EX-10.25 4 dex1025.htm MANUFACTURING & SERVICE CONTRACT  
Exhibit 10.25  
Manufacturing and Service Contract  
For Commercial and Developmental Products  
Targanta Therapeutics Corporation  
 [\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.  
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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 August 22, 2008 (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 Targanta Therapeutics Corporation, a corporation organized and existing under the laws of Delaware, with its principal place of business at 000 X. Xxxx Xxxxxx, Xxxxxxxxxxxx, 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 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 (as defined below) 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 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 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 those acts, 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, from time to time, for the sole purpose of Development and Manufacture of Product for Customer.  
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1.3. “Affiliate” shall mean: (a) any corporation or other 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 other 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). For purposes of this definition, the term “control” shall mean ownership, directly or indirectly, of fifty percent (50%) or more of the voting stock or voting equity interests of a corporation or other business entity.  
1.4. “Agency” and “Agencies” shall mean the regulatory entities for each respective country, states and/or territories in the Regulatory Territory, including, but not limited to, (a) in the United States, the FDA; in Canada and its Provinces, the Canadian Health Protection Branch; for any member state of the European Union, the European Medicines Agency (hereinafter the “EMEA”); and for 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 all or any part of the Regulatory Territory.  
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 and regulations (including without limitation, the Act and cGMP or its equivalent) for each country or territory within the Regulatory 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 Improvements” shall have the meaning set forth in Section 11.4.  
1.10. “BVL Indemnitees” shall have the meaning ascribed thereto in Section 8.1.  
1.11. “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 Confidential Information of Customer and is not a Customer Improvement or Customer Technology.  
1.12. “cGMP” shall mean (i) the Current Good Manufacturing Practices set forth in 21 C.F.R. 210 and 21 C.F.R. 211 and relevant regulations and FDA guidance documents; (ii) 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, and (iii) any other Applicable Laws in those countries or territories within the Regulatory Territory in which Product  
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will be distributed, sold or used governing manufacturing practices and standards that pertain to the Manufacture of Product. 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.  
1.13. “Certificate of Analysis” shall mean a summary of the test results from testing to be conducted by BVL in accordance with the applicable Specifications, including the test methods, specification parameters, and the pass/fail criteria, used to show that the Batch meets applicable Specifications and to confirm the identity, strength, quality, purity and other characteristics of a specific Batch of Product, including review and approval by the appropriate quality assurance department at BVL.  
1.14. “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 and in accordance with the Manufacturing Process.  
1.15. “Claims” shall have the meaning ascribed thereto in Section 8.1.  
1.16. “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 are to be supplied by either BVL or Customer, as indicated in the Attachment.  
1.17. “Confidential Information” shall have the meaning set forth in Section 9.1.  
1.18. “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.  
1.19. “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.  
1.20. “Customer Improvements” shall have the meaning set forth in Section 11.3.  
1.21. “Customer Indemnitees” shall have the meaning ascribed thereto in Section 8.2.  
1.22. “Customer Technology” shall mean: (a) API; (b) Product and any intermediates or derivatives thereof; (c) Specifications and documentation provided by Customer or developed for Customer by BVL under this Agreement, including the Product-specific portions of the Master Production Record; (d) the Technology of Customer owned, developed or obtained by or on behalf of Customer prior to the Effective Date, or developed or obtained by or on behalf of Customer after the Effective Date independent of this Agreement and without reliance upon the Confidential Information of BVL, BVL Improvements or BVL Technology; and (e) any Technology, whether or not if falls within the definition of (a) through (d) above, that is a Customer Improvement.  
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1.23. “Development,” “Develop,” “Developmental” shall mean all of the services provided by BVL to Customer under this Agreement in support of the development of the processes and procedures for the Manufacture of Product as defined by proposals submitted by BVL to Customer and agreed upon by Customer.  
1.24. “Disclosing Party” means the party which is directly or indirectly disclosing Confidential Information to the other Party pursuant to this Agreement. The Disclosing Party may also act as the Receiving Party of the other party’s Confidential Information.  
1.25. “Drug Master File” or “DMF” means a drug master file providing detailed information about the facility, the equipment and manufacturing processes as relevant to 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 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.  
1.26. “Equipment” shall mean the equipment described in the Master Production Record which is: (a) owned or leased by BVL or (b) owned or leased by Customer and provided to BVL, as listed 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.  
1.27. “Facility” and “Facilities” shall mean BVL’s facility located at 000 Xxxxxxxxxx Xxxx, Xxxxxxx, Xxxx, and its facility located at 00000 Xxxxx Xxxx, Xxxxxx Xxxxx, Xxxx, and 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 of the use of any such facility in the Development or Manufacture of Products.  
1.28. “FDA” shall mean the U.S. Food and Drug Administration and any successor agency.  
1.29. “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.  
1.30. “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.  
1.31. “[\*] Forecast” shall have the meaning ascribed thereto in Section 5.1.  
1.32. “Force Majeure” shall have the meaning set forth in Article 17.  
1.33. “Forecasts” shall mean the collective reference to the [\*] Forecast and the Rolling Forecast.  
1.34. “Immediately” shall mean within twenty-four (24) hours.  
1.35. “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 whole or in part by BVL or any permitted agents in the use of API or the Manufacture of Product or in the performance by BVL or any of its agents of services related to the Product under this Agreement.  
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1.36. “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 or at Customer’s request) 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.  
1.37. “Manufacture,” “Manufacturing,” and “Manufactured” shall mean all operations of BVL in the scheduling, procuring and handling of components for, production, packaging, labeling, warehousing, quality control testing (including in-process, release and stability testing when applicable), handling, storage, release and shipping of Product to meet the Specification for Product.  
1.38. “Manufacturing Process” shall mean any and all processes (or any step in any process) to be used by BVL to Manufacture Product in conformance with the Master Production Record, as evidenced in the Batch Records, and other mutually agreed upon standard operating procedures.  
1.39. “Marketing Authorization” shall mean an NDA filed with an Agency outside the United States.  
1.40. “Obsolete Materials” shall have the meaning set forth in Section 6.4.2.  
1.41. “Master Production Record” shall mean the documents that specify or reference the complete set of formal instructions for the Manufacture of Product, including material descriptions, in process testing and production specifications used in the production process, developed and mutually approved by BVL and Customer under the terms of this Agreement.  
1.42. “NDA” shall mean a New Drug Application filed with the FDA or an equivalent filing outside the United States.  
1.43. “Order Deficit” shall have the meaning set forth in Paragraph 5.4.  
1.44. “Party” or “Parties” shall have that meaning as set first in the first unnumbered paragraph of this Agreement.  
1.45. “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.  
1.46. “Product Improvement” shall mean any Improvement under this Agreement that (i) constitutes an improvement or new use of API or Product, including, but not limited to: (i) new formulations of API or Product; or (ii) improvements or new methods in the manufacture of API or Product.  
1.47. “Promptly” shall mean within [\*].  
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1.48. “Purchase Order” shall mean a written form submitted by Customer to BVL authorizing BVL to perform the Manufacture of Product or Development or other services as specified on the document and which references this Agreement or a quotation number provided by BVL or another document provided by BVL outlining the services to be performed, the price to be paid, and containing each of the requirements set forth on Attachment “B.”  
1.49. “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.  
1.50. “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.  
1.51. “Receiving Party” shall mean the party to which Confidential Information is directly or indirectly disclosed.  
1.52. “Records” shall have the meaning ascribed thereto in Section 3.8.  
1.53. “Regulatory Territory” shall mean the United States, the European Union and its member states, Canada and its provinces, Japan, Australia, China, India, Brazil, and Mexico, and such additional countries and/or territories that the Parties agree to include as part of the Regulatory Territory in accordance with Section 3.5.  
1.54. “Representative” shall have the meaning ascribed thereto in Section 2.4.  
1.55. “Rolling Forecast” shall have the meaning ascribed thereto in Section 5.3.  
1.56. “SOP’s” of a Party shall mean such Party’s standard operating procedures as defined in the controlled written documentation of such Party. All SOPs shall be consistent with Applicable Law and generally prevailing industry standards.  
1.57. “Specification” shall mean the written specifications and quality standards, including tests, analytical procedures and acceptance criteria that are established to confirm the characteristics and quality of Product which are mutually agreed to in writing and are contained or referenced in the Master Production Record for Product or as otherwise mutually agreed to in writing by the Parties in accordance with the procedures set forth in Section 3.3 and the Quality Agreement.  
1.58. “Technology” shall mean all methods, techniques, trade secrets, copyrights, inventions, know-how, data, documentation, processes, procedures, regulatory submissions, specifications and other intellectual property of any kind (whether or not protectable under patent, trademark, copyright or similar laws).  
1.59. “Temporary Storage Period” shall have that meaning ascribed in Section 6.6.  
1.60. “Territory” shall mean worldwide.  
1.61. “Third Party” shall mean any person or entity other than a Party to this Agreement.  
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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 other Customer-supplied Composition needed for the Development or Manufacture of Product, as specified in the Purchase Orders, in order to meet Customer’s requirements as set forth in Section 4.1 for commercial, Developmental and/or other quantities of Product in finished dosage form. Customer will provide API and any other mutually agreed Customer-supplied Composition at least thirty (30) calendar days in advance of the scheduled Manufacturing date in accordance with BVL’s SOP’s that are acceptable to Customer, which such acceptance shall not be unreasonably withheld, or in accordance with such other inventory procedures as may from time to time be mutually agreed upon by the Parties in writing. 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 six (6) months supply of API except as otherwise mutually agreed-to by the Parties in writing.  
BVL agrees: (i) to account for all API, Customer-supplied Composition and Product and to provide Customer with monthly inventory reports, in BVL’s standard format provided such format is consistent with industry standards, and, in addition, to provide stand-alone inventory reports from time to time at Customer’s specific 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) to handle, store and use API and other Customer-supplied Composition in accordance with SOPs or other instructions provided by Customer; (iv) not to provide API or Customer-supplied Composition to any Third Party without the express prior written consent of Customer; (v) not to use API or Customer-supplied Composition for any purpose other than the Manufacture of Product or conducting other services under this Agreement, and with such restriction on use to include, but not be limited to, BVL’s agreement 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 (vi) 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 under clause (vi) above 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. BVL will do ID-only, by-label verification of any API or active drug substance, and will not perform any additional testing of API or active drug substance unless requested by Customer in writing. If Customer requests BVL to perform additional testing, then subject to BVL’s acceptance and a reasonable proposal which is acceptable to Customer and which Customer shall approve in writing, BVL will perform such additional testing in accordance with the standard operating procedures and specifications to be agreed upon by the Parties in writing.  
2.1.3. BVL will release all materials provided by BVL. In the event the Product is being Manufactured for sale in 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 in accordance with the responsibilities set forth in  
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Xxxxxxxx X of this Agreement, provided that BVL will continue to be responsible for release testing and issuance to Customer of the Certificate of Analysis and Certificate of Compliance.  
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 Product and, if applicable to the testing to be performed by BVL under this Agreement, quality control testing requirements, methods, specifications and reference standards for the API. BVL will obtain Customer’s approval in writing of initial testing documents, the Master Production Record and any revisions of the documents thereafter prior to first use in accordance with the change control procedures set forth in the Quality Agreement. Revisions of approved documents requested by Customer within eight (8) 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, provided that BVL has given Customer written notice of the amount of such additional costs and expenses prior to implementation of Customer’s requested change, and Customer has decided to proceed.  
2.1.5. Customer is responsible for notifying BVL with instruction for any special disposition of tailings and rejects, which such special instructions will be incorporated into the Master Production Record and include a shipment address for tailing and rejects if Customer requests return of tailings and rejects. If no special instructions are provided, BVL shall dispose of tailings and rejects in accordance with BVL’s SOPs and Applicable Law.  
2.1.6. For the avoidance of doubt, reference to API in this Agreement shall not be construed as a non-compete and/or a covenant not to use the same pharmacologically active compound for a different product for an entity other than Customer.  
2.2. Product Manufacture. Pursuant to the provisions of this Agreement and subject to the limitations set forth in Article 5, BVL shall Manufacture and deliver to Customer the quantities of Product ordered by Customer under this Agreement in finished packaged dosage form as defined in each Attachment “A#.2” (i.e., A1.2). Such Product will be delivered in the amounts and in accordance with the delivery schedule set forth in the applicable Purchase Order. Such Product shall meet the Specification, and have been Manufactured in accordance with the Manufacturing Process and the requirements of cGMP and all Applicable Law and shall not be contaminated, adulterated or misbranded.  
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. In performing Development services, BVL shall meet the standard for performance set forth in the applicable proposal or work description and shall comply with all Applicable Law and relevant professional standards.  
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  
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“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 other than in the event of a termination of employment. 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.  
2.5. Observation. Subject to the requirements of BVL’s policies and procedures, Customer shall have the right to have one or more employees present at the Facility to observe Manufacturing operations related to Product. Customer shall provide at least two (2) weeks advance notice to be on site at BVL during Manufacture operations.  
2.6. Product Handling. BVL agrees: (i) to handle, store and ship Product in accordance with SOPs or other instructions provided by Customer; (ii) not to provide Product to any Third Party, other than in connection with services pursuant to Customer’s shipping instructions or other written instructions of Customer; (iii) not to use Product for any purpose other than conducting the services to be provided under this Agreement, and (iv) not to analyze, characterize, modify or reverse engineer any Product or take any action to determine the structure or composition of any Product, unless the foregoing is required under this Agreement.  
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 Facilities and to Manufacture Product at the Facilities. BVL represents that 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 least [\*] 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, and/or filing of any required regulation submissions in connection with use of the new facility and approval of such submissions by the FDA or other applicable Agency). 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. If practicable, BVL will notify Customer in writing at least [\*] prior to making any change to the Facility or operations at the Facility that may impact Manufacturing operations or that will require notification to a regulatory Agency.  
3.3. Change Control. Any changes proposed by BVL or Customer to the Specification, Master Production Record, Manufacturing Process, Equipment, testing procedures, validation, suppliers of raw materials and components, or documentation systems that are specific to Product or that might affect Product quality and any other changes proposed by BVL or Customer that are likely to affect any government submission or approval required for Product, either foreign or domestic as applicable for the Regulatory Territory or will require notice to or  
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approval of an Agency, shall be made only with the prior written consent of the Parties and in accordance with the change control provisions of the Quality Agreement. In the event such changes are required by an Agency, the Party receiving notice of the change will Promptly notify the other Party. 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. Product Compliance. Product delivered to Customer pursuant to this Agreement shall conform to the Specifications and shall have been Manufactured in compliance with all Applicable Law, including but not limited to the requirements of cGMP, and shall not be contaminated, adulterated or misbranded. 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 to the Agency, or, if needed in connection with a regulatory filing of Customer, shall be provided directly to Customer, within five (5) days of Customer’s request, and BVL shall submit to all inquiries and inspections by any such Agency. All Product-specific documents provided directly by BVL to any Agency shall be provided to Customer in a reasonable amount of time in advance of submission to such Agency to allow Customer to comment, and in no case shall final copies of 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 or unscheduled Product-specific Agency inspections, and Customer shall have the right to be present for such inspection, including, but not limited to, daily and post-inspection wrap-up sessions. BVL shall notify Customer Promptly of any inspections that are not Product-specific, but are directed generally at a Facility used to Manufacture Product, but Customer shall not 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 BVL to Customer no later than two (2) business days after such communications are received by BVL. Any and all other written communications or notices of inspection received from any Agency that are likely to impact Product shall be provided by BVL to Customer no later than two (2) business days after BVL has reasonably identified that such communications are likely to impact Product; provided, however, BVL 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 an Agency regarding any deficiencies that have or are likely to have a material adverse effect on the Product or BVL’s ability to perform its obligations under this Agreement, and BVL shall discuss with Customer BVL’s plans to address such deficiencies and shall keep Customer apprised of its progress in remedying such deficiencies.  
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 or Customer to access the DMF. This may be used by the Customer only to prepare any required regulatory filing.  
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In the event Customer plans to file for regulatory approval of Product in a country that is not at such time included as part of the Regulatory Territory, the Parties shall meet to discuss any regulatory requirements in such country that are different than the regulatory requirements BVL is otherwise obligated to meet under this Agreement, and BVL shall provide to Customer an assessment of any additional costs that will be incurred by BVL if it is required to meet such additional regulatory requirements. Upon mutual agreement by the Parties on reasonable additional fees to be paid by Customer, if any, with respect to Manufacturing of Product in compliance with such additional regulatory requirements, and, unless compliance with such additional regulatory requirements cannot reasonably be achieved by BVL without undue burden, the Parties will execute a written amendment to this Agreement to add the applicable country to the Regulatory Territory.  
3.6. Health, Safety and Environmental Compliance. Unless otherwise agreed by the Parties, BVL will conduct all Manufacturing operations required for the Manufacture of Product under this Agreement and all Development activities in accordance with health, safety and environmental procedures that comply with Applicable Law and industry standards. 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. BVL may not subcontract with any Third Party or use any of its Affiliates to perform all or any part of its obligations hereunder without the prior written consent of Customer. In the event that Customer permits BVL to subcontract with a permitted Third Party or use of an Affiliate of BVL pursuant to this Section 3.7, BVL shall be solely responsible for the performance of any permitted subcontractors and Affiliates, 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. BVL shall cause any such permitted subcontractor or Affiliate to be bound by, and to comply with, all confidentiality, quality assurance, regulatory, intellectual property and other obligations and requirements as set forth in this Agreement.  
3.8. Records and Audits. 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 audits or at otherwise mutually agreed to times for inspection, examination and review by or on behalf of Customer. Customer will also have audit rights as described in the Quality Agreement. 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  
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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, provided that BVL shall give Customer at least ninety (90) days prior written notice of such planned destruction.  
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 in accordance with this Agreement. Each Batch of Product will be sampled and tested by BVL against the Specification in accordance with the Master Production Record. BVL will provide to Customer a Certificate of Analysis showing the results of the testing performed under the preceding sentence. The quality assurance department of BVL will review the Certificate of Analysis and the other Records relating to the Manufacture of the Batch and will assess if the Manufacture has taken place in compliance with cGMP and other Applicable Law 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 and delivered to Customer. 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, but not limited to, 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. 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 the complete Batch Records and test samples relating to such Batch. If no acceptance or rejection in writing is received by BVL within such 30 days, the Batch will be deemed accepted for purposes of Section 6.3.1. During this review period, the Parties agree to respond punctually, but in any event within ten (10) calendar days, to any reasonable inquiry by the other Party with respect to the Batch Records. Customer has no obligation to accept a Batch if such Batch (i) does not comply with the Specification, (ii) was not Manufactured in compliance with cGMP and/or the Manufacturing Process or (iii) is otherwise contaminated, adulterated or misbranded other than as a result of defective, adulterated or misbranded API or contamination, adulteration or misbranding caused by Customer or its agents.  
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 and be of recognized standing in the industry. Consent to the appointment of such laboratory shall not be unreasonably withheld or delayed by either Party.  
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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 with respect to the determination as to whether the Specifications were met. 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 a Batch of Product (i) does not conform to the Specification, (ii) was not Manufactured in compliance with cGMP , other Applicable Laws, the Manufacturing Process or the requirements of this Agreement, or (iii) is otherwise contaminated, adulterated or misbranded, other than as a result of defective, adulterated or misbranded API or contamination, adulteration or misbranding caused by Customer’s agents, then BVL shall, after consultation with and written agreement from Customer:  
3.9.5.1. refund [\*] paid by Customer on a pro rata basis over the usable portion for such Batch; or  
3.9.5.2. [\*] produce a new Batch of Product as soon as reasonably possible.  
3.9.6. BVL may postpone all scheduled Manufacture of the Product until such time as final disposition of a rejected Batch 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. Under circumstances where BVL has postponed scheduled Manufacture of Product under the preceding sentence, Customer may request in writing that BVL resume Manufacture prior to completion of an investigation root cause analysis and corrective actions, and BVL will comply with such request, provided, Customer agrees to [\*] during such period for reasons substantially similar to the issue that is the subject of the investigation.  
3.9.7. The Parties shall meet to discuss, evaluate and analyze the reasons for and implications of any failure to meet the Specification or comply with the cGMP or other Applicable Law and/or the Manufacturing Process.  
ARTICLE 4 - VOLUMES AND ALTERNATE SOURCE  
4.1. Product Purchase and Supply Obligations. BVL shall supply Customer with such quantities of Product for use in the Territory as are ordered by Customer in accordance with the terms of this Agreement, subject to the limitations on BVL’s supply obligation set forth in Sections 5.1 and 5.4. In the event that BVL, at any time during the term of this Agreement, 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. 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. Customer may qualify, at its discretion and cost, one or more Third Parties or itself or any of its Affiliates as contract manufacturers of Product (an “Alternate Source”) as it deems necessary or desirable for any reason, and, subject to Customer’s minimum purchase obligations set forth in Section 5.4 of this Agreement, may obtain Product from such Alternate Source. Customer will notify BVL within [\*] of any decision to retain and or  
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qualify an Alternate Source in addition to those already qualified. Quantities of Product to be obtained from an Alternate Source will not be included in the Forecasts. Furthermore, Customer’s minimum purchase obligations under this Agreement shall not apply if: (a) BVL has failed to fulfill Customer’s Purchase Orders of Product for a period of more than [\*] 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 [\*]; 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 12.4.  
4.3. Technical Transfer. BVL shall assist Customer in transferring the Manufacturing Process to at least one 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 Production Record for Product is not Confidential Information of BVL and may be disclosed to the Alternate Source.  
ARTICLE 5 - FORECASTS AND PURCHASE ORDERS  
5.1. [\*] Forecast. Attached hereto as part of each Attachment “A#.4.1” (i.e., A1.4.1) is Customer’s non-binding forecast of its requirements of Product from BVL for the [\*] of the term of this Agreement (“[\*] Forecast”). Such [\*] Forecast, including any updates or extensions under Section 5.1.1 or 5.1.2, represents Customer’s good faith projection of its requirement of Product(s) from BVL, but is an estimate and is in no way binding on Customer. BVL shall not be obligated to Manufacture Product for Customer in excess of the amounts shown in the [\*] Forecast as updated and supplemented under Section 5.1.1 and 5.1.2 below. 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.  
5.1.1. Updates to [\*] Forecast. Increases to the [\*] Forecasts shall be permissible, and then only upon written acceptance by BVL. Accordingly, any increase in the volume identified by the [\*] Forecast shall be provided by Customer to BVL in writing not later than [\*] of each [\*] for the remaining [\*] of this Agreement. Any proposed increases to the [\*] Forecast shall be subject to acceptance in BVL’s sole and complete discretion. BVL shall have no obligation to accommodate any proposed update to Customer’s [\*] Forecast.  
5.1.2. Extension of Agreement by Amending the [\*] Forecast. Customer may unilaterally offer to extend the Agreement by providing BVL, pursuant to Section 5.1.1., with an update to the [\*] Forecast which exceeds the duration of the initial or then-current [\*] Forecast. BVL may, in its sole discretion, accept the offer and confirm the requested extension (in whole or in part) in writing which shall serve to amend the Agreement to extend it for the duration of the updated [\*] Forecast. Notwithstanding anything to the contrary set forth herein, the [\*] Forecast and any Customer-proposed updates thereto shall not exceed a period greater than [\*].  
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5.2. [\*] Product Forecast and Scheduling. Customer and BVL shall cooperate in estimating and scheduling the Manufacturing of Product. If commercially reasonable for Customer to do so, the [\*] order of Product for commercial use will be divided into individual Batch Purchase Orders evenly distributed over the course of any [\*] 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 [\*] requirements due to market conditions, Development requirements or other needs.  
5.3. Rolling [\*] Distribution Forecasts. Within [\*] after [\*], and thereafter [\*] in advance of the first day of each [\*] during the term of this Agreement commencing with the first full quarter that is [\*] after such approval, Customer will provide BVL with a [\*] rolling distribution forecast for all presentations of Product (“Rolling Forecast”). The [\*] of such Rolling Forecast of the Product in the Territory will be considered a Firm Order for which Customer will provide non-cancelable Purchase Orders for each Batch of Product in such period of the Rolling Forecast. Customer shall also submit Purchase Orders for any amounts required from BVL prior to the first Firm Order under this Section, provided such Purchase Orders shall be submitted at least [\*] prior to the requested delivery date.  
5.4. Obligation of Supply and Purchase. Commencing with [\*] after [\*], Customer [\*] for [\*] of Product (“Minimum Purchase Obligation”) specified for each [\*] in the Rolling Forecast that was sent to BVL by Customer under Section 5.3 immediately preceding the start of such [\*] (the “Base Forecast”). In the event that Customer’s Purchase Orders for any [\*] are [\*] for such [\*] (an “Order Deficit”), then BVL shall have the option, in its sole and complete discretion, to [\*] for each [\*] in which an Order Deficit occurs, and Customer shall [\*] the Order Deficit at [\*] within 30 days of receipt of [\*]. BVL shall endeavor in good faith to mitigate any potential loss by utilizing the unused and/or underutilized capacity that had been allocated and/or reserved for Customer (a “Mitigation”). In the event that BVL is able to partially Mitigate Customer’s Order Deficit for each given period, Customer shall [\*]. Notwithstanding anything to the contrary in this Agreement, Customer shall not have an obligation under this Section 5.4 with respect to any [\*] during which BVL has been unable to deliver Product to Customer for a period of [\*] following the agreed-upon delivery date as a result of: (i) its breach of its obligations under this Agreement; or (ii) as the result of a Force Majeure.  
BVL shall not be obligated to Manufacture quantities of Product in any [\*] that are greater than [\*] of the quantities set forth in the Base Forecast for such [\*]. In the event Customer’s requirements for Product from BVL in any [\*] exceed [\*] of the amount shown for such [\*] on the Base Forecast, BVL shall, nonetheless, use reasonable efforts to satisfy Customer’s requirements.  
5.5. Scheduling. Customer and BVL shall cooperate in estimating and scheduling the Manufacture of Product.  
5.6. Additional and Development Services.  
5.6.1. 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 quotations and estimated timelines for such Development activities. Customer will issue a non-cancelable Purchase Orders referencing the quotation provided prior to BVL initiating the  
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Development services. In the event, Customer requests changes in the Development services that will cause the Development work to exceed the quoted amount, BVL will provide a revised quotation, and will not proceed with the changes unless and until Customer has decided to proceed and has provided a new or revised Purchase Order reflecting the revised amount. BVL’s charges for Development Services will not exceed the amount set forth on the applicable quotation unless there has been a scope change and a new or revised Purchase Order has been provided and accepted under the preceding sentence.  
5.6.2. In the event that Customer requests or an Agency requires additional services in support of Product that go beyond the services that would normally be included in the Manufacture of Product or are already otherwise contemplated by this Agreement, BVL will provide Customer with a quotation for such services. BVL will provide such services only upon receipt from Customer of a binding Purchase Order referencing the quotation provided for the required service.  
5.7. 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 [\*] 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 thirty (30) calendar days in advance of the scheduled Manufacture 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 such 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 all Customer-supplied Composition.  
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 [\*]. [\*] shall assume title and risk of loss of the finished Product [\*]. 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 [\*] on the Purchase Order; and (ii) in accordance with the instructions for shipping included on the Purchase Order or otherwise provided in writing by Customer and packaging and shipping conditions specified in the Master Production Record or as otherwise agreed to by the Parties in writing. A xxxx of lading shall be furnished to Customer with respect to each shipment. [\*] is responsible for all shipment costs and shipping charges will be paid directly by [\*].  
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6.2. Price Adjustments.  
6.2.1. [\*] 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 [\*] 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 [\*] during the term of this Agreement for the [\*]. Prices for Product will be adjusted on an [\*] basis by BVL for [\*] 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. [\*] Price adjustments will automatically be made by [\*] in the Producer Price Index for commodity code 06-38 Pharmaceutical Preparation as published by the U.S. Department of Labor, Bureau of Labor Statistics for [\*]. [\*]; or  
6.2.1.2. [\*] Price adjustments, not to exceed [\*] of Product price from [\*], may be made in the sole discretion of BVL.  
6.2.1.3. For the [\*] price adjustment methodology, Customer elects: (check only one): x 6.2.1.1 or ¨ 6.2.1.2  
6.2.2. Price Adjustment on Product or Process Specification Changes. BVL reserves the right to adjust prices based on any change to the Specification or Manufacturing Process for Product (regardless of the event or action causing the Specification or Manufacturing Process change) that is Product-specific (other than a change required as a result of BVL’s negligence action, willful misconduct or breach of this Agreement and other than a change required to conform to cGMP or other Applicable Law), including but not limited to changes in inspection, packaging and labeling, provided that BVL has, prior to implementing any such change, provided to Customer notice of the price adjustment that would result from such change, and has received Customer’s written approval to proceed on such basis.  
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 [\*] after the date of BVL’s invoice to Customer. BVL will issue an invoice for: (i) Product Manufacture at such time that the Batch is deemed accepted under Section 3.9.3 and delivered under Section 6.1.2; and (ii) or for other services, upon completion of such other services as described in the applicable proposal. Customer may request 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 describing 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.  
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6.3.2. In the event of nonpayment of balances without written notice and reasonable cause within [\*] of the invoice date, BVL shall provide written notice to Customer indicating such failure to pay, and if Customer continues to fail to pay the amount due within [\*] of such notice, BVL will have the right to charge to Customer a [\*] late payment charge equal to [\*] of the unpaid balance. Should unpaid balances on undisputed invoices extend beyond [\*] after the date of notice provided to Customer under the preceding sentence, BVL reserves the right to require Customer to pay [\*] of the full price for each Batch at the time of Purchase Order issuance or [\*] until such time as all unpaid overdue undisputed invoices, together with any and all late fees, have been paid.  
6.4. Payment for Non-Validated Services or Production.  
6.4.1. Unless otherwise covered as a Development service or unless otherwise set forth in a quotation covering Development Services, Customer will be required to pay BVL for all Product Manufactured at Customer’s request 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 or failure to follow the Manufacturing Process.  
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 because of a delay in scheduled Manufacture of Product caused by Customer (the “Obsolete Materials”). Customer must agree to disposition of any Obsolete Materials within ninety (90) days of notification from 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. Subject to Customer’s minimum obligation under Section 5.4, Customer may cancel any order including a Firm Order. Customer will pay a cancellation fee equal to [\*] of the price of any Batch that is the subject of a Firm Order if such Batch is cancelled or postponed by Customer [\*] in advance of the scheduled Manufacturing date. If cancellation or postponement is made less than [\*] in advance of the scheduled Manufacturing date, Customer is responsible for payment of [\*] of the price of the postponed or cancelled Batch(es), provided that 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 [\*] 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 [\*] beyond BVL’s release of such Product and delivery to Customer of the applicable Batch Records and test samples. Short-term storage of Product in BVL’s warehousing Facilities beyond [\*] 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 in accordance with the instructions for shipping included on the Purchase Order and packaging and shipping conditions specified in the Master Production Record.  
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6.7. Stability Program. During the term of this Agreement and upon Customer’s written request and BVL’s written agreement, BVL will conduct and support, at Customer’s expense, the agreed upon 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 and agreed upon by Customer in writing 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 AND LIABILITIES  
8.1. Customer Indemnity. Customer hereby holds harmless and indemnifies BVL, its Affiliates and its and their directors, officers, employees and agents (the “BVL Indemnitees”) against any and all claims, liabilities, lawsuits, proceedings, out-of-pocket costs and expenses, including, without limitation, reasonable attorneys’ fees, and the cost of recalls (collectively, “Claims”) [\*]: (a) [\*]; (b) any breach by Customer of its representations, warranties or covenants hereunder; or (c) any negligent act or the willful misconduct [\*] in performing [\*] obligations under this Agreement. However, such indemnity shall not apply to the extent that such Claims arise out of [\*] breach of this Agreement or any of the representations, warranties or covenants contained in this Agreement or the negligence or intentional misconduct of [\*].  
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 [\*]: (a) breach by BVL of this Agreement or any of its representations, warranties or covenants hereunder; or (b) the negligent act or the willful misconduct [\*] in performing [\*] obligations under this Agreement. However, such indemnity shall not apply to the extent that such [\*] labeling, marketing, handling, or storage of the Product; [\*]-supplied materials; or as a result of [\*] breach of this Agreement or any of the warranties contained in this Agreement.  
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, provided, however, that failure to provide such notice shall not relieve the indemnifying party of any of its obligations hereunder except to  
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the extent the indemnifying party is prejudiced by such failure. The indemnifying Party shall have the right, but not the obligation, to defend, to employ counsel of its choosing, 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 indemnified party shall not settle any claim without the prior written consent of the indemnifying party. The indemnifying party will not settle any claim without the prior written consent of the indemnified party unless the settlement includes a full release and no admission on the part of the indemnified party.  
8.4. Insurance. Customer and BVL will each, at its own cost and expense, obtain and maintain in full force and effect, [\*], Commercial General Liability insurance, written on the standard approved Policy Form, and Blanket Contractual Liability, with limits of liability of not less than [\*] Combined Single Limit Bodily Injury and Property Damage covering its duties and obligations under the Agreement. Furthermore, [\*], BVL shall obtain and maintain insurance valued at [\*], covering loss or damage to the Facility and Customer’s property and materials in the care, custody, and control of BVL. The coverage limits may be provided through a combination of Primary, Excess/Umbrella or Self-Insured Retention.  
8.5. Specific Limitation of Liability for Process-Related (i.e., during Manufacturing) Losses. Notwithstanding anything to the contrary set forth herein or in any collateral documents (invoices, purchase orders, etc.), the Parties acknowledge and agree that BVL’s [\*] for in-process Manufacturing losses is set forth exclusively in this section 8.5. BVL agrees to reimburse Customer up to a maximum of [\*] pro-rated over the usable portion of the [\*], if applicable, for any loss of [\*] for each [\*] that does not meet Specification or was not Manufactured in accordance with the Manufacturing Process or cGMP or is adulterated or misbranded, 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 gross 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 [\*] or the insurance levels identified in Section 8.4 or elsewhere, in no event shall BVL’s liability to Customer for in process [\*] be in excess of the [\*] set forth in this Section 8.5.  
8.6. Specific Limitation of Liability for Non-Process-Related (i.e., not during Manufacturing) Losses. Notwithstanding anything to the contrary set forth herein, BVL’s total liability for non-process-related losses to Customer property (for both insured and non-insured losses) shall be limited to [\*] in aggregate per [\*]. The Parties further understand and acknowledge that insurance limits identified herein shall not act as a bar to any recovery.  
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8.7. LIABILITY LIMITATION.  
 8.7.1. ELECTION OF REMEDIES. SECTION 3.9.5, 8.2, 8.5, 8.6 AND 25.1 ARE CUSTOMER’S [\*] REMEDY FOR ANY PRODUCT THAT DOES NOT COMPLY WITH THE SPECIFICATIONS CONTAINED IN THE MASTER BATCH RECORD AND/OR WERE NOT MANUFACTURED IN ACCORDANCE WITH THE REQUIREMENTS SET FORTH IN THIS AGREEMENT.  
 8.7.2. SPECIAL DAMAGES. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES, INCLUDING WITHOUT LIMITATION, LOST PROFITS, LOST MARKET SHARE OR DAMAGES STEMMING FROM AN INTERRUPTION OF SUPPLY ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (THE “SPECIAL DAMAGES”).  
 8.7.3. BVL CAP ON LIABILITY. BVL’S TOTAL MAXIMUM AGGREGATE LIABILITY UNDER THIS AGREEMENT IN ANY [\*] SHALL NOT EXCEED THE GREATER OF [\*] (THE “LIABILITY CAP”). FOR THE AVOIDANCE OF DOUBT, A CLAIM ARISES IN THE YEAR IN WHICH THE CONDUCT GIVING RISE TO THE CLAIM ARISES, AND SHALL INCLUDE THE FEES RECEIVED BY BVL IN THE YEAR IN WHICH THE CLAIM AROSE, EVEN IF THE FEES ARE RECEIVED BY BVL IN THE SAME YEAR BUT AFTER THE CLAIM AROSE.  
 8.7.4. EXCEPTIONS TO LIABILITY CAP. THE LIABILITY CAP SET FORTH IN SECTION 8.7.3 SHALL NOT APPLY TO DAMAGES RESULTING FROM: BREACHES BY A PARTY OF A DUTY IMPOSED UNDER ARTICLE 9 (CONFIDENTIALITY) OR ARTICLE 11 (INTELLECTUAL PROPERTY); OR BREACH BY BVL OF ITS NON-INFRINGEMENT REPRESENTATION AND WARRANTY UNDER SECTION 10.1(c) OR DUE TO A PARTY’S RECKLESS DISREGARD FOR THE CONSEQUENCES OF ITS NEGLIGENT CONDUCT OR WILLFUL MISCONDUCT.  
 8.7.5. INTEGRAL PROVISIONS. THESE LIMITATIONS SET FORTH IN THIS SECTION 8.7 SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY. 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. For purposes of this Agreement Confidential Information developed by BVL for Customer under this Agreement shall be deemed Confidential Information of Customer. 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  
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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 and without restrictions on further disclosure; 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 and other than as part of services under this Agreement. Disclosing Party is not obligated to xxxx 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 or any other BVL Manufacturing processes, techniques, know-how, other than Customer Technology and Customer Improvements, and BVL pricing information. Confidential Information of Customer includes, but is not limited to, Customer Technology and Customer Improvements. Except as expressly set forth in Article 11, 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, Third Party contractors and agents provided that in each case such individuals and entities have a specific need to know such Confidential Information in connection with this Agreement or activities contemplated under the Quality Agreement, have been informed of the confidential nature of the information and the restrictions on use and are previously bound by written obligations of confidentiality and restrictions at least as rigorous as those set forth herein; (ii) Confidential Information or Improvements of the other Party to the extent required to exploit or consistent with the rights specifically granted to it under Article 11 of this Agreement; (iii) Confidential Information of the other Party in connection with Regulatory filings and submissions made or contemplated under this Agreement; and (iv) 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 under clause (iv), 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 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 existing in tangible form, and shall delete all electronic copies, except for in each case a single copy for the purpose of determining compliance with its obligations under this Agreement or as required to be maintained under Applicable Law and provided that the Receiving Party shall not be required to delete the Disclosing Party’s Confidential Information included in regulatory submissions previously filed consistent with this Agreement and Customer shall not be obligated to return any Confidential Information of BVL that is included in the assignment of rights or license granted to Customer under Article 11. The foregoing nondisclosure and nonuse obligations shall survive termination or expiration 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  
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written consent of the other Party which shall not be unreasonably withheld, 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 without any further approval by BVL except to the extent approval of BVL is required under any other applicable section of this Agreement.  
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 any Third Party, 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 BVL 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 will meet the Specification, and (ii) will not be adulterated, or misbranded under the FDCA or other Applicable Law; 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 Customer 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 any Third Party, 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 by BVL in the 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  
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Member States of the European Union. In the event that Product is being Manufactured for sale in 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 Product is being Manufactured for sale in an EU member nation, or in a country within the Territory that 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. All rights to and interests in Customer Technology 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, non-transferable, non-sublicensable 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.  
11.2. BVL Technology. All rights to and interests in BVL Technology 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.  
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11.3. Customer Improvements. The Parties agree that all Improvements whether generated solely or jointly by employees or agents of BVL or Customer that (i) constitute a Product Improvement; or (ii) are based on or derived from Confidential Information of Customer; or (iii) are Product-specific, and in each case all related intellectual property rights shall be the sole and exclusive property of Customer (“Customer Improvements”), and BVL hereby assigns to Customer (or its designee) all of BVL’s right, title and interest in such Customer Improvements and related intellectual property rights, 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 or Customer Technology shall be the sole and exclusive property of BVL (“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 BVL Improvements to manufacture, have manufactured, use, sell, have sold and/or import Products worldwide. This grant shall be perpetual and shall survive termination of this Agreement, 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 is sublicensable, but otherwise shall only be transferable as provided in Article 15. For the avoidance of doubt, the foregoing grant is limited to solely the Product and its derivatives and shall not be used for any other product.  
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 by mutual agreement reflecting in a written amendment or as provided for in Section 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 prior written notice to the other Party. Notwithstanding such no-fault termination, Customer shall be liable for any outstanding Development services or Purchase Orders, and, unless Customer otherwise directs, BVL will complete delivery of such services and Purchase Orders.  
12.3. Termination by Customer. Customer may terminate this Agreement as to any Product upon ninety (90) days written notice in the event the Product is withdrawn from the market, in which case Section 5.4 shall no longer apply with respect to such Product. In such event, if Customer is not at such time commercializing any other Product, Customer may terminate this Agreement in its entirety upon at least ninety (90) days written notice to BVL.  
12.4. 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 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  
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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 [\*], 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) [\*] without liability until such default is cured.  
12.5. 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.  
12.6. 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.  
12.7. Consequences of Termination.  
12.7.1. 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 enable Customer to transfer manufacturing services to a Third Party but so as not to 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 [\*] after the date of termination notice of this Agreement. The Parties will cooperate during such transition period to continue any such ongoing services and BVL shall perform such functions and provide such documentation as reasonably necessary or required in connection with the orderly transfer of Manufacturing to a Third Party and wind-down of any active project being conducted under this Agreement and Applicable Law.  
12.7.2. 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, existing in tangible form, and shall delete all electronic copies, except for one copy that may be retained for archive purposes. Furthermore, BVL shall promptly return all Customer-supplied Composition, Customer 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 by or licensed to Customer, excepting that required to be retained by Applicable Law.  
12.7.3. 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.  
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12.7.4. Upon any termination of this Agreement by Customer, Customer: (a) shall purchase from BVL any existing inventories of Product that are the subject of a Firm Order conforming to the Specification and Manufactured in accordance with cGMP and the Manufacturing Process and not adulterated, or misbranded, 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 that was made pursuant to a Firm Order, 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 in connection with a Firm Order and direct BVL to dispose of such material at Customer’s cost. Customer shall not have any further obligation under Section 5.3 or 5.4 in the event of termination, except in the event that BVL terminates the Agreement under Section 12.4 for breach by Customer.  
12.7.5. If Customer terminates this Agreement for any reason other than a breach by BVL, Customer shall reimburse BVL for the costs of any BVL-supplied Composition Purchased in connection with a Firm Order or ordered in connection with inventory SOPs mutually agreed upon by the Parties 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.  
12.7.6. Upon the effective date of termination or expiration of this Agreement, and subject to 12.7.1, Customer shall have no further obligations to BVL with respect to the Forecasts and BVL will have no further obligations to Manufacture Product.  
12.8. 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 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.  
12.9. 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. Notwithstanding anything in this Agreement to the contrary, the representations and warranties (Article 10), duties of confidentiality (Article 9), indemnification (Article 8), intellectual property (Article 11), termination (Article 12) governing law and jurisdiction (Article 16) and the provisions specified in the survival clause of the Quality Agreement (Attachment “E”) of this Agreement shall survive termination or expiration of this Agreement. Notwithstanding anything to the contrary set forth herein, the obligations identified in Article 9 shall survive for a period of [\*] from any termination or expiration of this Agreement.  
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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  
Xxxxxxx, Xxxx 00000  
Attn: Vice President, Contract Manufacturing Services  
With copy to:  
Ben Venue Laboratories, Inc.  
000 Xxxxxxxxxx Xxxx  
Xxxxxxx, Xxxx 00000  
Attn: Legal Department, Division Counsel  
If to Customer:  
Targanta Therapeutics Corporation  
000 Xxxxx Xxxx, Xxxxx 000  
Xxxxxxxxxxxx, XX 00000  
Attn: Procurement Specialist  
With a copy to:  
Targanta Therapeutics Corporation  
000 Xxxxx Xx., Xxxxx 0000  
Xxxxxxxxx, XX 00000  
Attn: General Counsel  
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  
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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 (without application of conflict of law principles) 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 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 or 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.  
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ARTICLE 18 - TITLE OF GOODS AND EQUIPMENT  
18.1. Title to Customer-supplied Composition. Title to API and Customer-supplied Composition shall remain with [\*] 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, the Master Production Record 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. Handling of Customer-supplied Composition. 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.  
18.3. Customer-Supplied Equipment  
18.3.1. Equipment owned by BVL and located at the Facility, shall not be dedicated to any single customer unless otherwise agreed to in writing, but shall be available for Manufacturing of Product according to BVL’s Manufacturing Processes requirements.  
18.3.2. Customer and BVL shall mutually agree on the terms and conditions of any special equipment required to be purchased for the Manufacturing of the Product(s). Equipment which Customer has agreed to purchase, for which it shall be financially responsible, is identified in proposals and/or Attachment “F” and shall be dedicated to the production of the Product(s) (the “Customer Equipment”). Customer may at times authorize BVL, with BVL’s written consent, to select and order equipment that will be invoiced to Customer and for which Customer agrees to be financially liable.  
18.3.3. BVL shall obtain Customer’s Purchase Order for approval for all costs and expenses associated with installation and qualification of Customer-supplied Equipment (including without limitation labor and engineering costs) and Customer shall remit in advance an amount equal to [\*] of such cost to BVL upon issuance of Customer’s Purchase Order with the remaining balance to be invoiced to Customer upon receipt of Equipment by BVL. Title to, and risk of loss of, all such Customer Equipment paid for by Customer shall be retained by Customer. BVL will cause each item of Customer Equipment to be marked to indicate that it is dedicated to Customer’s Product and to be tagged in such a way as to identify it as property of Customer. BVL shall not change the location of the Customer Equipment from the Facility without the prior written consent of Customer. BVL agrees to perform ordinary, routine maintain of the Customer Equipment as set forth in a quotation to be mutually approved by BVL and Customer. Customer shall remain liable for non-routine maintenance and servicing of Customer Equipment. BVL shall notify Customer via proposal prior to the performance of any maintenance. BVL shall maintain Customer Equipment free and clear of any liens and encumbrances. At Customer’s request, BVL shall execute such documents and take such actions as Customer may from time to time reasonably deem necessary to maintain or protect Customer’s ownership interest in the Customer Equipment.  
 30  
18.3.4. BVL shall use the Customer Equipment solely for purpose of Manufacture of Products under this Agreement. BVL shall use the Customer Equipment in a careful and proper manner, and shall cause the Customer Equipment to be maintained, at BVL’s expense, in as good an operating condition as when provided by Customer, ordinary wear and tear resulting from proper and normal use alone excepted. Except to the extent otherwise specified in the approved Purchase Order, Customer shall be responsible for the cost of non-routine maintenance and servicing of Customer Equipment. BVL shall notify Customer via proposal prior to the performance of any non-routine maintenance or servicing, unless required during Manufacturing, and Customer shall issue a Purchase Order for the service or maintenance of Customer Equipment. BVL shall not make any material alterations to Equipment without the prior written consent of Customer.  
18.3.5. CUSTOMER AND BVL EACH EXPRESSLY DISCLAIMS AND MAKE NO WARRANTY OR REPRESENTATION TO THE OTHER, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR AGAINST LATENT DEFECTS OR OTHERWISE, EACH WITH RESPECT TO THE CUSTOMER EQUIPMENT. NEITHER PARTY IS RESPONSIBLE OR LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOSSES TO THE OTHER PARTY OR ANY THIRD PARTY RESULTING FROM INSTALLATION, OPERATION OR USE OF CUSTOMER EQUIPMENT, EXCEPT TO THE EXTENT THAT SUCH DAMAGES OR LOSSES ARISE FROM THE NEGLIGENCE OR WILLFUL MISCONDUCT OF SUCH PARTY IN THE INSTALLATION OR OPERATION OF THE EQUIPMENT.  
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 related to the subject matter hereof 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.  
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.  
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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 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) Customer determines (after consultation with BVL if the issue relates to Manufacturing operations under this Agreement) that Product should be recalled, the Parties shall take all appropriate corrective action. Customer retains the right to conduct a Product recall for any safety or other reason Customer deems appropriate without input from BVL, but prior to making any such decision or taking any such recall action, shall notify BVL if practicable. BVL shall Immediately bring to the attention of Customer any issue that is likely to require recall of Product. In the event 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 the negligence or willful misconduct of BVL or its agents is directly responsible, and, in any event, notwithstanding anything to the contrary, BVL’s total liability for any event of recall (including without limitation, API, materials, shipping, notices, destructions costs, etc.) shall be capped at a maximum aggregate of [\*] pro-rated per [\*]. For purposes of clarity it is understood that the obligations of the Parties under this Section 25.1 shall only apply to Product Manufactured under this Agreement.  
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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:  
FOR: BEN VENUE LABORATORIES, INC.  
 Signature:   
/s/ Xxxxx Xxxxxxxx  
 Date: 8/22/08  
 Xxxxx X. Xxxxxxxx RPh   
 Vice President, Contract Manufacturing Services   
For: Targanta Therapeutics Corporation  
 Signature:   
/s/ Xxxxx Xxxxxx for Xxxx Xxxxxxxxxxxxxx  
 Date: 8/28/08  
 Xxxx Xxxxxxxxxxxxxx   
 President and Chief Executive Officer   
 33  
Attachment “A1”  
Product Supplements  
A1.1(a) PRODUCT IDENTIFICATION  
 Product Description  
(INCLUDING PACKAGING DESCRIPTION FOR EACH END ITEM NUMBER FROM THE SAME NUDE VIAL)  
 BVL End Item Number BVL Nude Vial Number Customer Item Number Batch Size/Order Quantity   
Oritavancin 100mg in a lyo in a 20 cc vial, bulk packed unlabeled  
 9999900598 2451-08 n/a [ \*]  
 34  
Attachment “A1”  
Product Supplements  
A1.2(a) PRODUCT TESTING SPECIFICATION  
 Product Description  
(INCLUDING PACKAGING DESCRIPTION FOR EACH END ITEM NUMBER FROM THE SAME NUDE VIAL)  
 BVL End Item Number BVL Nude Vial Number BVL Final Product Specification Number  
Oritavancin 100mg in a lyo in a 20 cc vial, bulk packed unlabeled  
 9999900598 2451-08 245108FP  
 35  
Attachment “A”  
Product Supplements  
A1.3(a) MATERIALS SUPPLIED BY CUSTOMER AND BVL  
 BVL Item Number [\*] [\*] [\*] [\*]  
BNVL411 [\*] [\*] [\*] [\*]  
BNSL2331 [\*] [\*] [\*] [\*]  
BNST1853 [\*] [\*] [\*] [\*]  
BNCH3716 [\*] [\*] [\*] [\*]  
BNCH3092 [\*] [\*] [\*] [\*]  
TACH3991 [\*] [\*] [\*] [\*]  
BNPK8002 Corrugated shipper No N/A Yes  
BNPK8102 Corrugated tray No N/A Yes  
BNPK8221 Corrugated partition No N/A Yes  
 36  
Attachment “A”  
Product Supplements  
A1.4.1 FORECASTS  
[\*] Forecast – to be submitted by Customer to BVL on [\*] basis by [\*] each [\*]. BVL will supply Customer with an electronic copy of the [\*] 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 [\*] of this Agreement.  
NOTE: PURSUANT TO SECTION 5.1.1 – 5.1.2, UPDATES OF THE [\*] FORECAST WHICH ARE ACCEPTED BY BVL SHALL BE AMENDMENTS TO THIS AGREEMENT AND SHALL EXTEND THE TERM OF AGREEMENT, UP TO [\*].  
CUSTOMER MAY ENTER A “ZERO” FIGURE FOR ANY [\*] 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 [\*] 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.  
[\*]  
 37  
Attachment “A”  
Product Supplements  
A1.4.2 ROLLING [\*] 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 [\*] periods for forecasting. Subject to Section 5.3, Customer shall provide the Rolling Forecast [\*] in advance of the first day of the each [\*].  
(The format is for representation only, do not enter information below)  
[\*]  
 38  
Attachment “A”  
Product Supplements  
A1.5(a) PRICING  
[\*]  
 A1.5(b) None  
 39  
Attachment “A”  
Non-binding, Preliminary plan for NDA and MAA Submissions  
A1.6 Non-binding, Preliminary plan for NDA and MAA Submissions  
The following table shows Customer’s preliminary, non-binding plan for anticipated launch dates for Product in the Territory. BVL acknowledges that (i) such plan creates no obligation on the part of Customer, (ii) actual time-lines may differ substantially, and (iii) Customer may choose not to file an NDA or MAA for Product in a particular country in the Territory, may not get approval in a country in which it chooses to file an NDA or MAA or may choose not to launch Product in a particular country in the Territory.  
[\*]  
 40  
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  
 41  
Attachment “C”  
[\*] STORAGE FEES  
Effective through [\*]  
BVL has limited storage capacity. Therefore, Customers are expected to have Product shipped to them no later than [\*] after BVL Quality Operations has released their Product and has shipped test samples and the documents identified Attachment D to Customer, unless there is a disagreement as to whether Product conforms to the requirements of this Agreement. Should unforeseen events lead to a request by a Customer for storage beyond this [\*] grace period, the Customer must request such storage by BVL in writing at least fifteen (15) days before the initial [\*] 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.  
[\*] storage fees are assessed on a per lot basis, and begin to accrue [\*] following the BVL release date of the Batch by BVL’s Quality Operations Dept and delivery to Customer of the test samples and applicable batch records, unless there is a disagreement as to whether Product conforms to the requirements of this Agreement. BVL will request that a separate Purchase Order be issued for the storage charges. These charges listed below will be reviewed and updated [\*].  
[\*] Storage Charge - per square foot per [\*]  
 Room Temperature Storage  
 [ \*]  
Refrigerated Storage  
 [ \*]  
Freezer Storage  
 [ \*]  
Minimum Storage Charge - per lot per [\*]  
 Room Temperature Storage  
 [ \*]  
Refrigerated Storage  
 [ \*]  
Freezer Storage  
 [ \*]  
 42  
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)  
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.  
 43  
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 August 22, 2008 to which it is attached and integrated. The term “this Agreement” as used in the Agreement includes this Quality Agreement. 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. This Quality Agreement will be updated by December 31, 2009.  
 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 or clinical distribution; (ii) completion of any ongoing stability studies; or (iii) two years after 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’s Quality Representatives:  
 Name: Xxxxx Xxxxxx  
Title: Director, Quality Assurance & Control  
Company: Targanta Therapeutics Corporation  
Street Address: 000 Xxxxx Xxxx Xxxxxx, Xxxxx 000  
Xxxx, Xxxxx Zip: Xxxxxxxxxxxx, XX 00000  
Phone: 000-000-0000  
Fax: 000-000-0000  
E-mail: xxxxxxx@xxxxxxxx.xxx  
 44  
This Quality Agreement has been reviewed and approved by:  
FOR CUSTOMER:  
 SIGNATURE:   
/s/ Xxxxx Xxxxxx  
 DATE: 8/25/08  
 E.1.2 BVL Quality Representatives:  
 Name: Xxxxx Xxxx  
Title: Vice President, Quality Operations  
Company: Ben Venue Laboratories, Inc.  
Street Address: 000 Xxxxxxxxxx Xxxx  
Xxxx, Xxxxx Zip: Xxxxxxx, XX 00000-0000  
Phone: 000-000-0000  
Fax: 000-000-0000  
E-mail: mailto:Xxxxx.Xxxx@Xxxxxxxxxx-Xxxxxxxxx.xxx  
FOR BVL:  
 SIGNATURE:   
/s/ Xxxxx Xxxx  
 DATE: 9/2/08  
 E.1.3 BVL Business Representative:  
 Name: Xxxxx X Xxxxxxxx RPh  
Title: Vice President, Contract Manufacturing Services  
Company: Ben Venue Laboratories, Inc.  
Street Address: 000 Xxxxxxxxxx Xxxx  
Xxxx, Xxxxx Zip: Xxxxxxx, XX 00000-0000  
Phone: 000-000-0000  
Fax: 000-000-0000  
E-mail: mailto:Xxxxx.Xxxxxxxx@Xxxxxxxxxx-Xxxxxxxxx.xxx  
 45  
FOR BVL:  
 SIGNATURE:   
/s/ Xxxxx Xxxxxxxx  
 DATE: 8/22/08  
 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: Xxxxxx Xxxxxxxx  
Title: Director, Technical Services & Supply Chain Management  
Company: Targanta Therapeutics Corporation  
Street Address: 000 Xxxxx Xxxx Xxxxxx, Xxxxx 000  
Xxxx, Xxxxx Zip: Xxxxxxxxxxxx XX 00000  
Phone: 000-000-0000  
Fax: 000-000-0000  
E-mail: xxxxxxxxx@xxxxxxxx.xxx  
A Party’s Representatives may be changed in the manner set forth in the Agreement.  
 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 for Human and Veterinary Use”, 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 Manufacture of each Batch of the Product as included or referenced in the Master Production 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.  
BVL is responsible for maintaining training records for all personnel that perform cGMP functions relating to the Manufacturing operations, 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 Product is being Manufactured for sale in the European Union, 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 of API 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. Changes may be requested by BVL or Customer or in response to a regulatory authority. Any changes related to Product or any changes which would require a regulatory submission or a regulatory approval in advance of the change or which may impact Product quality will not be made without mutual approval, including, but not limited to, those changes describe below. All other changes will be reported to Customer in accordance with procedures mutually agreed upon by the BVL and Customer. 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 MPR must be received at least eight (8) weeks prior to the start of manufacture.  
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 E.4.2 Specification  
Editorial or format changes to applicable specifications not affecting the scientific/technical content or intent of the specification will not require approval by Customer. All other specification changes require 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. Those documents requiring initial Customer approval and approval by Customer of any changes are as follows:  
Product Specification  
Master Production Records  
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 and Applicable Law.  
 E.4.5 Changes to the Plant  
BVL will notify Customer at least [\*] 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 or which will require a submission to a Regulatory Authority. 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 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 this Quality  
 48  
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 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 and BVL shall comply with such request.  
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 prior written 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 in advance by Customer.  
E.6.3 All materials purchased for use in the manufacture, storage and shipping of Product will be purchased, received, inspected as appropriate, tested as appropriate, stored, and handled in accordance with BVL’s SOP’s, the Master Production Record, if applicable, and Applicable Law. 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 and Customer to access the DMF. The DMF and information in the DMF may be used by the Customer to prepare regulatory filings. In addition, BVL shall, upon Customer’s request, assist Customer with all other applicable filings for the U.S. and 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, the Master Production Record, procedures mutually agreed to in writing between Customer and BVL and Applicable Law. 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 BVL will adhere to any regulations regarding storage of different types of Products.  
E.8.3 The Manufacturing of Customer’s Product by BVL must adhere to the Specification and the Master Production Record as mutually agreed upon, and BVL will Manufacture Product in compliance with all cGMPs and Applicable Law. 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 BVL shall test Product 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 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. BVL will be responsible for ensuring that the operations of any third party vendor are consistent with BVL’s obligations under this Agreement and comply with the terms of this Agreement. BVL will audit such third party vendors as part of BVL’s standard vendor audit program and at other times at the reasonable request of Customer.  
E.9.3 Customer will provide BVL with 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 investigate, and notify Customer within three (3) business days, whenever there is a significant deviation from stated procedures or specifications identified. A significant deviation is defined as any Out Of Specification (OOS) result, including results that are outside processing parameters, and/or any manufacturing, packaging, labeling, or testing deviation that may affect the quality, safety or efficacy of the Product. BVL will supply the result of any investigation to Customer Immediately upon completion but in any event prior to release of documents to  
 50  
Customer. Customer approval shall be obtained in writing (fax or PDF electronic document confirmation is acceptable) for any significant deviation. The approval or a request for additional information must be received within five (5) business days of the completion of the investigation and Customer’s having been furnished the full results. BVL will only release/reject a Batch as an outcome of a BVL and Customer approved investigation report and Applicable Law. In the event of conflict, BVL may release or reject any Batch at its sole discretion subject to Customer’s right to reject the Batch. Customer is responsible for the final product disposition of a product released by BVL.  
All deviations including, but not limited to, those covered by the preceding paragraph, will be investigated and fully documented by BVL in accordance to BVL procedures and Applicable Law. This documentation will be retained as part of the batch documentation for the Batch affected. When deemed necessary, Customer reserves the right to request that BVL perform a more in-depth investigation of a deviation and BVL will comply with such request. BVL and Customer will work together in determining the need for additional investigational work. 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 two (2) 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 and Applicable Law. Approval of the investigation report 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 (with a copy to Customer)  
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.  
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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 test results, test samples and supporting data, COC, COA and batch records as required.  
 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 forty-five (45) 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.  
 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 Applicable Law and BVL SOPs, which, as to the portions of such SOP that are Product-specific, shall be acceptable to Customer, which such acceptance shall not be unreasonably withheld.  
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, Master Production Records, Applicable Laws and BVL SOPs, which, as to the portions of such SOP that are Product-specific, shall be acceptable to Customer, which such acceptance shall not be unreasonably withheld.  
 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. Unless otherwise set forth in the applicable Proposal, all stability related activities under the responsibility of BVL shall be completed in accordance with Applicable Law and BVL SOPs, which, as to the portions of such SOPs that are Product-specific, shall be acceptable to Customer, which such acceptance shall not be unreasonably withheld.  
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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 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 mutually approved by BVL and Customer. The MPV will contain all of the required activities and the acceptance criteria. The MPV will be executed on at least [\*] 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 BVL shall communicate such problems to Customer. If the problems cannot be resolved, the MPV must be repeated on additional Batches until at least [\*] of Customer’s Product meet all specification requirements. Any problems encountered during the execution of the MPV must be documented by BVL. BVL will bear the cost of any repeat MPV, including the cost of the API, if caused by the negligence or intentional misconduct of BVL or any of its affiliates or any of their agents or employees, breach by BVL of any of its obligations under this Agreement or failure of BVL to follow the Master Production Record or cGMP; otherwise the expense will be borne by Customer, provided BVL has given Customer a revised quotation prior to commencing such additional work and has received a purchase order from Customer authorizing BVL to proceed.  
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, or sooner as required, of complaints involving potential Product issues that may be related to Manufacturing. Upon written request by Customer, BVL will investigate the complaints as required and 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 its 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 an FDA inspection.  
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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.  
 E.18 Recall of the Marketed Product  
In the event of recall, withdrawal, or field correction of Product Manufactured under this Agreement, 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 one annual audit per Contract Year and other audits for cause to: (i) observe, inspect, and audit the manner in which BVL conducts Manufacture of Product(s); (ii) inspect BVL’s Facilities and records relating to Manufacture of Product, including 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 and Customer Equipment. Customer annual audits will be limited to 2 auditors for 2 days. BVL shall make such books and records available to Customer for review. In addition to audits, 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 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 except as set forth in a particular Proposal related to Development services. In addition to the other rights set forth in this Section, BVL agrees that Customer shall have the right to conduct a mock pre-approval inspection, which shall not count as an annual audit. BVL and Customer will review and mutually agree to requirements of the pre-approval inspection audit and BVL will provide a quotation if necessary.  
 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 are Product-specific or may impact Product or BVL’s ability to comply with the terms of this Agreement. BVL will provide Customer with the applicable or redacted written observations of all such regulatory audits in no more than 5 business days. If the inspection is specific to Product, Customer will have the right to have up to 2 representatives on site  
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 during the inspection to address product specific questions, and these representatives will be permitted to participate in the inspection, including, but not limited to daily and post-inspection wrap-up sessions related to Products. Customer shall provide to BVL any requested documents belonging to Customer 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.  
 E.19.4 BVL will use commercially reasonable efforts to remedy any defects, or issues identified in any audit conducted by Customer or a regulatory agency or other enforcement body as soon as possible.  
 E.19.5 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 two (2) weeks 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 and BVL will jointly be responsible for preparing an Annual Product Review (APR). In the event the documentation requirements for such APR are beyond what is customarily provided, BVL will provide such additional documentation for the APR to Customer in accordance with a proposal prepared by BVL and acceptable to Customer.  
The APR will include, but not be limited to data from all batches Manufactured during the year:  
 (i) Analytical data;  
 (ii) Critical in-process results;  
 (iii) Failure to meet specifications;  
 (iv) Significant deviations, non-conforming events and related investigations;  
 (v) Changes to processes and analytical methods;  
 (vi) Results of stability monitoring programs;  
 (vii) Quality-related returns, complaints, recalls and rejections;  
 (viii) A list of corrective actions and preventative actions taken during the year.  
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BVL and Customer will meet at a minimum of once a year to review process metrics, including, but not limited to (i) cycle time, (ii) yield, (iii) time to resolving deviations, and (iv) other metrics reasonably requested by Customer or agreed upon by the parties. At each such meeting, BVL and Customer will also discuss ways to improve the process, including any recommendations as to whether any corrective actions or revalidation should occur.  
 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)  
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Quality Agreement Distribution of Responsibility Matrix:  
 Responsible Party  
Item  
 Activity  
 Customer  
 BVL  
1. Purpose and Term of the Quality Agreement   
 Define purpose and term of the Quality Agreement X X  
2. Quality Responsibility   
 Assure that all activities associated with production of Customer’s Product are performed in compliance with cGMP as set forth in 21 CFR part 211, the European GMPs, and any other regulatory region the drug is for distribution for clinical or commercial use, as provided in the Regulatory Territory. X X  
 Review all batch documentation and test results, approve, and release Product to Customer. X  
 Review appropriate batch documentation and test results, and release and disposition Product for clinical or commercial use X   
 Maintain training records for all BVL personnel that perform cGMP functions relating to the Product. X  
3. Regulatory Compliance and Product Licensure   
 Responsible for product licensure, annual reports, and other regulatory filings as defined in 21 CFR 314 or other regulatory agencies for the Territory. X   
 Provide Customer with information required for regulatory filings pursuant to written proposals provided by BVL X  
 Prepare and submit regulatory filings to the appropriate authorities X   
4. Change Control   
 Establish and maintain appropriate change control procedures, including but not limited to revisions, changes or modifications to documentation, processes, equipment, utilities or facilities that affect the defined operation and processes or have the potential to affect the quality, purity, safety, or efficacy of the Product. X  
 57  
 Responsible Party  
Item  
 Activity  
 Customer  
 BVL  
 Prepare and submit a change request or notification to Customer for all proposed changes to documentation, facilities/equipment, manufacturing process, test methods, and specifications that affect Customer manufacturing process. X  
 Review proposed changes, assess the impact on regulatory filings, and approve changes. X X  
4.1 Master Production Record  
 Draft and maintain MPR X  
 Review and approve MPR X X  
4.2 Specifications  
 Draft and approve non-compendial raw material specifications X X  
 Draft and approve API specification X X  
 Draft and approve Product Specification X X  
4.3 Packaging and Labeling Specifications  
 Prepare draft packaging and labeling specifications X X  
 Approve label and packaging specifications X X  
 Implement packaging and labeling procedures X  
4.4 Product Changeover  
 Perform cleaning validation studies as necessary to demonstrate and document suitable clearance of other products for the equipment used for Customer per BVL SOPs. X  
4.5 Changes to the Plant  
 Notification to Customer of all changes to the facility that could impact Customer’s Product X  
5. Documentation   
 Retain Batch production documentation for 7 years after a batch is manufactured. X  
 Mutually agree upon disposition of documentation following the 7 year retention period. X X  
 Maintain product specific documentation (e.g., master batch records, SOPs, validation documentation, etc.) in accordance with BVL SOPs. X  
6. Materials   
 Establish quality requirements for raw materials, process components, and packaging material. X X  
 Establish raw material specifications. X X  
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 Responsible Party  
Item  
 Activity  
 Customer  
 BVL  
 Establish a vendor qualification program for vendors of all raw materials to be used in GMP manufacturing (excluding API). X  
 Qualify API vendor X   
 Promptly provide vendor change notifications X X  
 Approve vendor changes X X  
 Ensure that all raw materials (excluding API), consumables, and packaging component suppliers are qualified or reviewed according to defined requirements and procedures, and to maintain file of vendor qualifications X  
 Prepare and maintain a xxxx of materials that includes specifications and acceptable grades for required raw materials and consumables. X X  
 Perform raw material and supplies procurement, QC testing, and material handling and submission of samples to outside testing laboratories (as applicable) for BVL Supplied Composition. X  
 Perform API procurement, QC testing, and material handling X   
 Maintain programs and procedures for returning unused or damaged goods. X X  
 Maintain and archive raw material C of A’s for final release. X  
 Maintain and archive API C of A’s X   
 Obtain approval from Customer if BVL needs to subcontract the analytical release testing of raw materials X  
 Approve BVL subcontracted analytical testing facility per BVL SOP X   
7. Product Specification   
 Establish and approve Specification X X  
 Perform Product testing according to validated procedures and approved Specification X  
8. Manufacturing and Packaging of the Product   
 Ensure all manufacturing operations are conducted in compliance with cGMPs, SOPs, and the Master Production Record X  
9. Testing of Product   
 Review and approve all test methods and validation protocols and reports. X X  
 Validate all test methods, as appropriate X X  
 Maintain Reference Standard according to BVL SOP’s and specifications X  
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 Responsible Party  
Item  
 Activity  
 Customer  
 BVL  
 Store QC stability samples for specified time period X  
 Qualify and approve any contract lab used for product testing X X  
10. Notification and Approval of Deviations   
 Ensure a thorough investigation and justification of any deviation to stated procedures or out of specification (OOS) result X  
 Ensure all investigation reports are reviewed and completed prior to completion of the batch production record review X  
 Promptly notify Customer within 3 business days of initiation of investigation of any deviation or OOS that affects the material or Product being tested per BVL SOP. X  
 Provide technical, compliance, and regulatory oversight in support of the investigation X   
 Hold and segregate material or Product that does not conform to in-process or release specifications. X  
 Prepare and approve investigation report X  
 Review and release/reject material or Product Batch as an outcome of an approved investigation report. X X  
 Disposition Product as an outcome of the approved investigation X   
 Establish procedures for the releasing/rejecting failed Batches of raw material or Product. X  
 Promptly notify Customer of cause for investigation and proposed action plan for raw material or Product failures. X  
 Participate in Product investigations, as needed. X   
 Generate Investigation Report. X X  
 Review and approve Investigation Report X X  
11. Release and Shipment of Product   
 Provide a copy of executed Batch Records, deviations and investigation reports, and any applicable documentation within 1 week of BVL Batch release X  
 Generate BVL Certificate of Analysis X  
 Generate BVL Certificate of Compliance X  
 60  
 Responsible Party  
Item  
 Activity  
 Customer  
 BVL  
 Perform Product disposition X   
 Establish and maintain shipping procedures and documentation. X X  
 Insure Shipping of Product from BVL to Customer destination is in compliance with the Specifications for the Product, specifically including without limitation temperature shipping requirements X   
 Approve shipping configuration and procedures. X X  
 Package Product for shipment to specified distributors. Store and transport Product to conform to label copy storage conditions. X  
 Request shipment of Product, specifying date of shipment, shipping address, lot number, quantity, etc. X   
 Ship Product as specified in Batch PO per SOP. X  
12. Retained Samples of the Product   
 Store retain samples of all Product composition X  
 Specify the number of Product retains per lot, the retain period, and arrange for the appropriate storage of the Product retains X   
13. Storage of Product   
 Define storage conditions for Product. X   
 Securely store Product under controlled temperature and storage conditions as specified in Product Specification. X  
 Establish and maintain an appropriate environmental monitoring program of storage conditions X  
14. Stability Activities   
 Prepare stability protocols. X  
 Review and approve stability protocols X X  
 Conduct stability studies per approved protocols. X  
 Compile data on a regular basis, and provide regular updates to Customer. X  
 Prepare and approve final stability reports. X   
 Provide stability updates to Regulatory Authorities in Annual Reports or as needed. X   
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 Responsible Party  
Item  
 Activity  
 Customer  
 BVL  
15. Process Validation   
 Prepare Manufacturing Process Validation (MPV) Plan X  
 Review and approve MPV X X  
 Generate process validation protocols X  
 Review and approve process validation protocols X X  
 Perform validation studies per approved protocols. X  
 Generate validation data in a timely fashion and maintain raw data and supporting documentation X  
 Prepare validation reports. X  
 Review and approve all final reports. X X  
16. Product Complaints   
 Receive notice of complaints X   
 Inform BVL within 5 business days, or sooner as required, of complaints involving potential product tampering or adverse medical event X   
 Upon a suspected manufacturing issues and upon mutual agreement of the Parties, perform investigation and provide a written report within 30 business days, or sooner if mutually agreed X  
 Respond to Product complaints with respect to known adverse events related to the Product X   
 Support the investigation of a potential SAE and provide information allowing for meeting regulatory reporting requirements X  
 Maintain a record of all complaints, and notify Health Authorities as required. X   
17 Returned Goods   
 Specify and document handling of returned goods. X   
18 Recall of Marketed Product   
 Notify BVL, regulatory authorities, and Customers, and all relevant Parties of product recall. X   
 Perform investigation, as appropriate. X X  
 Maintain copies of all recall investigations performed on behalf of a Customer and as required by regulations. X  
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 Responsible Party  
Item  
 Activity  
 Customer  
 BVL  
19 Audits and Inspections of Facilities and Product   
 Perform audit of BVL on an annual basis, as a mock PAI, or as needed on a “for cause” basis X   
 Conduct periodic audits of raw material vendor’s quality systems in accordance with BVL SOPs. X  
 Manage, coordinate and host regulatory inspections: PAI, general GMP, for-cause, MHRA, and EMEA GMP inspections etc. X  
 Support product specific PAI or other inspection with up to 2 Customer staff on site during the inspection. As appropriate, Customer staff will be permitted to respond to product specific questions and participate in Product-specific wrap up sessions. X   
 Notify Customer within 24 hrs of receipt of notification of inspection by regulatory authorities for Customer specific inspection. X  
 Prepare written responses to regulatory actions specific to facility, operations and site specific, non-Customer related processes X  
 Prepare written responses to written regulatory observations specific to Product. X X  
 Prepare, review, and approve responses to agency observations issued directly to the site. Respond to PAI observations within 15 days and all other inspection observations within 30 days or the time specified by that agency, which ever is less. X  
 Provide a copy of redacted inspection observations and responses to Customer within one week of completion of said documents. X X  
 Support product specific regulatory inspections and participate in the Development of product specific responses or inquiries. X X  
 Support the preparation of regulatory responses that support inquires made to Customer by authorized regulatory agencies X X  
 Observe operations on an as needed basis and notify BVL in advance. X   
20 Reprocessing   
 Initiate reprocessing request X X  
 Document rationale, justification, and directions for reprocessing X X  
 Approve reprocessing X X  
 63  
 Responsible Party  
Item  
 Activity  
 Customer  
 BVL  
21. Annual Product Review   
 Preparation and submission of the Annual Product Review (APR) X X  
 Providing data for APR X X  
22. Certifications   
 Provide certification of Customer supplied Composition to be free from BSE/TSE X   
 Provide certification of QP when applicable for Products shipped for use in EU countries X   
 Provide Certification of facility which produced API for use in Products when applicable for Products shipped for use in the EU countries X   
 Provide Certificate of Analysis and Certification of each batch of API shipped to BVL for use in Product to be shipped to EU countries X   
 Customer’s Qualified Person shall generate and approve a Certificate of Batch Release and Certificate of Compliance to EU GMP for each Batch of Product Manufactured by BVL for Customer which is distributed for clinical or commercial use in EU countries X   
 64  
Attachment “F”  
Customer Supplied Equipment  
This page left intentionally blank.  
 65  
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  
Xxxxxxx, Xxxx 00000  
Dear BVL COMPLIANCE MANAGER,  
Please take notice that Targanta Therapeutics Corporation, 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 Targanta Therapeutics Corporation. 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  
 66  
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 Targanta Therapeutics Corporation  
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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:  
Oritavancin for Injection 100mg  
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  
 68  
Attachment “J”  
Certificate of Analysis for use in the European Union Member States  
Ben Venue Laboratories, Inc.  
A Boehringer Ingelheim Company  
000 Xxxxxxxxxx Xxxx  
Xxxxxxx, Xxxx 00000  
Phone: (000) 000-0000  
Fax: (000) 000-0000  
Site of Manufacture: Ben Venue Laboratories, Inc.  
Certificate of Analysis  
 Targanta Therapeutics Corporation Certificate Date:   
000 X. Xxxx Xxxxxx, Xxxxx 000 Delivery References:   
Xxxxxxxxxxxx, XX 00000 XXX Purchase References:   
(000) 000-0000 Order References:   
(000) 000-0000 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 Targanta Therapeutics Corporation  
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