Exhibit 10.1  
CONFIDENTIAL TREATMENT  
REQUESTED PURSUANT TO RULE 24b-2  
 CONFIDENTIAL  
Manufacturing and Service Contract  
For Commercial and Developmental Products  
Vion Pharmaceuticals, Inc.  
11/28/2006  
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Manufacturing and Service Contract  
For Commercial and Developmental Products  
This Manufacturing and Service Contract for Commercial and Developmental Products (hereinafter this “Agreement”) is made effective as of November 28, 2006 (the “Effective Date”), by Ben Venue Laboratories, Inc., a corporation organized and existing under the laws of Delaware, with its principal office at 000 Xxxxxxxxxx Xxxx, Xxxxxxx, Xxxx, 00000 (hereinafter “BVL”) and Vion Pharmaceuticals, Inc. a corporation organized and existing under the laws of Delaware, with its principal place of business at 0 Xxxxxxx Xxxx, Xxx Xxxxx, XX 00000 (hereinafter “Customer”). BVL and Customer may be referred to in this Agreement jointly as the “Parties” or individually as a “Party.”  
WITNESSETH:  
WHEREAS, Customer is active in the pharmaceutical business and is the owner or licensee of all rights to certain proprietary technical information, patents and/or patent applications relating to Product (as defined below); and  
WHEREAS, BVL provides services to the pharmaceutical industry as a contract manufacturer which supplies its customers with sterile finished dosage forms which it has converted from materials supplied by those customers and/or supplied by BVL and provides Developmental services for sterile dosage forms; and  
WHEREAS, Customer and BVL desire to formalize their relationship through this Agreement for the Development and Manufacture of Product and intend for this Agreement to govern the Parties’ relationship; and  
WHEREAS, BVL possesses the requisite expertise, personnel and Facilities (as defined below) for the Development and Manufacture of finished sterile dosage forms of Product and is willing to provide Development services, allocate and commit resources and Manufacture (as defined below) such Product(s) on a contract basis, for Customer; and  
WHEREAS, Customer desires for BVL to reserve capacity and resources in order to provide Development and Manufacturing services for Customer. Customer also desires to have its Product exclusively Manufactured by BVL for its requirement of Product in the Territory, per the terms of this Agreement.  
NOW, THEREFORE, Customer and BVL agree as follows:  
ARTICLE 1 - DEFINITIONS  
In this Agreement, the following terms shall have the meanings set forth below:  
 1.1.  
“Act” means the US Federal Food, Drug and Cosmetic Act of 1938, the Public Health Service Act of 1944 and the regulations promulgated under that Act, as may be amended from time to time.  
 1.2.  
“Active Pharmaceutical Ingredient” or “API” shall mean bulk supplies of the pharmacologically active compound(s) comprising Product and listed in each Attachment “A#.3,” (i.e., A1.3) which Customer will provide to BVL in bulk form,  
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 from time to time, for the sole purpose of Development and Manufacture of Product for Customer.  
 1.3.  
“Affiliate” shall mean: (a) any corporation or business entity, fifty percent (50%) or more of the voting stock or voting equity interests of which are owned directly or indirectly by a Party; or (b) any corporation or business entity which directly or indirectly owns fifty percent (50%) or more of the voting stock or voting equity interests of a Party; or (c) any corporation or business entity directly or indirectly controlling or under control of a corporation or business entity as described in (a) or (b).  
 1.4.  
“Agency” and “Agencies” shall mean the regulatory entities for each respective country, states and/or territories as identified in and limited to each Product’s definition of the Territory (i.e., for Product A1 see Attachment A1.6); if Territory includes the United States, the FDA; if Territory includes Canada and its Provinces, the Canadian Health Protection Branch; if Territory includes any member state of the European Union, the European Agency for Evaluation of Medicinal Products (hereinafter the “EMEA”), if Territory includes Japan, the Japanese Ministry of Health, Labor and Welfare; (b) any successor organization of any such entity; and (c) any other government regulatory authority with regulatory oversight of the Manufacturing or use of Product in or for the Territory, as such other authorities are mutually agreed upon by the Parties in writing.  
 1.5.  
“Alternate Source” shall have the meaning ascribed thereto in Section 4.2.  
 1.6.  
“Applicable Law” 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.  
 1.7.  
“Batch” shall mean a specific quantity of Product that is intended to be of uniform character and quality and is produced during the same cycle of Manufacture as defined by the applicable Batch Record. The Batch size for each Product is specified in each Attachment “A#.1” (i.e., A1.1) to this Agreement. “Lot” shall have the same meaning as Batch.  
 1.8.  
“Batch Records” shall have the meaning ascribed thereto in Section 3.9.2.  
 1.9.  
BVL Indemnitees” shall have the meaning ascribed thereto in Section 8.1.  
 1.10.  
“BVL Technology” shall mean the Technology of BVL that: (a) exists prior to the Effective Date; or (b) is developed or obtained by or on behalf of BVL independent of this Agreement and without reliance upon Confidential Information of Customer; or (c) is developed by BVL after the Effective Date without reference to Customer Confidential Information and which is not Customer Product-specific.  
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 1.11.  
“cGMP” shall mean the Current Good Manufacturing Practices in the Territory (Attachment “A#.6”, i.e., A1.6) as may be amended or supplemented from time to time; if in the United States, then cGMP shall including without limitation, the Current Good Manufacturing Practices set forth in 21 C.F.R. 210 and 21 C.F.R. 211 and relevant FDA guidance documents; and if in the European Union, then cGMP shall include, without limitation, the European Community Directive 91/356/EEC, Directive 2001/20/EC, Directive 2001/83/EC and all relevant implementations of such directives and relevant guidelines including the EC Guidelines, as may be amended or supplemented from time to time In the event of any conflict among Applicable Laws pertaining to the Manufacture of Product, current Good Manufacturing Practices as specified in the United States Code of Federal Regulations will be applied unless the Parties agree otherwise in writing.  
 1.12.  
“Certificate of Analysis” shall mean a summary of the test results, including the test methods, specification parameters, and the pass/fail criteria, used in the determination of the quality and suitability of a specific Batch of Product, including review and approval by the appropriate quality assurance department at BVL  
 1.13.  
“Certificate of Compliance” shall mean a document, signed by an authorized representative of BVL, attesting that a particular Batch was manufactured in accordance with cGMP and other Applicable Law.  
 1.14.  
“Claims” shall have the meaning ascribed thereto in Section 8.1.  
 1.15.  
“Composition” shall mean any components and/or raw materials that are used in the Manufacturing of Product and listed in each Attachment “A#.3” (i.e., A1.3) hereto, which may be supplied by BVL or Customer.  
 1.16.  
“Confidential Information” shall have the meaning set forth in Section 9.1.  
 1.17.  
“Contract Quarter” shall mean each three (3) month period commencing on January 1, April 1, July 1, or October 1, during the term of this Agreement, provided that the first Contract Quarter shall commence on the Effective Date and end on the last day of the then-existing quarter and the last Contract Quarter shall end on the expiration or termination of this Agreement.  
 1.18.  
“Contract Year” shall mean each twelve (12) month period commencing on January 1, and each successive twelve month period thereafter ending on December 31 of the same year; provided that regardless of the Effective Date, the Contract Year of the initial year of the Agreement shall commence on the Effective Date and end on December 31 of the initial year; the Contract Year for the final year of the Agreement shall end on December 31 or in the event of a termination of the Agreement, upon the effective date of termination, whichever occurs first.  
 1.19.  
“Customer Indemnitees” shall have the meaning ascribed thereto in Section 8.2.  
 1.20.  
“Customer Technology” shall mean: (a) API; (b) Product and any intermediates or derivatives thereof; (c) Specification; and (d) the Technology of Customer owned, developed or obtained by or on behalf of Customer prior to the Effective  
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 Date, or developed or obtained by or on behalf of Customer independent of this Agreement and without reliance upon the Confidential Information, Improvements or Technology of BVL.  
 1.21.  
“Development,” “Develop,” “Developmental” – shall mean all of the services provided in support of the Manufacture of Product as defined by proposals submitted by BVL to Customer.  
 1.22.  
“Disclosing Party” means the party which is directly or indirectly disclosing Confidential Information to the Receiving Party pursuant to this Agreement. The Disclosing Party may also act as the Receiving Party of the other party’s Confidential Information.  
 1.23.  
“Drug Master File” or “DMF” means a drug master file providing detailed information about the facility, the equipment and manufacturing processes relating to the API and Product 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 in under Applicable Laws including as required by the Committee for Proprietary Medicinal Products Note for Guidance on the European Drug Master File Procedure for Active Ingredients.  
 1.24.  
“Equipment” shall mean the equipment described in the BVL master batch record which is: (a) owned or leased by BVL or by the Customer; and (b) included in Attachment “F” to this Agreement, and in each case will be used by BVL for the Development and/or Manufacture of Product in accordance with the terms and conditions of this Agreement.  
 1.25.  
“Facility” and “Facilities” shall mean BVL’s Facility located at 000 Xxxxxxxxxx Xxxx, Xxxxxxx, Xxxx, and 00000 Xxxxx Xxxx, Xxxxxx Xxxxx, Xxxx, all other BVL facilities used in the Manufacturing of Product; provided that such other facilities have been agreed upon by the Parties in writing in advance.  
 1.26.  
“FDA” shall mean the U.S. Food and Drug Administration and any successor agency.  
 1.27.  
“FDCA” shall mean the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§321 et seq., as amended from time to time.  
 1.28.  
“Firm Order” shall mean a binding commitment, as established by a Purchase Order issued by Customer, to have a Batch of Product Manufactured by BVL hereunder.  
 1.29.  
“Five-Year Forecast” shall have the meaning ascribed thereto in Section 5.1.  
 1.30.  
“Force Majeure” shall have the meaning set forth in Article 17.  
 1.31.  
“Forecasts” shall mean the collective reference to the Five-Year Forecast and the Rolling Forecast.  
 1.32.  
“Immediately” shall mean within twenty-four (24) hours.  
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 1.33.  
“Improvements” shall mean all Technology and discoveries, inventions, developments, modifications, innovations, updates, enhancements, improvements, writings or rights (whether or not protectable under patent, trademark, copyright or similar laws) that are conceived, discovered, invented, developed, created, made or reduced to practice in the Manufacture of Product or performance of other services related to the Product under this Agreement.  
 1.34.  
“Investigation” shall mean a detailed and thorough review of any atypical Manufacturing deviation (or any other matter requiring review pursuant to the terms of this Agreement) that is documented in a written report and approved at a senior management level. Each such written report shall include, without limitation, a detailed description of the atypical event, deviation or other matter, all steps taken to review such atypical event, deviation or other matter, a root cause analysis, which other lots of Customer Product were affected, if any, the proposed and/or taken corrective actions with applicable timelines and a recommendation for permanent correction.  
 1.35.  
“Manufacture,” “Manufacturing,” and “Manufactured” shall mean all operations of BVL in the scheduling, production, packaging, labeling, warehousing, quality control testing (including in-process, release and stability testing when applicable), release and shipping of Product to meet the Specification for Product.  
 1.36.  
“Manufacturing Process” shall mean any and all processes (or any step in any process) used or planned to be used by BVL to Manufacture Product, as evidenced in the Batch Records.  
 1.37.  
“Marketing Authorization” shall mean a New Drug Application filed with an Agency outside the United States.  
 1.38.  
“NDA” shall mean a New Drug Application filed with the FDA.  
 1.39.  
“Obsolete Materials” shall have the meaning set forth in Paragraph 6.4.2.  
 1.40.  
“Order Deficit” shall have the meaning set forth in Paragraph 5.4.  
 1.41.  
“Party” or “Parties” shall have that meaning as set first in the first unnumbered paragraph of this Agreement.  
 1.42.  
“Product” and “Products” shall mean each of the final packaged dosage forms of the product(s) listed separately in each Attachment “A#.1” (i.e., A1.1) to this Agreement, as each such Attachment “A” may be amended from time to time in writing by the Parties.  
 1.43.  
“Promptly” shall mean within thirty calendar (30) days.  
 1.44.  
“Purchase Order” shall mean a written form submitted by Customer to BVL authorizing the Manufacture of Product, Development or other services as specified on the document which references this Agreement or a quotation number provided by BVL or other document provided by BVL outlining the  
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 services to be performed, the price to be paid, and contains each of the requirements set forth on Attachment “B.”  
 1.45.  
“Qualified Person” shall have the meaning set forth within the European Union Directives, including without limitation, identified in Article 49 of Directive 2001/82/EC.  
 1.46.  
“Quality Agreement” shall mean the separate quality agreement to be executed at the same time as this Agreement by BVL and Customer and attached hereto as Attachment “E.” The Quality Agreement constitutes an integrated part of this Agreement and defines the quality assurance and regulatory responsibilities of the Parties as they relate to this Agreement.  
 1.47.  
“Receiving Party” shall have the meaning ascribed thereto in Section 9.1.  
 1.48.  
“Records” shall have the meaning ascribed thereto in Section 3.8.  
 1.49.  
“Representative” shall have the meaning ascribed thereto in Section 2.4.  
 1.50.  
“Rolling Forecast” shall have the meaning ascribed thereto in Section 5.1.2.  
 1.51.  
“SOP’s” of a Party shall mean such Party’s standard operating procedures as defined in the controlled written documentation of such Party.  
 1.52.  
“Specification” shall mean the quality standards, including tests, analytical procedures and acceptance criteria that are established to confirm the quality of Product which are mutually agreed to in writing and are contained or referenced in the master batch record for Product or as otherwise mutually agreed to in writing by the Parties.  
 1.53.  
“Technology” shall mean all methods, techniques, trade secrets, copyrights, know-how, data, documentation, regulatory submissions, specifications and other intellectual property of any kind (whether or not protectable under patent, trademark, copyright or similar laws).  
 1.54.  
“Temporary Storage Period” shall have that meaning ascribed in Section 6.6.  
 1.55.  
“Territory” shall mean those countries and territories set forth in each Attachment “A#.6” (i.e., A1.6) for the Product identified in each such Attachment “A,” it being understood that different Products may have different Territories for purposes of this Agreement.  
 1.56.  
“Third Party” shall mean any person or entity other than a Party to this Agreement or such Party’s Affiliate.  
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 ARTICLE 2 - DESCRIPTION OF WORK  
 2.1.  
API and Composition.  
 2.1.1.  
Customer shall, at its own expense, supply BVL with sufficient quantities of API and Customer-supplied Composition, including API, needed for the Development or Manufacture of Product, as specified in the Forecasts and suppor[\*]ting Purchase Orders, in order to meet Customer’s requirements for commercial and/or Developmental quantities of Product in finished dosage form. Customer will provide API and any other mutually agreed, Customer-supplied composition at least [\*] calendar days in advance of scheduled Manufacturing date in accordance with BVL’s SOP’s. Customer’s provision of API to BVL shall not exceed that amount required for the existing, open Purchase Orders and, in any event, not to exceed [\*] months supply of API except as otherwise mutually agreed-to by the Parties in writing.  
BVL agrees: (i) to account for all API and Customer-supplied Composition and to provide Customer with standard inventory reports upon request; (ii) to notify Customer when the amount of Customer-supplied Composition available at BVL reaches the minimum quantity of material as agreed by both Parties; (iii) not to provide API or Customer-supplied Composition to any Third Party without the express prior written consent of Customer; (iv) not to use API or Customer-supplied Composition for any purpose other than the Manufacture of Product or conducting other services under this Agreement, including, without limitation, not to analyze, characterize, modify or reverse engineer any API, or take any action to determine the structure or composition of any API, unless the foregoing is required under this Agreement; and (v) to destroy or return to Customer or its designee all unused quantities of API and Customer-supplied Composition according to Customer’s written directions. If no written directions are provided to BVL within thirty (30) days following termination of this Agreement, BVL may dispose of such Composition per cGMP(s) without liability to Customer.  
 2.1.2.  
Customer must give written permission to BVL to do ID-only, by-label verification of any API or active drug substance if no identification test is requested by Customer to be performed by BVL.  
 2.1.3.  
BVL will release all materials provided by BVL. In the event the Territory (Attachment “G”) includes the European Union, then Customer’s Qualified Person shall be responsible to certify compliance of the Customer-supplied API and for the release of Product within the European Union.  
 2.1.4.  
Customer will provide, or cause BVL to Develop at mutually agreed upon fees, written quality control testing requirements, methods, specifications and reference standards for the API and Product. Customer will approve in writing initial testing documents, the Master Production Record and any revisions of the documents thereafter. Revisions of approved documents  
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[\*] Confidential Treatment Requested  
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 requested within [\*] weeks prior to scheduled manufacturing or other services may cause a delay or postponement of manufacturing and/or other services requested by the Customer. BVL shall not be responsible for any losses or other expenses resulting from any such delay. Further, BVL shall be entitled to reimbursement for any and all additional costs and expenses incurred by BVL in connection with any such revision or delay.  
 2.1.5.  
Customer is responsible for notifying BVL with instruction for disposition of tailings and rejects, which will be incorporated into the Master Batch Record and include a shipment address for tailing and rejects if Customer requests return of tailings and rejects.  
 2.2.  
Product Manufacture. Pursuant to the provisions of this Agreement, BVL shall Manufacture Customer’s requirements for commercial and developmental quantities of Product in finished packaged dosage form as defined in each Attachment “A#.4.1” (i.e., A1.4.1) Such Product shall meet the Specification, the requirements of cGMP and all Applicable Law.  
 2.3.  
Development Services. Upon Customer’s request and at Customer’s expense, BVL will perform Development work on Product in accordance with proposals and quotations that are: (a) submitted to Customer at Customer’s request by BVL based on information provided to BVL by Customer; and (b) agreed upon by both Parties in writing via a Purchase Order for the service that references such applicable proposal or quotation.  
 2.4.  
Representatives. Each Party shall appoint a representative having primary responsibility for day-to-day interactions with the other Party for the services under this Agreement (each, a “Representative”). Both Parties shall use reasonable efforts to provide the other with at least forty-five (45) days prior written notice of any change in its Representative. Except for notices or communications required or permitted under this Agreement, which shall be subject to Article 13, or unless otherwise mutually agreed by the Parties in writing, all communications between BVL and Customer regarding the conduct of the services under this Agreement shall be addressed to or routed directly through the respective Representatives of each Party, as appropriate.  
 ARTICLE 3 - MANUFACTURE  
 3.1.  
BVL Compliance. BVL has obtained, and will maintain at its sole cost and expense throughout the term of this Agreement, all non-Product-specific licenses, permits, certifications and approvals required under Applicable Law for its Manufacturing Facilities; BVL’s Facilities conform, and will throughout the term of this Agreement conform to cGMP and other Applicable Law.  
 3.2.  
Facility. BVL shall perform all services under this Agreement at the Facility, and shall hold at such Facility all Equipment, API, Composition and other items used in such services. BVL shall not change the location of such Facility or use any additional facility for the performance of services under this Agreement without at  
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 least one hundred and fifty (150) days’ prior written notice to, and prior written consent from, Customer, which consent shall not be unreasonably withheld or delayed (it being understood and agreed that Customer may withhold consent pending satisfactory completion of a quality assurance audit and/or regulatory impact assessment of the new location or additional facility, as the case may be). BVL shall maintain, at its own expense, the Facility and all Equipment required for the Manufacture of Product in a state of repair and operating efficiency consistent with the requirements of the cGMP and all other Applicable Law.  
 3.3.  
Change Control. Any changes to the Specification, Manufacturing Process, Equipment, testing procedures, validation, suppliers of raw materials and components, or documentation systems that are specific to Product and utilized or implemented by BVL and any changes effected by BVL that do or could affect any government submission or approval required for Product, either foreign or domestic as applicable for the Territory, shall be made only with the prior written consent of the Parties and in accordance with change control provisions of the Quality Agreement. In the event such changes are required by an Agency, BVL will Promptly notify Customer. Customer may, from time to time, change Specification upon mutual written consent of the Parties, and BVL will not unreasonably withhold its consent to such change and will use reasonable efforts to implement such change.  
 3.4.  
Facilities and Product Compliance. Product delivered to Customer pursuant to this Agreement shall conform to the Specification and be in compliance with all Applicable Law, including but not limited to the requirements of cGMP. In the event of conflicting Applicable Law, Product will comply with United States cGMP requirements unless otherwise agreed to by the Parties.  
 3.5.  
Regulatory Communications and Inspections. All information, documents and updates with regard to the Manufacture of Product which are required by any Agency shall be provided by BVL in a timely manner, and BVL shall submit to all inquiries and inspections by any such Agency. All Product-specific documents provided by BVL to any Agency shall be provided to Customer in advance of submission to such Agency if feasible, and in no case shall such documents be provided to Customer later than five (5) business days after such documents are provided to any Agency. BVL shall notify Customer Immediately (or, if during a weekend, upon the next business day) of all scheduled Product-specific Agency inspections, and Customer shall have the right to be present for such inspection. Any and all Product-specific written communications or notices of inspection received from any Agency shall be provided by Customer and BVL to the other Party no later than five (5) business days after such communications are received by such Party; provided, however, that if such document is from BVL, it may redact the confidential information of Third Parties from such communications prior to providing same to Customer.  
 3.5.1.  
BVL shall also notify Customer Immediately of any notices, observations or other written communications from such Agency regarding any deficiencies that have or may have a material adverse effect on the Product or BVL’s ability to perform its obligations under this Agreement.  
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 3.5.2.  
Customer shall provide BVL with copies of all Agency approval letters for Product for both clinical studies and commercial use. In addition, Customer shall provide BVL on an annual basis with its anticipated schedule of material Agency regulatory filings for the next two calendar years. BVL acknowledges that such schedule may change at any time.  
 3.5.3.  
BVL will provide, at CUSTOMER’s request, a copy of the BVL Drug Master File (DMF) and authorization for FDA to access the DMF. This may be used by the CUSTOMER only to prepare any required Regulatory filing.  
 3.6.  
Health, Safety and Environmental Compliance. Unless otherwise agreed by the Parties, BVL will conduct all Manufacturing and Development operations required for the Manufacture of Product under this Agreement. Dispensing and other Manufacturing operations are to be performed using appropriate safety measures and containment techniques as dictated by Applicable Law and industry standards. BVL shall be solely responsible for implementing and maintaining health and safety procedures for the Manufacture of Product and performance of services under this Agreement and for the handling of any materials or hazardous waste used in or generated by such activities. BVL, in consultation with Customer, shall develop safety and handling procedures for API and Product; provided, however, that Customer shall have no responsibility for BVL’s health and safety program. The generation, collection, storage, handling, transportation, movement and release of hazardous materials and waste generated in connection with the Manufacture of Product and other services under this Agreement shall be the responsibility of BVL at BVL’s cost and expense, unless otherwise agreed to in writing by the Parties for special situations or conditions. Without limiting other legally applicable requirements, BVL shall prepare, execute and maintain, as the generator of waste, all licenses, registrations, approvals, authorizations, notices, shipping documents and waste manifests required under Applicable Law.  
 3.7.  
Subcontractors. Neither Party may subcontract with any Third Party to perform any of its obligations hereunder without the prior written consent of the other Party. In the event that a Party does subcontract with a permitted Third Party pursuant to this Section 3.7, it shall be solely responsible for the performance of any permitted subcontractor, and for costs, expenses, damages, or losses of any nature arising out of such performance as if such performance had been provided by itself under this Agreement. Each Party shall cause any such permitted subcontractor to be bound by, and to comply with, all confidentiality, quality assurance, regulatory and other obligations and requirements as set forth in this Agreement. Notwithstanding the above, Customer does use a subcontractor to produce API.  
 3.8.  
Records. BVL shall keep complete and accurate Product-specific records of (including, without limitation, reports, accounts, notes, data, and records of all information and results obtained from) all work done by it under this Agreement (collectively, the “Records”). BVL shall not transfer, deliver or otherwise provide any such Records to any Third Party, except to an Agency when requested by an Agency, without the prior written approval of Customer. While in the possession or control of BVL, Records shall be available during annual audits or as  
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 otherwise mutually agreed to times for inspection, examination and review by or on behalf of Xxxxxxxx. All original Records of the Development services and Manufacture of Product hereunder shall be retained and archived by BVL in accordance with cGMP and Applicable Law, but in no case for less than a period of seven (7) years following completion of the applicable work or project. Upon Customer’s request, BVL shall promptly provide Customer with additional copies of such Records at Customer’s cost. Seven (7) years after completion of the applicable work or project, all of the aforementioned records shall be destroyed unless Customer instructs BVL in writing as to a contrary disposition for such files.  
 3.9.  
Product and Process Failure.  
 3.9.1.  
Product shall be Manufactured in accordance with cGMP and the Manufacturing Process approved mutually by Customer and BVL. Each Batch of Product will be sampled and tested by BVL against the Specification. The quality assurance department of BVL will review the Records relating to the Manufacture of the Batch and will assess if the Manufacture has taken place in compliance with cGMP and the Manufacturing Process.  
 3.9.2.  
If, based upon such tests, a Batch of Product conforms to the Specification and was Manufactured according to cGMP and the Manufacturing Process, then a Certificate of Compliance will be generated and approved by the quality assurance department of BVL. This Certificate of Compliance, a Certificate of Analysis, and a complete and accurate copy of the executed Batch records (collectively, the “Batch Records”) for each Batch of Product (including all the Batch documentation described in Attachment “D” to this Agreement) will be delivered to Customer by a reputable overnight courier or by registered or certified mail, postage prepaid, return receipt requested to verify delivery date. Unless the Batch is shipped under Quarantine (as defined in Section 6.3 below), in the event that Customer has not received all such Batch Records at the time of receipt of BVL’s invoice for such Batch, Customer will notify BVL in writing and BVL shall provide Customer a copy at no additional cost. In the event that Customer requires additional copies of the Batch Records, these will be provided by BVL to Customer at mutually agreed upon fees.  
 3.9.3.  
Customer will review the Batch Records for each Batch of Product and may test samples of the Batch of Product against the Specification. Customer will notify BVL in writing of its acceptance or rejection of such Batch within 30 calendar days of receipt of BVL batch release documents (Attachment D) relating to such Batch. If no acceptance or rejection in writing is received by BVL within [\*]days, the Batch will be conclusively deemed accepted. During this review period, the Parties agree to respond punctually, but in any event within [\*] calendar days, to any reasonable inquiry by the other Party with respect to such Batch Records. Customer has no obligation to accept a Batch if such Batch does not  
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 comply with the Specification and/or was not Manufactured in compliance with cGMP and the Manufacturing Process.  
 3.9.4.  
In case of any disagreement between the Parties as to whether Product conforms to the applicable Specification, a representative sample of such Product shall be submitted to an independent testing laboratory mutually agreed upon by the Parties for tests and final determination of whether such Product conforms to such Specification. The laboratory must meet cGMP requirements, be of recognized standing in the industry, and consent to the appointment of such laboratory shall not be unreasonably withheld or delayed by either Party. Such laboratory shall use the validated test methods contained in the applicable Specification. The determination of conformance by such laboratory with respect to all or part of such Product shall be final and binding on the Parties. The fees and expenses of the laboratory incurred in making such determination shall be paid by the Party against whom the determination is made.  
 3.9.5.  
Subject to Section 6.4 and 8.5, if the Batch of Product does not conform to the Specification, or was not Manufactured in compliance with cGMP and the Manufacturing Process, then BVL shall, after consultation with and written agreement from Customer:  
 3.9.5.1.  
refund any fees and expenses paid by Customer on a pro rata basis over the usable portion for such Batch; or  
 3.9.5.2.  
at BVL’s cost and expense produce a new Batch of Product as soon as reasonably possible.  
 3.9.6.  
BVL or Customer may postpone all scheduled Manufacture of the Product until such time as final disposition of rejected Batch(s) has been determined and complete investigations have been finalized with root cause analysis and corrective actions determined to prevent further Batch rejections which will be agreed to in writing by the Parties. BVL will perform such investigations, root cause analysis and corrective actions diligently and expeditiously. Customer may request Manufacture in writing with Customer’s assumption of financial responsibility in the event of further batch rejection for similar reasons.  
 3.9.7.  
Moreover, the Parties shall meet to discuss, evaluate and analyze the reasons for and implications of the failure to meet the Specification or comply with the cGMP and/or the Manufacturing Process.  
 ARTICLE 4 - VOLUMES AND ALTERNATE SOURCE  
 4.1.  
Product Purchase and Supply Obligations. BVL shall supply Customer with all of Customer’s requirements of Product in accordance with the terms of this Agreement for the Territory. Subject to the provisions of Section 4.2, Customer will purchase exclusively from BVL, and BVL will exclusively supply to Customer, one-hundred percent (100%) of Customer’s forecasted amounts of Product for commercial sale and Developmental use for the Territory during the term of this Agreement. In the event that BVL, at any time during the term of this Agreement,  
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 has reason to believe that it will be unable to perform or complete the Manufacturing and other services under this Agreement, BVL shall timely notify Customer thereof.  
 4.1.1.  
In the event that Customer, at any time during the term of this Agreement, has reason to believe that it will be unable to meet its ordering obligations under this Agreement, Customer shall promptly notify BVL thereof. Compliance by Customer with this Section 4.1 shall not relieve Customer of any other obligation or liability under this Agreement.  
 4.2.  
Alternate Source. Notwithstanding the provisions of Section 4.1, Customer may qualify, at its discretion and cost, one or more Third Parties as contract manufacturers of Product (an “Alternate Source”) as it deems necessary to ensure uninterrupted supply of Product in the Territory, and may obtain a quantity as mutually agreed in writing between the Parties of Product from such Alternate Source in order to qualify and maintain such Alternate Source as a Product manufacturer. Customer will notify BVL within thirty (30) days of any decision to retain and or qualify an Alternate Source. Quantities of Product to be obtained from an Alternate Source for such purposes will not be included in the Forecasts. Furthermore, Customer’s exclusive purchase obligations under Section 4.l shall not apply if: (a) BVL has failed to fulfill Customer’s Purchase Orders of Product for a period of more than three (3) consecutive months and such Purchase Orders have been placed according to the terms of this Agreement; (b) BVL does not accept a Purchase Order placed by Customer in accordance with the terms of this Agreement; (c) BVL is not in compliance with Applicable Law with respect to the Facilities or the Manufacture of Product and is unable to cure such non-compliance within thirty (30) days following receipt of written notice from Customer; (d) an event of Force Majeure has occurred which affects or which Customer reasonably believes will affect BVL’s ability to supply Product for a period of at least three (3) months; or (e) BVL remains in material breach of this Agreement after written notice by Customer and an opportunity to cure such defect pursuant to Section 12.3. In the case of a Force Majeure or other failure to supply compliant Product to Customer, Customer may use an Alternate Source to supply Customer’s requirements of Product until BVL is objectively able to recommence production.  
 4.3.  
Technical Transfer. BVL shall assist Customer in transferring the Manufacturing Process to an Alternate Source by providing such technical assistance and documentation as necessary at reasonable fees mutually agreed upon by the Parties. BVL shall provide such assistance at no charge in the event that Customer is qualifying such Alternate Source due to a breach of this Agreement by BVL, including without limitation, a failure by BVL to fulfill its supply obligations hereunder for any reason other than a Customer breach or Force Majeure. No Confidential Information of BVL shall be disclosed to such Alternate Source, it being understood that any Product-specific information contained in the master batch record for Product is not Confidential Information of BVL and may be disclosed to the Alternate Source.  
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 ARTICLE 5 - FORECASTS AND PURCHASE ORDERS  
 5.1.  
Five-Year Forecast and Binding Minimum Commitment. Attached hereto as part of each Attachment “A#.4.1” (i.e., A1.4.1) is Customer’s forecast of its requirements of Product for the first five (5) Contract Years of the term of this Agreement (“Five-Year Forecast”). [\*].  
 5.1.1.  
Updates to Five-Year Forecast. As the Five-Year Forecast represents Customer’s minimum commitment of Product for the period five-years from the Effective Date, only increases to the Five-Year Forecasts shall be permissible, and then only upon written acceptance by BVL. [\*].  
 5.1.2.  
Extension of Agreement by Amending the Five-Year Forecast. [\*].  
 5.2.  
Five Year Product Forecast and Scheduling. Customer and BVL shall cooperate in estimating and scheduling the Manufacturing of Product. If commercially  
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 reasonable for Customer to do so, the annual order of Product for commercial use will be divided into individual Batch Purchase Orders evenly distributed over the course of any twelve (12) month period; provided that the total quantities ordered by these Purchase Orders meets the requirements of this Article 5. Customer and BVL will make alternate arrangements in writing regarding the distribution of annual requirements due to market conditions, Development requirements or other needs.  
 5.3.  
Rolling Twelve (12) Month Distribution Forecasts. One hundred twenty (120) days in advance of the first day of each Contract Quarter during the term of this Agreement, Customer will provide BVL with a twelve (12) month rolling distribution forecast for all presentations of Product (“Rolling Forecast”). The initial Rolling Forecast will be included in each Attachment “A#.4.2” (i.e., A1.4.2) to this Agreement. The first Contract Quarter of such Rolling Forecast will be considered a Firm Order for which Customer will provide non-cancelable Purchase Order for each Batch of Product in such period of the Rolling Forecast.  
 5.4.  
Obligation of Supply and Purchase. BVL shall be obligated to Manufacture Product only in accordance with quantities forecasted and accepted by BVL in the Five-Year Forecast in accordance with this Article 5 and each Attachment “A#.4.1” (i.e., A1.4.1) of this Agreement. [\*].  
 5.5.  
Additional and Development Services.  
 5.5.1.  
Development services required in advance of Manufacture or in support of Manufacture will be mutually agreed to by BVL and Customer. BVL will provide Customer with estimated quotations and timelines for such Development activities. Customer will issue a non-cancelable Purchase Orders referencing the quotation provided prior to BVL initiating the Development services. In the event that Customer changes the scope of the Development work such that the cost exceeds the quoted amount, BVL will issue a revised quotation for which Customer will provide a new or revised Purchase Order reflecting the revised amounts for services required.  
 5.5.2.  
In the event that Customer requests or an Agency requires additional services directly impacting the Product, BVL will provide Customer with a quotation for such services. BVL will provide such services only upon  
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 receipt from Customer of a binding Purchase Order referencing the quotation provided for the required service.  
 5.6.  
Supply of Composition. It is BVL’s responsibility to maintain a sufficient inventory of BVL-supplied Composition from mutually approved vendors, in order to meet the Forecasts; provided, however, that with respect to non-stock items BVL will not maintain an inventory of BVL-supplied Composition in excess of the inventory required to Manufacture the quantity of Product specified in the first Contract Quarter of the current Rolling Forecast without Customer’s prior written consent, which consent shall not be unreasonably withheld. It is Customer’s responsibility to supply API and Customer-supplied Composition as indicated in Attachment “A#.3” (i.e., A1.3) Customer-supplied Composition shall be delivered to BVL at least four (4) weeks in advance of the scheduled Manufacturing date and in accordance with BVL SOP’s. Customer will provide adequate supply of reference standards upon request by BVL. Customer will coordinate with BVL Materials Management Department according to BVL SOP’s on the specifics related to each shipment of material. BVL will be responsible to receive, sample, store and maintain the inventory at BVL in accordance with BVL SOP’s and mutually agreed to Specifications. At the beginning of each month BVL will provide a standard monthly inventory report of Customer-supplied Composition.  
 5.7.  
Notwithstanding anything to the contrary set forth herein, this Section 5 shall survive any termination or expiration of the Agreement for not less than the duration remaining on the Five-Year Forecast.  
 5.8  
Notwithstanding the above obligations and commitments of this Article 5, such obligations and commitments shall not be enforced if conditions to evoke Section 3.9.5 are in effect and if BVL has postponed scheduled Manufacture of the Product under Section 3.9.6. In such case the parties agree to meet and determine the manufacturing and purchase obligations of each party after corrective action has occurred.  
 ARTICLE 6 - PRICE AND PAYMENT  
 6.1.  
Price and Shipment.  
 6.1.1.  
The prices to be paid by Customer for the services and/or quantities of Product purchased pursuant to Article 5 of this Agreement are specified in each Attachment “A#.5” (i.e., A1.5) or in applicable quotations provided to Customer and confirmed by Customer’s Purchase Orders.  
 6.1.2.  
Delivery terms for Products shall be FCA Facility (at BVL’s dock) (Incoterms 2000). Customer shall assume title and risk of loss of the finished Product upon delivery to carrier at BVL Facility (BVL’s dock). BVL shall ensure that each Batch shall be delivered to Customer, or Customer’s designee: (i) on or about the delivery date and to the destination designated by Customer on the Purchase Order; and (ii) in accordance with the instructions for shipping included on the Purchase Order and packaging specified in the Master Batch Record or as otherwise agreed to by the Parties in writing. A bill of lading shall be furnished to Customer with respect to each shipment. Customer is  
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 responsible for all shipment costs and shipping charges will be paid directly by Customer.  
 6.2.  
Price Adjustments.  
 6.2.1.  
Annual Price Adjustments. For Products subject to pricing as set forth on Attachment A#.5(a) (i.e., this section does not apply to pricing arrangements entered into pursuant to A#.5(b) which are not subject to annual price adjustments), BVL shall notify Customer of any price adjustments for each presentation of Product included in Attachment “A#.1” (i.e., A1.1) by October 31 of each year during the term of this Agreement for the following year beginning January 1. Prices for Product will be adjusted on an annual basis by BVL for the next succeeding year based upon one of two methodologies set forth below. At the outset of the Agreement, Customer shall choose one of the following two methodologies for the duration of the Agreement:  
 6.2.1.1.  
Annual Price adjustments [\*]  
[\*]  
 6.2.1.3.  
For the annual price adjustment methodology, Customer elects: [\*]  
 6.2.2.  
Price Adjustment on Product or Process Specification Changes. BVL reserves the right to adjust prices based on changes to the Specification or Manufacturing Process for Product regardless of the event or action causing the Specification or Manufacturing Process change (other than a change required as a result of BVL’s negligence action, willful misconduct or breach of this Agreement), including but not limited to changes in inspection, packaging and labeling.  
 6.2.3.  
Prices for Development Services and Development Manufacture. Pricing for Product and Manufacturing Process Development services will be provided to Customer in written proposals provided to Customer by BVL based on the services requested by Customer. Customer will confirm its acceptance of a proposal by issuing a Purchase Order referencing the quotation number provided on the proposal.  
 6.3.  
Payment.  
 6.3.1.  
The purchase price for Product or services in an undisputed invoice shall be paid to BVL no later than thirty (30) days after the date of BVL’s invoice to Customer. BVL will issue an invoice for: (i) Product Manufacture at such time that BVL’s Quality Control Department has completed its testing, found Product suitable to be shipped and has shipped the documents identified in Attachment “D” pursuant to release of Product; and (ii) or for other services, upon completion of such other services as described in the applicable proposal. Customer may request  
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 that a Batch be shipped before Customer release (i.e., shipment in “Quarantine”). In the event a Quarantine shipment is made, BVL will invoice on the shipment day. Customer will notify BVL in writing that a lot can be shipped in Quarantine and BVL will make all reasonable efforts to honor this request. Within thirty (30) days from the date of any disputed invoice, Customer must provide a written notice that conforms to the requirements of this Agreement of the disputed invoices and the reason such invoice is disputed. The Parties will negotiate in good faith to resolve such dispute within thirty (30) days following notice of such dispute. If the Parties are unable to reach an agreement, either party may pursue any remedies available to it under this Agreement at law or in equity.  
 6.3.2.  
In the event of nonpayment of balances without written notice and reasonable cause within sixty (60) days of the invoice date, Customer agrees to pay BVL a monthly late payment charge equal to one and one-half percent (1.5%) of the unpaid balance. Should unpaid balances on undisputed invoices extend beyond ninety (90) days after an invoice has been issued, BVL reserves the right to require Customer to pay one hundred (100%) of the full price for each Batch at the time of Purchase Order issuance or may cancel all scheduled Manufacture until such time as all unpaid overdue invoices, together with any and all late fees, have been paid.  
 6.4.  
Payment for Non-Validated Services or Production and Obsolete Materials.  
 6.4.1.  
Customer will be required to pay BVL for all Product Manufactured during any period when any Manufacturing Process and material testing procedures have not been fully developed and validated, regardless of whether Product is accepted or rejected by the Customer, unless such rejection is due to BVL’s negligence, willful misconduct or breach of this Agreement by BVL.  
 6.4.2.  
Customer will be required to pay BVL for all packaging components and raw materials which were purchased by BVL for use specifically in the Manufacture of Product covered by this Agreement, should any of the BVL-supplied Composition become obsolete for any reason other than BVL’s negligence, willful misconduct or breach of this Agreement (the “Obsolete Materials”). Customer must agree to disposition of any Obsolete Materials within 90 days from notification by BVL. If BVL does not receive notification of where to ship unused or obsolete materials, BVL has the right to dispose of such materials per governing cGMP(s) without liability to Customer.  
 6.5.  
Cancellation Fees. In addition to any remedy set forth in Paragraph 5.4, Customer will pay a cancellation fee equal to five percent (5%) of the price of any Batch that is the subject of a Firm Order if such Batch is cancelled or postponed by Customer 30 or more days in advance of the scheduled Manufacturing date, unless such cancellation is under Section 3.9.6. If cancellation or postponement is made less than 30 days in advance of the scheduled Manufacturing date, unless such cancellation is under Section 3.9.6, Customer is responsible for payment of one hundred (100%) of the price of the postponed or cancelled  
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 Batch(es). BVL will use commercially reasonable efforts to mitigate and will attempt to use the capacity created by such postponement or cancellation and if it does so, Customer will only be responsible for payment of fifty percent (50%) of the full price of the postponed or cancelled Batch.  
 6.6.  
Storage Fees. Customer is responsible for storage charges as specified in Attachment “C” for Product stored for more than thirty (30) beyond BVL’s release of such Product. Short-term storage of Product in BVL’s warehousing Facilities beyond 30 calendar days must receive prior written approval from BVL. Such approval will be granted only on a space-available basis. If Customer and BVL agree to a storage arrangement and duration for such temporary storage (the “Temporary Storage Period”), then not less than thirty (30) days prior to the conclusion of the Temporary Storage Period, BVL will provide written notice to Customer regarding the expiration of the Temporary Storage Period. In response to such notice, Customer shall provide BVL with shipment instructions for the Product in temporary storage. Should Customer fail to provide written instructions, at the expiration of the Temporary Storage Period, BVL shall ship the Product to Customer at Customer’s cost at the Customer’s shipping address listed on the Purchase Order.  
 6.7.  
Stability Program. During the term of this Agreement and upon Customer’s request and BVL’s written agreement, BVL will conduct and support, at Customer’s expense, all stability studies in progress or planned (e.g., NDA annual stability studies) as of the Effective Date until such studies are concluded. Customer shall be responsible for all costs of conducting any stability studies. Stability program costs will be covered in a separate quotation provided by BVL to Customer based on the agreed upon protocol. Customer may also make arrangements for stability work to be performed at a facility other than BVL at Customer’s expense.  
 6.8.  
Inspection, Packaging and Labeling. Customer shall be responsible for and bear all costs associated with the design, Development, quality release and regulatory approval of all labeling and packaging materials for Product. Customer shall perform its design, development, quality release and regulatory approval obligations hereunder in a timely manner sufficient for BVL to satisfy its Manufacturing obligations hereunder for Product. Labeling and packaging developed by Customer will conform to labeling and packaging Specification mutually agreed to in writing by the Parties and will conform to all Applicable Law.  
ARTICLE 7 - QUALITY AGREEMENT  
 7.1.  
Quality Agreement. Certain quality matters relating to Product are included in the Quality Agreement which is attached and incorporated herein by reference as Attachment “E.” If any provision of the Quality Agreement is inconsistent with the terms of this Agreement, the terms of this Agreement shall prevail.  
ARTICLE 8 - INDEMNIFICATION  
 8.1.  
Customer Indemnity. Customer hereby holds harmless and indemnifies BVL, its Affiliates and its and their directors, officers, employees and agents (the “BVL  
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 Indemnitees”) against any and all claims, losses, liabilities, lawsuits, proceedings, costs and expenses of any Third Party, including, without limitation, reasonable attorneys’ fees, and the cost of recalls (collectively, “Claims”) incurred by any BVL Indemnitee, based on, resulting from, arising out of or in connection with: (a) injuries and/or death resulting from, arising out of or in connection with any use of Product Manufactured by BVL, including, without limitation, Claims based on negligence, warranty, strict liability or any other theory of liability or violation of any Applicable Law; (b) any breach by Customer of its representations, warranties or covenants hereunder; or (c) any negligent act or the willful misconduct of any Customer Indemnitees in performing Customer’s obligations under this Agreement. However, such indemnity shall not apply to the extent that such injury to persons or property or death arises out of BVL’s breach of this Agreement or any of the warranties contained in this Agreement or its gross negligent or willful misconduct.  
 8.2.  
BVL Indemnity. BVL hereby holds harmless and indemnifies Customer, its Affiliates and its and their directors, officers, employees and agents (the “Customer Indemnitees”) against any and all Claims based on, resulting from, arising out of or in connection with any: (a) breach by BVL of its representations, warranties or covenants hereunder; or (b) negligent act or the willful misconduct of any BVL Indemnitees in performing BVL’s obligations under this Agreement. However, such indemnity shall not apply to the extent that such injury to persons or property or death arises out of Customer’s labeling, marketing, handling, or storage of the Product; Customer’s API or Customer-supplied materials; or as a result of Customer’s breach of this Agreement or any of the warranties contained in this Agreement or its gross negligent or willful misconduct.  
 8.3.  
Indemnification Procedures. Each Party agrees to notify the other Party within ten (10) business days of receipt of any Claims, demands or threats of suit for which the other Party may be liable under Section 8.1 or 8.2 as the case may be. The indemnifying Party shall have the right, but not the obligation, to defend, to employ counsel of its choosing (such counsel to be reasonably acceptable to the indemnified Party), to control, to negotiate, and to settle such claims; provided, however, that the indemnified Party shall be entitled to participate in the defense of such matter and to employ counsel at its expense to assist therein. The Party seeking indemnification shall provide the indemnifying Party with such information and assistance as the indemnifying Party may reasonably request, at the expense of the indemnifying Party. The Parties understand that no insurance deductible shall be credited against losses for which a Party is responsible under this Article 8.  
 8.4.  
Insurance. Customer and BVL will each, at its own cost and expense, obtain and maintain in full force and effect, during the term of this Agreement, Commercial General Liability insurance, written on the standard approved Policy Form, and Blanket Contractual Liability, with limits of liability of not less than $3,000,000 Combined Single Limit Bodily Injury and Property Damage covering its duties and obligations under the Agreement. Furthermore, during the term of this Agreement, BVL shall obtain and maintain “All Risk” property insurance valued at replacement cost, covering loss or damage to the Facility and Customer’s property and materials in the care, custody, and control of BVL. Said policy or policies of insurance shall include the other Party as an Additional Insured. The  
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 coverage limits may be provided through a combination of Primary, Excess/Umbrella or Self-Insured Retention. The coverage limit for Customer property shall be limited to $1,250,000 in aggregate per Contract Year.  
 8.5.  
Reimbursement for Loss of API and Customer-Supplied Composition. After such time as all Production and testing procedures have been fully developed and validated and a complete and successful technical transfer to BVL’s production department has occurred, BVL agrees to reimburse Customer up to a maximum of $[\*] per Batch pro-rated over the usable portion of the Batch, if applicable, for any loss of API or Customer-supplied Composition for each Batch that does not meet Specification or was not Manufactured in accordance with the Manufacturing Process or cGMP and therefore can not be released; provided that the loss of such materials can be shown after Investigation to be caused solely and directly by: (a) the failure of BVL to follow its SOP’s; or (b) BVL’s negligence, willful misconduct or breach of this Agreement. In addition to this payment, BVL will be responsible for all Manufacturing fees incurred during the Manufacture of the failed Batch, pro-rated over the usable portion of the Batch, if applicable. The monetary values of all Customer-supplied raw ingredients, materials and/or components must be disclosed by Customer to BVL in writing prior to production in the questionnaire provided by BVL to Customer. The Customer is responsible for notifying BVL in writing of any changes in the value of the ingredients, raw materials and/or components supplied to BVL, and BVL shall not be liable for any increase in the cost of the foregoing if Customer fails to provide the abovementioned notice or timely updates thereto. Notwithstanding the foregoing or any declared value of API costs in excess of $[\*], in no event shall BVL’s liability to Customer for API be in excess of the $[\*] set forth in this Section 8.5.  
 8.6.  
LIABILITY LIMITATION. SECTION 8.5 IS CUSTOMER’S SOLE AND EXCLUSIVE REMEDY FOR ANY PRODUCT THAT DOES NOT COMPLY WITH THE SPECIFICATIONS CONTAINED IN THE MASTER BATCH RECORD. IN NO EVENT SHALL BVL BE LIABLE FOR ANY LOSS, INJURY OR DAMAGE, HOWSOEVER ARISING, EXCEPT AS SET FORTH IN PARAGRAPHS 8.2 AND 8.5. 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 A DUTY IMPOSED UNDER ARTICLE 9 (CONFIDENTIALITY) OR TO ANY THIRD-PARTY LOSS, INJURY OR DAMAGE FOR WHICH BVL SHALL BECOME LIABLE. UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR LOST PROFITS, LOST MARKET SHARE OR ANY DAMAGES STEMMING FROM AN INTERRUPTION OF SUPPLY. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY. EXCEPT AS EXPLICITLY SET FORTH TO THE CONTRARY HEREIN, IN NO EVENT SHALL BVL’S MAXIMUM TOTAL AGGREGATE LIABILITY HEREUNDER EXCEED THE TOTAL FEES  
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 ACTUALLY PAID BY CUSTOMER FOR THE SERVICES PROVIDED PURSUANT TO THIS AGREEMENT. SUCH LIMITED WARRANTIES, LIMITATION OF LIABILITY AND SPECIAL PROVISIONS ARE INTEGRAL PARTS OF THIS AGREEMENT.  
ARTICLE 9 - CONFIDENTIALITY  
 9.1.  
Confidential Information. As used in this Agreement, “Confidential Information” means any scientific, technical, trade or business information related to the subject of the Agreement, irrespective of whether in human or machine-readable form, tangible or intangible, which is: (a) given by the Disclosing Party to the Receiving Party or otherwise acquired or perceived by the Receiving Party from the Disclosing Party; or (b) which is developed by one Party for the other under the terms of this Agreement. Confidential Information does not include information that: (a) is in possession of the Receiving Party at the time of disclosure, as demonstrated by written records and without obligation of confidentiality; (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 breach of an obligation of confidentiality; or (d) is developed independently by the Receiving Party without any use of, access to, reference to, or reliance upon the Disclosing Party’s Confidential Information, in whole or in part. Disclosing Party is not obligated to mark information as “CONFIDENTIAL” to be deemed Confidential Information under this Agreement. Confidential Information of BVL includes, but is not limited to, BVL Technology, BVL Improvements and BVL Manufacturing processes, techniques, know-how and pricing information. Confidential Information of Customer includes, but is not limited to, Customer Technology and Customer Improvements. This Agreement shall not be construed as a grant of any right or license to the Receiving Party with respect to Confidential Information of the Disclosing Party or as a requirement of either Party to enter into any further arrangement with respect to Confidential Information of the Disclosing Party.  
 9.2.  
Disclosure and Use. The Receiving Party shall: (a) maintain the confidentiality of the Disclosing Party’s Confidential Information; (b) not disclose the Disclosing Party’s Confidential Information to any Third Party without the prior written consent of the Disclosing Party; and (c) use the Disclosing Party’s Confidential Information only as necessary to fulfill its obligations or in the reasonable exercise of rights granted to it hereunder. Notwithstanding the foregoing, a Receiving Party may disclose: (i) Confidential Information of the Disclosing Party to its Affiliates, and to its and their directors, employees, consultants, and agents provided that in each case such individuals and entities have a specific need to know such Confidential Information and are previously bound by written obligation of confidentiality and restriction at least as rigorous as those set forth herein; (ii) Improvements to the extent required to exploit the grant of its rights under Article 11 of this Agreement; and (iii) Confidential Information of the Disclosing Party to the extent such disclosure is required to comply with Applicable Law or to defend or prosecute litigation; provided, however, that prior to any such use or disclosure, the Receiving Party shall provide written notice of such potential disclosure to the Disclosing Party, and cooperate with Disclosing Party’s lawful decision to avoid or minimize the degree of such disclosure. Receiving Party shall permit the Disclosing Party the opportunity, if desired, to  
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 seek an appropriate protective order or other remedy with respect to narrowing the scope of such use or disclosure. Upon request, the Receiving Party shall return all copies of the Disclosing Party’s Confidential Information to the Disclosing Party, except for a single copy for the purpose of determining compliance with its obligations of this Agreement.  
 9.3.  
Publicity. Neither Party will issue any press release or other public announcement concerning this Agreement or the transactions contemplated by this Agreement without the prior written consent of the other Party, except where such announcements are required by Applicable Law or the rules of any stock exchange or NASDAQ. The Parties will use all reasonable efforts to consult with each other and to cooperate with respect to the wording of any such announcement. Product labeling (primary, secondary, and any insert) and government filings may indicate that Product has been Manufactured for Customer by BVL.  
ARTICLE 10 - REPRESENTATIONS AND WARRANTIES  
 10.1.  
Representations of BVL. BVL represents and warrants to Customer that: (a) it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind held by other Parties, private or public, materially inconsistent with the provisions of this Agreement; (b) the services provided by BVL shall be performed with requisite care, skill and diligence, in accordance with Applicable Laws and industry standards, and by individuals who are appropriately trained and qualified; (c) to the best of its knowledge, the services provided by BVL will not infringe the intellectual property rights of any Third Party and it will promptly notify Customer in writing should it become aware of any claims asserting such infringement; (d) at the time of delivery to Customer, Product Manufactured under this Agreement: (i) will have been Manufactured in accordance with cGMP and all other Applicable Laws, the Manufacturing Process, the requirements of the Quality Agreement, and Specification, and (ii) will not be adulterated or misbranded under the FDCA or other Applicable Law; and (iii) upon receipt of payment by BVL, the product correlating to such payment should be free and clear of all liens and encumbrances; and (e) it has not been debarred, nor is it subject to a pending debarment, and that it shall not use in any capacity in connection with the services provided under this Agreement any person who has been debarred pursuant to section 306 of the FDCA, 21 U.S.C. § 335a, or who is the subject of a conviction described in such section. BVL agrees to inform Xxxxxxxx in writing Immediately if BVL or any person who is performing services on its behalf under this Agreement is debarred or is the subject of a conviction described in section 306, or if any action, suit, claim, investigation, or proceeding is pending relating to the debarment or conviction of BVL or any person performing such services.  
 10.2.  
Representations of Customer. Customer represents and warrants to BVL that: (a) it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights held by other Parties or Third Parties, private or public, inconsistent with the provisions of this Agreement; (b) to the best of its knowledge the use of Customer Technology, Customer Improvements, and Customer Confidential Information in the  
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 performance of services under this Agreement will not infringe the intellectual property rights of any Third Party and that it will promptly notify BVL in writing should it become aware of any claims or threats asserting such infringement; (c) that the API provided by Customer will be provided to BVL free and clear of any liens and encumbrances; (d) Customer’s further distribution of the Product will not cause the Product to be adulterated or misbranded under the FDCA or other Applicable Law; and (e) Customer has not been debarred, nor is it subject to a pending debarment pursuant to section 306 of the FDCA, 21 U.S.C. § 335a, nor is it the subject of a conviction described in such section. Customer agrees to inform BVL in writing Immediately if Customer is debarred or is the subject of a conviction described in section 306, or if any action, suit, claim, investigation, or proceeding is pending relating to the debarment or conviction of Customer.  
 10.3.  
Additional Representations of Customer in the event that Product(s) will be Offered for Sale, Sold, Marketed or Distributed for Developmental or Clinical Applications within the Member States of the European Union. In the event that the Territory includes the European Union or any member states thereof, then in addition to all other warranties and representations set forth herein, Customer also represents and warrants: (a) that Customer has properly appointed one or more Qualified Person(s) in compliance with EU standards, including without limitation, Article 49 of Directive 2001/82/EC, with respect to the Product(s) subject to this Agreement; and (b) that Customer’s Qualified Person(s) shall fully comply with all EU standards, directives and rules, including without limitation, as set forth in Article 51 of 2001/83/EC. It is Customer’s obligation to notify BVL as to whether the Territory includes an EU member nation, or if a country within the Territory subsequently becomes a member of, or subject to, the European Union.  
 10.4.  
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 NON-INFRINGEMENT. THIS IS FOR ANY MATTER ARISING OUT OF OR RELATING TO THIS AGREEMENT, WHETHER SUCH LIABILITY IS ASSERTED ON THE BASIS OF CONTRACT, TORT OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.  
ARTICLE 11 - INTELLECTUAL PROPERTY  
 11.1.  
Customer Technology. Customer represents and warrants that the Product(s) to be Manufactured by BVL do not infringe any U.S. Patent or other intellectual patent rights in the Territory. All rights to and interests in Customer Technology that qualifies as Confidential Information under Article 9.1 of this Agreement shall remain solely in Customer and no right or interest therein is transferred or granted to BVL. BVL acknowledges and agrees that it does not acquire a license or any other right to Customer Technology except for the limited purpose of carrying out its duties and obligations under this Agreement and that such limited, non-exclusive, license shall expire upon the completion of such duties and obligations or the termination or expiration of this Agreement, whichever is the first to occur.  
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 11.2.  
BVL Technology. All rights to and interests in BVL Technology that qualifies as Confidential Information under Article 9.1 of this Agreement shall remain solely in BVL and no right or interest therein is transferred or granted to Customer. Customer acknowledges and agrees that it shall not acquire a license or any other right to BVL Technology except as otherwise set forth in this Agreement.  
 11.3.  
Customer Improvements. The Parties agree that all Improvements that relate exclusively to the Confidential Information of Customer or are Product-specific, shall be the sole and exclusive property of Customer (“Customer Improvements”) and are hereby assigned to Customer (or its designee) without additional compensation to BVL. BVL shall take such steps as Customer may reasonably request (at Customer’s expense) to vest in Customer (or its designee) ownership of the Customer Improvements.  
 11.4.  
BVL Improvements. The Parties agree that all Improvements that are not Customer Improvements shall be the sole and exclusive property of BVL (“BVL Improvements”) and Customer hereby assigns the same to BVL (or its designee) without additional compensation to Customer. Customer shall take such steps as BVL may reasonably request (at BVL’s expense) to vest in BVL (or its designee) ownership of the BVL Improvements. To the extent that BVL incorporates a BVL Improvement into the Manufacturing Process of Customer’s Product(s), BVL agrees to grant to Customer a non-exclusive, sub-licensable, royalty-free license to use such Customer-approved, BVL Improvement to manufacture, have manufactured, use, sell, have sold and/or import the Products specifically covered by this Agreement in and for the Territory. This grant shall be perpetual, but subject to termination in the event that BVL is notified that such BVL Improvement infringes a Third Party’s intellectual property rights, in which case the grant set forth in this paragraph 11.4 is terminable with a 10-day written notice to Customer. The foregoing license shall only be transferable as provided in Article 15.  
ARTICLE 12 - TERM AND TERMINATION  
 12.1.  
Term. This Agreement shall become effective on the Effective Date and, except as otherwise provided herein, shall be in effect for an initial term of five (5) Contract Years. This Agreement may be extended exclusively by amendment provided for in Section 5.1.1 – 5.1.2, unless otherwise agreed to by the Parties in writing.  
 12.2.  
Termination by Either Party Without Cause. Either Party may terminate this Agreement without cause by providing twenty-four (24) months written notice to the other Party. Notwithstanding such no-fault termination, Customer shall be liable for the reserved capacity as set forth in Article 5, and for any outstanding Development services or Purchase Orders.  
 12.3.  
Termination for Breach. Either Party may terminate this Agreement for a material breach by the other Party by giving the breaching Party written notice, specifying the breach, and giving the breaching Party three (3) months to cure such breach. If the default has not been cured at the end of the three (3) month period, then, upon written notice thereof to the breaching Party by the other Party this Agreement shall terminate. Termination for breach will have no effect on  
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 performance obligations or amounts to be paid which have accrued up to the effective date of such termination. Notwithstanding the foregoing, if Customer’s unpaid, undisputed balance extends in any event beyond ninety (90) days, BVL shall have the right to require pre-payment for all future Manufacturing until such time as Customer has established a satisfactory payment history in BVL’s sole discretion. Notwithstanding anything to the contrary, in the event that Customer’s unpaid, undisputed balance extends in any event beyond one-hundred twenty (120) days, then BVL shall be entitled to: (a) terminate this Agreement without liability to Customer unless such payment default is cured in its entirety by Customer within thirty (30) days of written notice from BVL of its intent to terminate; or (b) cease production and/or service performance without liability until such default is cured.  
 12.4.  
Termination for Bankruptcy. In the event of any proceedings, voluntary or involuntary, in bankruptcy or insolvency, by or against Customer or BVL, or the appointment with or without the Parties’ consent of a receiver for either Party, the other Party shall be entitled to immediately terminate this Agreement upon written notice to the other Party without any liability whatsoever. Such termination shall not affect any claim for damages available to the terminating Party or for costs or fees accrued to date.  
 12.5.  
Termination for Force Majeure. In the case of a Force Majeure event that will, or continues to, prevent performance (in whole or substantial part) of this Agreement by a Party for a period of at least six (6) months, the other Party shall be entitled to terminate this Agreement upon prior written notice to the other Party without any liability whatsoever.  
 12.6.  
Consequences of Termination.  
 12.6.1.  
In the event of termination of this Agreement, the Parties will endeavor to transition the Manufacturing services and technology transfer in such a manner as to not cause unreasonable inconvenience to either Party. Termination by BVL shall not be effective until Customer has located and arranged for continuation of Manufacture of Product with another supplier, but in no event shall such supply obligation continue for more than two (2) years after the date of termination notice of this Agreement. The Parties will cooperate during such period to continue any such ongoing services and BVL shall perform such functions reasonably necessary or required in connection with the orderly wind-down of any active project as required by the terms of this Agreement and Applicable Law.  
 12.6.2.  
Promptly upon a termination of this Agreement or at the request of the Disclosing Party, the Receiving Party shall return to the Disclosing Party all Confidential Information of the Disclosing Party in its possession, except for one copy that may be retained for archive purposes. Furthermore, BVL shall promptly return all Customer-supplied Composition, Customer-supplied Equipment, API, retained samples, reference standards, data, reports and other property, information and/or know-how in recorded form that was provided by Customer, or Developed in the performance of the services under this Agreement, that are owned  
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 by or licensed to Customer, excepting that required to be retained by Applicable Law.  
 12.6.3.  
In the event of termination by BVL pursuant to Section 12.2, Customer shall pay BVL for Manufacturing, Development and other services completed up to the effective date of such termination within thirty (30) days of Customer’s receipt of all results, reports, data, samples, and other deliverables to be provided pursuant to this Agreement. In the event the funds received by BVL prior to such termination exceed costs incurred to the date of termination, BVL shall refund the difference to Customer within thirty (30) days after the effective date of termination. In the event of a no-fault termination by BVL pursuant to Section 12.2, Customer shall not be liable under Section 5.4 for that portion of the Five-Year Forecast following the effective date of the termination.  
 12.6.4.  
Upon any termination (i) other than BVL’s breach of this Agreement; or (ii) for BVL’s breach of this Agreement and subject to the mutual agreement of the parties, Customer: (a) shall purchase from BVL any existing inventories of Product conforming to the Specification and Manufactured in accordance with cGMP and the Manufacturing Process, at the then-current price for such Product; and (b) may either: (i) purchase any Product in process held by BVL as of the date of the termination, at a price to be mutually agreed (it being understood that such price shall reflect, on a pro rata basis, work performed and non-cancelable, out-of-pocket expenses actually incurred by BVL with respect to the Manufacture of such in-process Product) or (ii) reimburse BVL for all work performed and non-cancelable costs, and out-of-pocket expenses incurred by BVL and direct BVL to dispose of such material at Customer’s cost.  
 12.6.5.  
If Customer terminates this Agreement for any reason, Customer shall reimburse BVL for the costs of any BVL-supplied Composition that cannot be canceled, unless these materials can be utilized by BVL on other projects. This reimbursement shall be made within thirty (30) days after receipt by Customer of an invoice itemizing the material costs. BVL agrees to transfer to Customer any materials for which Customer has paid under this provision. Termination shall have no effect on payment obligations that have accrued up to the effective date of termination. Furthermore, unless Customer has terminated this Agreement pursuant to Sections 12.3, 12.4, or 12.5, Customer shall pay BVL as provided in Section 5.4.  
 12.6.6.  
Upon the effective date of termination or expiration of this Agreement, and subject to 12.6.1, Customer shall have no further obligations to BVL with respect to the Forecasts and BVL will have no further obligations to Manufacture Product.  
 12.7.  
Injunctive Relief for Breach or Threatened Breach. The Parties agree that should this Agreement be breached, money damages may be inadequate to remedy such a breach. As a result, the non-breaching Party shall be entitled to seek, and a court of competent jurisdiction may grant, specific performance and  
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 injunctive or other equitable relief as a remedy for any such breach or threatened breach of this Agreement. Such remedy shall be in addition to all other remedies, including money damages, available to a non-breaching Party at law or in equity.  
 12.8.  
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 or of any rights and obligations of the Parties that by their terms survive termination or expiration of this Agreement, including, without limitation, the representations and warranties (Article 10), duties of confidentiality (Article 9), indemnification (Article 8), intellectual property (Article 11), governing law and jurisdiction (Article 16) and Quality Agreement (Attachment “E”) of this Agreement. Notwithstanding anything to the contrary set forth herein, the obligations identified in this Paragraph 12.8 shall survive for a period of not less than ten (10) years from any termination or expiration of this Agreement.  
ARTICLE 13 - NOTICES  
 13.1.  
All notices concerning this Agreement shall be given in writing, as follows: (i) by actual delivery of the notice into the hands of the Party entitled to receive it, in which case such notice shall be deemed given on the date of delivery; or (ii) by Federal Express, UPS, DHL or any other overnight carrier, in which case the notice shall be deemed given two (2) days from the date of transmission. All notices which concern this Agreement shall be addressed as follows:  
If to BVL:  
Ben Venue Laboratories, Inc.  
000 Xxxxxxxxxx Xxxx  
Bedford, Ohio 44146  
Attn: Vice President, Contract Manufacturing Services  
With copy to:  
Ben Venue Laboratories, Inc.  
000 Xxxxxxxxxx Xxxx  
Bedford, Ohio 44146  
Attn: Legal Department, Division Counsel  
If to Customer:  
Vion Pharmaceuticals, Inc.  
4 Science Park  
New Haven, CT 06511  
Attn: Xxxxxx X. Xxxxxxx, President & CFO  
With a copy to:  
Vion Pharmaceuticals, Inc.  
4 Science Park  
New Haven, CT 06511  
Attn: Xxxxx Xxxxxxxxx, Vice-President, Finance & Chief Accounting Officer  
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 ARTICLE 14 - WAIVER  
 14.1.  
No failure on the part of either Party to exercise, and no delay in exercising, and no course of dealing with respect to, any right, power or privilege under this Agreement shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege under this Agreement preclude any other or further exercise thereof or the exercise of any other right, power or privilege.  
ARTICLE 15 - ASSIGNMENT OF AGREEMENT  
 15.1.  
Neither this Agreement, nor any rights or obligations hereunder, may be assigned by either Party hereto without the prior written consent of the other Party, which consent shall not be unreasonably withheld; provided, however, that either Party may, without such consent, but with notice to the other Party, assign this Agreement, in whole or in part: (a) in connection with the transfer or sale of all or substantially all of the assets of such Party or the line of business or Product to which this Agreement relates; (b) to the successor entity or acquirer in the event of the merger, consolidation or change of control of a Party hereto; or (c) to any Affiliate of the assigning Party. Any subsequent assignee, purchaser, or transferee shall be bound by the terms of this Agreement.  
ARTICLE 16 - GOVERNING LAW  
 16.1.  
This Agreement and the rights and obligations of the Parties hereunder shall be governed by Delaware law and, to the extent the laws of the State of Delaware are preempted or otherwise made inapplicable by federal law, the laws of the United States of America. Each of the Parties irrevocably and unconditionally:  
 16.1.1.  
agrees that any suit, action or legal proceeding arising out of or relating to this Agreement shall be instituted in the United States District Court for Delaware, or if such court does not possess subject matter jurisdiction, of any type, or will not accept jurisdiction, in any court of general jurisdiction in Wilmington, Delaware;  
 16.1.2.  
consents and submits to the exclusive jurisdiction of such foregoing courts in any such suit, action or proceeding;  
 16.1.3.  
consents to personal jurisdiction in such courts;  
 16.1.4.  
waives any objection which it may have to laying of venue of any such suit, action or proceeding in said courts; and  
 16.1.5.  
waives any claim or defense of inconvenient forum.  
ARTICLE 17 - FORCE MAJEURE  
 17.1.  
No Party shall be liable for a failure or delay in performing any of its obligations under this Agreement if, and only to the extent that, such failure or delay (directly or indirectly) is due to causes beyond the reasonable control of the affected  
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 Party, including: (i) acts of God; (ii) fire, explosion, or unusually severe weather; (iii) war, whether declared or undeclared, invasion, riot or other material civil unrest; (iv) enactment or change of laws and regulations by any Agency or Government, conflict of laws or regulations by any Agency or government, orders, restrictions, actions, embargoes or blockages; (v) national or regional emergency; (vi) injunctions, strikes, lockouts, labor trouble or other industrial disturbances (regardless of the reasonableness of the demands of labor); and (vii) acts of terrorism (“Force Majeure”).  
 17.2.  
The Party whose performance of this Agreement is affected or potentially affected by an event of Force Majeure shall promptly notify the other Party of the Force Majeure condition, explaining the nature, details and expected duration thereof, and shall exert reasonable efforts to eliminate, cure or overcome any such condition and to resume performance of its obligations under this Agreement as soon as possible. Upon termination of the event of Force Majeure, the performance of any suspended obligation or duty shall promptly recommence.  
ARTICLE 18 - TITLE OF GOODS  
 18.1.  
Title to API and Customer-supplied Composition shall remain with Customer at all stages of the Manufacturing Process. BVL shall provide within the Facility an area or areas where the API, Customer-supplied Composition, Product, any intermediates (and components thereof), and any work in process are segregated and stored in accordance with the Specification and cGMP, and in such a way as to be able at all times to clearly distinguish the same from products and materials belonging to BVL, or held by it for a Third Party’s account.  
 18.2.  
BVL shall at all times take such measures as are required to protect the API, Customer-supplied Composition, Product, and any work in process from risk of loss or damage at all stages of the Manufacturing Process. BVL shall ensure that the API, Customer-supplied Composition, Product, and any work in process are free and clear of any liens or encumbrances resulting from any act or omission of BVL. BVL shall Immediately notify Customer if at any time it believes any API, Customer-supplied Composition or Product have been damaged, lost or stolen.  
ARTICLE 19 - ENTIRE AGREEMENT  
 19.1.  
This Agreement, together with the Attachments identified herein that shall form part of this Agreement, constitutes the entire understanding between the Parties and is intended as a final expression of their agreement and as a complete statement of terms and conditions thereof, and shall not be amended except in writing signed by an authorized representative of each Party and specifically referring to this Agreement. If there is any inconsistency between this Agreement and any other writings, which are referred to or are incorporated herein, or any Purchase Orders, invoices, or other documents relating to Product, the terms and conditions of this Agreement shall take precedence in any contract construction. This Agreement supersedes any previous agreements or arrangements between the Parties and any customary practice of the Parties at variance with the terms hereof. Neither Party may rely upon oral representations that are inconsistent with the terms of this Agreement.  
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 ARTICLE 20 - SEVERABILITY  
 20.1.  
In the event any provision of this Agreement is held to be invalid or unenforceable, the valid or enforceable portion thereof and the remaining provisions of this Agreement will remain in full force and effect.  
ARTICLE 21 - INDEPENDENT CONTRACTORS  
 21.1.  
Neither Party shall have the right to control the activities of the other in the performance of this Agreement and each shall perform as an independent contractor, and nothing herein shall be construed to be inconsistent with that relationship or status. Under no circumstances shall the employees or agents of one Party be considered employees or agents of the other. This Agreement shall not constitute, create, or in any way be interpreted as a joint venture, partnership, or formal business organization of any kind.  
ARTICLE 22 - AMENDMENTS  
 22.1.  
No provision of this Agreement or the Attachments attached hereto may be modified or supplemented, except by an instrument in writing signed by both BVL and Customer.  
ARTICLE 23 - HEADINGS  
 23.1.  
The Article headings appearing herein are included only for the convenience of reference and are not intended to affect the interpretation of any provision of this Agreement.  
ARTICLE 24 - REVIEW BY LEGAL COUNSEL  
 24.1.  
Each Party has carefully reviewed this Agreement, and understands its terms. Each Party has been given sufficient opportunity to seek legal advice prior to signing this Agreement, and has either sought legal advice with counsel experienced in issues of confidentiality in regards to this Agreement, or has relied wholly upon that Party’s own judgment and knowledge in executing this Agreement. Each Party fully understands and voluntarily accepts each and every provision contained in this Agreement. Failure to seek legal advice prior to signing this Agreement does not excuse either Party from failure to understand the terms and conditions set forth in this Agreement. This Agreement has been prepared on the basis of the mutual understanding of the Parties and in the event of an ambiguity, such ambiguity shall not be strictly construed against either Party as a drafter of this Agreement.  
ARTICLE 25 - RECALL  
 25.1.  
In the event: (a) any Agency or governmental authority issues a request, directive, or order that Product be recalled; or (b) a court of competent jurisdiction orders such a recall; or (c) the Parties reasonably determine after consultation with each other that Product should be recalled, the Parties shall take all appropriate corrective action. Customer shall also retain the right to conduct a Product recall for any safety reasons Customer deems significant. In the event  
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 that Product is recalled or that Customer is required to disseminate information regarding Product covered by this Agreement, Customer shall so notify BVL and, not later than may be required to permit Customer to meet such obligations, BVL shall provide Customer with such assistance in connection with such recall as may reasonably be requested by Customer. BVL will only be financially responsible for the costs of any recall for which its negligence or willful misconduct is solely responsible for such recall, subject to the limitations defined in Section 8.5.  
ARTICLE 26 - ENGLISH LANGUAGE  
 26.1.  
This Agreement, all schedules, attachments, and exhibits hereto, and all reports, documents and notices required hereunder, referred to herein or requested by the Parties, in connection with this Agreement shall be written in the English language. Except as otherwise required by Applicable Law, the binding version of all of the foregoing shall be the English version.  
ARTICLE 27 - EXPORT PROVISION  
 27.1.  
Customer agrees and understands that the information and any materials provided by BVL under this Agreement are subject to United States laws and regulations, which may restrict exports, re-exports or other transfers to other countries and Parties. Customer agrees that no materials or information provided to it under this Agreement will be exported re-exported, transferred or disclosed contrary to the applicable laws and regulations of the United States, or to any country, entity or other Party which is ineligible to receive such items under U.S. laws and regulations, including the regulations of the U.S. Department of Commerce and the U.S. Department of Treasury.  
ARTICLE 28 - ACKNOWLEDGEMENT OF COMPETITION FOR COMPETITIVE PRODUCTS OR SERVICES  
 28.1.  
Each Party understands and acknowledges that the other Party individually or in collaboration with others may now or hereafter develop or market products which compete with its own products or services. Subject to the confidentiality obligations set forth in Article 9, nothing in this Agreement shall impair the right of either Party to develop, make, use, procure, or market other products or services now or in the future which may be competitive to those products or services offered by the other Party to this Agreement, including without limitation the Products or services Manufactured pursuant to this Agreement. Neither Party is under a duty to disclose any planning or other information relating to competition with the other’s products or services.  
ARTICLE 29 - EXECUTION  
IN WITNESS WHEREOF, the Parties hereto have executed this Agreement by their duly authorized representatives as of the dates set forth below:  
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 FOR: BEN VENUE LABORATORIES, INC.:  
Signature:\_\_\_\_[\*]\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_12/7/2006\_\_\_\_\_\_\_\_\_\_  
[\*]  
Vice President, Contract Manufacturing Services  
 For:  
Vion Pharmaceuticals, Inc.  
 Signature:\_/s/ /Xxxxxx X. Xxxxxxx\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_12/1/2006\_\_\_\_\_\_\_\_\_\_  
 Xxxxxx X. Xxxxxxx, President & CFO  
 \_\_\_\_\_\_\_\_\_\_\_\_\_\_  
[\*] Confidential Treatment Requested  
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 Attachment “A1”  
Product Supplements  
A1.1(b) PRODUCT IDENTIFICATION  
As per proposal sent to Customer by BVL dated December 5, 2006. Quotation Number: 101180 and 101361.  
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 Attachment “A1”  
Product Supplements  
A1.2(b) PRODUCT TESTING SPECIFICATION  
As per proposal sent to Customer by BVL dated December 5, 2006. Quotation Number: 101180 and 101361.  
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 Attachment “A1”  
Product Supplements  
A1.3(b) MATERIALS SUPPLIED BY CUSTOMER AND BVL  
As per proposal sent to Customer by BVL dated December 5, 2006. Quotation Number: 101180 and 101361.  
\* Customer shall provide updates to the prices of Customer-supplied composition prices whenever Customer orders and/or purchases Customer-supplied composition. BVL shall have the right, upon demand, to audit any documentation (without limitation, including purchase orders, invoices, manifests, payments, etc.) to substantiate Customer’s price claims.  
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 Attachment “A1”  
Product Supplements  
A1.4.1 FORECASTS  
Five-Year Forecast – to be submitted by Customer to BVL on an annual basis by [\*] each year. BVL will supply Customer with an electronic copy of the Five-Year Forecast form. Subject to the terms of the Agreement, the following represents the understanding of the Parties with respect to the volumes to be associated with this Agreement for the five (5) Contract Years of this Agreement.  
NOTE: PURSUANT TO SECTION 5.1.1 – 5.1.2, UPDATES OF THE FIVE-YEAR FORECAST [\*]  
CUSTOMER MAY ENTER A “ZERO” FIGURE FOR ANY YEAR IN WHICH IT DOES NOT WISH TO HAVE BVL ALLOCATE CAPACITY; HOWEVER, IN THE ABSENCE OF A WRITTEN CONFIRMATION ACCEPTING CUSTOMER’S OFFER TO AMEND THE FIVE-YEAR FORECAST, BVL MAKES NO REPRESENTATION THAT IT WILL HAVE CAPACITY AND/OR MANUFACTURE CUSTOMER’S PRODUCT FOR SUCH PERIODS, WHICH SHALL REMAIN EXCLUSIVELY IN BVL’S DISCRETION.  
PURSUANT TO SECTION 5.1, NOTWITHSTANDING THE FOREGOING, ADDITIONAL VOLUMES OF PRODUCT MAY BE REQUESTED FROM TIME TO TIME BY THE CUSTOMER AND SUCH ADDITIONAL VOLUME MAY BE MUTUALLY AGREED TO IN WRITING AT THE DISCRETION OF THE PARTIES.  
 Contract Year 1  
Initial (Partial)  
Year in which  
the Agreement  
is Executed  
2007  
 Contract  
Year 2  
2008  
 Contract  
Year 3  
2009  
 Contract  
Year 4  
2010  
 Contract  
Year 5  
2011  
 Product Description  
 BVL End Item Number  
 Batch Size/Order Quantity  
 Batches  
 Batches  
 Batches  
 Batches  
 Batches  
 [\*] 10mg/ml liquid, 10ml in a 10ml vial labeled vials bulk packaged  
 TBD  
 [\*]  
 [\*]  
 [\*]  
 [\*]  
 [\*]  
 [\*]  
 [\*] 10mg/ml liquid, 10ml in a 10ml vial labeled vials bulk packaged  
 TBD  
 [\*]  
 [\*]  
 [\*]  
 [\*]  
 [\*]  
 [\*]  
 \_\_\_\_\_\_\_\_\_\_\_\_\_\_  
[\*] Confidential Treatment Requested  
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 Attachment “A1”  
Product Supplements  
A1.4.2 ROLLING 12 MONTH FORECAST  
Pursuant to Section 5.3, Customer shall provide a Rolling Forecast quarterly to BVL. BVL will provide Customer with an electronic copy utilizing Microsoft Word of the following form for submission, which will include twelve (12) monthly periods for forecasting. Customer shall provide the Rolling Forecast one hundred twenty (120) days in advance of the first day of each Contract Quarter.  
(The format is for representation only, do not enter information below)  
 Product Description  
 BVL End Item Number  
 Batch Size/Order Quantity  
 Month 1  
 Month 2  
 Month 3  
 . . .  
 Month 12  
 Enter Product Description including packaging for each end item  
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 Attachment “A1”  
Product Supplements  
A1.5(b) PRICING  
As per proposal sent to Customer by BVL dated October 12, 2006. Quotation Number: 101180 and 101361.  
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Attachment “A1”  
Territory  
A1.6 TERRITORY  
As used herein, “Territory” shall have the following meaning for the Product identified in this Attachment “A1.1”:  
 Country  
 Filing Type  
 Date Filed or  
Approximate Date of  
Planned Filing  
 Registration  
Number if Filed  
[\*]  
 [\*]  
 [\*]  
 [\*]  
[\*]  
 [\*]  
 [\*]  
 \_\_\_\_\_\_\_\_\_\_\_\_\_\_  
[\*] Confidential Treatment Requested  
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Attachment “B”  
Purchase Order Requirements  
The following Information shall be provided on each Purchase Order:  
1.  
BVL end item number  
2.  
BVL Product description  
3.  
Batch Size in vials from Quotation or as described in Attachment “A”  
4.  
Number of Batches  
5.  
Delivery Date (Date for BVL to release the lot and deliver product & Batch Records)  
6.  
BVL Quotation Number if Product/Service not included in Attachment “A”, or Reference this Agreement Date  
7.  
Delivery Address  
8.  
Shipping requirements & Instructions (temperature, dedicated trucks, preferred carrier, overnight etc.) Contact name for Preferred Carrier, Temperature Monitors, Ship on BVL Release or Hold for Customer Authorization to Ship.  
9.  
Billing Address  
10.  
Special Instructions for Specific Batch  
(Examples)  
“Annual Stability Batch”  
“Process Validation Batch”  
“Special Sampling Instructions mutually agreed to and included in Batch Record”  
11.  
Customer Lot# and Expiration Date if Applicable  
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Attachment “C”  
MONTHLY STORAGE FEES  
Effective through December 31, 2007  
BVL has limited storage capacity. Therefore, Customers are expected to have Product shipped to them no later than thirty (30) days after BVL Quality Operations has released their Product and has shipped the documents identified Attachment D to Customer. Should unforeseen events lead to a request by a Customer for storage beyond this thirty (30) day grace period, the Customer must request such storage by BVL in writing at least fifteen (15) days before the initial thirty (30) day grace period has expired. The request will be granted only if BVL has sufficient storage capacity to accommodate the request. Then, the following terms will apply.  
Monthly storage fees are assessed on a per lot basis, and begin to accrue thirty (30) days following the BVL release date of the Batch by BVL’s Quality Operations Dept. BVL will request that a separate Purchase Order be issued for the storage charges. These charges listed below will be reviewed and updated annually.  
Monthly Storage Charge - per square foot per month  
 Room Temperature Storage  
 [\*]  
Refrigerated Storage  
 [\*]  
Freezer Storage  
 [\*]  
Minimum Storage Charge - per lot per month  
 Room Temperature Storage  
 [\*]  
Refrigerated Storage  
 [\*]  
Freezer Storage  
 [\*]  
\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
[\*] Confidential Treatment Requested  
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Attachment “D”  
Documents to be supplied by BVL to Customer as part of Batch release  
1.)  
BVL Certificate of Analysis  
2.)  
BVL Certificate of Compliance  
3.)  
Copies of the executed Batch Record  
4.)  
Raw Material Certificates of Analysis generated by BVL used in the lot (Part of Batch Record)  
5.)  
Reports documenting deviations and Investigations (Part of Batch Record)  
6.)  
Out Of Specification Results and Investigations (Part of Batch Record)  
7.)  
Testing Documentation (Part of Batch Record)  
NOTE: Raw analytical data, Environmental data (Airborne particulates, Pressure differential between Manufacturing rooms and the other data BVL is monitoring) is not copied or otherwise provided to a Customer except that these data can be inspected as part of scheduled or for cause audits by the Customer.  
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Attachment “E”  
Quality Agreement  
This Quality Agreement (“Quality Agreement”) is a required and integral part of the Manufacturing and Service Contract (“Agreement”) with an Effective Date of November 28, 2006 to which it is attached and integrated. This Quality Agreement defines the roles and responsibilities for BVL quality operations when providing services for Customer and further defines how BVL and Customer will interact with each other.  
E.1 Purpose and Term of the Quality Agreement  
Capitalized terms used in this Quality Agreement and not otherwise defined shall have the meanings ascribed thereto in the Agreement unless otherwise specified. This Quality Agreement outlines the responsibilities of Customer and BVL with respect to the quality assurance and cGMP compliance of the Product and is the Quality Agreement referenced in the Agreement. In the event of any conflict between the terms of this Quality Agreement and the Agreement, the terms of the Agreement will control.  
A matrix of responsibilities included at the end of this document delineates the primary responsible Party for the various aspects of this Quality Agreement.  
This Quality Agreement commences with the Effective Date of the Agreement and remains in effect through the term of that Agreement. In the event that the Agreement is terminated for any reason provided for therein, the Quality Agreement will terminate on the later of: (i) the expiration date of the last Batch of Product produced by BVL for commercial distribution; (ii) completion of any ongoing stability studies; or (iii) two years of the termination of the Agreement.  
All changes in this Quality Agreement must be documented in writing as an Addendum to the original Quality Agreement and reviewed and approved in writing by representatives from Customer and BVL.  
This Quality Agreement is between Customer and BVL.  
E.1.1 Customer Quality Representatives:  
 Name:  
 Xxxxx Xxxxxx  
Title:  
 Director, Quality Assurance & Regulatory Affairs  
Company:  
 Vion Pharmaceuticals, Inc.  
Street Address:  
 0 Xxxxxxx Xxxx  
City, State Zip:  
 New Haven, CT 06511  
Phone:  
 000-000-0000  
Fax:  
 000-000-0000  
E-mail:  
 xxxxxxx@xxxxxxxxx.xxx  
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This Quality Agreement has been reviewed and approved by:  
FOR CUSTOMER:  
SIGNATURE:\_\_/s/ /Xxxxx Xxxxxx\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
 DATE:\_\_12/1/2006\_\_\_\_  
E.1.2 BVL Quality Representatives:  
 Name:  
 [\*]  
Title:  
 [\*]  
Company:  
 Ben Venue Laboratories, Inc.  
Street Address:  
 000 Xxxxxxxxxx Xxxx  
City, State Zip:  
 Bedford, OH 00000-0000  
Phone:  
 [\*]  
Fax:  
 [\*]  
E-mail:  
 [\*]  
FOR BVL:  
 SIGNATURE:\_\_\_\_\_\_\_\_\_\_[\*]\_\_\_\_\_\_\_\_\_\_\_\_\_  
DATE: 12/11/2006   
E.1.3 BVL Business Representative:  
 Name:  
 [\*]  
Title:  
 [\*]  
Company:  
 Ben Venue Laboratories, Inc.  
Street Address:  
 000 Xxxxxxxxxx Xxxx  
City, State Zip:  
 Bedford, OH 00000-0000  
Phone:  
 [\*]  
Fax:  
 [\*]  
\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
[\*] Confidential Treatment Requested  
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 E-mail:  
 [\*]  
FOR BVL:  
 SIGNATURE:\_\_\_\_\_\_\_\_\_\_[\*]\_\_\_\_\_\_\_\_\_\_\_\_\_  
DATE:\_12/7/2006\_\_\_\_\_\_\_\_\_\_\_  
 E.1.4  
On-Call Customer Representative:  
In addition to the foregoing contact information, Customer will provide the name and phone numbers of a contact person(s) who may be called at any hour during the times when BVL is Manufacturing the Product, as follows:  
 Name:  
 Xxxxx Xxxxxx  
Title:  
 Director, Quality Assurance & Regulatory Affairs  
Company:  
 Vion Pharmaceuticals, Inc.  
Street Address:  
 0 Xxxxxxx Xxxx  
City, State Zip:  
 New Haven, CT 06511  
Phone:  
 000-000-0000 / cell 000-000-0000  
Fax:  
 000-000-0000  
E-mail:  
 xxxxxxx@xxxxxxxxx.xxx  
E.2 Quality Responsibilities  
The activities for and associated with the manufacturing of the Product must meet the current cGMPs as set forth in the “Code of Federal Regulations of the U.S. Food and Drug Administration”, 21 CFR Parts 210 & 211, as well as “The Rules Governing Medicinal Products in the European Community”, volume IV, “Guide to good manufacturing practice for medicinal products”, as well as the requirements of any applicable national guidelines to which the Product has been registered. In the event of a conflict in cGMPs, the U.S. Code of Federal Regulations shall apply.  
BVL is responsible for review and approval of all manufacturing, testing, and support documentation executed in the Production of each Batch of the Product as included or referenced in the Master Batch Record and for providing formal release to Customer. Customer is responsible for further release of each Batch of the Product for commercial and any other use.  
Any dispute between Customer and BVL with regard to acceptance of the Product shall be subject to the procedures as set out in the Agreement between Customer and BVL. Customer’s disposition will be independent of BVL’s review and release.  
\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
[\*] Confidential Treatment Requested  
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BVL is responsible for maintaining training records for all personnel that perform cGMP functions relating to the Customer operations performed at the site, including personnel in QA/QC, manufacturing, etc.  
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 E.3  
Regulatory Compliance and Product Licensure  
 E.3.1  
Customer is the owner of the Product and is responsible for product licensure, annual reports, and any other regulatory filings that are required for the marketing of Product, and is responsible to ensure that all of such filings with regulatory authorities are consistent with the Specification and the Master Production Record. This includes the supplement of product registration to update commitments, methods, records, or specifications based upon regulatory requirements defined in 21 CFR Part 314.  
 E.3.2  
In the event that the Territory as defined herein includes the European Union or any member states thereof, then in addition to all other responsibilities, Customer shall also:  
 E.3.2.1  
certify in writing to BVL that it has properly appointed one or more Qualified Person(s) in compliance with EU Directives, standards and rules, including without limitation, Article 49 of Directive 2001/82/EC, with respect to the Product(s) subject to this Agreement; and further that Customer’s Qualified Person(s) shall fully comply with all EU standards, directives and rules, including without limitation, as set forth in Article 51 of 2001/83/EC, in a form substantially similar to that set forth as Attachment “G”;  
 E.3.2.2  
as appropriate, cause its Qualified Person to certify that the Facility supplying the API complies with EU GMP in a form substantially similar to that set forth as Attachment “H”;  
 E.3.2.3  
cause its Qualified Person to certify the GMP status of the manufacturing and supply of an Active Pharmaceutical Ingredient in a form substantially similar to that set forth as Attachment “I”; and  
 E.3.2.4  
for each batch of Product Manufactured by BVL, as appropriate, provide a Certificate of Analysis in a form substantially similar to that set forth as Attachment “J.”  
E.4  
Change Control  
BVL will utilize a documented system of procedures for the control of changes to raw materials, packaging materials, utilities, facilities, equipment, manufacturing methods, and Product specifications and requirements, sampling, test methods, and release requirements. BVL will be responsible for contacting Customer to discuss changes which impact the Manufacturing license for any Territory. Product-specific changes will not be made without mutual approval. Customer will be responsible for applying for any necessary variation to the Manufacturing license(s) to allow production of the Product(s).  
 E.4.1  
Master Production Records  
Master Production Records (MPRs) are documents that specify or reference the manufacturing instructions, related bills of material, in process testing, and production specifications used in the production process. These documents are developed and approved by BVL and Customer. Customer’s approval of the initial MPR must be received at least eight (8) weeks prior to the start of manufacture. Subsequent revisions  
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 and edits to the MPR shall be submitted at least eight (8) weeks and approved at least two (2) weeks prior to manufacture.  
 E.4.2  
Specification  
Specification initiation or revision that affects the scientific or technical content requires approval in writing by BVL and Customer before proposed changes are implemented. This applies to manufacturing, testing, storage, and labeling of the Product, as well as any changes to the specifications for raw materials and Product. Editorial or format changes to applicable specifications not affecting the scientific/technical content or intent of the specification will not require approval by Customer. Those documents requiring Customer approval are as follows:  
Product Specification to include Analytical Methods  
Master Production Records to include In Process Limits and Manufacturing Site Changes  
Raw Material Specifications  
When Customer initiates a change request on all applicable specifications, the appropriate BVL department shall be provided the proposed specification and appropriate documentation that summarizes and justifies each change.  
 E.4.3  
Packaging and Labeling Specifications  
The packaging and labeling specifications are documents that describe the labeling artwork, container/closure, Product packaging for shipment, shipper specifications and drawings used in the packaging of the Product. These packaging and labeling specifications are Developed and approved by BVL and Customer. This information will be incorporated into the MPR, associated Product Specific SOPs, and raw material specifications, as appropriate.  
 E.4.4  
Product Changeover  
BVL will follow its validated cleaning protocols based on product classifications per BVL SOP’s.  
 E.4.5  
Changes to the Plant  
BVL will notify Customer in advance of any changes of utilities, in the layout or structure of the equipment or in the operation and structure of the plant, which could have an adverse impact on the manufacturing of the Product or the quality of the Product. BVL shall not be obligated to obtain prior approval for changes required as a result of an Agency’s order, provided BVL promptly notifies Customer of any such proposed change and consults with Customer before implementation of such changes and its potential impact on Customer Product.  
E.5  
Documentation Retention  
Batch specific documentation (e.g., executed batch records, investigation reports, Certificates of Analysis) will be retained by BVL for one (1) year beyond the expiration date of the Agreement, or in the event the Agreement is ongoing, then for not more than seven (7) years from the Manufacturing date BVL will notify Customer prior to destruction of the records and customer  
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 must provide a response to BVL as to the disposition of the documents within thirty (30) calendar days or the record will be destroyed. Customer may request that such records be transferred to Customer at Customer’s expense.  
For the basic product specific documentation (e.g., master production records, SOPs, validation documentation) the retention should be for the life of the product, i.e., until the registration for the product has been withdrawn and the responsibility of Customer with support from BVL. Such documents will be returned to the Customer in the event of termination of the Agreement, withdrawal of all registrations for the Product, or upon cessation of the business relationship between Customer and BVL and completion of BVL’s compliance with Applicable Laws.  
E.6  
Materials  
E.6.1 BVL is responsible for performing raw material and supplies procurement, QC testing, and material handling and submission of samples to outside testing laboratories (as applicable). BVL will obtain approval from Customer if BVL needs to subcontract the analytical release testing of raw materials provided by Customer.  
E.6.2 BVL shall maintain an approved suppliers list in accordance with BVL’s procedures. BVL will provide the material name and supplier name upon request. Changes to non-compendial raw materials, such as a new supplier or process changes, shall be approved by Customer. Copies of vendor audit reports will be available for review during annual audits to confirm approval status of the vendors. BVL has the right to redact such audit reports.  
E.6.3 All materials purchased for use in the manufacture, storage and shipping of product will be purchased, received, inspected as appropriate, sampled (see E6.1) tested as appropriate, stored, and handled in accordance with BVL’s SOP’s. BVL agrees to sample and retain sufficient amounts of all raw materials, except water, compressed gases and any highly volatile compounds. The amount of retained samples is specified in BVL’s raw material specifications. All materials shall be in accordance with the approved specifications.  
E.6.4 BVL will qualify primary vendors of all raw materials and components. Vendor qualification will be in accordance with BVL SOP’s.  
E.6.5 BVL will provide, at Customer’s request, a copy of the BVL Drug Master File (DMF) and authorization for FDA to access the DMF. This may be used by the Customer to prepare a regulatory filing. BVL shall, upon Customer’s request, assist Customer with all other applicable filings for the non-US market in accordance with proposals submitted to Customer and confirmed by Purchase Order.  
E.7  
Product Specification  
The Product must be manufactured, packaged, labeled, and handled according to the Specifications and procedures mutually agreed to in writing between Customer and BVL. Customer and BVL shall develop all in-process and Product release specifications, including acceptance limits for each required test. Establishment of appropriate test methods and supporting test method validation will be performed by BVL and approved by Customer. Each lot of Product manufactured by BVL for Customer will be sampled and tested in accordance with the Specification.  
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 E.8  
Manufacturing and Packaging of the Product  
E.8.1 The manufacturing of the Product will be done under cGMP and in accordance with specific procedures and instructions mutually agreed upon between Customer and BVL, and documented in the MPR. The Date of Manufacture will be as specified in the Product Specification.  
E.8.2 Any regulations regarding storage of different types of products shall be adhered to.  
E.8.3 The manufacturing of Customer’s Product by BVL must be in adherence to the Specification as mutually agreed upon, and in compliance with all cGMPs and any other applicable regulatory requirements. BVL will provide documentation for each Batch as agreed upon between Customer and BVL and specified in Attachment “D.”  
E.9  
Testing of the Product  
E.9.1 The testing of the Product is carried out by BVL according to the Specification. For those procedures which appear in the current USP/NF or other recognized standard references, qualification of the method for the Product and a statement indicating the reference shall suffice. For all Product-specific test methods utilized by BVL, documentation supporting the validation of the test method shall be available for review during annual audits by Customer.  
E.9.2 If any Third Party is utilized to perform testing of raw materials or release/stability testing the vendor(s) must be qualified by BVL as required by BVL SOPs and approved for use by Customer. The Third Party vendor must utilize validated or qualified test methods and provide complete documentation and copies of associated raw data upon request.  
E.9.3 Customer will provide BVL a reference standard in accordance with BVL procedures for use in Product testing, as needed, and BVL will maintain the reference standard under appropriate storage conditions with appropriate controls. Customer is responsible for performing qualification of the reference standard in accordance with approved validated protocols.  
E.9.4 BVL will provide to Customer a Certificate of Analysis and any other associated testing documentation for each Batch of Product manufactured as specified in Attachment “D.” Customer reserves the right to inspect and/or test all Batches of the Product produced by BVL prior to Customer’s acceptance and distribution.  
E.10  
Notification and Approval of Deviations  
BVL must notify Customer within three (3) business days from the initiation of the investigation, whenever there is a significant deviation from stated procedures or specifications. A significant deviation is defined as any Out Of Specification (OOS) result and/or any manufacturing, packaging, labeling, or testing deviation that may affect the quality, safety or efficacy of the Product. BVL will only release/reject a Product Batch as an outcome of a BVL and Customer approved investigation report. In the event of conflict, BVL may release or reject any Product Batch at its sole discretion. Customer is responsible for the final product disposition of a product released by BVL.  
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 All deviations will be investigated and fully documented by BVL in accordance to BVL procedures. This documentation will be retained as part of the batch documentation for the Batch affected. When deemed necessary, Customer reserves the right to request the need for a more in-depth investigation of the deviation by BVL. BVL and Customer will work together in determining the need for additional investigational work. Customer approval shall be obtained in writing (fax or PDF electronic document confirmation is acceptable) for any significant deviation. The approval must be received within three (3) business days of the completion of the investigation. Customer and BVL will jointly provide the documented product impact assessment for all deviations that impact the Product. The documented assessment must be received within 5 (five) business days of the completion of the investigation. In cases where Customer requests a deviation, the request must be submitted in writing. Customer is responsible for notifying the FDA regarding any required Field Alert Report according to 21 CFR 314.81. BVL shall be notified by the Customer of any Field Alerts filed for Product.  
The Investigation Report for significant deviations will be approved by both BVL and Customer as stated below. The approved document will become part of the batch record of that specific lot of material. Any resulting corrective and preventative actions shall be followed through timely closure in accordance to BVL procedure. Approval by the appropriate Quality Assurance functions is solicited and may be obtained via fax or electronic copy.  
 Failure  
 Approval Requirements  
Product  
 Customer and BVL  
Raw Materials sourced and used by BVL  
 BVL  
In the event of a dispute regarding the failure of Product, an independent, mutually acceptable qualified Third Party may be engaged to determine failure. The Third Party’s decision will determine acceptance of the Product and shall be subject to the procedures as set out in the Agreement.  
Reprocessing would always be considered a significant deviation, and would only be performed if validated by BVL and approved by BVL and Customer.  
E.11  
Release and Shipment of the Product  
E.11.1 A Certificate of Compliance (COC), a Certificate of Analysis (COA), copies of executed batch records, deviations and investigation reports, and any applicable documentation shall be provided to Customer by BVL within one (1) week after the Batch is released by BVL QA as specified in Attachment D.  
E.11.2 Customer is responsible for acceptance and disposition of the Product after review of BVL’s documents to be supplied by BVL to Customer as part of Batch release as specified in Attachment D. Customer shall reserve the right to revoke any acceptance of a Product if a latent defect is discovered and: (i) such defect is solely attributable to BVL; and (ii) Customer notifies BVL of a latent defect within five (5) days of discovery of such latent defect; in which case Customer shall have thirty (30) days from such notice to investigate such defect and reject the Product.  
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 E.11.3 The disposition of the Product, which is defined as the release for clinical or commercial distribution, is the responsibility of Customer. BVL has the responsibility to release the Product to Customer. BVL will not ship any of Customer’s Product to any destination until the final disposition by Customer, unless prior approval has been received in writing from Customer to perform such shipments. Such receipt of written shipping approval will not exceed thirty (30) days beyond BVL’s release to Customer unless Customer provides written notice disputing the release of the Batch.  
E.11.4 BVL will control and coordinate all shipping activity unless specified by Customer. Shipping instructions will be provided in the associated Batch Purchase Order (PO). Shipping validation will be Customer’s responsibility, but will be performed in collaboration with BVL and appropriate qualified contractors.  
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 E.12  
Retained Samples of the Product  
BVL agrees to store retained samples for all BVL composition used in the Product(s) in accordance with BVL SOP’s.  
Final Product retains shall be the responsibility of Customer.  
E.13  
Storage of Product  
BVL will store Product prior to final Customer disposition and shipment in accordance with the Specification and BVL SOPs.  
E.14  
Stability Activities  
The responsibility for stability testing and reporting shall belong to BVL so long as Customer contracts such activities with BVL. Stability protocols will be prepared by BVL and jointly reviewed and approved by BVL and Customer. BVL will provide stability reports to Customer in accordance with specifications contained in stability proposals. Data interpretation and the updating of stability information to regulatory documents for the Product is the responsibility of Customer. All stability related activities under the responsibility of BVL shall be completed in accordance with BVL SOPs.  
E.15  
Process Validation  
E.15.1 The Manufacturing Process and control procedures (including, but not limited to cleaning procedures; aseptic procedures, process hold times, in-process stability, and development and justification of all processing parameters) shall be validated and qualified by BVL according to the Manufacturing Process Validation (MPV) plan for Product in the facility and using the equipment BVL intends to employ to make Customer’s Product, as further defined in Section 15.2.  
E.15.2 The MPV will be created with input from both BVL and Customer for Customer’s process. The MPV will be jointly generated and approved by BVL and Customer. The MPV will contain all of the required activities and the acceptance criteria and is approved and documented. The MPV is executed on at least three (3) consecutive Batches of Product produced by BVL for Customer as mutually agreed to between Customer and BVL. If there are any problems during the execution of the MPV, then, upon discovery shall be communicated to Customer. If the problems cannot be resolved, the MPV must be repeated on additional Batches until at least three (3) consecutive Batches of Customer’s Product meet all specification requirements. Any problems encountered during the execution of the MPV must be documented by BVL.  
E.15.3 All related validation/qualification documents will be assembled in a process validation summary report and reviewed and approved by BVL and Customer. Customer will retain copies of the approved protocols and final reports.  
E.16  
Product Complaints  
E.16.1 Customer, or their agent, will receive complaints and communicate with their Customers and close all complaints related to the Product. Customer will inform BVL within 5 business days of registration of a complaint, or sooner as required, of complaints involving potential Product issues that may be related to Manufacturing. Upon written request by Xxxxxxxx, BVL will investigate the complaints as required and  
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 provide a written report on the results of the investigation to Customer in no more than thirty (30) working days, or sooner if agreed to by the Parties. Customer will communicate with the Customers and/or regulatory authorities the results of the complaint investigation, if necessary.  
E.16.2 In the event of a notification by Customer to BVL of a serious adverse event (SAE) potentially related to Manufacturing of the Product, BVL will provide all necessary support and assistance in the relevant phase of the investigation and provide a written response within an agreed upon time frame that allows Customer to respond to the applicable regulatory agency within 15 days of their notification.  
E.16.3 Customer shall provide complaint files to BVL onsite, or via fax or other electronic means, within one (1) business day if they are required during a FDA inspection.  
E.17  
Returned Goods  
Customer will be responsible for returned goods. The specific handling of returned goods will be specified and documented by Customer, as required. BVL will not have responsibility for returned goods unless if a latent defect is discovered and: (i) such defect is solely attributable to BVL; and (ii) Customer notifies BVL of a latent defect within five (5) days of discovery of such latent defect; in which case Customer shall have thirty (30) days from such notice to investigate such defect and reject the Product.  
E.18  
Recall of the Marketed Product  
In the event of recall, withdrawal, or field correction of Product, i.e., if the Product violates applicable laws, regulations, agreed upon specifications, or is deemed unacceptable for some other reason, whether or not such action is requested by any governmental agency, Customer shall immediately notify BVL Quality Assurance in writing. During a Product recall, withdrawal, or field correction, BVL shall fully cooperate with Customer in conducting the necessary investigational activities when appropriate.  
E.19  
Audits and Inspections of Facilities and Product  
E.19.1 Upon scheduling in advance, Customer shall have the right to [\*] annual audit [\*] per Contract Year and at such other times as mutually agreed upon by the Parties for cause to: (i) observe, inspect, and audit the manner in which BVL conducts Manufacture of Customer Product(s); (ii) inspect BVL’S Facilities and records relating to BVL’S quality and other controls related to its Manufacture of the Product(s); or (iii) observe and audit the books and records of BVL relating to the existence, safeguard, use and maintenance by BVL of the Customer Composition. Customer annual audits will be limited to [\*] auditors for 2 days. If resources are requested by the Customer to accommodate additional auditors or audit days outside the defined limit, then subject to the mutual agreement of the parties, BVL will provide Customer with a quotation of such services. BVL shall make such books and records available to Customer for review. Customer and any third-Party consultant appointed by Customer shall have reasonable access to observe and inspect BVL’S Facilities and SOPs with respect to the Product, including all analytical and Manufacturing documentation related to the Product upon reasonable prior notice to and scheduling in advance by BVL. Any such Customer appointed third-Party consultant must be pre-approved by BVL, although such approval shall not be  
\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
[\*] Confidential Treatment Requested  
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 unreasonably or untimely withheld. Information provided during audits will be limited to technical information related to the Manufacture of Product. No financial information is provided for auditing.  
E.19.2 Customer employees and Customer’s consultants who inspect BVL’S Facilities shall at all times comply with BVL’s rules, regulations and SOPs relating to their inspection, and Customer assumes responsibility for the presence and actions of its employees and consultants on BVL’s premises.  
E.19.3 BVL will notify Customer of any inspections or actions by regulatory agencies or other enforcement bodies which impact Product. BVL will provide Customer with the applicable or redacted written observations of all such Product Specific regulatory audits in no more than 5 business days. If the inspection is specific to Product, Customer will have up to 2 representatives on site during the inspection to address product specific questions, and these representatives will be permitted to participate in the inspection when required. Customer shall provide to BVL any requested documents if they are required for a regulatory inspection. Customer must notify BVL immediately of any activities or communications that may result in an inspection of BVL. BVL will respond to regulatory authority PAI observations within 15 days if possible and all other Product-specific inspection observations within 30 days or the time specified by that agency, which ever is less and will consult with Customer as appropriate.  
E.19.4 Customer reserves the right to be on-site at BVL during the manufacture of Product, and/or during the inspection of Product by any regulatory agencies. Customer shall provide at least one (1) week advance notice to be on site at BVL during manufacture.  
E.20  
Reprocessing  
Reprocessing can only be performed per written agreement between both BVL and Customer. Reprocessing directions must be established to define the process. If the Product is registered, reprocessing parameters must be validated, submitted, and approved prior to implementation and batch release. Reprocessing of material or product must be documented to state rationale and justification.  
E.21  
Annual Product Review (APR)  
Customer will be responsible for the Annual Product Review (APR).  
E.22  
Annual Quality Agreement Review  
Not less than once per Contract Year during the term of the Agreement, the Parties shall meet and confer in good faith to review the Quality Agreement and make such changes as may be mutually agreed upon in writing by the Parties.  
(Quality Matrix begins on following page)  
 Manufacturing and Service Agreement (BVL and Vion Pharmaceuticals, Inc.)  
Page 56  
 CONFIDENTIAL  
Quality Agreement Distribution of Responsibility Matrix:  
 Responsible Party  
Item  
 Activity  
 Customer  
 BVL  
1. Purpose and Term of the Quality Agreement  
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2. Quality Responsibility  
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3. Regulatory Compliance and Product Licensure  
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 4. Change Control  
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[\*] Confidential Treatment Requested  
 Manufacturing and Service Agreement (BVL and Vion Pharmaceuticals, Inc.)  
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 Responsible Party  
Item  
 Activity  
 Customer  
 BVL  
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4.1 Master Production Record  
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4.2 Specifications  
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4.3 Packaging and Labeling Specifications  
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4.4 Product Changeover  
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4.5 Changes to the Plant  
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5. Documentation  
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[\*] Confidential Treatment Requested  
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 6. Materials  
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 Manufacturing and Service Agreement (BVL and Vion Pharmaceuticals, Inc.)  
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Item  
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7. Product Specification  
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8. Manufacturing and Packaging of the Product  
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9. Testing of Product  
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10. Notification and Approval of Deviations  
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[\*] Confidential Treatment Requested  
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11. Release and Shipment of Product  
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[\*] Confidential Treatment Requested  
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Item  
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 12. Retained Samples of the Product  
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 13. Storage of Product  
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14. Stability Activities  
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 15. Process Validation  
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16. Product Complaints  
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[\*] Confidential Treatment Requested  
 Manufacturing and Service Agreement (BVL and Vion Pharmaceuticals, Inc.)  
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 17. Returned Goods  
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 18. Recall of Marketed Product  
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19. Audits and Inspections of Facilities and Product  
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[\*] Confidential Treatment Requested  
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 20. Reprocessing  
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21. Annual Product Review  
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 22. Certifications  
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[\*] Confidential Treatment Requested  
 Manufacturing and Service Agreement (BVL and Vion Pharmaceuticals, Inc.)  
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 Customer  
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[\*] Confidential Treatment Requested  
 Manufacturing and Service Agreement (BVL and Vion Pharmaceuticals, Inc.)  
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 Attachment “F”  
Customer Supplied Equipment  
[PAGE INTENTIONALLY LEFT BLANK]  
 Manufacturing and Service Agreement (BVL and Vion Pharmaceuticals, Inc.)  
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 Attachment “G”  
Representation regarding Customer’s Qualified Person  
CUSTOMER LETTERHEAD  
Customer Address  
BEN VENUE LABORATORIES, INC.  
ATTN: COMPLIANCE MANAGER  
A Boehringer Ingelheim Company  
000 Xxxxxxxxxx Xxxx  
Bedford, Ohio 44146  
Dear BVL COMPLIANCE MANAGER,  
Please take notice that Vion Pharmaceuticals, Inc., hereby certifies in writing to BVL that it has properly appointed one or more Qualified Person(s) in compliance with EU Directives, standards and rules, including without limitation, Article 49 of Directive 2001/82/EC, with respect to the Product(s) subject the agreement between Ben Venue Laboratories, Inc. and [Company]. Said Qualified Person shall fully comply with all EU standards, directives and rules, including without limitation, as set forth in Article 51 of 2001/83/EC, and shall be responsible for release of Product(s) into EU member states.  
 Sincerely,  
   
Name  
Title  
 Manufacturing and Service Agreement (BVL and Vion Pharmaceuticals, Inc.)  
Page 67  
 CONFIDENTIAL  
 Attachment “H”  
GMP Facility Compliance Certificate FOR API SUPPLIER  
 Manufacturing Facility:  
 NAME OF API SUPPLIER  
ADDRESS  
Phone:  
Fax:  
I INSERT NAME have reviewed the audit report for the above listed facility and I am satisfied that:  
 •  
The named site has an acceptable level of compliance with GMP.  
 •  
The auditors were adequately qualified to conduct such audits on an impartial basis.  
Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_  
Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Title: Qualified Person   
CUSTOMER NAME  
CUSTOMER ADDRESS  
CITY, STATE ZIP COUNTRY  
TELEPHONE  
FAX  
 THE CONTENTS OF THIS DOCUMENT ARE CONFIDENTIAL TO CUSTOMER  
 Manufacturing and Service Agreement (BVL and Vion Pharmaceuticals, Inc.)  
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 Attachment “I”  
Statement relating to GMP Status of the Manufacture & Supply of EACH BATCH OF API  
QUALIFIED PERSON’S STATEMENT CONCERNING THE GMP STATUS OF THE MANUFACTURE AND SUPPLY OF A SPECIFIC ACTIVE PHARMACEUTICAL INGREDIENT BATCH  
I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ being a Qualified Person Responsible for the certification of the manufacture of:  
[Name of pharmaceutical finished or intermediate products]  
Manufacturer’s Authorization No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ EEA member state: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Confirms the following:  
The Active Pharmaceutical Ingredient:  
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Grade (Insert manufacturer’s grade or identifying code): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Manufactured by the company: (company name)  
at the following site address: (company address)  
Supplied by: (Company acting as agent/vendor as applicable)  
At (address)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
has been assessed by me and that the stated products are certified as complying with the requirements of the European Union and are compliant with standards of GMP equivalent to those laid down in Directive 2003/94/EC and/or Directive 91/412/EEC and Annex 18 of the EU GMP Guide to Good Manufacturing Practice.  
 Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
QP CUSTOMER NAME  
QP CUSTOMER ADDRESS  
CITY, STATE ZIP COUNTRY  
TELEPHONE  
FAX  
 Manufacturing and Service Agreement (BVL and Vion Pharmaceuticals, Inc.)  
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 Attachment “J”  
Certificate of Analysis for use in the European Union Member States  
Ben Venue Laboratories, Inc.  
A Boehringer Ingelheim Company  
000 Xxxxxxxxxx Xxxx  
Bedford, Ohio 44146  
Phone: (000) 000-0000  
Fax: (000) 000-0000  
Site of Manufacture: Ben Venue Laboratories, Inc.  
 Certificate of Analysis  
 CUSTOMER NAME  
CUSTOMER ADDRESS  
CITY, STATE ZIP COUNTRY  
PHONE  
FAX  
 Certificate Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Delivery References:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Purchase References:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Order References:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Customer References:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Description of API:  
Regulatory Statements:  
This material has been manufactured, packed and tested in accordance with current GMP. The documentation for this batch has been reviewed and it is confirmed that this batch complies with GMP and licensed details.  
Batch Number:  
Date of manufacture:  
Expiry date:  
 Test Description  
Specification  
Result  
 Authorized Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
 THE CONTENTS OF THIS DOCUMENT ARE CONFIDENTIAL TO CUSTOMER  
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