license, agreement, lease or other instrument or obligation to which such Party is a party or by which its assets may be bound; or (iii) violate any law or regulation applicable to such Party or any of its assets.  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 24  
  
 15.1.5 Consents and Approvals. All material consents, approvals, qualifications, orders or authorizations of, filings with, or notices to any governmental authority or any other person required in connection with such Party’s execution, delivery or performance of: (i) this Agreement; and (ii) the consummation of any other transaction contemplated on the part of such Party hereby, have been obtained, made or given.  
 15.1.6 No Violation of Law; Permits. Such Party is not in violation of any law or regulation (nor is such Party aware of any violation of any law or regulation by any other person), which violation could reasonably be expected to adversely affect such Party’s performance of its obligations hereunder or the ability of the other Party to realize the intended benefits to such other Party under this Agreement, and, except as otherwise contemplated hereby, such Party holds each of the licenses, permits, approvals or authorizations necessary with respect to its current business and operations (and its rights and obligations contemplated hereby) in compliance with all laws and regulations.  
 ARTICLE 16  
MISCELLANEOUS  
 16.1 Independent Contractors. The relationship of HOVIONE to COMPANY is that of an independent contractor and nothing herein shall be deemed to constitute the relationship of partners, joint ventures, nor of principal and agent between COMPANY and HOVIONE. Neither Party shall have an express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any third party.  
 16.2 Performance by Affiliates. HOVIONE agrees that COMPANY’s rights or obligations hereunder may be exercised or performed by one or more of COMPANY’s Affiliates; provided that COMPANY shall remain liable for the performance of any such obligations by any of its Affiliates.  
 16.3 Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided, however, either Party: (i) may, without such consent, assign this Agreement to an Affiliate of such Party; and (ii) [\*\*\*\*\*]. Any purported assignment in violation of the preceding sentence shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.  
 16.4 Continuing Obligations. Termination, assignment or expiration of this Agreement shall not relieve either Party from full performance of any obligations accruing prior thereto to the extent such obligations survive such termination, assignment or expiration.  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 25  
  
 16.5 Waiver. Neither Party’s waiver of any breach or failure to enforce any of the terms and conditions of this Agreement, at any time, shall in any way affect, limit or waive such Party’s right thereafter to enforce and compel strict compliance with every term and condition of this Agreement.  
 16.6 Survival. Expiration or termination of this Agreement for any reason shall not relieve either Party of any obligation accruing prior to such expiration or termination, and rights and obligations of the Parties under the following articles and sections shall survive any termination or expiration of this Agreement: definitions (Article 1), ownership (Article 3), payment obligations (Article 6), obligations on termination (Sections 9.2 (last sentence only), 9.3 (last two sentences only), 9.5 and 9.6), recalls (Article 11), indemnification (Article 12), confidentiality obligations (Article 13), representations and warranties (Articles 5 and 15) and miscellaneous (Article 16) provisions of this Agreement. In addition, HOVIONE’s obligations under Section 4.1 shall survive, for the time period specified in Section 4.1, any expiration of this Agreement or termination of this Agreement by COMPANY under Sections 9.2(ii), 9.3 or 9.4.  
 16.7 Severability. Each Party hereby expressly agrees that it has no intention to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries, and that if any word, sentence, paragraph, clause or combination thereof in this Agreement is found by a court or executive body with judicial powers having jurisdiction over this Agreement or either Party hereto, in a final unappealed order, to be in violation of any such provisions in any country or community or association of countries, such words, sentences, paragraphs, clauses or combination shall be inoperative in such country or community or association of countries and the remainder of this Agreement shall remain binding upon the Parties, so long as enforcement of the remainder does not violate the Parties’ overall intentions in this transaction.  
 16.8 Headings. The headings in this Agreement are for convenience of reference only and shall not affect its interpretation.  
 16.9 Exhibits. All exhibits referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.  
 16.10 Notices. All notices and other communications required or permitted to be given under this Agreement shall be in writing and shall be delivered personally or sent by: (i) registered or certified mail, return receipt requested; (ii) a nationally-recognized courier service guaranteeing next-day delivery, charges prepaid; or (iii) facsimile (with the original promptly sent by any of the foregoing manners), and shall be deemed to have been given three (3) days following mailing, one (1) day following dispatch by courier service, or upon transmission by facsimile, as the case may be. Any such notices shall be  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 26  
  
 addressed to the receiving Party at such Party’s address set forth below, or at such other address as may from time to time be furnished by similar notice by either Party.  
 If to HOVIONE:  
Hovione LLC  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 And to:  
 Hovione FarmaCiencia SA  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 [\*\*\*\*\*]  
 If to COMPANY:  
Anacor Pharmaceuticals, Inc.  
 0000 X. Xxxxxx Xxxxxx  
 Xxxx Xxxx, XX 00000  
 Attn: General Counsel  
 16.11 Counterparts. This Agreement and any amendment or supplement hereto may be executed in any number of counterparts, and any Party hereto may execute any such counterpart, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument. The execution of this Agreement and any such amendment or supplement by any Party hereto will not become effective until counterparts hereof have been executed by both Parties hereto.  
 16.12 Governing Law; Entire Agreement. The validity, interpretation and performance of this Agreement shall be governed and construed in accordance with the laws of the State of New York, without regard to the conflicts of laws provisions thereof. This Agreement, along with the Exhibits, constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the subject matter herein. Without limiting the generality of the foregoing, this Agreement (a) supersedes in its entirety the Mutual Nondisclosure Agreement dated [\*\*\*\*\*] entered into by and between COMPANY and HOVIONE (it being agreed that disclosures under  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 27  
  
 the Confidentiality Agreement shall be treated confidentially after the Effective Date as though they were made under this Agreement). No terms, conditions, understanding, or agreement purporting to modify or vary the terms of this Agreement shall be binding unless hereafter made in writing and signed by the Party to be bound. No modification to this Agreement shall be effected by the acknowledgment or acceptance of any purchase order or shipping instruction forms or similar documents containing terms or conditions at variance with or in addition to those set forth herein.  
 16.13 Dispute Resolution. The Parties recognize that bona fide disputes may arise which relate to the Parties’ rights and obligations under this Agreement. Except as otherwise expressly set forth in this Agreement the Parties agree, prior to proceeding under Section 16.14, to try to settle such disputes amicably among themselves by referring any such dispute, controversy or claim (a “Dispute”) (a) to the joint project team for resolution, and (b) if the joint project team fails to come to consensus on such Dispute within twenty (20) days of referral, then referring such Dispute to the Parties’ respective chief executive officers, or any other executive officers designated by such chief executive officers (the “Executive Officers”). A dispute shall be referred to such Executive Officers upon one Party providing the other Party with written notice of referral of such Dispute to the Executive Officers. The Parties agree to attempt to resolve such Dispute through good faith discussions. If the Executive Officers fail to come to consensus on such Dispute within twenty (20) days of receipt of such written notice then either Party is free to initiate the dispute resolution procedures set forth in Section 16.14.  
 16.14 Arbitration: Except as otherwise expressly set forth in this Agreement, the Parties agree that any dispute not resolved by the Parties pursuant to Section 16.13 will be resolved by arbitration in accordance with the then current Commercial Arbitration Rules of the American Arbitration Association (“AAA”) except that, to the extent such rules are inconsistent with this Section 16.14, this Section 16.14 will control. The following rules will apply to any such arbitration:  
 (a) Any demand for arbitration must be made in writing to the other Party.  
 (b) There will be three arbitrators, one of whom shall be appointed by each Party and a third of whom shall be the chairman of the panel and be appointed by mutual agreement of the two arbitrators appointed by the Parties. If the two arbitrators cannot agree on the appointment of the third arbitrator within thirty (30) days, then the AAA shall select the arbitrator. All three arbitrators will have at least five (5) years of (i) dispute resolution experience (including judicial experience) or (ii) legal or business experience in the biotech or pharmaceutical industry. Any arbitration involving patent rights, other intellectual property rights or intellectual property will be heard by arbitrators who are expert in such areas.  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 28  
  
 (c) The arbitration will be held in New York City, New York, or such other place as the Parties agree. The arbitrators will apply the substantive law specified in Section 16.12 except that the interpretation and enforcement of this arbitration provision will be governed by the United States Federal Arbitration Act, 9 U.S.C. Section 1 et. seq.  
 (d) There shall be a stenographic record of the proceedings. The decision of the arbitrators will be final and binding upon both Parties. The arbitrators will render a written opinion setting forth findings of fact and conclusions of law on each issue. Each Party agrees that, notwithstanding any provision of applicable law, it will not request, and the arbitrators shall have no authority to award damages against any Party that exceed [\*\*\*\*\*].  
 (e) The expenses of the arbitration will be borne by the Parties in proportion as to which each Party prevails or is defeated in arbitration. Each Party will bear the expenses of its counsel and other experts.  
 16.15 Injunctive Relief. Notwithstanding anything contained in Sections 16.12, 16.13 and 16.14, either Party may seek preliminary or injunctive measures or relief in any competent court having jurisdiction.  
 16.16 Acknowledgement. The Parties acknowledge and agree that, in entering into this Agreement, each Party (i) is making and providing only those acknowledgments, confirmations, representations and warranties explicitly stated in this Agreement as made and provided by such Party, and (ii) is not, and shall not be deemed as, making or providing any other acknowledgments, confirmations, representations or warranties or undertaking covenants of any kind.  
 [Remainder of page left blank intentionally.]  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 29  
  
 IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives as of the day and year first above written.  
 ANACOR PHARMACEUTICALS, INC.  
 By:  
/s/ Xxxxxx Xxxxxx  
 Name:  
Xxxxxx Xxxxxx  
 Title:  
SVP, Drug Development  
 HOVIONE FARMACIENCIA SA  
 By:  
/s/ Xxxxx Xxxxxxx  
 Name:  
Xxxxx Xxxxxxx  
 Title:  
VP Sales and Business Development  
 CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 240.24b-2. [\*\*\*\*\*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.  
 30