

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

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**FORM 10-Q/A**

(Amendment No. 1)

(Mark One)

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

For the quarterly period ended March 31, 2012

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 333-169785

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**LANTHEUS MEDICAL IMAGING, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State of incorporation)

**51-0396366**  
(IRS Employer Identification No.)

**331 Treble Cove Road, North Billerica,  
MA**  
(Address of principal executive offices)

**01862**  
(Zip Code)

**(978) 671-8001**  
(Registrant's telephone number, including area code)

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

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

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

The registrant had 1,000 shares of common stock, \$0.01 par value per share, issued and outstanding as of May 14, 2012.

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#### **EXPLANATORY NOTE**

The registrant has prepared this Amendment No. 1 (the "Amendment") on Form 10-Q/A to its Quarterly Report on Form 10-Q for the period ended March 31, 2012 (the "Form 10-Q") solely for the purpose of refileing Exhibits 10.2, 10.4, 10.5 and 10.6 to the Form 10-Q in response to comments received from the Staff of the Securities and Exchange Commission regarding a request for confidential treatment of certain portions of such exhibits when they were initially filed with the Form 10-Q. No revisions are being made to the Company's financial statements and this Amendment does not reflect events occurring after the filing of the Form 10-Q, or modify or update those disclosures that may be affected by subsequent events, and no other changes are being made to any other disclosure contained in the Form 10-Q.

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**Item 6. Exhibits**

- 10.1\*† Second Amendment, effective as of January 1, 2012, to the Distribution Agreement, dated as of October 31, 2001, by and between Lantheus Medical Imaging, Inc., formerly known as Bristol-Myers Squibb Medical Imaging, Inc., and Medi-Physics, Inc., doing business as G.E. Healthcare Inc.
- 10.2† Manufacturing and Supply Agreement, dated as of February 1, 2012, for the manufacture of DEFINITY® by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterStier LLC.
- 10.3\*† Amendment No. 1, effective as of February 9, 2012, to the Amended and Restated Cardiolite License and Supply Agreement by and between Lantheus Medical Imaging, Inc. and Cardinal Health 414, LLC entered into as of January 1, 2009 and effective as of January 1, 2004.
- 10.4† Settlement and Mutual Release Agreement, effective as of March 20, 2012, by and between Ben Venue Laboratories, Inc. and Lantheus Medical Imaging, Inc.
- 10.5† Transition Services Agreement, effective as of March 20, 2012, by and between Ben Venue Laboratories, Inc. and Lantheus Medical Imaging, Inc.
- 10.6† Manufacturing and Service Contract for Commercial Products, entered into as of March 20, 2012, by and between Ben Venue Laboratories, Inc. and Lantheus Medical Imaging, Inc.
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14 Securities Exchange Act Rules 13a-14(a) and 15d-14(a), pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14 Securities Exchange Act Rules 13a-14(a) and 15d-14(a), pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002.

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\* Previously filed.

† Confidential treatment requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

LANTHEUS MEDICAL IMAGING, INC.

By: /s/ Donald R. Kiepert

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Name: Donald R. Kiepert  
Title: *President and Chief Executive Officer*  
Date: September 27, 2012

LANTHEUS MEDICAL IMAGING, INC.

By: /s/ Jeffrey E. Young

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Name: Jeffrey E. Young  
Title: *Chief Financial Officer*  
Date: September 27, 2012

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## EXHIBIT INDEX

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[Item 6. Exhibits](#)

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CONFIDENTIAL TREATMENT REQUESTED

INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND NOTED WITH "\*\*\*\*\*". AN UNREDACTED VERSION OF THIS DOCUMENT HAS ALSO BEEN PROVIDED TO THE SECURITIES AND EXCHANGE COMMISSION.

CONFIDENTIAL

Execution Version

## MANUFACTURING AND SUPPLY AGREEMENT

**[DEFINITY® (Perflutren Lipid Microsphere) Injectable Suspension]**

This Manufacturing and Supply Agreement (this "Agreement"), dated as of February 1, 2012 (the "Effective Date"), is hereby entered into by and between **Lantheus Medical Imaging, Inc.**, a corporation organized and existing under the laws of Delaware with its principal place of business at 331 Treble Cove Road, North Billerica, MA 01862 ("LMI"), and **Jubilant HollisterStier LLC**, a limited liability company organized and existing under the laws of Delaware with a place of business at 3525 North Regal Street, Spokane, Washington, 99207 ("HSL"). LMI and HSL are referred to herein individually as a "Party" and collectively as the "Parties".

## RECITALS

WHEREAS, HSL is experienced in the manufacture and supply of products;

WHEREAS, LMI desires that HSL manufacture the Product (as defined below) for and supply the Product to LMI on the terms and conditions set forth in this Agreement; and

WHEREAS, HSL is willing to manufacture the Product for and supply the Product to LMI on the terms and conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the Parties, intending to be legally bound, hereby agree as follows:

1. DEFINITIONS

1.1 *Defined terms.* As used herein, the following terms shall have the following meanings:

(a) "Affiliate" means any corporation or other entity which controls, is controlled by, or is under common control with, a Party to this Agreement. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other ownership interest of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint fifty percent (50%) or more of the members of the governing body of the corporation or other entity.

(b) "API" means the pharmacologically active drug substance, specifically

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\*\*\*\*, which is used to manufacture Product pursuant to the Product NDA.

(c) “Batch” means a specific quantity of Product that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(d) “cGMPs” means the current good manufacturing practices in each Territory, as may be amended or supplemented from time to time, including the current good manufacturing practices required by the FDA pursuant to 21 CFR Parts 210 and 211 and ICH Q7, each as amended from time to time.

(e) “CMC” means (i) manufacturing process development for all presentations of Product; (ii) all chemistry, manufacturing and control procedures necessary for the manufacturing, testing and quality control release of all presentations of the Product; and (iii) sourcing and testing of all raw materials and components used in the production of all presentations of Product.

(f) “Calendar Quarter” means any period of three consecutive calendar months commencing with the first day of any January, April, July, or October.

(g) “DMF” means a Drug Master File as described in 21 CFR 14.420.

(h) “FDA” means the United States Food and Drug Administration or any successor entity thereto.

(i) “Forecast” has the meaning set forth in Section 2.2(a).

(j) “Initial Forecast” has the meaning set forth in Section 2.2(a).

(k) “Intellectual Property” means all right, title and interest in or relating to intellectual property, whether protected, created or arising under the laws of the United States or any other jurisdiction, including: (i) all patents and applications therefor, including all continuations, divisionals, and continuations-in-part thereof and patents issuing thereon, along with all reissues, reexaminations and extensions thereof; (ii) all copyrights and all mask work, database and design rights, whether or not registered or published, all registrations and recordings thereof and all applications in connection therewith, along with all reversions, extensions and renewals thereof; (iii) all trade secrets; and (iv) all other intellectual property rights arising from or relating to Technology.

(l) “LMI Materials” means the materials supplied by LMI to HSL, as identified in the Proposal(s) (including, but not limited to, the API), which shall be used to manufacture Product pursuant to the Product NDA.

(m) “Lot” means a Batch, or a specific identified portion of a Batch, which consists of at least \*\*\*\*L of bulk solution for conversion into Product.

(n) “Product” means the final finished dosage form presentations of

DEFINITY® (Perflutren Lipid Microsphere) Injectable Suspension (or such other name as LMI may choose to use in the Territory) manufactured pursuant to the Product NDA and suitable for distribution in commerce in the Territory.

(o) “Product NDA” means the New Drug Application filed with the FDA for the Product pursuant to the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, and any amendments or Supplemental New Drug Applications thereto, or documents incorporated by reference.

(p) “Proposals” means proposals and quotations submitted by HSL to LMI and mutually accepted by both Parties in writing (including the final version of Quotation No: 973-5-11), copies of which shall be attached hereto, and are a part hereof. In the event of any conflict between the Proposal(s) and this Agreement, the terms of this Agreement shall control.

(q) “Quality Agreements” means the agreements described in Section 5.7.

(r) “Specifications” means the written specifications for the Product attached hereto as Exhibit 1.1, as the same may be amended from time-to-time pursuant to the provisions of Section 2.7, and the quality standards, including tests, analytical procedures and acceptance criteria, that are established to confirm the quality of the Product which are mutually agreed to in writing and contained or referenced in the Master Batch Record for the Product or as otherwise mutually agreed to in writing by the Parties.

(s) “Subsequent Forecast” has the meaning set forth in Section 2.2(a).

(t) “Technology” means, collectively, all information, designs, formulae, algorithms, procedures, methods, techniques, ideas, know-how, research and development, technical data, programs, subroutines, tool design, material specifications, processes, inventions (whether patentable or unpatentable and whether or not reduced to practice), apparatus design, creations, improvements, works of authorship and other similar materials, and all recordings, graphs, drawings, reports, analyses, and other writings, and other tangible embodiments of the foregoing, in any form whether or not specifically listed herein, and all related technology, that are used in, incorporated in, embodied in, displayed by or relate to, or are used in connection with the foregoing. For clarification Technology specifically excludes actual equipment.

(u) “Term” shall have the meaning set forth in Section 3.1 of this Agreement.

(v) “Territory” means the countries or regions described in Exhibit 1.2. Additional countries or regions may be added to the Territory at LMI’s request and reasonable cost and expense (including, as evidenced by reasonable documentation made available to LMI, HSL’s reasonable internal personnel costs and out-of-pocket expenses) upon at least thirty (30) days prior written notice.

1.2 *Interpretation.* References in this Agreement to the singular include references to the plural and vice versa. Unless the context otherwise requires, references in this Agreement to Articles, Sections, and Exhibits shall be deemed references to Articles and Sections of, and

Exhibits to, this Agreement. Unless the context otherwise requires, the words “hereof”, “hereby” and “herein” and words of similar meaning when used in this Agreement refer to this Agreement in its entirety and not to any particular Article, Section or provision of this Agreement. Any reference to any federal, state or local statute or law shall be deemed also to refer to all rules and regulations promulgated thereunder, unless the context requires otherwise.

2. DEVELOPMENT SERVICES AND PRODUCT SUPPLY TERMS

2.1 *Services.*

(a) *Development.* HSL shall perform development services in support of the manufacture of Product as defined by the Proposal(s) and for the compensation set forth for such development services in the Proposal(s). HSL hereby represents and warrants that it has the experience, capability and resources, including but not limited to sufficient personnel and supervisors, to efficiently and expeditiously perform such development services in a professional, competent and timely manner. HSL further represents and warrants that it will at all times devote the necessary personnel and supervisors to perform such development services and that, in fulfilling its obligations, HSL shall assign only persons with the appropriate training and qualifications to perform such services. LMI and HSL shall use commercially reasonable efforts to qualify HSL as a supplier of Product under the Product NDA.

(b) *No Debarment.* HSL represents that neither it, nor any of its employees, agents or consultants performing services under this Agreement, have been debarred, suspended, or otherwise excluded by the FDA or any other regulatory authority from conducting business and, to the best of its knowledge after due inquiry, are not under consideration to be debarred, suspended or otherwise excluded. HSL agrees to notify LMI as soon as practicable upon HSL’s learning of the occurrence of any such debarment, conviction, investigation or inquiry relating to a potential debarment, suspension or exclusion, of any person performing services pursuant to this Agreement and agrees that said person shall be immediately prohibited from performing services under this Agreement.

(c) *No Conflict.* Each Party warrants and represents that no trade secrets or other confidential information of any other person, firm, corporation, institution or other entity will be wrongfully disclosed by it to the other Party or any third party in connection with any of the services called for hereunder. Each Party further warrants and represents that none of the provisions of this Agreement, nor the services which will be performed by HSL pursuant to the work to be performed hereunder, contravenes or is in conflict with any agreement of such Party or its Affiliates with, or obligation to, any other person, firm, corporation, institution or other entity including, without limiting the generality of the foregoing, employment agreements, consulting agreements, service agreements, disclosure agreements or agreements for assignment of inventions. HSL shall not subcontract with any third party or use Affiliates or agents to perform any of its obligations hereunder without the prior written consent of LMI (not to be unreasonably withheld, delayed or conditioned). HSL shall cause all of its employees and any permitted subcontractor, agent or Affiliate to be bound by, and to comply with, all

confidentiality, quality assurance, regulatory and other obligations and requirements as set forth in this Agreement.

2.2 *Purchase and Sale.* HSL shall manufacture, sell and deliver to LMI, and LMI shall purchase from HSL, the Product for jurisdictions in the Territory (with respect to each such jurisdiction, following HSL's qualification to manufacture Product in such jurisdiction) on the terms and conditions set forth in this Agreement. The following provisions shall apply with respect to these Products:

(a) (i) *Forecasts; Orders.* LMI shall send to HSL an \*\*\*\* (\*\*\*\*) month forecast (the "Initial Forecast") for the volume of Product which LMI expects to have delivered from HSL during such \*\*\*\*-month period. LMI shall provide the Initial Forecast for Product to HSL within \*\*\*\* (\*\*\*\*) days after HSL is approved as a supplier of Product under the Product NDA. LMI shall thereafter update such forecast at least \*\*\*\* prior to the first business day of each calendar month thereafter (a "Subsequent Forecast", and together with the Initial Forecast, a "Forecast"), providing HSL with a rolling \*\*\*\* month forecast for Product. Each Forecast shall include an estimated number of Batches for each month during the \*\*\*\*-month period covered by such Forecast. Amounts set forth in a Forecast are estimates, to be used for planning purposes only, and Forecasts shall not constitute binding purchase orders, except that the first \*\*\*\* (\*\*\*\*) months of each Forecast shall be binding upon LMI and LMI shall place purchase orders corresponding to the binding portion of such Forecast. In the event LMI does not place purchase orders against the binding portion of a Forecast, HSL may (but shall not be required to) deem such binding Forecast as a purchase order for Product covered by the binding portion of the Forecast. HSL will use all commercially reasonable efforts to accommodate any changes in quantities of Product ordered by LMI.

(ii) Subject to the terms of this Agreement (including, but not limited to, Sections 5.1, 5.5 and 9.5), LMI agrees that, during each calendar year of this Agreement (with a pro-rata adjustment as applicable for any portion thereof), it shall place orders with HSL for at least \*\*\*\* percent (\*\*\*\*%) of its aggregate requirements for Product in the jurisdictions in the Territory where HSL is approved as a qualified supplier of the Product. This requirement shall commence on the \*\*\*\* day after HSL is qualified as a supplier of the Product under the Product NDA and end on the earlier of the termination or expiration of this Agreement with respect to periods thereafter. In addition, this requirement is expressly conditioned upon reasonably acceptable notice of HSL's approval as a supplier of Product for a jurisdiction in the Territory. During any period in which HSL's manufacture for a jurisdiction is not in compliance with cGMPs for such jurisdiction and/or not in material compliance with the applicable laws of such jurisdiction, LMI's requirements for such jurisdiction shall not be included in the aggregate requirements of LMI for purposes of computing the amount of Product required to be ordered from HSL. In the event HSL cannot fill a purchase order issued in accordance with a Forecast, the quantities in such purchase order shall be deemed to have been ordered from HSL for purposes of LMI's requirements for placing orders pursuant to this section.

(iii) Without limiting HSL's remedies in the event of a breach of the preceding

paragraph, in the event LMI fails to order the requirements set forth above the Parties may discuss and agree on making HSL whole (including recovery of lost profits), such as by way of example through one or more of the following mechanisms: \*\*\*\*.

(iv) LMI shall maintain accurate and complete books and records of its purchases for the jurisdictions in the Territory where HSL is a qualified supplier of the Product as to enable LMI and its Affiliates to verify their purchases of Product in such jurisdictions. Upon reasonable advance written notice and subject to a confidentiality agreement reasonably acceptable to LMI, at the written request of HSL, LMI shall permit an independent certified public accounting firm or consultant selected by HSL and reasonably acceptable to LMI to have access during normal business hours to such of the records of LMI as may be reasonably necessary to verify the accuracy of LMI's orders for the immediately preceding calendar year.

(b) *Purchase Orders; Rejection of Orders.* LMI will provide HSL with a firm purchase order at least \*\*\*\* (\*\*\*\*) days prior to the earliest delivery date specified in such purchase order. All purchase orders will be in multiples of the minimum Batch size. All purchase orders will be sent by facsimile or electronic mail to the address specified by HSL. HSL shall use commercially reasonable efforts to accept each purchase order and confirm the date of manufacturing and shipment within \*\*\*\* (\*\*\*\*) business days of receipt thereof. Such purchase order shall be deemed accepted by HSL if HSL does not reject a purchase order within the \*\*\*\* business-day period. In addition, HSL will use commercially reasonable efforts to accommodate any increase in quantities of Product Forecasted by LMI. LMI reserves the right to cancel any purchase order after acceptance by HSL. Unless otherwise agreed to by a duly authorized representative of HSL in writing, however, should LMI cancel or postpone all or any portion of any purchase order (or deemed purchase order pursuant to section 2.2(a)) for commercial or pre-commercial batches within \*\*\*\* (\*\*\*\*) calendar days of the acceptance date of such purchase order, LMI shall pay HSL a fee of \*\*\*\* for each vial in a cancelled or postponed purchase order. Should LMI cancel or postpone all or any portion of any purchase order (or deemed purchase order pursuant to section 2.2(a)) for pre-commercial or commercial batches \*\*\*\* (\*\*\*\*) and \*\*\*\* (\*\*\*\*) calendar days of the acceptance date, LMI shall pay HSL a fee of \*\*\*\* for each vial in a cancelled or postponed purchase order. LMI may not cancel all or any portion of any purchase order (or deemed purchase order pursuant to Section 2.2(a)) after \*\*\*\* (\*\*\*\*) days after the acceptance date of such purchase order. HSL will make a good faith effort to \*\*\*\*.

(c) *Prices.* Commercial pricing for Product supplied by HSL shall be based on the amounts of Product purchased for each calendar year, as set forth in Exhibit 1.3. Because the Parties do not know the amount of Product that will be purchased in a calendar year, the estimated price will be invoiced by HSL and adjusted as provided herein. The estimated price will be based upon the most recent Forecast provided by

LMI. For purposes of calculating the price per vial, LMI shall be credited with purchasing amounts ordered from HSL (in each case up to \*\*\*\*% of Forecasted amounts), but, in the Parties' reasonable and good faith determination, could not be supplied by HSL through no fault of LMI, and the registration lots shall be deemed to be commercial quantities of Product ordered by LMI during the first calendar year of commercial production. Pricing does not include stability testing since stability testing is being conducted by LMI.

Beginning on \*\*\*\* and on each succeeding anniversary thereafter during the term of this Agreement, prices in the then current schedule of vial prices shall be increased by \*\*\*\*. Price increases shall be effective for all new purchase orders placed after the applicable anniversary. Pricing for pre-commercial and other activities is as in the Proposal, and shall be paid on the schedule set forth therein or, if none is set forth therein, then as provided in Section 2.4.

(d) *Superiority of Agreement.* The terms of this Agreement and of the Quality Agreements shall prevail over any inconsistent terms in any proposal, purchase order, acknowledgment or invoice, and no additional terms other than those set forth in this Agreement and the Quality Agreements or allowed pursuant to the terms of this Section 2.2 in a purchase order, acknowledgement or invoice shall be binding on either Party.

### 2.3 *Delivery.*

(a) *Schedule; Quantities.* HSL will ship, and LMI will take delivery, of all Product within \*\*\*\* (\*\*\*\*) days of the delivery date set forth in the applicable accepted purchase order. In the event that HSL, at any time during the term of this Agreement, has reason to believe that it will be unable to perform any of the services under this Agreement or meet the requested delivery date(s) specified in the purchase orders, HSL shall promptly notify LMI in writing of such delay(s) within \*\*\*\* (\*\*\*\*) business days of such determination. In the event that a Lot is delivered less than \*\*\*\* days after the specified delivery date, HSL shall not be liable, but if delivered \*\*\*\* (\*\*\*\*) or more days after the specified delivery date which had previously been accepted by HSL, as LMI's sole remedy therefor, HSL will invoice LMI for such Lot at \*\*\*\*. Cost of shipping, customs, duties and tariffs will be the responsibility of LMI.

(b) *Terms of Delivery.* Delivery terms shall be FCA HSL's manufacturing facility (which shall be HSL's facility in Spokane, WA), at which time risk of loss and responsibility for Product will transfer to LMI. FCA has the meaning assigned it in the ICC Incoterms, 2010. HSL shall ship the Product using LMI's designated carrier in accordance with LMI's instructions regarding destination, delivery date, temperature

control and such other factors as LMI reasonably believes are relevant for purposes of the delivery. HSL shall ship all Product to the locations designated by LMI.

2.4 *Payment Terms.* Invoices for commercial Product will reflect actual quantities of Product properly delivered in accordance with the applicable purchase order. Invoicing for commercial Product will be initiated by HSL upon HSL's review and approval of the Batch records and other certifications and documentation for such Product. All undisputed portions of invoices issued by HSL to LMI shall be paid within \*\*\*\* (\*\*\*\*) days after the date of receipt of the corresponding invoice. Such payments shall be made in U.S. dollars by check or wire transfer or by such other method as HSL and LMI shall reasonably designate from time to time. In no event shall LMI be responsible for any payments related to Product for which HSL was unable to satisfy its obligations under this Agreement, whether by Force Majeure Event or otherwise. Interest shall be payable on all undisputed amounts not paid on the due date at a rate of \*\*\*\*% for each month the amounts remain unpaid.

2.5 *\*\*\*\* Qualification.* LMI shall have the right to qualify \*\*\*\* as a manufacturer of Product, and to seek and obtain regulatory approval(s) of such \*\*\*\*. If LMI desires to exercise its rights in this Section 2.5, LMI shall notify HSL of such decision in writing ("\*\*\*\* Qualification Notice"). Upon receipt of such \*\*\*\* Qualification Notice, the Parties will agree in good faith upon a reasonable schedule for commencement and completion of the \*\*\*\* qualification. Any \*\*\*\* qualification under this provision will be pursuant to a protocol established by LMI and mutually agreed to by the Parties. Such Protocol shall include the delivery of copies of relevant Product-specific documents required to carry out the \*\*\*\* qualification. HSL hereby agrees to use reasonable efforts to \*\*\*\*. LMI shall pay \*\*\*\* as well as \*\*\*\* in carrying out the requested \*\*\*\* qualification, provided that \*\*\*\* has been made available to LMI.

2.6 *Inventory; Packaging Information.* HSL shall, at all times commencing \*\*\*\* (\*\*\*\*) days after LMI's first Forecast, during the Term, maintain inventory levels of components and raw materials required to manufacture the volume of Products forecasted by LMI for the next \*\*\*\* (\*\*\*\*) \*\*\*\* pursuant to Section 2.2(a) of this Agreement. At HSL's option, within \*\*\*\* (\*\*\*\*) \*\*\*\* of each calendar year, LMI shall purchase from HSL, at the price paid by HSL, such unused raw materials and components in good, saleable condition purchased by HSL in reliance on Forecasts (as set forth above) that could not be returned to the original supplier by HSL or used by HSL in the supply of Product to LMI during such calendar year due to lower orders of Product than Forecast to the extent not the fault of HSL, it being understood that HSL's suppliers generally do not accept returns, unless the Parties mutually agree that such materials will be used in the following calendar year. LMI shall provide HSL with all packaging and labeling information and designs, if applicable, including without limitation, all art work and usage instructions to be applied to each Product at least \*\*\*\* (\*\*\*\*) days in advance of any requirement that Product be delivered in packaged form to enable HSL to obtain the necessary packaging materials and meet such delivery requirements (provided, however, HSL shall use all commercially reasonable efforts to accommodate any changes requested by LMI with less than \*\*\*\* days advance notice). LMI will be fully responsible and

liable for the content and format of all labeling and artwork provided by LMI and used in connection with the supply of Product hereunder. HSL shall be solely responsible for ensuring that the content and format of all labeling and artwork used in connection with the supply of the Product, as provided by LMI, are accurately and consistently produced in accordance with the Specifications. The Parties shall cooperate to ensure that all packaging and labeling information and materials are compatible with HSL's equipment and specifications.

2.7 *Changes in Manufacturing Processes.* HSL reserves the right to implement reasonable process changes and improvements for manufacturing the Product during the Term, at its cost, but in all instances subject to LMI's prior written approval (not to be unreasonably withheld, delayed or conditioned). HSL agrees to notify LMI promptly and in advance of any such change or improvement. If any such change or improvement requires, in LMI's reasonable judgment, regulatory approval, HSL will provide drafts of the proposed filing(s) to LMI for review and LMI will provide its approval or comments within \*\*\*\* (\*\*\*\*) days from the date of receipt. In addition, HSL will make any changes to the process for manufacturing the Product requested by LMI, which changes shall be made at LMI's reasonable cost and expense (including the allocable cost of HSL personnel as evidenced by reasonable documentation made available to LMI). The Parties hereby agree to negotiate in good faith an adjustment to the \*\*\*\* of the Product to reflect any \*\*\*\* caused by the changes described in this Section 2.7. The Parties will in all events reasonably cooperate with the other Party in effecting any process changes or improvements reasonably requested by such Party.

2.8 *API and Other LMI Materials.* LMI will supply, at its expense, sufficient quantities of the LMI Materials to HSL's facility prior to \*\*\*\* to enable HSL to meet its obligations hereunder. HSL will provide LMI with an inventory report for the LMI Materials on a \*\*\*\* basis (or as otherwise agreed to by the Parties). All such LMI Materials shall conform to the specifications agreed to by HSL and LMI. Title to the LMI Materials shall remain at all times with LMI.

### 3. TERM; TERMINATION

3.1 *Term; Renewal.* Unless terminated sooner in accordance with the terms of this Agreement, this Agreement shall commence on the Effective Date and shall have an initial term of five (5) years, unless earlier terminated as provided herein. LMI shall have the right to extend this Agreement for an additional five (5) year period upon at least six (6) months prior written notice prior to the end of the initial term. Following the initial term and any additional term, this Agreement shall be automatically renewed for additional one year periods, unless either Party gives written notice to the other of its election to terminate this Agreement at least six (6) months prior to the end of the initial term or subsequent term. The initial term and any subsequent periods shall be referred to collectively as the "Term".

3.2 *Termination by Mutual Agreement.* This Agreement may be terminated by mutual written agreement of HSL and LMI at any time.

3.3 *Termination for Cause.* This Agreement may be terminated by a Party as follows:

(a) If a Party files a petition or similar action for its protection or is the subject of an involuntary petition or similar action not dismissed within ninety (90) days, under bankruptcy, insolvency, reorganization or receivership law, or such Party is placed in receivership, makes an assignment for benefit of creditors or is unable to meet its debts in the regular course of business, the other Party may elect to terminate this Agreement immediately by written notice to the first Party without prejudice to any right or remedy the other Party may have under the Agreement, including damages for breach, if any.

(b) In the event that a Party materially defaults under or materially breaches any of the provisions of this Agreement or the Quality Agreements, the other Party shall have the right to terminate this Agreement upon sixty (60) days' prior written notice, unless such material default or breach is cured during such sixty (60) day period (or in the event any breach is incapable of being cured in such time period, the other Party presents a plan to attempt cure of such breach and prevent similar breaches, which plan is reasonably acceptable to the terminating Party), in which event this Agreement shall continue in full force and effect.

(c) If LMI is the Party with the right to terminate this Agreement in accordance with Sections 3.3(b) due to the uncured material breach of HSL, LMI shall have the option to delay the termination and continue to have HSL supply LMI under this Agreement upon written notice to HSL detailing the same, until such time as (i) \*\*\*\* or (ii) the Parties mutually agree upon a terminal supply of Product under Section 3.4(d) of this Agreement so as to avoid any disruption of LMI's supply or sale of Products. For purposes of this Agreement, "terminal supply" means the amount of Product reasonably requested by LMI so as to avoid any disruption to LMI's supply or sale of Product. During any such period LMI must pay all invoices upon delivery.

(d) If HSL is not a qualified supplier of Product in the United States under LMI's NDA for the Product before the end of the \*\*\*\* (\*\*\*\*) \*\*\*\* of this Agreement, senior management of the Parties will attempt in good faith to resolve any outstanding issues and to negotiate any necessary adjustments to the terms of this Agreement. For purposes of clarity, LMI acknowledges that it shall not have the right to extend this Agreement for an additional five year period as described in Section 3.1 of this Agreement in the event that HSL is unable to be qualified as a supplier of Product in the United States before the end of the initial five-year term.

3.4 *Effect of Expiration or Termination; Accrued Rights; Surviving Obligations.* Upon any expiration or termination of this Agreement:

(a) *Product on Hand.* HSL shall notify LMI of the amount of Product it has on hand as of the effective date of any termination or expiration as a result of purchase orders placed by LMI, and LMI shall purchase such Product at the applicable price as set forth in this Agreement, but LMI shall not be required to purchase any Product (i) that fails to meet Specifications, (ii) for which HSL is unable to provide the certificates of analysis specified in Section 5.4 of this Agreement, (iii) for which HSL is unable to

provide the certificates of manufacturing compliance specified in Section 5.5, or (iv) that is appropriately rejected by LMI pursuant to Section 5.6. In addition LMI shall purchase from HSL, within \*\*\*\* (\*\*\*\*) days of HSL's request, at the price paid by HSL, unused raw materials or components purchased or ordered by HSL by HSL pursuant to any binding portion of the Forecast issued by LMI (subject to different periods for certain materials and components if such periods are set forth in the Proposal or otherwise pre-approved by the Parties in writing) or pursuant to requirements for pre-commercial batches to the extent such materials or components are in good, saleable condition and cannot be returned to the original supplier by HSL (if such return is requested by LMI) it being understood that HSL's suppliers generally do not accept returns and LMI shall also pay HSL's reasonable out-of-pocket expenses in connection with the foregoing returns. Upon signing of this agreement or shortly thereafter, JHS will provide to LMI a list of components associated with the manufacturing of Product, showing the respective lead time for procurement. If LMI does not object to such lead times in writing within ten days of receipt then such lead times for the associated components shall be deemed to be pre-approved. If LMI objects, the Parties shall mutually agree on same.

(b) *Regulatory Information.* On and as of the effective date of any termination or expiration (other than for LMI's breach of insolvency), or such earlier date as LMI may reasonably request prior to an upcoming termination or expiration (but no earlier than \*\*\*\* months prior to such termination or expiration), HSL shall provide reasonable assistance at LMI's cost and expense (including payment of HSL's reasonable internal personnel costs as evidenced by reasonable documentation made available to LMI) in transitioning to another supplier. HSL shall, at LMI's request promptly provide to LMI \*\*\*\* in the case of all of the foregoing to the extent needed to enable LMI or a third party to manufacture and obtain regulatory approval for the Product for commercial sale. LMI and its nominees may only use any information of HSL received pursuant to this Section 3.4(b) and Section 2.5 in connection with the Product. LMI and its nominees shall keep such information confidential as Confidential Information of HSL.

(c) *Orders in Progress.* In the event of any termination or expiration of this Agreement, HSL shall, unless such termination has occurred because of a material uncured breach or default by LMI under this Agreement, or LMI's insolvency, notwithstanding the effective date of any termination or expiration, upon written request of LMI, complete any purchase orders for Product that were placed by LMI and accepted by HSL prior to such date and LMI shall pay HSL for any Product produced in accordance with such purchase orders at the applicable price as set forth in this Agreement. Upon termination or expiration for any reason (other than HSL's breach or insolvency), LMI will pay HSL for services properly performed by HSL pursuant to one

or more Proposals, including in process pre-commercial batches, including all initiated media fills, technical transfer study batches, process justification lots, process performance qualification/process validation lots and all components ordered in anticipation of conducting the foregoing.

(d) *Terminal Supply; Post-Termination or Expiration Acceptance of Orders.* Unless HSL terminates this Agreement pursuant to Sections 3.3(a) or 3.3(b), upon LMI's request, HSL shall use commercially reasonable efforts to provide LMI with a terminal supply of Product so as to minimize disruption of LMI's supply or sale of Products. Any acceptance by HSL of any purchase order from LMI or the sale of any Products by HSL to LMI after the delivery of notice of termination or after the expiration or termination of the Term shall not be construed as a renewal or extension of this Agreement or as a waiver of termination thereof.

(e) *Termination of\*\*\*\*.* If HSL terminates this Agreement for LMI's breach under Section 3.3(b) or LMI's insolvency under Section 3.3(a) then the \*\*\*\* shall terminate.

(f) *Prior Obligations.* Termination or expiration of this Agreement, in whole or in part, for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such termination or expiration, and such termination or expiration shall not relieve either Party from obligations which are expressly indicated to survive termination or expiration of the Term.

#### 4. REGULATORY ISSUES.

4.1 *Regulatory Obligations.* All obligations relating to the Product NDA shall, at all times during the Term, remain with LMI, including without limitation (a) the obligation to prepare and make any updates or amendments to the Product NDA or CMC, (b) to pay any fees or other costs associated with such filings, or (c) to collect, investigate and report to the FDA and other appropriate regulatory authorities any Product-related adverse experience reports, quality reports, and complaint reports. HSL shall provide LMI with access to any such information reasonably required to enable LMI to comply with its obligations under this Section 4.1. HSL shall remain solely responsible, at its expense, for compliance with (A) cGMPs (including any comparable requirements imposed by foreign authorities), but limited to those jurisdictions that are within the Territory as set forth in any amendment to this Agreement for which it has been qualified to produce Product; (B) obtaining or maintaining establishment registrations and all other required permits and licenses for all relevant facilities; and (C) the preparation and submission of all records and reports required by FDA and other appropriate regulatory authorities in connection with the manufacture and sale to LMI of the Product, including, without limitation, updating the DMF in countries or regions within the Territory and providing LMI with the necessary DMF Authorization Letters, if applicable at additional cost to LMI, unless the Proposal includes such activities. All information, documents and updates with regard to the manufacture of Product which are required by any governmental agency shall be provided by HSL in a timely manner, and HSL shall submit to all inquiries and inspections by any such agencies. All documents directly related to the Product and a summary of all information provided by HSL to any such agency shall be provided to LMI in advance of submission to such

agency. LMI shall not file any documents relating to HSL with regulatory authorities without HSL's prior written consent, which shall not be unreasonably withheld or delayed. HSL shall provide comments on proposed submissions within five business days of receipt and in the absence of delivery of such comments LMI may proceed with its filing. Notwithstanding the foregoing, LMI and HSL acknowledge that the regulatory support described in Proposal No. 973-5-11 sets forth the costs for filings in the Territory and the scope of HSL's responsibility for such filings. Any costs associated with additional applications will require a separate quotation as described in Proposal No. 973-5-11.

#### 4.2 *Product Recalls.*

(a) If either Party reasonably decides or is required by any government authority or court of competent jurisdiction, to initiate a product recall, withdrawal or field correction with respect to, or if there is any governmental seizure of, the Product, the Party initiating or required to initiate such action will notify the other Party promptly of the details regarding such action, including providing copies of all relevant documentation concerning such action. The Parties will assist each other in investigating any such situation and all regulatory contacts that are made and all activities concerning seizure, recall, withdrawal or field correction will be jointly coordinated by HSL and LMI.

(b) If any such recall, withdrawal, field correction or seizure occurs due solely to (i) failure of any Product produced by HSL hereunder to conform to Specifications (including, without limitation, being adulterated or misbranded) or any warranty or other requirement set forth in this Agreement, (ii) the failure of HSL to comply in all material respects with any applicable law, rule, regulation, guideline, standard, court order or decree or (iii) the negligent or intentional wrongful act or omission of HSL in connection with the production of Product hereunder, then HSL shall bear the \*\*\*\* of any such seizure, recall, withdrawal or field correction and shall reimburse LMI for its \*\*\*\*, including any purchase price payments made to HSL and related taxes to the extent related to such recalled Product. To the extent any such recall, withdrawal, field correction or seizure occurs for any reason other than that set forth in the immediately preceding sentence, then LMI shall bear the \*\*\*\* of any such seizure, recall, withdrawal or field correction. If both HSL and LMI contribute to the cause of a seizure, recall, withdrawal or field correction, the cost and expense thereof will be shared in proportion to each Party's contribution to the problem. For the purposes of this Agreement, the expenses of any recall, withdrawal, field correction or seizure shall include, without limitation, the out-of-pocket expenses of notification and destruction or return of the recalled Product and all other out-of-pocket costs incurred in connection with such recall but shall not include a Party's lost profits. HSL's reimbursement for the costs of LMI Materials related to such recall, withdrawal or field correction is limited by Section 5.6(c).

4.3 *Sharing of Information.* HSL shall promptly advise LMI of any information of which it obtains knowledge that may affect the safety, efficacy or labelling of the Products and any actions in response to such information.

4.4. *Adverse Events and Product Quality Complaints.* The Parties agree to the following provisions regarding adverse events and complaints:

(a) LMI shall be responsible to (a) report adverse events involving the Product to the FDA and other regulatory authorities, and (b) respond to quality complaints and medical and technical inquiries, respecting the Product.

(b) In the event HSL (i) receives information regarding any adverse event relating to the Product, (ii) receives any complaints relating to the Product, (iii) receives any medical or technical inquiry relating to the Product, or (iv) discovers or is notified of any material defect in the Product, it shall immediately notify LMI, through its agent for global pharmacovigilance, as follows (or to such other address, contact person, telephone number, facsimile number or e mail address as may be specified by LMI):

<u>Phone</u>	<u>Fax</u>	<u>Email</u>
1-800-343-7851 or 978-667-9531	1-866-880-9343 or 734-929-6688	lantheussafety@i3global.com

HSL shall also conduct an investigation in accordance with its normal procedures for complaints, inquiries or discoveries of that nature and promptly report the results of such investigation to LMI. The Parties shall reasonably cooperate with and assist each other in connection with any such matter. In addition, HSL will ensure that all relevant personnel are sufficiently informed and trained on the terms and procedures outlined in this Agreement, including without limitation, the process for the receipt, recordation, exchange, communication and submission of safety data for the Product(s) and all relevant regulations and laws thereto. HSL agrees to document the training activities, including the training material(s) used, and make these documents reasonably accessible to LMI upon request.

5. WARRANTIES AND QUALITY ASSURANCE

5.1 *HSL Warranties.* HSL warrants that all Product delivered to LMI: (a) will have been manufactured, packaged, labeled, tested and/or re-tested in compliance with applicable provisions of the Federal Food, Drug and Cosmetic Act (the "Act"), regulations thereunder, and any other comparable laws and regulations applicable in the Territory where the Product is being distributed, relating to development, manufacture and supply under this Agreement, and in compliance with the specific U.S. or other applicable regulatory approvals regarding the Product; (b) shall conform to the Specifications; (c) shall comply with the Quality Agreement, the Master Batch Record and the cGMPs where the Product is being distributed; and (d) will, at the time of such delivery, not be adulterated within the meaning of the Act or other applicable law where the Product is being distributed, as such Act or law is constituted and effective at the time of delivery, and will not be an article which may not, under the provisions of such Act, be introduced into interstate commerce. HSL further warrants that, at the time of manufacture for jurisdictions in the Territory, its facility shall conform to cGMP and other applicable laws of such jurisdictions in the Territory where Product is being distributed and that, to its knowledge, the services provided by HSL and the use, practice or exploitation of the Technology or Intellectual Property provided by HSL shall not infringe, violate or misappropriate the

intellectual property rights of any third party. At the time of delivery, the Product shall have a minimum shelf life of not less than \*\*\*\* less than the maximum shelf life set forth in the Product NDA, but in no event less than \*\*\*\*, provided however, that if after manufacture of Product HSL launches an investigation that causes Product shipment to be delayed and the investigation results in delayed release of one or more batches or Lots of Product and the investigation determines that the deviations in such batch or Lot that triggered the investigation were the fault of LMI Materials that did not meet specifications or LMI's specified process was at fault then LMI shall accept and pay for such Product (at full price, notwithstanding Section 2.3(a)), even if Product has less than a \*\*\*\* shelf life. HSL shall use commercially reasonable efforts to expeditiously determine the cause of any such failures. In addition to the foregoing, in all other cases, LMI shall use commercially reasonable efforts to accept Product with less than a \*\*\*\* shelf life.

5.2 *LMI Warranties.* LMI represents, warrants and covenants that:

(a) the marketing, distribution and sale of the Products in the Territory and any products packaged or included with the Product shall at all times comply with the Act and all other applicable laws, rules and regulations;

(b) that, to its knowledge, neither any Technology nor specifications provided by LMI to HSL shall infringe, violate or misappropriate the intellectual property rights of any third party;

(c) except for the Technology and intellectual property provided by HSL, to its knowledge, LMI has all necessary Technology and intellectual property rights to enable HSL to process the Product for LMI in accordance with the terms and conditions of this Agreement;

(d) all laboratory, scientific, technical and/or other data(including any processes) submitted by LMI to HSL relating to the Product shall be complete and correct and shall not contain any material misrepresentation or omission; and

(e) all LMI Materials shall conform to the specifications set forth in the applicable regulatory approvals for the Product.

5.3 ***DISCLAIMER OF ALL OTHER WARRANTIES.*** THE WARRANTIES SET FORTH IN THIS AGREEMENT ARE THE PARTIES' ONLY WARRANTIES WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT AND ARE MADE EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WHICH ARE HEREBY DISCLAIMED, INCLUDING ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, OR ARISING FROM THE COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OF TRADE OR OTHERWISE.

5.4 *Certificates of Analysis.* HSL shall perform, or cause to be performed, sample tests on each Lot or Batch of Product supplied pursuant to this Agreement before delivery to LMI, and shall produce a test report setting forth the results of such testing. Each test report

shall set forth, for each Lot or Batch of Product delivered hereunder, the items tested, specifications and test results in a certificate of analysis, containing the types of information reasonably agreed upon by HSL and LMI. HSL shall send such certificates to LMI concurrent with delivery of each Lot or Batch of Product.

5.5 *Certificates of Manufacturing Compliance.* HSL shall provide or cause to be provided for each Lot or Batch of Product purchased under this Agreement a certificate of manufacturing compliance, containing the type of information reasonably agreed upon by HSL and LMI, which will certify that the Lot or Batch of Product was manufactured in accordance with the Specifications and cGMP, including without limitation 21 CFR 210 and 211 and ICH Q7, as the same may be amended from time to time, and a copy of the fully executed batch record. HSL shall send such certificates and batch record to LMI concurrent with delivery of each Lot or Batch of Product. HSL agrees that it shall maintain all of the facilities used for the manufacture of the Product in material compliance with all applicable state, local, federal or international laws and regulations and shall permit the relevant governmental agencies to inspect the manufacturing facilities used for the manufacture of the Product whenever deemed necessary by such agencies. HSL shall advise LMI \*\*\*\* if an authorized agent of the FDA or other governmental agency visits any of HSL's facilities where the Product is being manufactured, or where any component of the Product is manufactured, processed or controlled, or of any official contact concerning the Product; provided, however, that LMI shall have the right to be present for all scheduled inspections relating to the manufacture of Product. HSL shall furnish to LMI the report by such agency, appropriately redacted, that relates to such visit to the extent that such report relates to the Product, Facility or Quality system, within (i) \*\*\*\* of HSL's receipt of such report if such report relates to urgent matters such as Product recall, facility shutdown or similar events ("Urgent Incident") and (ii) \*\*\*\* after HSL's receipt of such report for other matters. In addition to the observation rights set forth in the Proposals, upon reasonable advance notice to HSL, HSL shall allow LMI and its consultants (subject to entering into suitable confidentially agreements reasonably acceptable to HSL) reasonable access during normal business hours throughout the Term to any of HSL's facilities where the Product is being manufactured, or where any component of the Product is manufactured, processed or controlled to verify compliance with HSL's obligations under this Agreement; provided that such access shall be limited to \*\*\*\*during any consecutive \*\*\*\*, except in the event of an Urgent Incident, in which event HSL shall allow LMI and its consultants (subject to entering into suitable confidentially agreements reasonably acceptable to HSL) reasonable access during normal business hours as necessary to allow LMI to evaluate HSL's planned response to the Urgent Incident. Notwithstanding anything to the contrary hereunder, LMI shall have the right to postpone all pending and future purchase orders hereunder (and adjust all Forecasts and the requirements described in Section 2.2(a) accordingly), without penalty, in the event of \*\*\*\* issued to HSL until the same are resolved. In addition, in the event of a \*\*\*\*, LMI or HSL shall have the right to postpone all scheduled manufacture of the Product (with LMI adjusting all Forecasts, without penalty to the Parties, and LMI being given credit for orders placed elsewhere for the purposes of meeting its minimum requirements of Section 2.2(a)), until such time as final disposition of all affected or rejected Batch(es) have been determined and complete investigations have been finalized with root cause

analysis and the appropriate corrective actions. HSL shall cooperate with LMI to perform all investigations diligently and expeditiously. Notwithstanding the foregoing if the investigation reveals that the triggering events for the postponement of the manufacture of the Product and adjustment of Forecasts was due to faulty LMI Materials or incorrect LMI processes then no credit shall be given for the minimum commitment of Section 2.2(a) for orders placed with other vendors, and LMI shall pay the fees specified in Section 2.2(b) for cancelled or postponed orders and be liable for failure to order binding portions of Forecasts.

5.6 *Acceptance.*

(a) LMI shall have \*\*\*\* (\*\*\*\*) days from the date of delivery of Product and the corresponding certificate of manufacturing compliance to confirm conformance with the Specifications and to claim any shortage in quantity of any shipment of the Product. Any notice of rejection or shortage of any shipment of Product must be given in writing, must contain a report of the reason for such rejection or shortage and be received by HSL within said \*\*\*\* (\*\*\*\*) day period or such shipment will be deemed to have been accepted; provided, however that this limitation shall not apply to \*\*\*\*. HSL shall assist in necessary analytical Technology transfers to accomplish such testing by LMI.

(b) HSL shall have \*\*\*\* (\*\*\*\*) days following receipt of rejected Product in which to test such Product. If HSL does not dispute a rejection, HSL shall \*\*\*\* the rejected Product promptly, at HSL's expense (including, but not limited to\*\*\*\*). If HSL disputes a rejection, HSL shall provide LMI with written notice of such dispute within thirty (30) days after receiving the returned Product, and the Parties shall use commercially reasonable efforts to resolve the dispute amicably and promptly. If the Parties are unable to reach a resolution within \*\*\*\* (\*\*\*\*) days after HSL's notice of dispute, the returned Product shall be submitted to any independent laboratory or consultant mutually acceptable to the Parties, whose decision as to the conformity of such Product with the Specifications shall be final and binding. The Party against whom the dispute is decided shall pay any charges for such laboratory or consultant. If the laboratory or consultant determines that the returned Product did not conform to the Specifications. HSL shall, at LMI's option, \*\*\*\* the rejected Product at no charge to LMI. HSL shall make arrangements with LMI for the return or disposal of any rejected Product, such return shipping or disposal charges to be paid by HSL.

(c) HSL shall reimburse LMI for the actual replacement costs of any damaged or lost LMI Materials if (i) \*\*\*\* or (ii) such damage or loss is the result of\*\*\*\*, provided that reimbursement for the LMI Materials costs will be limited to the \*\*\*\* of (i) (A) \*\*\*\* Dollars (\$\*\*\*\*) and (B) LMI's costs for same (as demonstrated by reasonable evidence and documentation therefor provided to HSL), per Lot, (ii) \*\*\*\* Dollars (\$\*\*\*\*) in the aggregate for the manufacture of Product in any

\*\*\*\*, and (iii) \*\*\*\* Dollars (\$\*\*\*\*) in the aggregate over each \*\*\*\* (all of which shall be adjusted \*\*\*\* in a manner consistent with the second paragraph of Section 2.2(c) (i.e., by the \*\*\*\* of \*\*\*\*% and the \*\*\*\*)), and further provided that, unless otherwise reasonably agreed to by the Parties, such reimbursement may be issued in the form of a credit. Any credits hereunder not settled within \*\*\*\* (\*\*\*\*) \*\*\*\* of issuance, or within \*\*\*\* (\*\*\*\*) \*\*\*\* of the effective date of any termination or expiration of this Agreement, will be refunded to LMI. This limitation of liability for LMI Materials shall also be applicable to any charge for LMI Materials payable by HSL under this Agreement, including without limitation for recall. LMI shall bear the risk of loss for LMI Materials for \*\*\*\*, except in the event of \*\*\*\* (in which case liability for such LMI Materials shall be limited as with respect to \*\*\*\* and the \*\*\*\* and \*\*\*\* caps set forth above shall apply to \*\*\*\* batches taken together).

5.7 *Quality Agreements.* The Parties agree that they will enter into one or more separate Quality Agreements that will cover arrangements for quality control, testing documentation, quality assurance and other related matters no later than thirty (30) days after the Effective Date.

5.8 *Health, Safety and Environmental Compliance.*

(a) Manufacturing operations are to be performed by HSL using appropriate safety measures and containment techniques as dictated by applicable law, regulations and industry standards. HSL 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. HSL, in consultation with LMI, shall develop safety and handling procedures for Product; provided, however, that LMI shall have no responsibility for HSL'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 HSL, at HSL's cost and expense, unless otherwise agreed to in writing by the Parties for special situations and conditions. Without limiting other legally applicable requirements, HSL shall prepare, execute and maintain, as the generator of waste, all licenses, registrations, approvals and authorizations, notices, shipping documents and waste manifests required under applicable law and regulations.

(b) LMI has established a program for systematic assessment of its supplier's EHS programs ("TPM EHS Assessment Program") and HSL agrees to participate and reasonably cooperate with LMI in effectively implementing this TPM EHS Assessment Program.

(c) HSL will review LMI's TPM EHS Assessment Program and, if applicable, provide quotations for additional resources required to address the program. HSL policies will govern the implementation and use of such resources, except in the event

that LMI is willing to bear the cost of compliance (including, without limitation, allocations of cost of HSL internal personnel) stated in such quotations and otherwise. Specifically and subject to the foregoing, HSL agrees to:

(i) promptly respond to reasonable requests from LMI for non-confidential information made as part of LMI's TPM EHS Assessment Program. LMI will provide a questionnaire to HSL and HSL is expected to provide the complete response within thirty (30) days;

(ii) reasonably cooperate with LMI to clarify and supplement any information related to its facilities and operations; and

(iii) provide to LMI, upon request, copies of HSL's environmental, health and safety permits required by any governmental authority which are associated with the Products and all facility operation related thereto.

(d) HSL agrees that LMI or its appointed agent(s) (subject to entering into suitable confidentiality agreements reasonably acceptable to HSL, provided such agents(s) are reasonably acceptable to HSL) shall be entitled to conduct inspections and audits no more than once per year upon \*\*\*\* notice and mutually convenient times of any areas or facilities used to produce the Products or required for production of the Products no more than \*\*\*\* (such audit to be conducted with the audit of Section 5.5, if any, for no more than two days and using no more than two individuals) including the following reasons (i) to assist in completion of LMI's TPM EHS Assessment Program; and (ii) to allow for a loss prevention inspection of the facility by LMI's insurance underwriting company as necessary for LMI to obtain contingent business interruption insurance.

(e) HSL shall take reasonable and appropriate precautions to ensure that its personnel (including its employees, contractors and agents) are protected from the Product and/or the Product's manufacturing process exposures through either engineering infrastructure, personnel protective equipment or a combination of both. Upon request, within ninety (90) days, HSL shall provide workplace monitoring data which demonstrates the effectiveness of controls.

5.9 *Facility.* HSL shall perform all services under this Agreement at the agreed upon facility located at \*\*\*\*. HSL shall not change the location of such facility or use any additional facility for the performance of services under this Agreement without the prior written consent of LMI, such consent not to be unreasonably withheld, delayed or conditioned. HSL will be responsible for all applicable costs and expenses in connection with any such change of location of the facility or use of any additional facility for the performance of services under this Agreement (including, but not limited to, costs for qualification and validation batches).

## 6. INTELLECTUAL PROPERTY; NONDISCLOSURE; CONFIDENTIALITY

### 6.1 *Intellectual Property.*

(a) As between the Parties, subject to the licenses granted under Section

6.1(b) below, each Party retains all right, title and interest in and to the Intellectual Property and Technology that each Party currently owns, licenses and/or uses to the extent related to the purposes of this Agreement (“Pre-Existing Intellectual Property and Technology”). Under no circumstances will the licenses granted in Section 6.1(b) below be construed as a sale of any of the Pre-Existing Intellectual Property and Technology by either Party. As between the Parties, each Party shall, subject to the licenses granted in Section 6.1(b) below, own all right, title and interest in and to any modifications, derivative works, enhancements or improvements of or to any of the Pre-Existing Intellectual Property and Technology related to this Agreement that such Party creates, develops, discovers, conceives and/or reduces to practice in the course of performing under this Agreement (“Improvements”); provided, however, (i) HSL agrees that LMI shall own, and shall and hereby does assign to LMI, all right, title and interest in and to all \*\*\*\* developed by HSL during the Term in the course of performing under this Agreement (provided, for purposes of clarity, such \*\*\*\* shall be limited to \*\*\*\*) and (ii) LMI agrees that HSL shall own, and shall and hereby does assign to HSL, all right, title and interest in and to all \*\*\*\* developed by LMI during the Term in the course of performing under this Agreement, to the extent \*\*\*\*. Subject to the foregoing, the Parties shall jointly own and have the right to use and license (without accounting to the other) all inventions and developments, whether modifications, derivative works, enhancements or improvements to any Intellectual Property and/or Technology related to this Agreement, which are jointly created or developed during the Term. In addition, for purposes of clarity, the Parties acknowledge that HSL shall own all right, title and interest in and to all Improvements to HSL’s Pre-Existing Intellectual Property and Technology developed by HSL during the Term and LMI shall own all right, title and interest in and to all Improvements to LMI’s Pre-Existing Intellectual Property and Technology developed by LMI during the Term.

(b) HSL hereby grants to LMI a \*\*\*\* license, with right to sublicense, in and to HSL-owned Pre-Existing Intellectual Property and Technology and Improvements relating to such Pre-Existing Intellectual Property and Technology for use in connection with the Product to the extent such Intellectual Property and Technology has been incorporated by HSL into the Product hereunder. This license shall \*\*\*\* of the Agreement and shall be included within the scope of the \*\*\*\* of Sections 2.5 and 3.3.

## 6.2 *Nondisclosure and \*\*\*\* Obligations.*

(a) Except as specifically provided by Section 2.5 or in this Article 6, during the Term of this Agreement and for a period of \*\*\*\* thereafter, both Parties shall maintain in confidence (i.e., not disclose to any third party) and use only for purposes specifically authorized under this Agreement information and data received from or on behalf of the other Party, whether such information is contained in a written or electronic document, whether it is oral or whether it is disclosed by means of inspection.

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(b) For purposes of this Article 6, information and data described in clause (a) shall be referred to as “Information.” For purposes of clarity, HSL acknowledges and agrees that LMI’s Information includes, without limitation, the \*\*\*\* developed by HSL specifically for LMI (provided such Information shall not include information developed independently by HSL without reference to LMI’s Pre-existing Intellectual Property and Technology or LMI Information). LMI shall not use the format of HSL’s underlying forms provided to it other than for the Product, and the same shall be HSL’s Information. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement, a Party may disclose Information it is otherwise obligated under this Section not to disclose, to its Affiliates, employees, officers, directors, lenders, sublicensees, consultants, outside contractors and clinical investigators on a need-to-know basis and on condition that such entities or persons agree in writing to only use such Information for purposes specifically authorized under this Agreement and to keep the Information confidential for the same time periods and to the same extent as such Party is required to keep the Information confidential; notwithstanding the foregoing the Party so disclosing Information will be liable to the other Party hereunder for any misuse or improper disclosure of any such Information by any such firms or individuals. A Party or its sublicensees may disclose such Information to government or other regulatory authorities to the extent that such disclosure is reasonably necessary to obtain patents or authorizations to conduct clinical trials of, and to commercially market, the Product. The obligation not to disclose Information shall not apply to any part of such Information that (i) is or becomes part of the public domain other than by unauthorized acts of the Party obligated not to disclose such Information or its Affiliates or sublicensees, (ii) can be shown by written documents to have been disclosed to the receiving Party or its Affiliates or sublicensees by a third party, provided such Information was not obtained by such third party directly or indirectly from the other Party under this Agreement pursuant to a confidentiality agreement, (iii) prior to disclosure under this Agreement can be shown by written documents to have been already in the possession of the receiving Party or its Affiliates or sublicensees, provided such Information was not obtained directly or indirectly from the other Party under this Agreement pursuant to a confidentiality agreement, or (iv) can be shown by written documents to have been independently developed outside of this Agreement by the receiving Party or its Affiliates without breach of any of the provisions of this Agreement. The Party asserting the applicability of one of the exclusions set forth in the immediately preceding sentence shall have the burden of proving the applicability of any such exclusion in any particular circumstance. If a receiving Party is required to disclose Information of the other Party pursuant to interrogatories, requests for information or documents, subpoena, civil investigative demand of a court or governmental agency, it shall use commercially reasonable efforts to do so on a confidential basis (and provided that the disclosing Party furnishes only that portion of the Information which is legally required), and, in any event, it shall provide the other Party prompt notice after receipt of any such official requests to enable the other Party to seek a protective order or similar relief.

(c) HSL understands and acknowledges that LMI’s Information, Intellectual Property, and Technology related to the Product has been developed or obtained by the investment of significant time, effort and expense by LMI, and that such Information,

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Intellectual Property, and Technology is a valuable, special and unique asset of LMI which provides LMI with a significant commercial advantage, and needs to be protected from improper use and disclosure (including, but not limited to, any improper use by HSL and its Affiliates). HSL will not disclose the LMI Information to its Affiliates or otherwise use the LMI Information for the benefit of such Affiliates. HSL further recognizes that \*\*\*\* and, as a result, HSL (excluding \*\*\*\* other than \*\*\*\*) agrees and agrees to cause \*\*\*\* (while the same is \*\*\*\*) \*\*\*\* and HSL agrees and agrees to cause \*\*\*\* (while the same is \*\*\*\*) \*\*\*\*, in each case using a \*\*\*\*, for\*\*\*\*. For purposes of clarity, an \*\*\*\* shall include \*\*\*\* or \*\*\*\*, as applicable. HSL agrees that there may be no adequate remedy at law for any such breach and, upon any such breach or any threat thereof, LMI shall be entitled to appropriate equitable relief in courts located in New York, including injunctive relief, in addition to whatever other remedies it might be entitled. In addition, in order to protect against the disclosure of LMI's Information, upon termination or expiration of this Agreement, or as otherwise requested by LMI, HSL will promptly deliver to LMI or, at the request of LMI, destroy all copies of LMI's Information in its possession; provided, in each case, that HSL may retain, in a secure location, a copy of such documents and records for purposes of defending any legal proceedings or as is required to be maintained in order to satisfy any law, rule, or regulation to which HSL is subject.

6.3 *Terms of this Agreement.*

(a) LMI and HSL each agree not to disclose, whether by press release or in any other manner, the existence of this Agreement or any terms or conditions of this Agreement, to any third party without the prior written consent of the other Party or except as required by applicable law; it being understood that either Party will be able to file this Agreement with the U.S. Securities and Exchange Commission and other government agencies to the extent it reasonably determines such filing is required under applicable rules and regulations, but such Party shall use reasonable efforts to seek confidential treatment of pricing and other commercially sensitive information. In addition, each Party may disclose the terms and conditions of this Agreement to a lender or third party to which it is considering transferring all or substantially all of its interests in the assets to which this Agreement relates; provided, however, that such third party executes a confidentiality agreement by which such third party is bound to hold the disclosed information in confidence.

(b) The Parties shall agree in good faith upon the substance of Information that can be used as a routine reference in the usual course of business to describe the

terms of this transaction and each of them may disclose such Information, as modified by mutual agreement from time to time, without the other Party's consent.

6.4 *Injunctive Relief.* The Parties hereto understand and agree that remedies at law may be inadequate to protect against any breach of any of the provisions of this Article 6 by a Party or its employees, agents, officers or directors or any other person acting in concert with it or on its behalf. Accordingly, each Party shall be entitled to seek injunctive relief or any other equitable relief appropriate under the circumstances by a court of competent jurisdiction against or with respect to any action that constitutes any such breach of this Article 6.

#### 7. INDEMNIFICATION; INSURANCE.

7.1 *By HSL.* To the extent LMI is not responsible to indemnify HSL and/or others under Section 7.2, HSL will indemnify and hold LMI, its Affiliates, and its and their directors, officers, agents and employees harmless against any and all liability, damages, losses, costs or expenses, including without limitation, reasonable fees and disbursement of attorneys (collectively, "Liability") resulting from any third party claims made or suits brought against them to the extent such Liability arises from (i) HSL's services in developing the Product not in material compliance with this Agreement, (ii) HSL's manufacturing, supplying, processing or otherwise manufacturing the Product not in compliance with the Specifications and the representations contained in Section 5.1, (iii) HSL's negligent acts or omissions or willful misconduct in the manufacture, storage, packaging, labeling, handling or shipping of the Product or (iv) HSL's breach of any representation, warranty or covenant, or failure to perform any of its obligations, hereunder.

7.2 *By LMI.* To the extent HSL is not responsible to indemnify LMI and/or others under Section 7.1, LMI will indemnify and hold HSL and its directors, officers, agents and employees harmless against any and all Liability resulting from any third party claims made or suits brought against them to the extent such Liability arises from (i) any packaging or labeling of any Product to the extent that such packaging or labeling has been supplied by or at the direction of LMI and applied in accordance with instructions from LMI, (ii) LMI's negligence or willful misconduct in the storage, handling, shipping, use, marketing, distribution or sale of the Product; (iii) LMI's breach of any representation, warranty or covenant, or failure to perform any of its obligations, hereunder; (iv) any product distributed by LMI which is similar to or identical to Product (other than Product which is manufactured by HSL); (v) personal injuries or death resulting from the use of the Product properly manufactured and delivered by HSL; or (v) any product shipped by LMI with the Product or included with the Product.

7.3 *Conditions of Indemnification.* A Party or any of its Affiliates or their respective directors, officers, employees or agents (the "Indemnitee") that intends to claim indemnification under this Article 7 shall promptly notify the other Party (the "Indemnitor") of any Liability in respect of which the Indemnitee intends to claim such indemnification reasonably promptly after the Indemnitee is aware thereof, and the Indemnitor shall have the right to assume the defense of any related third party action, suit or proceeding with counsel mutually satisfactory to the Parties; provided, however, that an Indemnitee shall have the right to retain its own counsel and participate in the defense thereof at its own cost and expense. The indemnity agreement in this Article 7 shall not apply to amounts paid in settlement of any claim, loss, damage or expense if

such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure of an Indemnitee to deliver notice to the Indemnitor within a reasonable time after becoming aware of any such matter, if prejudicial to the Indemnitor's ability to defend such action, shall relieve the Indemnitor of any liability to the Indemnitee under this Article 7 to the extent of such prejudice. The Indemnitee under this Article 7 and its directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any matter covered by this indemnification.

7.4 *Insurance.* LMI and HSL will each, at its own cost and expense, obtain and maintain in full force and effect, during the term of this Agreement and for a period of one year following the expiration or other termination of this Agreement, commercial general liability insurance (including Products Completed Operations) with an insurance carrier reasonably acceptable to the other Party, with limits of liability, including excess coverage, of not less than \$10,000,000 combined single limit bodily injury and property damage covering its duties and obligations under the Agreement.

8. ALTERNATIVE DISPUTE RESOLUTION.

(a) The Parties will attempt in good faith to resolve any controversy, claim or dispute ("Dispute") arising out of or relating to this Agreement promptly by negotiations. Any such Dispute which is not settled by the Parties within thirty (30) days after notice of such Dispute is given by one Party to the other in writing shall be referred to a senior executive of LMI and a senior executive of HSL who are authorized to settle such Disputes on behalf of their respective companies ("Senior Executives"). If the Dispute has not been resolved within thirty (30) days after the end of the thirty (30) day negotiation period referred to above (which period may be extended by mutual agreement), subject to any rights to injunctive relief and unless otherwise specifically provided for herein, any Dispute shall be settled by binding arbitration as described in subsection (b) below, if the Parties so choose.

(b) Any Dispute which is not resolved by the Parties within the time period described in subsection (a) shall be settled by final and binding arbitration to be conducted by a single arbitrator in New York, New York, pursuant to the then-existing Commercial Rules of the American Arbitration Association. The decision or award of the arbitrator shall be final, and judgment upon such decision or award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such decision or award and an order of enforcement. The arbitrator shall allocate the costs of the arbitration to one or both of the Parties as it sees fit.

(c) Nothing contained in this Section or any other provision of this Agreement shall be construed to limit or preclude a Party from bringing an action in any court of competent jurisdiction for injunctive or other provisional relief to compel the other Party to comply with its obligations hereunder before or during the pendency of mediation or arbitration proceedings.

9. MISCELLANEOUS.

9.1 *Relationship of the Parties.* In making and performing this Agreement, the Parties are acting, and intend to be treated, as independent entities and nothing contained in this Agreement shall be construed or implied to create an agency, partnership, joint venture, or employer and employee relationship between LMI and HSL. Each Party shall retain the exclusive right of control with respect to its employees and agents, and shall be responsible for all taxes, withholdings, and other statutory or contractual obligations of any sort in respect of its employees and agents providing Products and services hereunder including, but not limited to, workers' compensation insurance. Except as otherwise provided herein, neither Party may make any representation, warranty or commitment, whether express or implied, on behalf of or incur any charges or expenses for or in the name of the other Party. No Party shall be liable for the act of any other Party unless such act is expressly authorized in writing by both Parties hereto.

9.2 *Expenses.* Except as specifically provided herein, each Party shall each pay its own expenses (including the fees and expenses of their respective agents, representatives, counsel and accountants) incidental to the preparation, negotiation, and consummation of this Agreement and the transactions contemplated hereby.

9.3 *Survival.* The following provisions shall survive the termination or expiration of this Agreement (along with any payment obligations accruing during the Term under any other provision) for any reason in accordance with their respective terms:

- Article 1 (Definitions)
- Section 2.5 (\*\*\*\* Qualification)
- Section 3.4 (Effect of Expiration or Termination; Accrued Rights; Surviving Obligations)
- Article 4 (Regulatory Issues)
- Article 5 (Warranties and Quality Assurance)
- Article 6 (Intellectual Property; Nondisclosure; Confidentiality)
- Article 7 (Indemnification)
- Article 8 (Alternative Dispute Resolution)
- Article 9 (Miscellaneous)

9.4 *Notices.* All notices, demands and other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given (a) when personally delivered or sent by confirmed telecopy (with hard copy to follow); (b) one (1) business day after sent by reputable overnight express courier (charges prepaid); or (c) five (5) business days following mailing by certified or registered mail, postage prepaid and return receipt requested. Unless another address is specified in writing, notices, demands and communications to LMI and HSL shall be sent to the addresses indicated below:

Notices to LMI:

Lantheus Medical Imaging, Inc.  
331 Treble Cove Road  
North Billerica, Massachusetts 01862  
Attn: VP, Manufacturing and Operations

with a copy to:

Lantheus Medical Imaging, Inc.  
331 Treble Cove Road  
North Billerica, Massachusetts 01862  
Attn: General Counsel

Notices to HSL:

Jubilant HollisterStier LLC  
3525 North Regal Street  
Spokane, WA 99207  
Attention: Sitakant Chaudhury  
FAX: (509)482-1726

9.5 *Force Majeure*. If the performance of any obligation under this Agreement by either Party is prevented, restricted, interfered with or delayed by reason of natural disaster, casualty, acts of God, riots, acts of terrorism, shortages or unavailability of raw materials, labor strikes or such other events of a similar nature, all of which are outside the reasonable control of the affected Party ("Force Majeure Event"), the Party so affected shall, upon giving prompt written notice to the other Party (including a full description of particulars), be excused from such performance to the extent of such prevention, restriction, interference or delay; provided that the affected Party shall use its reasonable commercial efforts to avoid or remove such causes of non-performance and shall continue performance whenever such causes are removed.

9.6 *LIMITATIONS ON LIABILITY*. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR TO ANY THIRD PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY, OR CONSEQUENTIAL DAMAGES ARISING FROM THIS AGREEMENT, WHETHER THE BASIS OF THE LIABILITY IS BREACH OF CONTRACT, TORT, STATUTES, OR ANY OTHER LEGAL THEORY, EXCEPT AS PROVIDED IN SECTION 2.2(b) or 2.2(a)(ii) or 2.2(a)(iii) AND EXCEPT TO THE EXTENT NECESSARY TO SATISFY A THIRD PARTY CLAIM UNDER SECTION 7 OF THIS AGREEMENT OR TO THE EXTENT SUCH LIABILITY ARISES FROM HSL'S WILLFUL MISCONDUCT, FRAUD OR GROSSLY NEGLIGENT ACTS OR OMISSIONS OR A PARTY'S BREACH OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS SET FORTH HEREIN, AND WHETHER SUCH FIRST PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR NOT.

UNDER NO CIRCUMSTANCES SHALL HSL'S TOTAL LIABILITY TO LMI IN CONNECTION WITH THE SUBJECT MATTER OF THIS AGREEMENT EXCEED \*\*\*\* DOLLARS (\$\*\*\*\*), PROVIDED THAT THE LIMITATIONS DESCRIBED IN THIS SECTION SHALL NOT APPLY IN THE EVENT SUCH LIABILITY ARISES FROM HSL'S WILLFUL MISCONDUCT, FRAUD OR GROSSLY NEGLIGENT ACTS OR OMISSIONS OR HSL'S BREACH OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS SET FORTH HEREIN.

9.7 *Successors and Assigns; Assignment*. This Agreement shall be binding upon and

inure to the benefit of the Parties and their respective successors and permitted assigns. This Agreement or any part thereof, may not be assigned, in whole or in part, without the prior written consent of the other Party, which consent may be withheld in the sole discretion of the other Party; provided, however, that either Party may assign this Agreement without the consent of the other Party, (i) in whole or in part to any Affiliate of such Party, it being agreed that no such assignment to a Party's Affiliate shall release the assigning Party from its obligations hereunder, or (ii) for the benefit of any lenders under any financing arrangement, or (iii) in connection with the direct or indirect (x) transfer and sale of all or substantially all of the assets or business of such Party or any of its Affiliates or (y) the transfer and sale of all or substantially all of the assets or business of the specific business line, division or unit of such Party or any of its Affiliates to which this Agreement relates.

9.8 *Entire Agreement; Modification.* This Agreement supersedes all prior agreements and understandings between the Parties or any of their respective Affiliates (written or oral) relating to the subject matter hereof, including any term sheets, and this Agreement is the entire and complete statement of the terms of the agreement between the Parties with respect to the subject matter hereof. This Agreement may be amended, modified, or supplemented only in a writing signed by LMI and HSL.

9.9 *Waivers.* The failure of a Party at any time or times to require performance of any provision hereof shall in no manner affect its right at a later time to enforce the same. No waiver by a Party of any condition or of any breach of any term, covenant, representation or warranty contained in this Agreement shall be effective unless in writing, and no waiver in any one or more instances shall be deemed to be a further or continuing waiver of any such condition or breach in other instances or a waiver of any other condition or breach of any other term, covenant, representation or warranty.

9.10 *Section and Other Headings.* The section and other headings contained in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

9.11 *Governing Law.* This Agreement shall be exclusively interpreted in accordance with and governed by the laws of New York, without regard to the conflicts of law rules thereof.

9.12 *Severability.* Any provision of this Agreement which is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition and unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

9.13 *No Third Party Beneficiaries.* Neither this Agreement nor any provision hereof is intended to confer upon any person (other than the Parties hereto) any rights or remedies hereunder.

9.14 *Construction.* The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of

proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

9.15 *Counterparts.* This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original, and such counterparts shall together constitute one and the same instrument. A facsimile transmission of an executed counterpart signature page shall be deemed an original.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives as of the date first above written.

LANTHEUS MEDICAL IMAGING, INC.

By: /s/ Michael P. Duffy  
Name: Michael P. Duffy  
Title: Vice President and Secretary

JUBILANT HOLLISTERSTIER LLC

By: /s/ Marcelo Morales  
Name: Marcelo Morales  
Title: CEO

Exhibit 1.1

Specifications

The Specifications for Definity® and Luminity® have been established based on the regulatory approvals for the Product and have been separately acknowledged by the Parties in writing.

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Exhibit 1.2

Territory

United States	Israel	Australia
Canada	United Arab Emirates	New Zealand
Mexico	Singapore	Korea
European Union	India	[China, including Hong Kong and Macau]*

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\*Subject to approval of the Product in these jurisdictions.

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Exhibit 1.3

Pricing

COMMERCIAL BATCH/LOT PRODUCTION PRICES:

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**CONFIDENTIAL TREATMENT REQUESTED**

**INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND NOTED WITH “\*\*\*\*\*”. AN UNREDACTED VERSION OF THIS DOCUMENT HAS ALSO BEEN PROVIDED TO THE SECURITIES AND EXCHANGE COMMISSION.**

**SETTLEMENT AND MUTUAL RELEASE AGREEMENT**

THIS SETTLEMENT AND MUTUAL RELEASE AGREEMENT (“Settlement Agreement”) is entered into as of the date of signature of the last signatory to the Settlement Agreement (the “Signing Date”), and effective upon the date of receipt of the Settlement Payment (as defined below) (the “Effective Date”), by and between Ben Venue Laboratories, Inc. (“BVL”), and Lantheus Medical Imaging, Inc. (“LMI”). BVL and LMI are collectively referred to as the “Parties” or in the singular as a “Party.”

**RECITALS**

WHEREAS, BVL is a Delaware corporation that provides services to the pharmaceutical industry as a contract manufacturer which supplies its customers with sterile finished dosage forms, with its principal place of business located in Ohio; and

WHEREAS, LMI is a Delaware corporation engaged in the business of developing, manufacturing and distributing diagnostic medical imaging products, with its principal place of business located in Massachusetts; and

WHEREAS, BVL and LMI are parties to a certain Manufacturing and Service Contract For Commercial and Developmental Products dated August 1, 2008 (“Manufacturing Agreement”); and

WHEREAS, BVL has experienced a variety of issues that have challenged its ability to consistently manufacture and provide product to LMI pursuant to the Manufacturing Agreement between the Parties; and

WHEREAS, the Parties have cooperated in good faith to satisfactorily resolve all issues of concern and material disputes; and

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WHEREAS, the Parties desire to terminate the Manufacturing Agreement, which agreement is hereby terminated as of the Effective Date pursuant to the terms hereof; and

WHEREAS, it is the intent of the Parties to resolve fully and finally any and all disputes and/or claims whatsoever that LMI may have against the BVL Released Parties (defined herein), including but not limited to claims relating to, arising out of, or based upon the Manufacturing Agreement; and

WHEREAS, the Parties have mutually resolved, to each other's satisfaction, a compromise and resolution of all outstanding issues and disputes; and

WHEREAS, the Parties have mutually agreed that the consideration being paid by BVL is wholly and completely sufficient to resolve all claims arising under, or in any manner whatsoever related to, the Manufacturing Agreement; and

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, and for other good and valuable consideration, receipt and sufficiency of which is hereby acknowledged, and with full consultation or the opportunity for consultation with counsel and such other advisors as they deem appropriate, the Parties to this Settlement Agreement hereby agree as follows:

**TERMS & CONDITIONS**

1. The foregoing recitals are incorporated herein and constitute express terms of the Settlement Agreement.
2. In full and final satisfaction of LMI's claims and potential claims, both known and unknown, BVL shall provide the consideration described herein under the terms and conditions described herein. Provision of the consideration described herein is intended to fully resolve all claims, whether known or unknown, that LMI has or may have against the BVL

Released Parties, including but not limited to claims relating to, arising out of, or based upon the Manufacturing Agreement.

3. The Parties agree that on the Effective Date, the Manufacturing Agreement will be terminated by this Settlement Agreement and shall have no further force and effect, with the exception of the duties of Customer Indemnity (Section 8.1) and the duties under the Quality Agreement (Attachment "E", as amended) of the Manufacturing Agreement, which shall survive the termination of the Manufacturing Agreement.

**CONSIDERATION**

4. Settlement Payment: As consideration for the release set forth in Paragraph 5, which takes effect upon receipt of payment by LMI, BVL will pay LMI Thirty Million Dollars (\$30,000,000.00) (the "Settlement Payment"). Such payment will be by wire transfer per instructions to be provided by LMI no later than the Signing Date.

**RELEASE & COVENANT NOT TO SUE**

5. Effective immediately upon receipt by LMI of the Settlement Payment described in Paragraph 4, LMI, for itself and its predecessors, successors, affiliates, heirs, assigns, administrators, agents, shareholders, directors, principals, officers, partners, employees, agents, contractors, attorneys, and representatives, hereby releases and forever discharges BVL, its parent, subsidiaries, divisions, affiliates, predecessors, successors, assigns, shareholders, directors, principals, officers, employees, agents, contractors, insurers and attorneys (the "BVL Released Parties"), from any and all claims of any nature whatsoever through the Effective Date, whether such claims have accrued or not accrued as of the Effective Date, including, without limitation, any claims at law or in equity, requests for actual, compensatory, liquidated, special, incidental, consequential, exemplary and punitive damages, attorney's fees and equitable or injunctive relief, and all claims, causes of action, and damages whether or not LMI is aware of

such claims. This release and discharge is intended to be broad and expansive, to release and waive all claims and causes of action whatsoever, known or unknown, contingent or liquidated, direct or indirect that LMI has or may have against the BVL Released Parties as of the Effective Date, including, but not limited to, damages, claims and causes of action relating to, arising out of, or based upon the negotiation, execution, representations, warranties, duties, obligations, performance, non-performance, termination or breach of the Manufacturing Agreement.

6. Effective immediately upon receipt by LMI of the Settlement Payment described in Paragraph 4, BVL, for itself and its predecessors, successors, affiliates, heirs, assigns, administrators, agents, shareholders, directors, principals, officers, partners, employees, agents, contractors, attorneys, and representatives, hereby releases and forever discharges LMI, its parent, subsidiaries, divisions, affiliates, predecessors, successors, assigns, shareholders, directors, principals, officers, employees, agents, contractors, insurers and attorneys (the "LMI Released Parties"), from any and all claims of any nature whatsoever through the Effective Date, whether such claims have accrued or not accrued as of the Effective Date, including, without limitation, any claims at law or in equity, requests for actual, compensatory, liquidated, special, incidental, consequential, exemplary and punitive damages, attorney's fees and equitable or injunctive relief, and all claims, causes of action, and damages whether or not BVL is aware of such claims. This release and discharge is intended to be broad and expansive, to release and waive all claims and causes of action whatsoever, known or unknown, contingent or liquidated, direct or indirect that BVL has or may have against the LMI Released Parties as of the Effective Date, including, but not limited to, damages, claims and causes of action relating to, arising out of, or based upon the negotiation, execution, representations, warranties, duties, obligations, performance, non-performance, termination or breach of the Manufacturing Agreement.

7. Except as to enforcement of this Settlement Agreement, LMI and BVL covenant and agree that they will forever refrain from instituting, prosecuting, maintaining or pressing any claim, action, suit, or proceeding against the BVL Released Parties or LMI Released Parties relating to, arising out of, or based upon the Manufacturing Agreement or all other matters released in Paragraphs 5 and 6.

**OTHER PROVISIONS**

8. This Settlement Agreement shall in no event be construed as or be deemed to be evidence of an admission or concession on the part of any Party of any claim or any fault or liability or damages whatsoever.

9. LMI represents and warrants that no person or entity other than LMI has any interest in, and that LMI has not made any assignment or transfer of, any right, claim, demand, cause of action, or other matter covered by the release in Paragraph 5 of this Settlement Agreement.

10. BVL represents and warrants that no person or entity other than BVL has any interest in, and that BVL has not made any assignment or transfer of, any right, claim, demand, cause of action, or other matter covered by the release in Paragraph 6 of this Settlement Agreement.

11. The Parties and their counsel agree not to disclose to any person or entity, directly or indirectly, or by or through any agent, employee, or other representative, the terms or conditions of this Settlement Agreement other than as necessary to effectuate the provisions of this Settlement Agreement or as may be required by any applicable law, including United States securities laws, or the rules of any stock exchange or NASDAQ, provided, however, that prior to any announcement in accordance with applicable law or rules, the disclosing Party shall provide written notice of such potential announcement to the other Party, and cooperate with the other

Party's requests and lawful decision to avoid or minimize the degree of such disclosure. Notwithstanding the foregoing, the Parties may disclose the fact of settlement and that their disputes have been resolved.

12. This Settlement Agreement may not be introduced into evidence in any proceeding by any person or entity, nor may it be used in support of or for the prosecution of any cause of action against any Party except for enforcing the terms and conditions of this Settlement Agreement.

13. Each Party, on its own, has made such investigation of the facts pertaining to the claims released herein as it has deemed necessary. Each Party agrees and acknowledges that there may be facts of which it is presently unaware, but it nonetheless assumes the risk of entering into this Settlement Agreement. Each Party further agrees and acknowledges that there are or may be losses or claims arising out of or connected with the Manufacturing Agreement or the released claims that are as yet unknown to the Party and that may not be known until sometime in the future. Notwithstanding this fact, each Party has explicitly negotiated and bargained for the release herein. Thus, in furtherance of their intentions, the Settlement Agreement shall remain in full force and effect notwithstanding the discovery of any additional facts or law, or changes in facts or law, and the Settlement Agreement shall not be subject to rescission or modification by reason of any change or difference in facts or law.

14. By signing this Settlement Agreement, the Parties acknowledge that they have been advised with respect thereto by their respective attorneys, that they have been afforded ample opportunity to review this Settlement Agreement, that they have read and do understand this Settlement Agreement, and that they have executed this Settlement Agreement freely and voluntarily. The Parties specifically acknowledge that they have reviewed or have had the

opportunity to review this Settlement Agreement with their legal or other advisors, and are fully aware of all of their rights and alternatives.

15. LMI represents that it has carefully considered the terms of the Settlement Agreement and that its Board of Directors using their best business judgment have determined that it is in the best interest of the company and its shareholders to enter into this Settlement Agreement.

16. BVL represents that it has carefully considered the terms of the Settlement Agreement and that its Board of Directors using their best business judgment have determined that it is in the best interest of the company and its shareholders to enter into this Settlement Agreement.

17. This Settlement Agreement (i) contains the entire understanding of the Parties hereto, (ii) supersedes any and all prior agreements regardless of their nature, and (iii) shall not be amended or modified except by a written instrument hereafter signed by all Parties hereto.

18. EACH PARTY FURTHER ACKNOWLEDGES AND AGREES THAT, IN ENTERING INTO THIS SETTLEMENT AGREEMENT, IT HAS NOT IN ANY WAY RELIED UPON ANY ORAL OR WRITTEN AGREEMENTS, STATEMENTS, PROMISES, INFORMATION, ARRANGEMENTS, UNDERSTANDINGS, REPRESENTATIONS, OR WARRANTIES, EXPRESS OR IMPLIED, NOT SPECIFICALLY SET FORTH IN THIS SETTLEMENT AGREEMENT.

19. Should any provision of this Settlement Agreement be held illegal, invalid or nonbinding on any of the Parties, such holding shall not invalidate the whole of this Settlement Agreement. Instead, the Parties shall negotiate in good faith to reform this Settlement Agreement in order to give effect to the original intention of the Parties in all material respects.

All other provisions hereof shall remain in full force and effect and shall be liberally construed in order to carry out the intentions of the Parties as nearly as may be possible.

20. No waiver of the breach of any of the provisions of this Settlement Agreement shall be a waiver of any preceding or succeeding breach of that provision, or of any other provision(s) of this Agreement. No waiver of any provision of this Settlement Agreement shall be effective unless evidenced by a written instrument signed by the waiving Party.

21. The Parties each acknowledge that the terms and conditions of this Settlement Agreement have been the subject of active and arms-length negotiations, and that such terms and conditions should not be construed in favor of or against any Party by reason of the extent to which any Party or its professional advisors participated in the preparation of this Settlement Agreement. None of the Parties to this Agreement shall be considered the drafter of this Settlement Agreement or any included provision for the purpose of any statute, case law or rule of construction that would or might cause any provision to be construed against the drafter.

22. The Parties agree to execute any and all supplementary documents and to take all additional steps reasonably necessary to give full force and effect to the terms and intent of this Settlement Agreement.

23. All covenants and agreements herein shall bind and inure to the benefit of the respective successors of the Parties hereto.

24. This Settlement Agreement shall be construed and interpreted to effectuate the Parties' intent, which is to resolve completely any and all claims and potential claims, whether known or unknown, that LMI has or may have against the BVL Released Parties or that BVL has or may have against the LMI Released Parties, including, but not limited to, claims relating to, arising out of, or based upon the Manufacturing Agreement.

25. This Settlement Agreement and the rights and obligations of the Parties hereunder shall be governed by Delaware law and, to the extent the laws of the State of Delaware are preempted or otherwise made inapplicable by federal law, the laws of the United States of America. Each of the Parties irrevocably and unconditionally agrees that any suit, action or legal proceeding arising out of or relating to this Settlement 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; consents and submits to the exclusive jurisdiction of such foregoing courts in any such suit, action or proceeding; consents to personal jurisdiction in such courts; waives any objection which it may have to laying of venue of any such suit, action or proceeding in said courts; and waives any claim or defense of inconvenient forum.

26. In the event of an alleged breach of the Settlement Agreement or a dispute between or among the Parties in connection with the performance of the Settlement Agreement, the Parties shall be required to first provide notice and a reasonable opportunity to cure. Unless otherwise stated in writing subsequent to the Signing Date of this Settlement Agreement, all notifications and communications made pursuant to this Agreement shall be submitted to the persons and entities listed below by Federal Express, UPS, or any other overnight carrier in which case the notice shall be deemed given two (2) business days from the date of delivery to such carrier or by confirmed facsimile (followed by delivery of an original via overnight carrier), in which case the notice shall be deemed given on confirmation of transmission:

Lantheus Medical Imaging, Inc.:  
331 Treble Cove Road  
North Billerica, MA 08162  
Attn: General Counsel  
Telephone: (978) 671-8408  
Facsimile: (978) 671-8724

Ben Venue Laboratories, Inc.:

300 Northfield Road  
Bedford, OH 44146  
Attn: Vice President, Contract Manufacturing Services  
Telephone: (440) 232-3320  
Facsimile: (440) 439-6398

With a copy (that shall not constitute legal notice) to:

Division Legal Counsel  
Ben Venue Laboratories, Inc.  
300 Northfield Road  
Bedford, Ohio 44146  
Telephone: (440) 703-7899  
Facsimile: (440) 232-6264

27. The headings contained in this Settlement Agreement are for convenience only. If any conflict arises between the terms of this Settlement Agreement and the headings contained in this Settlement Agreement, the substantive terms of this Settlement Agreement shall control.

28. The undersigned individual signatories each represent that they are authorized to execute this agreement on behalf of the Party identified with respect to each.

29. This Settlement Agreement may be executed in counterparts and it is the intent of the parties that the copy signed by any Party will be fully enforceable against said Party.

30. Notwithstanding anything to the contrary contained herein, if more than \*\*\*\* Dollars (\$\*\*\*\*) of the Settlement Payment, in the aggregate, is recovered, rescinded, reduced in amount or otherwise required to be returned to BVL (and LMI actually pays and returns such funds to BVL or its trustee, as the case may be) whether as a result of any proceedings in bankruptcy or otherwise, including but not limited to as a "voidable preference" or "fraudulent conveyance", the Release & Covenant Not To Sue set forth in Sections 5, 6 and 7 hereof automatically shall be deemed null and void, and all rights and claims of LMI and BVL, as the case may be, as against the other Party, shall be restored retroactively to the date hereof as if the Parties had never entered into this Settlement Agreement; provided, however, that in no event

shall the aggregate claim against BVL as a result of the operation of this Section 30 ever exceed the difference between (A) \*\*\*\* Dollars (\$\*\*\*\*) and (B) the amount of the Settlement Payment that has not been required to be returned to BVL.

IN WITNESS WHEREOF, the Parties have executed this Settlement Agreement through their duly authorized representatives.

**BEN VENUE LABORATORIES, INC.**

**LANTHEUS MEDICAL IMAGING, INC.**

By: /s/ George Doyle  
Print: George Doyle  
Title: President, CEO  
Date Signed: 3/20/2012

By: /s/ Michael P. Duffy  
Print: Michael P. Duffy  
Title: Vice President and Secretary  
Dated Signed: 3/20/12

By: /s/ William A. Owen  
Print: William A. Owen  
Title: VP Finance  
Date Signed: 3/20/12

**CONFIDENTIAL TREATMENT REQUESTED**

**INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND NOTED WITH "\*\*\*\*\*". AN UNREDACTED VERSION OF THIS DOCUMENT HAS ALSO BEEN PROVIDED TO THE SECURITIES AND EXCHANGE COMMISSION.**

**CONFIDENTIAL  
EXECUTION VERSION**

**Transition Services Agreement**

Lantheus Medical Imaging, Inc.  
03/20/2012

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## ATTACHMENTS

### Attachment “A” — Product Supplements

A x.1 Product Identification

A x.2 Product Testing Specification

A x.3 Materials Supplied By Customer And BVL

A x.4 [Intentionally Omitted]

A1.4.1 [Intentionally Omitted]

A1.4.2 [Intentionally Omitted]

A x.5 Pricing

Ax.6 Territory (for Products identified in A x.1)

### Attachment “B” — Purchase Order Requirements

### Attachment “C” — Monthly Storage Fees

### Attachment “D” — Documents Supplied with Batch Release

### Attachment “E” — Quality Agreement

### Attachment “F” — Customer Supplied Equipment

### *Additional Attachment for Use if “Territory” for any Product Includes the European Union:*

### Attachment “G” — Representation regarding Customer’s Qualified Person

### Attachment “H” — Certificate of Compliance

## Transition Services Agreement

This Transition Services Agreement (hereinafter this "Agreement") is made effective as of March 20, 2012 (the "Effective Date"), by Ben Venue Laboratories, Inc., a corporation organized and existing under the laws of Delaware, with its principal office at 300 Northfield Road, Bedford, Ohio, 44146 (hereinafter "BVL") and as further defined in Article I) and Lantheus Medical Imaging, Inc., a corporation organized and existing under the laws of Delaware, with its principal place of business at 331 Treble Cove Road, North Billerica, MA 01862 (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 the owner or licensee of all rights to certain proprietary technical information, patents and/or patent applications relating to Product(s) (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

WHEREAS, BVL possesses the personnel and Facilities (as defined below) for the development and Manufacturing (as defined below) of finished sterile dosage forms of Product and is willing to allocate and commit resources and Manufacture such Product(s) pursuant to the terms of this Agreement; and

WHEREAS, Customer acknowledges that it is aware that in May 2011 and November 2011, BVL's manufacturing facility was inspected by the United States Food and Drug Administration and by the European Medicines Agency in March 2011 and November 2011. Customer further acknowledges that each of these inspections resulted in observations from the regulatory authority citing deviations from current Good Manufacturing Practices ("GMP"). Customer acknowledges The European Medicines Agency and the Therapeutic Goods Administration have issued BVL short-dated, restricted GMP licenses. Customer further acknowledges that it is aware (i) BVL voluntarily suspended manufacturing at its site as of November 2011, and (ii) \*\*\*\*. Customer has reviewed the records of inspection from the above mentioned regulatory authorities as well as BVL's corrective action responses to the regulatory agencies and is satisfied that the corrective actions set forth in BVL's corrective action plan should rectify the cGMP issues at the manufacturing facility that directly or indirectly affect Customer's Product. Based on the foregoing, Customer acknowledges that the GMP issues set forth above, as well as any prior deviations from cGMP by BVL, shall not constitute grounds for a claim of any breach of this Agreement, and Customer specifically waives any right to claim any breach under this Agreement based on any such prior deviations from cGMP. For the avoidance of doubt, any reference in this Agreement to BVL's compliance and/or conformance with GMP or cGMP, whether for facilities, manufacturing operations, personnel, products or otherwise, shall be deemed qualified by the terms of this paragraph.

WHEREAS, Customer and BVL were parties to that certain Manufacturing and Service Contract for Commercial and Developmental Goods dated as of July 1, 2008 (the "Manufacturing Agreement") which agreement was terminated pursuant to the terms of the certain Settlement and Release Agreement entered into between BVL and Customer as of March 20, 2012 (the "Settlement Agreement").

WHEREAS, the foregoing recitals constitute express terms of this Agreement.

NOW, THEREFORE, Customer and BVL agree as follows:

#### ARTICLE 1 - DEFINITIONS

In this Agreement, the following terms shall have the meanings set forth below:

- 1.1. “Act” means the US Federal Food, Drug and Cosmetic Act of 1938, the Public Health Service Act of 1944 and the regulations promulgated under that Act, as may be amended from time to time.
- 1.2. “Active Pharmaceutical Ingredient” or “API” shall mean bulk supplies of the pharmacologically active compound(s) comprising Product and listed in each Attachment “A#.3,” (*i.e.*, A1.3) which Customer will provide to BVL in bulk form, from time to time, for the sole purpose of development and Manufacture of Product for Customer.
- 1.3. “Affiliate” shall mean, with respect to Customer: (a) any corporation or business entity, fifty percent (50%) or more of the voting stock or voting equity interests of which are owned directly or indirectly by a Party; or (b) any corporation or business entity which directly or indirectly owns fifty percent (50%) or more of the voting stock or voting equity interests of a Party; or (c) any corporation or business entity directly or indirectly controlling or under control of a corporation or business entity as described in (a) or (b). For the purposes of this Agreement, the “Affiliate” shall mean, with respect to BVL, Bedford Laboratories. (along with its successors and assigns) (“Bedford”). For the avoidance of doubt, this Agreement will not be binding on affiliates of BVL other than (i) Bedford, (ii) BVL’s Agents as authorized hereunder, and (iii) as set forth in Articles 9 and 11.
- 1.4. “Agent” or “Agents” shall mean any individual or entity which performs on behalf of a Party under this Agreement, and in the case of any such individuals, the term “Agent” shall be understood to include the entity employing such individual.
- 1.5. “Agency” and “Agencies” shall mean the regulatory entities for each respective country, states and/or territories as identified in and limited to each Product’s definition of the Territory (as defined below) (*i.e.*, for Product A1 see Attachment A1.6); including: if Territory includes the United States, the FDA; if Territory includes Canada and its Provinces, the Canadian Health Protection Branch; if Territory includes any member state of the European Union, the European Agency for Evaluation of Medicinal Products (hereinafter the “EMA”); if Territory includes Japan, the Japanese Ministry of Health, Labor and Welfare; (b) any successor organization of any such entity; and (c) any other government regulatory authority with regulatory oversight of the Manufacturing, the Facilities or use of Product in or for its Territory, as such other authorities are mutually agreed upon by the Parties in writing.
- 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, without limitation, the bodies of law, regulations (including without limitation, cGMP or its equivalent) and environmental, health and safety for each country of the Territory.

1.7. “Batch” shall mean a specific quantity of Product that is intended to be of uniform character and quality and is produced during the same cycle of Manufacture as defined by the applicable Batch Record (as defined below). 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 Indemnities” shall have the meaning ascribed thereto in Section 8.1.

1.10. “BVL Inventions” shall have the meaning ascribed thereto in Section 11.4.

1.11. “BVL Technology” shall mean the Technology (as defined below) 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 or the Manufacturing Agreement and without reliance upon Product, any API supplied by Customer, or Confidential Information or Composition of Customer; or (c) is a BVL Invention or BVL’s Other Invention (as defined herein).

1.12. “cGMP” shall mean, with respect to each Product, the current Good Manufacturing Practices in such Product’s Territory (Attachment “A#.6”, i.e., A1.6) as may be amended or supplemented from time to time; including (i) if in the United States, then cGMP shall include without limitation, the current Good Manufacturing Practices set forth in 21 C.F.R. 210 and 21 C.F.R. 211 and relevant FDA guidance documents; and (ii) if in the European Union, then cGMP shall include, without limitation, the practices and standards described in the Guide to Good Manufacturing Practices for Medicinal Products as promulgated by the European Commission under European Directive 2003/94/EC, as may be amended or supplemented from time to time and the ICH Harmonised Tripartite Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients (ICH Q7), as each may be amended from time-to-time, or any successors thereto. In the event of any conflict among Applicable Laws pertaining to the Manufacture of Product, the most stringent among the conflicting Applicable Laws will govern unless the Parties agree otherwise in writing.

1.13. “Certificate of Analysis” shall mean a summary of the test results, including the test methods, specification parameters, and the pass/fail criteria, used in the determination of the quality and suitability of a specific Batch of Product, including review and approval by the appropriate quality assurance department at BVL

1.14. “Certificate of Compliance” shall mean, subject to the limitations set forth in the fourth Recital paragraph, a document, signed by an authorized representative of BVL, attesting that a particular Batch was manufactured in accordance with cGMP, the Specifications (as defined below) and other Applicable Law. As Customer is aware, the European Medicines Agency and Therapeutic Goods Administration have issued BVL restricted, short-dated GMP licenses. In addition, BVL’s GMP license in Canada has been restricted to medically necessary products. Based on these restricted GMP licenses, BVL has modified its Certificate of Compliance, a copy of which is included in Attachment “H”.

1.15. “Claims” shall have the meaning ascribed thereto in Section 8.1.

1.16. “Composition” shall mean any components and/or raw materials other than API that are used in the Manufacturing of Product and listed in each Attachment “A#.3” (i.e., A1.3) hereto, which may be supplied by BVL or Customer as required pursuant to such Attachment.

- 1.17. “Confidential Information” shall have the meaning set forth in Section 9.1.
- 1.18. [Intentionally Omitted]
- 1.19. [Intentionally Omitted]
- 1.20. “Customer Indemnitees” shall have the meaning ascribed thereto in Section 8.2.
- 1.21. “Customer Inventions” shall have the meaning ascribed thereto in Section 11.3.
- 1.22. “Customer Technology” shall mean all: (a) API and Customer-supplied Composition; (b) Products and any intermediates or derivatives thereof; (c) Specifications; (d) the Technology of Customer owned, developed or obtained by or on behalf of Customer or Customer’s Affiliates prior to the Effective Date, or owned, developed or obtained by or on behalf of Customer or its Affiliates independent of this Agreement and without reliance upon the Confidential Information, Improvements or Technology of BVL; and (e) Customers’ Improvement.
- 1.23. [Intentionally Omitted].
- 1.24. “Disclosing Party” means the party which is directly or indirectly disclosing Confidential Information to the Receiving Party (as defined below) 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 relating to the API and Product and such other information as required by Applicable Laws, including 21 C.F.R. Section 314.420 and to the extent applicable any equivalent requirement in under Applicable Laws including as required by the Committee for Proprietary Medicinal Products Note for Guidance on the European Drug Master File Procedure for Active Ingredients.
- 1.26. “Equipment” shall mean the equipment described in the Master Batch Record (as defined below) which is: (a) owned or leased by BVL; or (b) if supplied by Customer, then identified in Attachment “F” to this Agreement, and in each case will be used by BVL for the 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 300 Northfield Road, Bedford, Ohio, and 19200 Treat Road, Walton Hills, Ohio, 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 accordance with Section 3.2.
- 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. §§301 et seq., as amended from time to time.
- 1.30. “Firm Order” shall mean a binding commitment, as established by a Purchase Order (as defined below) issued by Customer, to have a Batch of Product Manufactured by BVL hereunder.

1.31. [Intentionally Omitted]

1.32. “Force Majeure” shall have the meaning set forth in Section 17.1.

1.33. [Intentionally Omitted].

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 the Manufacture of Product or otherwise arise in the performance of any services related to the Product under this Agreement.

1.36. “Investigation” shall mean a detailed and thorough review of any Manufacturing deviation (or any other matter requiring review pursuant to the terms of this Agreement) that is documented in a written report and approved at a senior management level. Each such written report shall include, without limitation, a detailed description of the atypical event, deviation or other matter, all steps taken to review such 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, if applicable.

1.37. “Losses” shall have the meaning ascribed thereto in Section 8.1.

1.38. “Manufacture,” “Manufacturing,” and “Manufactured” shall mean all operations of BVL in the scheduling, production, packaging, labeling, warehousing, quality control testing (including in-process, release and stability testing when applicable), release and shipping of Product to meet the Specifications for Products.

1.39. “Manufacturing Process” shall mean any and all processes (or any step in any process) used or planned to be used by BVL to Manufacture Product, as evidenced in the Batch Records.

1.40. “Manufacturing Date” shall mean the date on which BVL commences manufacture of a Batch.

1.41. “Marketing Authorization” shall mean a New Drug Application (as defined below) filed with an Agency outside the United States.

1.42. “Master Batch Record” or “MBR” means the document containing the mutually agreed to Manufacturing Process including but not limited to the instructions for formulation, filling, lyophilization if applicable, packaging, labeling and specifications for components and raw materials to be used in the Manufacture of the Product. In-process and finished Product Specifications for the Product will be referenced in the Master Batch Record. It may also be referred to as the “Master Production Record” or “MPR”. The MBR may be amended from time to time by mutual written agreement of the Parties

1.43. “NDA” shall mean a New Drug Application filed with the FDA.

- 1.44. [Intentionally Omitted]
- 1.45. “Party” or “Parties” shall have that meaning as set first in the first unnumbered paragraph of this Agreement.
- 1.46. “Products” shall mean the final packaged dosage forms of the following:

Transition Services Agreement Attachment	Product	Batches
A1.1	Sestamibi, **** mg lyo in a **** mL vial	****
A2.1	Neurolite ligand, **** mg lyo in a **** mL vial	****
A3.1	Eluant, **** mg/mL liquid, **** mL in a **** mL vial	****
A4.1	Eluant, **** mg/mL liquid **** mL in a **** mL vial	****
A5.1	Neurolite buffer, liquid, **** mL in a **** mL vial(1)	****
A6.1	(Intentionally Omitted)	
A7.1	Definity **** mg lyo in a **** mL vial(2)	****

If used in the singular rather than plural, “Product” shall apply to an individual product as listed in Attachment “A#.1”

1.47. “Promptly” shall mean within thirty calendar (30) days.

1.48. “Purchase Order” shall mean a written form submitted by Customer to BVL authorizing the Manufacture of Product or other services as specified on the document which references this Agreement or a quotation number provided by BVL or other document provided by BVL outlining the services to be performed, the price to be paid, and contains each of the requirements set forth on Attachment “B.”

1.49. “Qualified Person” shall have the meaning set forth in Article 48 of the European Directive 2001/83/EC, and as set forth elsewhere within the EU regulations, as may be amended from time to time.

1.50. “Quality Agreement” shall mean the separate quality agreement 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) The Parties may mutually agree to \*\*\*\* Neurolite buffer Batch of \*\*\*\* the normal Batch size contemplated by Attachment A5 hereof necessary to complement the \*\*\*\* Neurolite ligand Batches described above.
- (2) Inclusive of BVL’s release to Customer of \*\*\*\* lot of Definity Product as contemplated by Section 6.8.1.

1.51. “Receiving Party” means the party which is directly or indirectly in receipt of Confidential Information from the Disclosing Party pursuant to this Agreement. The Receiving Party may also act as the Disclosing Party of the other party’s Confidential Information.

1.52. “Records” shall have the meaning ascribed thereto in Section 3.8.

1.53. “Relevant Product” shall mean the Product; any product containing the same API as Customer’s Product, or any product developed or manufactured using the same API which competes in the same diagnostic class as the Product. For the avoidance of doubt, BVL shall not be prevented from manufacturing a product containing the same API which does not compete in the same diagnostic class as the Product.

1.54. “Representative” shall have the meaning ascribed thereto in Section 2.5.

1.55. [Intentionally Omitted]

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.

1.57. “Specification” or “Specifications” shall mean the quality standards, including tests, analytical procedures and acceptance criteria that are established to confirm the quality of Product which are mutually agreed to in writing and are contained or referenced in the Master Batch Record for Product or as otherwise mutually agreed to in writing by the Parties.

1.58. “Technology” shall mean all methods, techniques, trade secrets, copyrights, know-how, data, documentation, regulatory submissions, Product Specifications (which are solely owned by Customer, except for those portions of such Specifications that include routine BVL policies, procedures, etc. and that are not Product-specific) 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 6.5.

1.60. “Territory” shall mean those countries and territories set forth in each Attachment “A#.6” (i.e., A1.6) for the Product identified in each such Attachment “A,” it being understood that different Products may have different Territories for purposes of this Agreement.

1.61. “Third Party” shall mean any person or entity other than a Party to this Agreement or such Party’s Affiliate.

1.62. “United States” or “U.S.” shall mean the United States of America, its territories and possessions including Puerto Rico.

## ARTICLE 2 - DESCRIPTION OF WORK

2.1. Equipment.

2.1.1. 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.

2.1.2. 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 purchased is identified on Attachment "F" (title to which shall at all times remain with Customer) and shall be solely dedicated to the production of Products hereunder. 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. BVL shall, at all times and at its sole cost, be responsible for all normal and routine maintenance to the Equipment identified on Attachment "F" in accordance with current BVL's SOP's, which procedures have been reviewed and approved by Customer. Customer shall, at all times and at its sole cost, be responsible for upgrades, repairs, replacement, non-routine maintenance and/or enhancements to the Equipment identified on Attachment "F" and BVL shall obtain Customer's prior written approval prior to incurring such costs. Risk of loss of all Equipment identified on Attachment "F" shall be retained by BVL to the extent that loss and/or damage of equipment is caused by BVL's act of negligence, breach, willful misconduct. For the avoidance of doubt, BVL shall not be liable or bear risk of loss for repairs or upgrades to the equipment except if caused by BVL's failure to perform maintenance as required pursuant to this Agreement.

2.2. API and Composition.

2.2.1. Customer Supply of API & Composition. Customer shall, at its own expense, supply BVL with sufficient quantities of API and Customer-supplied Composition, including API, needed for the Manufacture of Product, as specified in the supporting Purchase Orders, in order to meet Customer's Purchase Orders for Product in finished dosage form. BVL shall have no liability for quantities of API or Customer-Supplied Composition shipped in excess of the requirement to Manufacture the amount of Product required to fill open Purchase Orders, but shall use such API or Composition for future Purchase Orders.

2.2.2. Certification of Customer Supplied Composition & Equipment. Upon BVL's request, Customer shall provide written confirmation of the review and approval of the quality systems of its designated vendors for Customer-supplied Composition/Equipment.

2.2.3. Reports for Customer Supplied Composition. BVL shall: (i) provide Customer with standard inventory reports for all API and Customer-supplier Composition for the prior \*\*\*\* not later than the \*\*\*\* (\*\*\*\*) business day of each \*\*\*\*; (ii) notify Customer when the amount of API or Customer-supplied Composition available at BVL reaches the minimum quantity of materials as agreed by both Parties; (iii) not provide API or Customer-supplied Composition to any Third Party without the express prior written consent of Customer; (iv) not use API or Customer-supplied Composition for any purpose other than the Manufacture of Product or conducting other services under this Agreement, including, without limitation, not to analyze, characterize, modify or reverse engineer any API, or take any action to determine the structure or composition of any API, unless the foregoing is required under this Agreement; and (v) destroy or return to Customer or its designee all unused quantities of API and Customer-supplied Composition according to Customer's written directions at Customer's cost. If no written directions are provided to BVL within thirty (30) days following termination of this Agreement, or any

postponement or cancellation of a Purchase Order, then without BVL having any liability to Customer, BVL may dispose of such API or Composition upon not less than ten (10) days prior written notification to Customer of BVL's intent to dispose of such API or Composition per cGMP(s). Customer shall be financially liable for the cost or expense associated with any such disposal.

2.2.4. Annual Physical Audit. In addition to Customer's annual GMP audit, Customer will be entitled to perform an annual physical audit of Customer-supplied Composition at a date and time to be agreed upon by both Parties. If the scope of the audit warrants (e.g., significant number of materials, number of personnel in attendance, BVL's involvement, etc.) a quotation will be provided to Customer.

2.2.5. ID Only Verification. Customer must give written permission to BVL to do ID-only, by-label verification of any API or active drug substance if no identification test is requested by Customer to be performed by BVL.

2.2.6. Release of Materials. BVL will release all materials provided by BVL. In the event the Territory (Attachment "A#.6") includes the European Union, then Customer's Qualified Person shall be responsible to certify compliance of the Customer-supplied API and for the release of Product within the European Union and for EU Directives, standards and rules, including without limitation, Article 51(3) of Directive 2001/83/EC, with respect to the Product(s).

2.2.7. Quality Control Testing Requirements. Customer will provide, or cause BVL to develop at mutually agreed upon fees, written quality control testing requirements, methods, specifications and reference standards for the API and Product, which shall be performed by BVL in accordance with the Specifications. Customer will approve in writing initial testing documents, the Master Production Record and any revisions of the documents thereafter. Revisions of approved testing documents requested within eight (8) weeks prior to the Manufacturing Date or other services related to the subject Product may cause a delay or postponement of such 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. Upon mutual agreement between the Parties which shall not be unreasonably or untimely withheld, BVL shall make revisions to the testing documents or MBR for a Product that are requested by Customer. Further, BVL shall be entitled to reasonable reimbursement for any and all additional costs and expenses incurred by BVL in connection with any such revision or delay as agreed upon by the Parties. The Parties shall cooperate in good faith to reach agreement for the changes and the associated costs.

2.2.8. Disposition of Tailings/Rejects. Customer is responsible for notifying BVL with instruction for disposition of tailings and rejects, which will be incorporated into the Master Batch Record and include a shipment address for tailing and rejects if Customer requests return of tailings and rejects.

2.2.9. Customer Liable for Changes to BVL Composition. BVL shall procure, at its cost, all BVL-supplied Composition listed as BVL's responsibility in Attachment A#.3 for a Product in order for BVL to meet Customer's Purchase Orders made pursuant to this Agreement. In the event that Customer makes changes to the vendor and/or specifications of any BVL-supplied Composition, any additional

expense due to such change shall be borne by the Customer as agreed upon, and the Parties shall negotiate, in good faith, an appropriate adjustment to the purchase price of the Product to reflect any increase or decrease in costs due to such changes. If Customer requires BVL utilize a specific vendor for any BVL supplied Composition and BVL is reasonably unable to utilize such vendor, then if Customer requires such vendor to be utilized, Customer shall have the responsibility to source such Composition and provide to BVL pursuant to the terms of this Agreement, which shall thereafter be deemed a Customer-supplied Composition under this Agreement.

2.3. Product Manufacture. Pursuant to the provisions of this Agreement, BVL shall Manufacture Customer's Purchase Order quantities of Product in finished packaged dosage form as defined in each Attachment "A#.1" (i.e., A1.1) For the avoidance of doubt, notwithstanding anything in this Agreement to the contrary, such Product shall meet the Specification, the requirements of cGMP and all Applicable Law. BVL, its Agents and Bedford (and any business, operations, personnel or assets owned or controlled by BVL and such Agents and any successors thereto, as the same may be reorganized from time to time) shall not during the term Manufacture for any Third Party, directly or through any Third Party any Relevant Product or provide or cause to be or assist in providing any products or services (including in manufacturing, development, or procurement) any Relevant Product, only in each case with the prior written consent of Customer (which may be given at its sole discretion).

2.4. [Intentionally Omitted].

2.5. Representatives. Each Party shall appoint a representative having primary responsibility for day-to-day interactions with the other Party for the services under this Agreement (each, a "Representative"). Both Parties shall use reasonable efforts to provide the other with at least forty-five (45) days prior written notice of any change in its Representative. Except for notices or communications required or permitted under this Agreement, which shall be subject to Article 13, or unless otherwise mutually agreed by the Parties in writing, all communications between BVL and Customer regarding the conduct of the services under this Agreement shall be addressed to, or routed directly through, the respective Representatives of each Party, as appropriate.

### **ARTICLE 3 - MANUFACTURE**

3.1. BVL Compliance. BVL has obtained, and will maintain at its sole cost and expense throughout the term of this Agreement, all licenses, permits, certifications and approvals required under Applicable Law for its Manufacturing Facilities and for its performance under this Agreement; BVL's Facilities conform, and will throughout the term of this Agreement conform to cGMP and other Applicable Law. Customer acknowledges that it is aware that in May 2011 and November 2011, BVL's manufacturing facility was inspected by the United States Food and Drug Administration and by the European Medicines Agency in March 2011 and November 2011. Customer further acknowledges that each of these inspections resulted in observations from the regulatory authority citing deviations from current Good Manufacturing Practices. Customer also acknowledges The European Medicines Agency and the Therapeutic Goods Administration have issued BVL short-dated, restricted GMP licenses. Customer further acknowledges that it is aware BVL voluntarily suspended manufacturing at its site as of November 2011. Customer has reviewed the records of inspection from the above mentioned regulatory authorities as well as BVL's corrective action responses to the regulatory agencies and is satisfied that the corrective actions set forth in

BVL's corrective action plan should rectify the cGMP issues at the manufacturing facility that directly or indirectly affect Customer's Product.

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 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 completion of a quality assurance audit and/or regulatory impact assessment satisfactory to it including without limitation an environmental, health and safety audit of the new location or additional facility, as the case may be); provided, that the Parties will meet and confer to discuss allocation of any applicable costs and expenses in connection with any change of location of the Facility or use of any additional facility for BVL's convenience. BVL will be responsible for all applicable costs and expenses in connection with any change of location of the Facility or use of any additional facility for BVL's convenience (including costs for qualification and validation batches). For the avoidance of doubt, it is the Parties' intent that changes to the Facility made by or on behalf of Customer, or for the convenience of Customer shall be borne by Customer; changes to the Facility made by or on behalf, or for the convenience of BVL shall be borne by BVL. In the event that a change to the Facility is initiated by BVL, the Parties shall meet and confer on the scope of reasonable regulatory requirements to be provided by BVL. In the event the Parties cannot in good faith reasonably agree to such filing requirements, then the Parties shall mutually agree upon a qualified, neutral regulatory expert who shall fully and finally allocate the costs after reviewing and hearing each Parties arguments. The costs of the expert shall be borne equally by the Parties. BVL shall maintain, at its own expense, the Facility and all Equipment required for the Manufacture of Product in a state of repair and operating efficiency consistent with the requirements of the cGMP and all other Applicable Law.

3.3. Change Control. Any changes to the Specification, Manufacturing Process, Equipment utilized to Manufacture such Product, its testing procedures, validation, suppliers of raw materials and components, or documentation systems that are specific or related to Product would likely impact any government submission or approval pending, received and/or required for such Product, either foreign or domestic as applicable for the Territory, shall be made only with the prior written consent of the Parties and in accordance with change control provisions of the Quality Agreement. In the event any such changes are required by an Agency, BVL will Promptly notify Customer. Customer may, from time to time, propose to change Specification which shall require mutual written consent of the Parties, and BVL will not unreasonably or untimely withhold its consent to such change and will use commercially reasonable efforts to implement such change. For the avoidance of doubt it is the Parties' intent that the costs of any changes made pursuant to this Section 3.3 at Customer's request shall be borne by Customer, and the costs of any changes made pursuant to this Section 3.3 made for the convenience of BVL shall be borne by BVL. In the event that a change made pursuant to this Section 3.3 is initiated by BVL, the Parties shall meet and confer on the scope of reasonable regulatory requirements to be provided by BVL. In the event the Parties cannot in good faith reasonable agree to such filing requirements, then the Parties shall mutually agree upon a qualified, neutral regulatory expert who shall fully and finally allocate the costs after reviewing and hearing each Parties arguments. The costs of the expert shall be borne equally by the Parties.

3.4. Product Compliance. Product delivered to Customer pursuant to this Agreement shall conform to the Specification and be in compliance with all Applicable Law, including but

not limited to the requirements of GMP. Customer acknowledges that it is aware that in May 2011 and November 2011, BVL's manufacturing facility was inspected by the United States Food and Drug Administration and by the European Medicines Agency in March 2011 and November 2011. Customer further acknowledges that each of these inspections resulted in observations from the regulatory authority citing deviations from current Good Manufacturing Practices. Customer acknowledges The European Medicines Agency and the Therapeutic Goods Administration have issued BVL short-dated, restricted GMP licenses. Customer further acknowledges that it is aware BVL voluntarily suspended manufacturing at its site as of November 2011. Customer has reviewed the records of inspection from the above mentioned regulatory authorities as well as BVL's corrective action responses to the regulatory agencies and is satisfied that the corrective actions set forth in BVL's corrective action plan should rectify the cGMP issues at the manufacturing facility that directly or indirectly affect Customer's Product. Based on the foregoing, Customer acknowledges that the GMP issues set forth above, as well as any prior deviations from cGMP by BVL, shall not constitute grounds for a claim of any breach of this Agreement, and Customer specifically waives any right to claim any breach under this Agreement based on any such prior deviations from cGMP. In the event of conflicting Applicable Law, Product will comply with the most stringent from the conflicting requirements unless otherwise agreed to by the Parties.

3.5. Regulatory Communications and Inspections. All information, documents and updates with regard to the Manufacture of Product which are required by any Agency shall be provided by BVL in a timely manner, and BVL shall submit to all inquiries and inspections by any such Agency. All documents directly related to Product shall be provided to Customer in advance of submission to such Agency if feasible, and in no case shall such documents be provided to Customer later than five (5) business days after such documents and information are provided to any Agency. The foregoing obligation of disclosure excludes any information which BVL is prohibited from disclosing and/or directed or requested by a regulatory agency not to disclose, including without limitation, drafts of any potential consent decrees. BVL shall notify Customer Immediately (or, if during a weekend, upon the next business day) of all scheduled Product-specific Agency inspections, and Customer shall have the right to be present for all scheduled inspections relating to the Manufacture of Product. Any and all written communications or notices of inspection directly related to Product received from any Agency shall be provided by Customer and BVL to the other Party no later than five (5) business days after such communications or notices are received by such Party; provided, however, that if such document is from BVL, it may redact the confidential information of Third Parties from such communications prior to providing same to Customer.

3.5.1. BVL shall also notify Customer Immediately of any notices, observations or other formal written communications from such Agency provided to BVL after the Effective Date regarding any deficiencies that have or may have an adverse effect on the Product or BVL's ability to perform its obligations under this Agreement. For the avoidance of doubt, the foregoing obligation of disclosure excludes any information which BVL is prohibited from disclosing and/or directed or requested by a regulatory agency not to disclose, including without limitation, drafts of any potential consent decrees. Notwithstanding anything to the contrary hereunder, Customer shall have the right to postpone all pending and future Purchase Orders hereunder in the event of (i) any such notices, observations or communications newly provided to Customer following the Effective Date; (ii) any regulatory or other concerns under Applicable Law newly discovered following the Effective Date; (iii) any material issues with the supply of Products hereunder (including atypical Manufacturing deviations of the sort

requiring investigation hereunder); (iv) any consent decree; or (v) violations of any of the Product quality provisions of this Agreement.

3.5.2. To the extent BVL does not already have copies, 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 (2) 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 Files (DMFs) and authorization for FDA to access the DMFs. This may be used by the Customer only to prepare any required Regulatory filing. Any other use of the DMF shall require BVL's prior written approval.

3.6. Health, Safety and Environmental Compliance.

3.6.1. Dispensing and other Manufacturing operations are to be performed by BVL 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. Notwithstanding the foregoing, Customer shall be solely responsible for the disposal of any waste generated by Customer disposition of Customer-supplied Composition or finished Product.

3.6.2. Customer has established a program for systematic assessment of its suppliers' EHS programs ("TPM EHS Assessment Program") and BVL agrees to participate and reasonably cooperate with Customer in effectively implementing this TPM EHS Assessment Program.

3.6.3. BVL will review Customer's TPM EHS Assessment Program and, if applicable, provide quotations for additional resources required to address the program. BVL policies will govern except in the event that Customer is willing to bear the cost of compliance. Specifically, BVL agrees to:

3.6.3.1. Promptly respond to reasonable Customer requests for non-confidential information made as part of TPM EHS Assessment Program. Customer will provide a questionnaire to BVL and BVL is expected to provide the complete response within thirty (30) calendar days;

3.6.3.2. Reasonably cooperate with Customer to clarify and supplement any information related to its facilities and operations; and

3.6.3.3. Provide to Customer, upon request, copies of BVL's environmental, health and safety permits required by any governmental authority which are associated with the Products and all facility operations related thereto.

3.6.4. BVL agrees that Customer or its appointed Agent(s) (which Agent shall be disclosed to BVL not less than 30-days in advance of an audit and which shall not be rejected by BVL in the absence of good cause shown) shall be entitled to conduct inspections and audits upon reasonable notice (at Customer's cost) and mutually convenient times of any areas or facilities used to produce the Products or required for production of the Products, including for the following reasons:

3.6.4.1. to assist in completion of TPM EHS Assessment Program described in this Section 3.6.2; and

3.6.4.2. to allow for a loss prevention inspection of the Facility by Customer's fire insurance underwriting company as necessary for Customer to obtain contingent business interruption insurance.

3.6.5. BVL shall take reasonable and appropriate precautions to ensure that its personnel (including its employees, contractors, and Agents) are protected from Product and/or the Product's Manufacturing process exposures through either engineering infrastructure, personnel protective equipment or a combination of both. Upon request, within 90 days, BVL shall provide workplace monitoring data which demonstrates the effectiveness of controls. For testing of Customer-supplied Composition or API, Customer will provide sampling method and media to allow samples to be collected at Customer's cost. If testing methods for the API or Customer-supplied Composition in question are unavailable, surrogates may be used. Workplace monitoring data will be performed in accordance with proposals provided to Customer.

3.7. Subcontractors. Neither Party may subcontract with any Third Party or use Agents to perform any of its obligations hereunder without the prior written consent of the other Party, provided that for the avoidance of doubt: (i) any rights of Customer to perform audits as authorized hereunder (and subject to the requirements of Section 3.6.4) are not subject to the foregoing, provided in any event that such auditor shall be required to enter into a reasonable and appropriate confidentiality agreement with BVL; and (ii) BVL shall have the right to subcontract nominal, non-Manufacturing Process tasks (such as pest control, cleaning, etc.). In the event that a Party does subcontract with a permitted Third Party or Agent pursuant to this Section 3.7, it shall be solely responsible for the performance of any permitted subcontractor, and for costs, expenses, damages, or losses of any nature arising out of such performance as if such performance had been provided by itself under this Agreement. Each Party shall cause any such permitted subcontractor and Agent to be bound by, and to comply with, all confidentiality, quality assurance, regulatory and other obligations and requirements as set forth in this Agreement.

3.8. Records. BVL shall keep complete and accurate 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 and on notice to Customer pursuant to Section 3.5, without the prior written approval of Customer. While in the possession or control of BVL, Records shall be available during annual audits or as otherwise mutually agreed to times for inspection, examination and review by or on behalf of Customer and its Agents (which Agent shall be subject to the requirements set forth in Section 3.6.4 as well as a reasonable and appropriate confidentiality agreement). All original Records of the Manufacture of Product hereunder shall be retained and archived by BVL in accordance with cGMP and Applicable Law, but in no case for less than a period of \*\*\*\* (\*\*\*\*) 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. \*\*\*\* (\*\*\*\*) years after completion of the applicable work or project or such longer period in accordance with cGMP and Applicable Law unless otherwise agreed to in advance by the Parties in writing all of the aforementioned records shall be destroyed unless Customer instructs BVL in writing as to a contrary disposition for such files.

### 3.9. Product and Process Failure.

3.9.1. Product shall be Manufactured in accordance with cGMP and the Manufacturing Process approved mutually by Customer and BVL. Customer acknowledges that it is aware that in May 2011 and November 2011, BVL's manufacturing facility was inspected by the United States Food and Drug Administration and by the European Medicines Agency in March 2011 and November 2011. Customer further acknowledges that each of these inspections resulted in observations from the regulatory authority citing deviations from current Good Manufacturing Practices. Customer acknowledges The European Medicines Agency and the Therapeutic Goods Administration have issued BVL short-dated, restricted GMP licenses. Customer further acknowledges that it is aware BVL voluntarily suspended manufacturing at its site as of November 2011. Customer has reviewed the records of inspection from the above mentioned regulatory authorities as well as BVL's corrective action responses to the regulatory agencies and is satisfied that the corrective actions set forth in BVL's corrective action plan should rectify the cGMP issues at the manufacturing facility that directly or indirectly affect Customer's Product. Each Batch of Product will be sampled and tested by BVL against the Specification. The Quality Assurance Department of BVL will review the Records relating to the Manufacture of the Batch and will assess if the Manufacture has taken place in compliance with cGMP and the Manufacturing Process.

3.9.2. If, based upon such tests and/or review, a Batch of Product conforms to the Specification and was Manufactured according to cGMP and the Manufacturing Process, then a Certificate of Compliance will be generated and approved by the Quality Assurance Department of BVL. This Certificate of Compliance, a Certificate of Analysis, if required, and a complete and accurate copy of the executed Batch records (collectively, the "Batch Records") for each Batch of Product (including all the Batch documentation described in Attachment "D" to this Agreement) will be delivered to Customer in advance of Product shipment by a reputable overnight courier or by registered or certified mail, postage prepaid, return receipt requested to verify delivery date. As Customer is aware, the European Medicines Agency and Therapeutic Goods Administration have issued BVL restricted, short-dated GMP licenses. In addition, BVL's GMP license in Canada has been restricted to medically necessary products. Based on these restricted GMP licenses, BVL has modified its Certificate

of Compliance, a copy of which is included in Attachment "H"). Unless the Batch is shipped under quarantine, in the event that Customer has not received all such Batch Records at the time of receipt of BVL's invoice for such Batch, Customer will notify BVL in writing, and unless the Batch (or a partial Batch) is shipped under quarantine, Customer shall be entitled to withhold payment until Customer receives the Batch Record. 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 lot disposition of such Batch within \*\*\*\* (\*\*\*\*) calendar days of receipt of the complete Batch Records relating to such Batch. If no acceptance or rejection in writing is received by BVL within \*\*\*\* (\*\*\*\*) days, the Batch will be conclusively deemed accepted. During this review period, the Parties agree to respond punctually, and shall endeavor in good faith to comply in the typical circumstance within five (5) calendar days, to any reasonable inquiry by the other Party with respect to such Batch Records. Customer has no obligation to accept a Batch to the extent such Batch does not comply with the Specification, Applicable Law (for purposes solely due to BVL or BVL's Manufacturing or services hereunder), and/or was not Manufactured in compliance with cGMP and the Manufacturing Process.

3.9.4. In case of any disagreement between the Parties as to whether Product conforms to the applicable Specification, a representative sample of such Product shall be submitted to an independent testing laboratory mutually agreed upon by the Parties for tests and final determination of whether such Product conforms to such Specification. The laboratory must meet cGMP requirements, be of recognized standing in the pharmaceutical industry, and consent to the appointment of such laboratory shall not be unreasonably withheld or delayed by either Party. Such laboratory shall use the validated test methods contained in the applicable Specification. The determination of conformance or not by such laboratory with respect to all or part of such Product shall be final and binding on the Parties. The fees and expenses of the laboratory incurred in making such determination shall be paid by the Party against whom the determination is made.

3.9.5. Subject to Article 8, if BVL does not manufacture any Batch of Products according to GMP or the Manufacturing Process and the Product does not meet the requirements of this Agreement then BVL shall, after consultation with and written agreement from Customer:

3.9.5.1. refund any Manufacturing fees and expenses paid by Customer to BVL on a *pro rata* basis over the usable portion for such Batch; or

3.9.5.2. at BVL's cost and expense produce a new Batch of Product as soon as reasonably possible; and

3.9.5.3. reimburse Customer for any loss of API or Customer-supplied Composition pursuant to the terms set forth in Section 8.5 to the extent the reimbursement is not provided in Section 3.9.5.1 or Section 3.9.5.2.

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3.9.6. BVL or Customer may postpone all scheduled Manufacture of the affected Product until such time as final disposition of rejected Batch(s) has been determined and complete Investigations have been finalized with root cause analysis and corrective actions determined to prevent further Batch rejections. BVL shall without any undue delay perform all Investigations (including for such rejected Batches) diligently and expeditiously. The Parties will use good faith efforts to Investigate and perform corrective actions to address Batches for which any Batch Record indicates an out-of-profile condition as defined by generally accepted practice and mutually agreed upon by the Parties. Customer may request, in writing, that BVL continue to Manufacture Product pending its Investigation, and in the event that BVL elects to Manufacture Customer's Product prior to the conclusion of an Investigation, then Customer shall assume financial responsibility in the event of further Batch rejection for similar reasons. If Customer requests postponement until completion of the Investigation, there shall be no fees charged.

3.9.7. Moreover, the Parties shall meet to discuss, evaluate and analyze the reasons for and implications of the failure to meet the Specification or comply with the cGMP and/or the Manufacturing Process.

#### ARTICLE 4 - VOLUMES

4.1. Product Purchase and Supply Obligations. BVL shall supply Customer with Customer's Product as identified in Section 1.46 in accordance with the terms of this Agreement for the Territory. 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 meet the requested delivery date, the Manufacturing of any Batch of Product or any other services under this Agreement, BVL shall promptly notify Customer thereof, but in any event, within \*\*\*\* (\*\*\*\*) business days.

#### ARTICLE 5 - PURCHASE ORDERS

5.1. [Intentionally Omitted]

5.1.1. [Intentionally Omitted].

5.1.2. [Intentionally Omitted].

5.2. [Intentionally Omitted]

5.3. Purchase Orders.

5.3.1. Customer shall provide BVL with Purchase Orders for Products upon execution of this Agreement and BVL shall provide manufacturing dates once a restart timeline has been established.

5.3.2. [Intentionally Omitted]

5.3.3. Notwithstanding the foregoing, in the event that Customer, in its good faith judgment, determines that a Product, if Manufactured, will not be marketable in the Territory and that the cause for such non-marketability is solely and proximately the responsibility of BVL then the Parties shall cooperate in good faith to schedule Manufacturing of such effected Products as soon as reasonably practicable.

5.4. Obligation of Supply. BVL shall be obligated to Manufacture Product only in accordance with the Purchase Orders for the specific products and quantities listed in Section 1.46.

5.5. Additional Services.

5.5.1. [Intentionally Omitted].

5.5.2. In the event that Customer requests or an Agency requires additional services in support of Product, 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.

5.6. Supply of Composition. It is BVL's responsibility to: (a) maintain at all times a quantity of BVL-supplied Composition from mutually approved vendors sufficient to meet Purchase Orders, (b) notify Customer of its requirements of API and Customer-supplied Composition needed in order to fulfill its obligations hereunder API and Customer-supplied Composition shall be delivered to BVL not less than \*\*\*\* (\*\*\*\*) days in advance of the scheduled Manufacturing Date. Customer will provide adequate supply of reference standards for the foregoing upon request by BVL. Customer will coordinate with BVL's Materials Management Department on the specifics related to each shipment of Customer-supplied Composition. 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.

**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 for other services in applicable quotations or proposals provided to Customer and confirmed by Customer's Purchase Orders.

6.1.2. Delivery terms for Products shall be \*\*\*\* (Incoterms 2000). Customer shall assume title and risk of loss of the finished Product upon delivery to \*\*\*\*. BVL shall ensure that each Batch shall be delivered to Customer, or Customer's designee: (i) within \*\*\*\* (\*\*\*\*) days in advance or \*\*\*\* (\*\*\*\*) days after the requested delivery date or as otherwise mutually agreed to and to the destination designated by Customer on the Purchase Order; and (ii) in accordance with the instructions for shipping included on the Purchase Order and packaging specified in the Master Batch Record or as otherwise agreed to by the Parties in writing. A bill of lading shall be furnished to Customer with respect to each shipment. Customer is responsible for all shipment costs and shipping charges will be paid directly by Customer.

6.2. Pricing

6.2.1. [Intentionally Omitted]

6.2.2. [Intentionally Omitted].

6.2.3. [Intentionally Omitted].

6.3. Payment of Invoices.

6.3.1. [Intentionally Omitted]

6.3.2. [Intentionally Omitted]

6.3.3. [Intentionally Omitted]

6.4. [Intentionally Omitted]

6.5. Storage Fees. Customer is responsible for storage charges as specified in Attachment “C” for Product stored for more than \*\*\*\* (\*\*\*\*) calendar days beyond BVL’s release of such Product the “Temporary Storage Period”. Storage beyond the Temporary Storage period of Product in BVL’s warehousing Facilities must receive prior written approval from BVL. Such approval will be granted only on a space-available basis. 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 applicable Purchase Order. Notwithstanding anything in this Agreement to the contrary, at no time shall Customer incur or be responsible to pay any storage charges if the reason for such storage is an investigation pursuant to Paragraphs 3.5 or 3.6.

6.6. Stability Program. During the term of this Agreement and upon Customer’s request and BVL’s written agreement, BVL will conduct and support, at Customer’s reasonable expense, all stability studies in progress or planned (e.g., NDA annual stability studies) as of the Effective Date until such studies are concluded. Customer shall be responsible for all costs of conducting any stability studies. Stability program costs will be covered in a separate quotation provided by BVL to Customer based on the agreed upon protocol. Customer may also make arrangements for stability work to be performed at a facility other than BVL at Customer’s expense.

6.7. Inspection, Packaging and Labeling. Customer shall be responsible for and bear all costs associated with the design, 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.

6.8. Weekly Payments by BVL. Commencing on the seventh (7<sup>th</sup>) calendar day following the execution of this Agreement, BVL agrees to make Weekly Payments on such date and on each successive seventh (7<sup>th</sup>) day thereafter, consisting of Transition Definity Payments and Transition Campaign Payments, each as described below, to Customer (“Weekly Payments”), not to exceed a maximum aggregate payment of Five Million Dollars (\$5,000,000) (the “Maximum Weekly Payment Cap”). If the date of payment for any of the Weekly Payments falls on a Saturday, Sunday, or bank holiday, payment shall be made on the first business day following the weekend or holiday

6.8.1. Transition Definity Payments: BVL agrees to pay Customer \*\*\*\* Dollars (\$\*\*\*\*) per week until the earlier of (a) \*\*\*\* (\*\*\*\*) days following BVL’s release to Customer of \*\*\*\* of the Definity Product Identified in Attachment A7.1 produced pursuant to the terms of this Agreement, provided such lot is not rejected pursuant to

this Agreement in good faith by Customer during this \*\*\*\* (\*\*\*\*) day period; (b) Customer's release to distribution of \*\*\*\* of Definity produced by BVL pursuant to the terms of this Agreement; or (c) the aggregate Transition Definity Payments made by BVL reach the Maximum Weekly Payment Cap.

6.8.2. Transition Campaign Payments: Should the Transition Definity Payments end for the reasons stated in subparagraph 6.8.1, then starting \*\*\*\* (\*\*\*\*) calendar days after the last Transition Definity Payment, BVL agrees to pay Customer \*\*\*\* dollars (\$\*\*\*\*) per week until the earlier of: (a) \*\*\*\* (\*\*\*\*) days following BVL's release to Customer of the final lot of Products produced by BVL, provided such final lots are not rejected pursuant to this Agreement in good faith by Customer during this \*\*\*\* (\*\*\*\*) day period; (b) Customer's release to distribution of the final lot of Products produced by BVL; or (c) the aggregate Transition Definity Payments plus the Transition Campaign Payments made by BVL reach the Maximum Weekly Payment Cap. Should the Transition Definity Payments end because the aggregate Transition Definity Payments made by BVL reach the Maximum Weekly Payment Cap as stated in subparagraph 6.8.1, BVL shall have no obligation to make any Transition Campaign Payments. In addition, should the Transition Definity Payments end for the reasons stated in subparagraph 6.8.1(a) and such lot is rejected by Customer within the \*\*\*\*-day period described above before Customer's release to distribution of one lot of Definity produced by BVL, BVL shall make a true up payment under Section 6.8.1, within \*\*\*\* (\*\*\*\*) business days of BVL's receipt of notice of such rejection, as if such Transition Definity Payments had not ended and will continue to make such payments under Section 6.8.1 until such time as the conditions set forth above have been met.

6.8.3. Method of Weekly Payments: BVL shall execute a wire transfer for the Weekly Payments so that each of the Weekly Payments shall be received by LMI by 10:00 AM EST, using the following information unless modified by LMI:

Wachovia Bank (a division of Wells Fargo Bank, N.A.)  
ABA # \*\*\*\*  
Account # \*\*\*\*  
FBO: Lantheus Medical Imaging  
Lantheus Contact: Charlie Lichtmann, 978-671-8703

#### 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 irreconcilably inconsistent with the terms of this Agreement, the terms of this Agreement shall prevail with respect to commercial issues, and the Quality Agreement shall prevail with respect to cGMP issues.

#### ARTICLE 8 - INDEMNIFICATION

8.1. Customer Indemnity. Customer hereby holds harmless and indemnifies BVL, its Affiliates and its and their directors, officers, employees and agents (the "BVL Indemnitees") against any and all losses, liabilities, damages, reasonable costs and expenses whatsoever, including, without limitation, reasonable attorneys' fees, and the cost of recalls and any and all

amounts reasonably paid in settlement of any claim or litigation, any settlement payments subject Section 8.3 below, (collectively, “Losses”) incurred by any BVL Indemnitee in investigating, preparing, or defending against any litigation, commenced or threatened by a Third Party, or any other claim, demand or proceeding of a Third Party (collectively, “Claims”), based on, resulting from, arising out of or in connection with any actual or alleged: (a) personal injuries and/or death resulting from, arising out of or in connection with any distribution or sale of a Product by Customer, its Affiliates or its distributors, including, without limitation, Claims based on negligence, warranty, strict liability or any other theory of liability or violation of any Applicable Law; (b) breach by Customer of its representations, warranties or covenants hereunder; or (c) negligent act or the willful misconduct of any Customer Indemnitees in performing Customer’s obligations under this Agreement; (d) Customer’s API and any Customer supplied Composition, materials, Equipment, Specifications, formulations, marketing, labeling, design, instructions, handling and/or storage; except, in each case, to the comparative extent such Claim arose out of or resulted from a matter for which BVL is responsible therefore pursuant to Section 8.2.

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 Losses incurred by any Customer Indemnitee in preparing, or defending against any Claims based on, resulting from, arising out of or in connection with any actual or alleged: (a) personal injuries and/or death that are proximately caused (as defined under Delaware law) by a Manufacturing Defect (as hereinafter defined); (b) breach by BVL of its representations, warranties or covenants hereunder, including personal injuries and/or death claims; (c) any recall pursuant to Article 25 of this Agreement due to BVL’s negligence, willful misconduct, or breach of any covenant, representation or warranty in this Agreement; or (d) negligent act or the willful misconduct of any BVL Indemnitees in performing BVL’s obligations under this Agreement except, in each case, to the comparative extent such Claim arose out of or resulted from a matter for which Customer is responsible therefor pursuant to Section 8.1. For the purposes of this Section 8.2, “Manufacturing Defect” means the negligence, recklessness (having a baseline not less than negligence), wrongful intentional acts or negligent omissions, or strict liability of or by BVL or its Affiliates or its Agents resulting from, or arising out of or in connection with the Manufacture of a Product by BVL.

8.3. Indemnification Procedures. Any BVL Indemnitees or Customer Indemnitees (collectively, “Indemnitees”) seeking indemnification under Section 8.1 or 8.2, agrees to notify the indemnifying Party within ten (10) business days of receipt of any Claims, demands or threats of suit for which such Party may be liable under Section 8.1 or 8.2 as the case may be; provided, however, that failure to give such notification shall not affect the indemnification to be provided hereunder except to the extent the indemnifying Party shall have been actually prejudiced as a result of such failure (except that the indemnifying Party shall not be liable for any expenses incurred during the period in which the Indemnitee(s) failed to give such notice). 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 Indemnitee(s) shall be entitled to participate in the defense of such matter and to employ counsel at its expense to assist therein. The Indemnitee(s) shall provide the indemnifying Party with such information and assistance as the indemnifying Party may reasonably request, at the expense of the indemnifying Party. The Parties understand that no insurance deductible shall be credited against losses for which a Party is responsible under this Article 8. No indemnifying Party under Section 8.1 or 8.2 may compromise or settle any Claim or pay any settlement amount in the connection with the compromise or settlement of

any Claim without the prior written consent of Indemnitee, such written consent not to be unreasonably withheld or delayed.

8.4. **Insurance.** Customer and BVL will each, at its own cost and expense, obtain and maintain in full force and effect, during the term of this Agreement and for a period of one year following the expiration or other termination of this Agreement, Commercial General Liability insurance, written on the standard approved Policy Form, and Blanket Contractual Liability, with limits of liability of not less than \$\*\*\*\* Combined Single Limit Bodily Injury and Property Damage covering its duties and obligations under the Agreement. The coverage limits may be provided, individually or jointly, through a combination of Primary, Excess/Umbrella or Self-Insured Retention. The Parties further understand and agree that the insurance limits identified herein shall not act as a bar to any recovery.

8.5. **Specific Limitation of Liability for Process-Related (i.e., during Manufacturing) Losses.**

8.5.1. Notwithstanding anything to the contrary set forth herein or in any collateral documents hereunder (invoices, purchase orders, etc.), the Parties acknowledge and agree that BVL's sole liability to Customer for in-process Manufacturing losses (i.e. loss of API, or Customer-supplied Composition) is set forth exclusively in this section 8.5. Except for Batches of *Definity* (where the maximum liability shall be \$\*\*\*\*), BVL agrees to reimburse Customer up to a maximum of \$\*\*\*\* per Batch pro-rated over the usable portion of the Batch, if applicable, for any loss of API or Customer-supplied Composition for each Batch that does not meet Specification or was not Manufactured in accordance with the Manufacturing Process or cGMP and therefore can not be released; provided that the loss of such materials can be shown after Investigation to be caused solely and directly by: (a) the failure of BVL to follow its SOP's; or (b) BVL's negligence, willful misconduct or breach of this Agreement; or (c) BVL's willful misconduct, where, solely for purposes of this Section 8.5.1, such "willful misconduct" shall have the meaning set forth under Delaware law. In the absence of a showing of (a), (b) or (c), above, then BVL shall have no liability to Customer for such Batch of Product. 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. Notwithstanding the foregoing, or any declared value of API costs in excess of \$\*\*\*\* or \$\*\*\*\*, as applicable, or the insurance levels identified in Section 8.4 or elsewhere, in no event shall BVL's liability to Customer for in-process loss of API or Customer-supplied Composition be in excess of \$\*\*\*\* or \$\*\*\*\*, as applicable, per Batch.

8.6. **LIABILITY LIMITATION.**

8.6.1. **ELECTION OF REMEDIES.** SECTION 3.9.4, 3.9.5, 8.2, 8.5, 8.6.3, 25.1 AND 34 ARE CUSTOMER'S SOLE AND EXCLUSIVE 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.

8.6.2. **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”).

8.6.3. **AGGREGATE AGREEMENT CAP ON COSTS, LOSSES, EXPENSES, DAMAGES AND MAXIMUM WEEKLY PAYMENT CAP.** THE PARTIES RECOGNIZE AND ACKNOWLEDGE THAT THIS ARTICLE 8 ATTEMPTS TO EQUITABLY ALLOCATE RISK WITH RESPECT TO EACH PARTIES’ RESPECTIVE INTEREST IN THE AGREEMENT AND THAT THE LIMITATIONS OF LIABILITY SET FORTH HEREIN ARE COMPROMISES. NOTWITHSTANDING ANYTHING TO THE CONTRARY SET FORTH HEREIN, BVL’S TOTAL MAXIMUM AGGREGATE LIABILITY FOR DAMAGES, LIABILITY AND INDEMNIFICATION OBLIGATIONS UNDER THIS AGREEMENT SHALL NOT EXCEED A TOTAL AGGREGATE CAP OF FIVE MILLION DOLLARS (USD\$5,000,000). THIS CAP ON DAMAGES AND LIABILITY (THE “BVL CAP”) IS INTEGRAL TO THIS AGREEMENT AND THE AGREEMENT WOULD NOT HAVE BEEN EXECUTED IN ITS ABSENCE.

8.6.4. **EXCEPTIONS TO LIABILITY CAP.** THE BVL CAP SHALL NOT APPLY TO DAMAGES RESULTING FROM: BREACHES BY A PARTY OF A DUTY IMPOSED UNDER ARTICLE 9 (CONFIDENTIALITY), SECTION 11 (INTELLECTUAL PROPERTY), OR DUE TO A PARTY’S WILLFUL MISCONDUCT OR FRAUD. FOR THE AVOIDANCE OF DOUBT, THE PARTIES EXPLICITLY ACKNOWLEDGE AND AGREE THAT BVL’S OFFERING TO ENTER INTO THIS AGREEMENT AND ENTERING INTO THIS AGREEMENT GIVEN BVL’S CURRENT AND POTENTIAL REGULATORY SITUATION AND THE POTENTIAL IMPACT OF THAT ON BVL’S ABILITY TO MANUFACTURE AND DELIVER PRODUCT UNDER THIS AGREEMENT SHALL NOT SERVE AS THE BASIS OF ANY CLAIM FOR WILLFUL MISCONDUCT, FRAUD OR FRAUD IN THE INDUCEMENT.

8.6.5. **INTEGRAL PROVISIONS.** THESE LIMITATIONS SET FORTH IN THIS SECTION 8.6 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, business or proprietary information related to the subject of the Agreement, irrespective of whether in human or machine-readable form, tangible or intangible, (a) which is or has been 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 was developed by BVL for Customer under the terms of the Manufacturing Agreement or is developed by BVL for Customer under the terms of this Agreement. Confidential Information does not include information that: (a) is lawfully in the possession of the Receiving Party, without restriction as to confidentiality or use, at the time of disclosure by the Disclosing Party, as demonstrated by competent written records of the Receiving Party; (b) is or later becomes part of the public domain through no fault of the Receiving Party (i.e., other than by breach of this Agreement by the Receiving Party); (c) is received, without restriction as to confidentiality or use, by the Receiving Party from a Third Party lawfully entitled to possession of such Confidential Information and who does not violate any contractual, legal or fiduciary obligation to the Disclosing Party by providing such Confidential Information to the Receiving Party; or (d)

is developed independently by the Receiving Party without any use of, or access or reference to, or reliance on, the Disclosing Party's Confidential Information, in whole or in part. Disclosing Party is not obligated to mark information as "CONFIDENTIAL" for such information to be deemed Confidential Information under this Agreement. Confidential Information of BVL includes, but is not limited to, BVL Technology, BVL Improvements, BVL pricing information and capabilities/capacities. Confidential Information of Customer includes, but is not limited to, Customer Technology, Customer Inventions and Customer Improvements. This Agreement shall not be construed as a grant of any right or license to the Receiving Party with respect to Confidential Information of the Disclosing Party or as a requirement of either Party to enter into any further arrangement with respect to Confidential Information of the Disclosing Party.

9.2. Disclosure and Use. The Receiving Party shall: (a) maintain the confidentiality of the Disclosing Party's Confidential Information; (b) not disclose the Disclosing Party's Confidential Information to any Third Party without the prior written consent of the Disclosing Party; and (c) use the Disclosing Party's Confidential Information only as necessary to fulfill its obligations or in the reasonable exercise of rights granted to it hereunder. Notwithstanding the foregoing, a Receiving Party may disclose: (i) Confidential Information of the Disclosing Party to its Affiliates, and to its and their directors, employees, consultants, and Agents provided, that in each case such individuals and entities have a specific need to know such Confidential Information and are previously bound by written obligation of confidentiality and restriction at least as rigorous as those set forth herein; (ii) Improvements or Inventions owned by the Receiving Party to the extent required to exploit the grant of its rights under Article 11 of this Agreement; and (iii) Confidential Information of the Disclosing Party to the extent such disclosure is required to comply with Applicable Law or to defend or prosecute litigation; provided, however, that prior to any such use or disclosure in accordance with Applicable Law, the Receiving Party shall provide written notice of such potential disclosure to the Disclosing Party (which shall include a copy of any applicable subpoena or order), and cooperate with Disclosing Party's requests and 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 confidential treatment or 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

9.3. Publicity. Neither Party will issue any press release or other public announcement concerning this Agreement or the transactions contemplated by this Agreement without the prior written consent of the other Party, except where such announcements are required by Applicable Law or the rules of any stock exchange or NASDAQ provided, however, that prior to any announcement in accordance with Applicable Law or rules, the disclosing Party shall provide written notice of such potential announcement to the other Party, and cooperate with the other Party's requests and lawful decision to avoid or minimize the degree of such disclosure. Such other Party shall permit the disclosing Party the opportunity, if desired, to seek an appropriate protective order or other confidential treatment or remedy with respect to narrowing the scope of such announcement. Product labeling (primary, secondary, and any insert) and government filings may indicate that Product has been Manufactured for Customer by BVL.

9.4. Customer's Agents. In the event that Customer desires for its Agents to perform an audit at the Facility and/or otherwise enter upon the Facility, then prior to any such visit, such Agent shall either be required to enter into an agreement with BVL in which it agrees to comply with the confidentiality obligations, restrictions and responsibilities imposed upon

Customer in this Section. In BVL's discretion, such agreement shall be acknowledged by Customer denoting that the individual identified thereon is Customer's Agent.

9.5 Non-Disclosure of Customer's Confidential Information to Third Parties or Bedford Laboratories. The Parties acknowledge that the actual Manufacturing Process may be performed by employees that perform routine and normal manufacturing services (e.g., in filling, packaging, sterile rooms, shipping, etc.) and who also perform similar services for BVL's other third-party customers and for Bedford Laboratories. Notwithstanding the foregoing, BVL agrees that it shall not disclose Customer's Confidential Information or Customer Technology to any Third Party or Affiliate of BVL, including any personnel of Bedford (except for those manufacturing employees referenced in the preceding sentence that require the use of such Customer Confidential Information or Customer Technology in order to Manufacture Product).

9.6 Notice to Senior Scientists and Manufacturing Personnel who Separate Employment with BVL. For senior members of BVL's Product and Process Development (PPD) Department and Manufacturing Department who separate employment from BVL, BVL shall, when it determines appropriate in its sole discretion, send a copy of such individual's "Invention & Secrecy Agreement" agreement to both the individual and his/her new company (if known). The cover letter enclosing the Invention & Secrecy Agreement shall remind the former employee and his/her new employer of the confidentiality, non-use and non-disclosure obligations pertaining to BVL and its customer's confidential and proprietary information.

#### **ARTICLE 10 - REPRESENTATIONS, WARRANTIES AND COVENANTS**

10.1. Representations of BVL. Subject to the qualifications set forth in the recitals, BVL represents, warrants and covenants to Customer that:

10.1.1. (a) it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind held by other parties, private or public, materially inconsistent or conflict with the provisions of this Agreement; and (b) the execution and delivery of this Agreement and the performance of such Party's obligations hereunder; and (c), other than the previously referenced findings of deviations by the United States Food and Drug Administration and by the European Medicines Agency at BVL's manufacturing facility and the issuance by the European Medicines Agency and the Therapeutic Goods Administration of short-dated, restricted GMP licenses to BVL, there are no, and shall be no, liens, conveyances, mortgages, assignments, encumbrances, or other contacts or agreements that would prevent or materially impair such Party's full and complete exercise of the terms and conditions of this Agreement.

10.1.2. the services provided by BVL shall be performed with requisite care, skill and diligence, in accordance with the terms of this Agreement, Applicable Laws and industry standards, and by individuals who are appropriately trained and qualified;

10.1.3. the services provided by BVL, and the use, practice or exploitation of the BVL Technology, Customer Improvements, Customer Inventions and BVL Confidential Information, will not infringe, misappropriate, or otherwise violate any patents, trademarks, copyrights, trade secrets, or any other intellectual property rights of any Third Party in the Territory and it will promptly notify Customer in writing should it become aware of any claims asserting such infringement, misappropriation or violation; and

10.1.4. 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 the Specifications, and shall be free of any manufacturing defects, (ii) will not be adulterated or misbranded under the FDCA or other Applicable Law; and (iii) will be provided free and clear of any liens and encumbrances of any kind; (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(b)(1)(B) of the FDCA (or who is the subject of a conviction described in such section) and will provide a certification that it has not, does not and will not use in any capacity the services of any person debarred under Section 306(b) of the FDCA in connection with the Manufacture of the Products. 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(b), 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, warrants and covenants to BVL that:

10.2.1. (a) it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights held by other parties, private or public, inconsistent with the provisions of this Agreement; and (b) the execution and delivery of this Agreement and the performance of such Party's obligations hereunder: (i) do not conflict with or violate any requirement of Applicable Law; (ii) do not, and will not conflict with or otherwise interfere with resulting in a violation, breach, or default under, or require any consent that has not been obtained under any contact or agreement between such Party or any of its Affiliates, Agents and any third party; and (iii) there are no, and shall be no, liens, conveyances, mortgages, assignments, encumbrances, or other contacts or agreements that would prevent or impair such Party's full and complete exercise of the terms and conditions of this Agreement;

10.2.2. the use, practice or exploitation of Customer Technology, Customer Improvements, and Customer Confidential Information in the performance of services under this Agreement will not infringe, misappropriate or otherwise violate the patents, trademarks, copyrights, trade secrets, or other 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, misappropriation or violation;

10.2.3. that the API and Customer-supplied Composition shall be free of defects of any kind, shall not be adulterated, shall conform to applicable Specifications and will be provided to BVL free and clear of any liens and encumbrances; and

10.2.4. Customer's further distribution of the Product will not cause the Product to be adulterated or misbranded under the FDCA or other Applicable Law.

10.3. Additional Representations of Customer in the event that Product(s) will be Offered for Sale, Sold, Marketed within the Member States of the European Union. In the event that the Territory includes the European Union ("EU") or any member states thereof,

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then in addition to all other warranties and representations set forth herein, Customer also represents and warrants that Customer shall be responsible for the release of the Products in the European Union in compliance with all applicable EU Directives and Standards. It is Customer's obligation to notify BVL as to whether the Territory for any Product includes an EU member nation, or if a country within the Territory subsequently becomes a member of, or subject to, the European Union.

## ARTICLE 11 - INTELLECTUAL PROPERTY

11.1. Customer Technology. All rights, title and interests in and to Customer Technology and Customer's Other Inventions (as defined below) shall remain solely in Customer and no right, title or interest therein or thereunder is transferred or granted to BVL, except as set forth in the following sentence. 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-sublicensable, non-transferable license shall (i) expire upon the completion of such duties and obligations or the termination or expiration of this Agreement, whichever is the first to occur, and (ii) does not require disclosure of any Customer Technology to any other persons or entities. Except as provided in Section 3.7 or Section 9.4, under no circumstances shall BVL share, convey, license, or otherwise transfer any Customer Technology or Customer's Other Inventions to any BVL Affiliate or BVL Agent

11.2. BVL Technology. All rights, title, and interests in and to BVL Technology shall remain solely in BVL and no right, title or interest therein is transferred or granted to Customer, except as set forth in the following two sentences. 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. BVL shall not incorporate any BVL Technology into any Inventions hereunder without the prior written consent of Customer, and, if BVL does incorporate any BVL Technology into any Inventions, absent an agreement to the contrary, Customer is granted a royalty-free, fully paid-up, sublicensable (solely for the Product), license to freely use (solely for the Product), practice and otherwise exploit the BVL Technology (solely for the Product). For the avoidance of doubt, to the extent that BVL incorporates BVL Technology into the Product, the foregoing grant shall be for the benefit of Customer and solely for the benefit of the Product, and shall not be utilized for any other product, whether by Customer or any of Customer's Agents.

11.3. Customer Improvements.

11.3.1. Customer shall own all right, title and interest in and to all inventions, discoveries, developments, improvements, new uses, processes, know-how, compounds, compositions, or syntheses that are conceived, reduced to practice or first demonstrated to have utility in the course of activities under this Agreement or the Manufacturing Agreement and that are API or Product-specific or are specific to the use of the API for use in the same therapeutic class, including but not limited to any process for making any Product, any use of any Product, any method of analyzing or characterizing any Product or any Product formulation, and any analysis or characterization of any Product or any Product formulation (collectively, "Customer Inventions"). As used in this Agreement, "Product-specific" shall mean relating to the Products, any intermediates or derivatives thereof, and the Manufacturing thereof but not routine manufacturing processes which are not specific to the Manufacturing of Product.



11.4. BVL Improvements.

11.4.1. BVL shall own all right, title and interest in and to all inventions, discoveries, developments, improvements, new uses, processes, know-how, compounds, compositions, or syntheses that are conceived, reduced to practice or first demonstrated to have utility in the course of activities under this Agreement or the Manufacturing Agreement and that are conceived, reduced to practice or first demonstrated to have utility in the course of activities under this Agreement or the Manufacturing Agreement and that relate to BVL's Technology, BVL Confidential Information or BVL Improvements but are not Product-specific (collectively, "BVL Inventions"). For the avoidance of doubt, where an invention relates to both the BVL's technology, equipment or equipment processes and to a Product or a Product formulation (e.g., a complex between a Product and a proprietary complexing agent of BVL), such invention to the extent it is "Product-specific" shall be a Customer Invention.

11.4.2. Ownership of any Invention which is not a Customer Invention or a BVL Invention ("Other Invention") shall be as follows: (x) where such Other Invention is jointly conceived, reduced to practice or first demonstrated to have utility under this Agreement or the Manufacturing Agreement by: (i) one or more employees, consultants or Agents of a Party or an Affiliate of such Party; and (ii) one or more employees, consultants or Agents of the other Party or an Affiliate of such other Party, such Other Invention shall be jointly owned by the Parties, and (y) where such Other Invention is conceived, reduced to practice or first demonstrated to have utility solely by an employee, consultant or Agent of a Party or an Affiliate of that Party, such Other Invention shall be owned by such Party.

11.4.3. The inventorship of all Inventions conceived, reduced to practice or first demonstrated to have utility in the course of activities under this Agreement will be determined in accordance with United States laws for inventorship. Each party hereby agrees to disclose to the other Party promptly and in writing all Inventions conceived or reduced to practice or first demonstrated to have utility in the course of activities under this Agreement by any employee, consultant or Agent of a Party or its Agents. BVL hereby assigns to Customer all right, title and interest of BVL in or to any Customer Inventions. Customer hereby assigns to BVL all right, title and interest of Customer in or to any BVL Inventions. Each Party shall cooperate (and cause its Agents and all employees to cooperate) with the other Party in taking all steps and actions (including but not limited to maintaining in confidence any Inventions that constitute trade-secrets, and executing appropriate documentation in connection with the filing of any patent application(s) on any Invention of the other Party) which such Party believes reasonably necessary or desirable to apply for and/or maintain intellectual property protection for the benefit of Customer or BVL as the case may be in any country, or to perfect or enforce such Party's ownership and right in the Inventions; provided, however, that the costs and expenses for taking such steps and actions are borne by the Party seeking to obtain IP registration or protection.

**ARTICLE 12 - TERM AND TERMINATION**

12.1. Term. This Agreement shall become effective on the Effective Date and shall expire upon the earlier to occur of (a) the final release of the final Customer-accepted Batch of

Product listed in Attachment A#-1, which acceptance or rejection shall not be unreasonably withheld or unreasonably delayed, or (b) December 31, 2013.

12.2. [Intentionally Omitted]

12.3. Termination for Breach. Either Party may terminate this Agreement for a material breach or default by the other Party by giving the breaching Party written notice, specifying the breach or default, and giving the breaching Party thirty (30) days to cure such breach or default. For the avoidance of doubt either Party may terminate with respect to any individual Product which termination shall not effect the viability of the Agreement with respect to any remaining Products. If the breach or default has not been cured within thirty (30) days after the receipt of such notice the Non-Defaulting Party shall be entitled, without prejudice, to terminate this Agreement; provided, however, that if such breach or default reasonably cannot be cured within such 30 day period, then upon the mutual agreement of the Parties the Defaulting Party may be granted an additional period of time during which it shall exercise reasonably diligent efforts to cure such breach, and the Non-Defaulting Party shall not be permitted to terminate this Agreement under this Section during any such mutually agreed extended cure period. Termination for breach or default will have no effect on performance obligations or amounts to be paid which have accrued up to the effective date of such termination. Customer acknowledges that it is aware that in May 2011 and November 2011, BVL's manufacturing facility was inspected by the United States Food and Drug Administration and by the European Medicines Agency in March 2011 and November 2011. Customer further acknowledges that each of these inspections resulted in observations from the regulatory authority citing deviations from current Good Manufacturing Practices. Customer acknowledges The European Medicines Agency and the Therapeutic Goods Administration have issued BVL short-dated, restricted GMP licenses. Customer further acknowledges that it is aware BVL voluntarily suspended manufacturing at its site as of November 2011. Customer has reviewed the records of inspection from the above mentioned regulatory authorities as well as BVL's corrective action responses to the regulatory agencies and is satisfied that the corrective actions set forth in BVL's corrective action plan should rectify the cGMP issues at the manufacturing facility that directly or indirectly affect Customer's Product. Based on the foregoing, Customer acknowledges that the cGMP issues set forth above, as well as any prior deviations from cGMP by BVL, shall not constitute grounds for a claim of any breach of this Agreement, and Customer specifically waives any right to claim any breach under this Agreement based on any such prior deviations from cGMP.

12.4. Termination for Bankruptcy. In the event of any proceedings, voluntary or involuntary, in bankruptcy or insolvency, by or against Customer or BVL, or the appointment with or without the Parties' consent of a receiver for either Party, the other Party shall be entitled to immediately terminate this Agreement upon written notice to the other Party without any liability whatsoever, subject to the payments of liquidated damages, if any, set forth in Article 34 if BVL is the party in bankruptcy or insolvency. Subject to the BVL Cap, such termination shall not affect any claim for damages available to the terminating Party or for costs or fees accrued to date.

12.5. Termination for Regulatory or Governmental Action. In the event the Products or any Product, Manufacture, or BVL's Facility are subject to an injunction, consent decree, administrative order or finding or any other regulatory or remedial action that prohibits or otherwise prevents BVL from manufacturing or distributing the Products or any Product for a period of more than (i) nine (9) months if such action occurs prior to April 1, 2013 or (ii) the balance of the term of this Agreement if such action occurs from and after April 1, 2013, then

BVL may terminate this Agreement with respect to the affected Products or Product by providing at least \*\*\*\* (\*\*\*\*) days prior written notice to Customer which notice may be provided by BVL concurrent with such period. In the event of a termination pursuant to this Section 12.5, then BVL shall pay Customer the liquidated damages, if any, set forth in Article 34.

12.6. Termination for Force Majeure. In the case of a Force Majeure (as defined herein) 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 \*\*\*\* (\*\*\*\*) months, the other Party shall be entitled to terminate this Agreement upon prior written notice to the affected Party without any liability whatsoever.

12.7. Termination based upon Wind-Down or Cessation of the Business. In the event that BVL sells all or substantially all of the company's assets, or otherwise ceases operations or takes material steps to wind-down its business, then, subject to the obligations set forth in Section 15.1, BVL may terminate this Agreement by providing \*\*\*\* (\*\*\*\*) days prior written notice to Customer. In the event of a termination pursuant to this Section 12.7, then BVL shall pay Customer the liquidated damages, if any, set forth in Article 34.

12.8. Consequences of Expiration/Termination. In the event of any expiration or termination of this Agreement, BVL shall perform such functions requested by Customer that are reasonably necessary or required in connection with the orderly conclusion of any active project as required by the terms of this Agreement and Applicable Law.

12.8.1. Promptly upon expiration or 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. Furthermore, BVL shall promptly return all Customer-supplied Composition, Customer-supplied Equipment, API, retained samples, reference standards, data, reports and other property, information and/or know-how in recorded form that was provided by Customer, or developed in the performance of the services under this Agreement, that are owned by or licensed to Customer, excepting that required to be retained by Applicable Law, litigation holds or for regulatory compliance.

12.8.2. [Intentionally Omitted]

12.8.3. BVL shall provide all reasonably requested assistance for technology transfer and otherwise to ensure the orderly transition of the Manufacturing and other services provided hereunder to an alternate source, which shall be provided at no cost to Customer provided, that no Confidential Information of BVL shall be disclosed to such alternate source, it being understood that any Product-specific information contained in the Master Batch Record for Product is not Confidential Information of BVL and may be disclosed to the alternate source; and upon the effective date of termination of this Agreement, Customer shall have no further obligation to BVL with respect to any Purchase Orders with delivery dates beyond such date and BVL will have no further obligations to Manufacture Product.

12.8.4. Notwithstanding anything to the contrary herein, if there is a termination event pursuant to Section 12.3 (Termination for Breach), Section 12.4 (Termination for Bankruptcy), Section 12.5 (Termination for Regulatory Action or Governmental Actions), or Section 12.7 (Termination based upon Wind-Down or Cessation of the

Business), then Customer's sole and exclusive remedy shall be the payment of liquidated damages pursuant to Article 34. Customer shall not be entitled to seek any other damages under Applicable Law.

12.9. Injunctive Relief for Certain Breach or Threatened Breach. The Parties agree that should this Agreement be breached for reasons other than provided under Section 12.4 (Termination for Bankruptcy), Section 12.5 (Termination for Regulatory Action or Governmental Actions), Section 12.6 (Force Majeure) or Section 12.7 (Termination based upon Wind-Down or Cessation of the Business) that 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 (up to the BVL Cap), available to a non-breaching Party at law or in equity.

12.10. Survival. Expiration or termination of this Agreement for any reason shall not relieve either Party of any obligation arising under this Agreement that accrue prior to such expiration or termination or of any rights and obligations of the Parties that by their terms survive termination or expiration of this Agreement, including, without limitation, duties of confidentiality (Article 9), indemnification (Article 8), intellectual property rights (Article 11), consequences of termination (Sections 12.8, 12.9 and 12.10), notices (Article 13), governing law and jurisdiction (Article 16) and under the Quality Agreement (Attachment "E") of this Agreement. Notwithstanding anything to the contrary set forth herein, the obligations identified in this Paragraph 12.10 shall survive for a period of ten (10) years from any termination or expiration of this Agreement, unless specified otherwise in the applicable Articles and Sections.

#### **ARTICLE 13 - NOTICES**

13.1. All notices concerning this Agreement shall be given in writing, as follows: (a) 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; (b) by Federal Express, UPS, DHL or any other overnight carrier, in which case the notice shall be deemed given two (2) business days from the date of delivery to such carrier or (c) by confirmed facsimile (followed by delivery of an original via overnight carrier), in which case the notice shall be deemed given on confirmation of transmission. All notices which concern this Agreement shall be addressed as follows (or at such other address for a Party as shall be specified in a notice given in accordance with this Section):

If to BVL:

Ben Venue Laboratories, Inc.  
300 Northfield Road  
Bedford, Ohio 44146  
Attn: Vice President, Contract Manufacturing Services  
Telephone: 440-232-3320  
Facsimile: 440-439-6398

Division Legal Counsel

Ben Venue Laboratories, Inc.  
300 Northfield Road  
Bedford, Ohio 44146  
Telephone: 440-703-7899  
Facsimile: 440-232-6264

If to Customer:

Lantheus Medical Imaging, Inc.  
331 Treble Cove Road  
North Billerica, MA 08162  
Attn: General Counsel  
Telephone: 978-671-8408  
Facsimile: 978-671-8724

With a copy (that shall not constitute legal notice) to:

Lantheus Medical Imaging, Inc.  
331 Treble Cove Road  
North Billerica, MA 08162  
Attn: General Manager of Manufacturing  
Telephone: 978-671-8853  
Facsimile: 978-671-9577

#### **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. The waiver of any term, condition, or provision of this Agreement must be in writing and signed by an authorized representative of the waiving Party. Any such waiver shall not be construed as a waiver of any other term, condition, or provision, nor as a waiver of any subsequent breach of the same term, condition, or provision, except as provided in a signed writing.

#### **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 or unreasonably delayed; except that either Party may assign this Agreement, without the other Party's prior written consent, to an entity that acquires all or substantially all of the business or assets of such Party to which this Agreement pertains (whether by merger, reorganization, acquisition, sale or otherwise); provided that, in the event of the acquisition or sale of BVL's business or assets to which this Agreement pertains, and prior to such acquisition or sale, the successor party shall agree in writing to be bound by the terms and conditions of this Agreement specifically pertaining to the duties with respect to confidentiality (Article 9) and intellectual property rights (Article 11) set forth herein. For the avoidance of doubt, it is the Parties' specific intent to protect the Customer Technology

and Customer's Confidential Information indefinitely in the event of an acquisition, sale or similar transaction with a third party. Any assignment not permitted by this Section 15.1 shall be void and of no effect whatsoever.

#### **ARTICLE 16 - GOVERNING LAW**

16.1. This Agreement and the rights and obligations of the Parties hereunder shall be governed by Delaware law and, to the extent the laws of the State of Delaware are preempted or otherwise made inapplicable by federal law, the laws of the United States of America. Each of the Parties irrevocably and unconditionally:

16.1.1. agrees that any suit, action or legal proceeding arising out of or relating to this Agreement shall be instituted in the United States District Court for Delaware, or if such court does not possess subject matter jurisdiction, of any type, or will not accept jurisdiction, in any court of general jurisdiction in Wilmington, Delaware;

16.1.2. consents and submits to the exclusive jurisdiction of such foregoing courts in any such suit, action or proceeding;

16.1.3. consents to personal jurisdiction in such courts;

16.1.4. waives any objection which it may have to laying of venue of any such suit, action or proceeding in said courts; and

16.1.5. waives any claim or defense of inconvenient forum.

#### **ARTICLE 17 - FORCE MAJEURE**

17.1. No Party shall be liable for a failure or delay in performing any of its obligations under this Agreement (but, for the avoidance of doubt, shall be liable for any performance actually rendered) 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 or regulations by any Agency or Government, conflict of laws or regulations by any Agency or government with the exception of enactments, changes or conflicts where notice of such enactments, changes or conflicts and a corresponding CAPA remediation plan cannot be satisfactorily agreed upon by BVL, Customer and the agency or government who enacted the change, orders, restrictions, actions, embargoes or blockages; (v) national or regional emergency; injunctions, strikes, lockouts, labor trouble or other industrial disturbances (regardless of the reasonableness of the demands of labor); or (vii) acts of terrorism ("Force Majeure"). For the avoidance of doubt, the Parties agree that an event shall only rise to the level of "Force Majeure" under section 17.1 (iv) when, following reasonable consultation with the other Party: (a) the Party claiming Force Majeure is substantially and materially prejudiced in its ability to comply with the requirements of this Agreement; (b) the claimed Force Majeure is due to an enactment or change of laws or regulations, and (c) performance is rendered impossible in the short-term or so manifestly burdensome that no reasonable pharmaceutical manufacturing facility of like size and circumstances to BVL would perform under such circumstances. For the avoidance of doubt, termination for regulatory action pursuant to Section 12.5 is not considered a Force Majeure event.

17.2. The Party whose performance of this Agreement is affected or potentially affected by a Force Majeure shall promptly notify the other Party of the Force Majeure condition, explaining the nature, details and expected duration thereof, and shall exert reasonable efforts to eliminate, cure or overcome any such condition and to resume performance of its obligations under this Agreement as soon as possible. Upon termination of the event of Force Majeure, the performance of any suspended obligation or duty shall promptly recommence.

#### **ARTICLE 18 - TITLE OF GOODS**

18.1. Title to API and Customer-supplied Composition shall remain with Customer at all stages of the Manufacturing Process and the foregoing shall be held in bailment by BVL. 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 Specifications and cGMP, and in such a way as to be able at all times to clearly distinguish the same from products and materials belonging to BVL, or held by it for a Third Party's account.

18.2. BVL shall at all times take such measures as are required to protect the API, Customer-supplied Composition, Product, and any work in process from risk of loss or damage at all stages of the Manufacturing Process. BVL shall ensure that the API, Customer-supplied Composition, Product, and any work in process are free and clear of any liens or encumbrances. BVL shall Immediately notify Customer if at any time it believes any API, Customer-supplied Composition, Product or work in process have been damaged, lost or stolen.

#### **ARTICLE 19 - ENTIRE AGREEMENT**

19.1. This Agreement, together with the Attachments identified herein, embody the entire agreement and understanding between BVL and Customer relating to the Products, superseding the Manufacturing Agreement that was terminated pursuant to the Settlement Agreement with respect to such Product. This Agreement is intended as a final expression of their agreement and as a complete statement of the Parties' agreement regarding the Products subject to this Agreement. For the avoidance of doubt, the parties acknowledge the existence of two separate documents, the Settlement Agreement, which is a settlement agreement of the prior Manufacturing Agreement, and the Manufacturing and Service Contract for Commercial Products dated as of March 20, 2012 (the "New Manufacturing Agreement"), which is a similar manufacturing agreement for Product. This Agreement is mutually exclusive from these other two agreements, and each of these agreements' terms and conditions are independent and do not impact the other agreement in any manner. In the event of any inconsistency between this Agreement and any other writings relating to the Products (other than the Settlement Agreement and the New Manufacturing Agreement), the terms and conditions of this Agreement shall take precedence in any contract construction. Other than the Settlement Agreement, which is independent and not impacted by the terms of this Agreement, 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 in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible.

## **ARTICLE 21 - INDEPENDENT CONTRACTORS**

21.1. Neither Party shall have the right to control the activities of the other in the performance of this Agreement and each shall perform as an independent contractor, and nothing herein shall be construed to be inconsistent with that relationship or status. Under no circumstances shall the employees or Agents of one Party be considered employees or Agents of the other. This Agreement shall not constitute, create, or in any way be interpreted as a joint venture, partnership, or formal business organization of any kind.

## **ARTICLE 22 - AMENDMENTS**

22.1. No provision of this Agreement or the Attachments attached hereto may be modified or supplemented, except by an instrument in writing signed by both BVL and Customer.

## **ARTICLE 23 - HEADINGS AND CONSTRUCTION**

23.1. The Article and Section 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. As used herein, "including", "includes" and derivatives thereof shall be deemed to be followed by "without limitation".

## **ARTICLE 24 - REVIEW BY LEGAL COUNSEL**

24.1. Each Party has carefully reviewed this Agreement, and understands its terms. Each Party has been given sufficient opportunity to seek legal advice prior to signing this Agreement, and has either sought legal advice with counsel experienced in issues of confidentiality in regards to this Agreement, or has relied wholly upon that Party's own judgment and knowledge in executing this Agreement. Each Party fully understands and voluntarily accepts each and every provision contained in this Agreement. Failure to seek legal advice prior to signing this Agreement does not excuse either Party from failure to understand the terms and conditions set forth in this Agreement. This Agreement has been prepared on the basis of the mutual understanding of the Parties and in the event of an ambiguity, such ambiguity shall not be strictly construed against either Party as a drafter of this Agreement.

## **ARTICLE 25 - RECALL**

25.1. In the event: (a) any Agency or governmental authority issues a request, directive, or order that Product be recalled; or (b) a court of competent jurisdiction orders such a recall; or (c) the Customer determines that the Product should be recalled or withdrawn, Customer, in cooperation with BVL, shall take all appropriate corrective action. Customer shall

also retain the right to conduct a Product recall for any safety reasons Customer deems significant. In the event 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. Customer shall consult with BVL prior to making any determination to recall Product if practicable. BVL will be financially responsible for the costs of any recall or withdrawal (including but not limited to the actual cost of manufacturing the Product, through final packaging, pro-rated over the usable portion of the batch, if any) to the extent its negligence, willful misconduct, or breach of any covenant, representation or warranty hereunder is responsible for such recall, provided, that, to the extent any recall or withdrawal includes any Batch(es) not yet released to Customer that are subject to Section 8.5, BVL's liability for such un-released Batch(es) shall be subject to the limitations set forth in Section 8.5 until such release. For the avoidance of doubt, the costs of recall shall be limited to direct costs and expenses associated with the recall (i.e., notices, collection, shipping, destruction) but shall specifically exclude lost profits, lost market share, interruption of business, harm to reputation, or any other indirect collateral cost, such as unrelated marketing, advertising, or any other cost, fee or charge not directly related to the recall of Product. For purposes of clarity, the Parties acknowledge that all potential claims under this Section 25.1 are subject to the BVL Cap.

#### **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. Each Party agrees and understands that the information and any materials provided by the other Party under this Agreement are subject to United States laws and regulations, which may restrict certain exports, re-exports or other transfers to other countries and parties. Each Party agrees that no materials or information provided to it under this Agreement by the other Party 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**

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 and Section 2.3, 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 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.

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#### **ARTICLE 29 - CHANGE NOTIFICATION.**

29.1. BVL shall notify Customer promptly of any change in ownership of BVL, and in no event later than three (3) days of such change being made public.

#### **ARTICLE 30 - BOOKS AND RECORDS.**

30.1. Any books and records to be maintained under this Agreement by a Party or its Affiliates shall be maintained in accordance with U.S. generally accepted accounting principles, consistently applied; *except* that the same need not be audited (but if any audits are conducted by a Party, the results of such audits shall be maintained along with such books and records).

#### **ARTICLE 31 - BINDING EFFECT.**

31.1. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

#### **ARTICLE 32 - USE OF NAME AND RESERVATION OF RIGHTS.**

32.1. Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation or intellectual property of the other Party or its Affiliates or any other trade name or trademark of the other Party or its Affiliates for any purpose in connection with the performance of this Agreement or otherwise.

#### **ARTICLE 33 - COUNTERPARTS.**

33.1. This Agreement may be executed in several counterparts, each of which is an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers.

#### **ARTICLE 34 - LIQUIDATED DAMAGES.**

34.1. Liquidated Damages. As set forth in Section 8.6.3, the parties recognize and acknowledge that each is seeking by this Agreement to equitably allocate risk with respect to each party's respective interest in the Agreement. For purposes of interpretation and to aid in any contract construction, the parties have elected to allocate a total BVL Cap on liability which serves to limit BVL's aggregate liability but also serves to compel performance so as to avoid forfeiture should BVL inexcusably not perform its obligations under this Agreement. As such, the limitations of liability and BVL Cap are highly negotiated and represent compromises between the parties, which the parties acknowledge are fair and reasonable under the present circumstances. In light of the fact that breach and/or non-performance by BVL may cause Customer to incur economic damages and losses of types and in amounts which are difficult to ascertain with any certainty as a basis for recovery of actual damages, the parties have agreed for the payment of liquidated

damages which each believes to represent a fair, reasonable and appropriate estimate thereof, as set forth herein. Such liquidated damages are intended to represent estimated actual damages as contemplated by the parties at the time of entering into this Agreement and are not intended as a penalty.

34.2. Calculation of Liquidated Damages. In the event that BVL is unable to perform its obligations under this Agreement due to Section 12.3, 12.4, 12.5, or 12.7, then as Customer's sole and exclusive remedy, it shall be entitled to seek, and BVL shall be obligated to pay, liquidated damages calculated as the difference between the BVL Cap and any payments or claims made under it. For the avoidance of doubt, and solely for purposes of illustration, if BVL was not able to deliver any Product to Customer and there were no other claims against the BVL Cap, then the liquidated damages payable to Customer would be Five Million Dollars (\$5,000,000). By way of a second example, if Customer had received \$\*\*\*\* for three Weekly Payments and had also been reimbursed \$150,000 for API costs for failed batches, then the BVL Cap of \$5,000,000 would be reduced by \$\*\*\*\*, thereby leaving \$\*\*\*\* available for liquidated damages. For the avoidance of doubt, the parties acknowledge that the Weekly Payments reduce the BVL Cap, and thereby also reduce the funds available for the potential liquidated damages. In the event that the BVL Cap is reduced to zero (\$0) for any reason, then the parties acknowledge and agree that the liquidated damages shall likewise be zero (\$0). The parties further acknowledge and agree that the liquidated damages provision shall not be deemed to have failed for any essential purpose or deprived Customer of any remedy because it was depleted, in whole or in part, by payments which reduced the BVL Cap.

\*\_\*\_\*\_\*

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement by their duly authorized representatives as of the dates set forth below:

**BEN VENUE LABORATORIES, INC.**

**LANTHEUS MEDICAL IMAGING, INC.**

By: /s/ George Doyle  
Print: George Doyle  
Title: President, CEO  
Date Signed: 3/20/12

By: /s/ Michael P. Duffy  
Print: Michael P. Duffy  
Title: Vice President and Secretary  
Dated Signed: 3/20/2012

By: /s/ William A. Owen  
Print: William A. Owen  
Title: VP Finance  
Date Signed: 3/20/12

**Attachment A**

**PRODUCT SUPPLEMENTS**

<b>Attachment A-1</b> —	<b>See Attached</b>
<b>Attachment A-2</b> —	<b>See Attached</b>
<b>Attachment A-3</b> —	<b>See Attached</b>
<b>Attachment A-4</b> —	<b>See Attached</b>
<b>Attachment A-5</b> —	<b>See Attached</b>
<b>Attachment A-6</b> —	<b>See Attached</b>
<b>Attachment A-7</b> —	<b>See Attached</b>

**Attachment "A1"**  
**Sestamibi**

**A1.1) PRODUCT Description:** Sestamibi, \*\*\*\* mg lyo in a \*\*\*\* mL vial

**BVL Project Code:** 0077-00

**CUSTOMER Project Code:**

**PRODUCT Description (INCLUDING  
PACKAGING DESCRIPTION FOR EACH  
END ITEM NUMBER FROM THE SAME  
NUDE VIAL)**

**BVL End Item  
Number**

**BVL Nude Vial  
Number**

**Batch  
Size/Order  
Quantity**

Sestamibi, \*\*\*\* mg lyo in a \*\*\*\* mL vial, unlabeled vial, bulk  
pack with foam partition

9999900573

0077-00

\*\*\*\*

Sestamibi, \*\*\*\* mg lyo in a \*\*\*\* mL vial, US labeled vial, 5 pk  
shelf carton with foam partition

9999993801

0077-00

\*\*\*\*

Sestamibi, \*\*\*\* mg lyo in a \*\*\*\* mL vial, CAN labeled vial, 2 pk  
shelf carton with foam partition

9999993802

0077-00

\*\*\*\*

Sestamibi, \*\*\*\* mg lyo in a \*\*\*\* mL vial, CAN labeled vial, 5 pk  
shelf carton with foam partition

9999993807

0077-00

\*\*\*\*

Sestamibi, \*\*\*\* mg lyo in a \*\*\*\* mL vial, unlabeled vial, bulk  
pack with foam partition

9999900738

0077-00

\*\*\*\*

Transition Services Agreement (BVL and Lantheus)

**Attachment A1**  
**Sestamibi**

**A1.2) PRODUCT Specifications - Sestamibi**

Per BVL Spec Number 0770FP effective 6/27/94 as may be amended, modified or supplemented from time to time in accordance with this Agreement.

**Attachment A1  
Sestamibi**

**A1.3) Materials supplied by CUSTOMER and BVL for Sestamibi**

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Attachment A1  
Sestamibi

A1.4) [[INTENTIONALLY OMITTED]]

A1.4.2 [INTENTIONALLY OMITTED]

**Attachment A1  
Sestamibi**

**A1.5.) Pricing for Sestamibi, \*\*\*\* mg lyo in a \*\*\*\* mL vial**

**BATCH PRICING**

<b>PRODUCT Description</b>	<b>BVL Nude Vial Number</b>	<b>BVL End Item Number</b>	<b>Batch Size/Order Quantity</b>	<b>Price Per Vial for End Item with No Split Pack-outs</b>
Sestamibi, CAN labeled vial, 2 pk carton with foam partition	0077-00	999993802	****	\$ ****
Sestamibi, CAN labeled vial 5 pk shelf carton with foam partition	0077-00	999993807	****	\$ ****
Sestamibi, unlabeled vial bulk pk with foam partition	0077-00	9999900573	****	\$ ****
Sestamibi, US labeled vial, 5 pk shelf carton with foam partition	0077-00	999993801	****	\$ ****
Sestamibi, unlabeled vial bulk pk with foam partition	0077-00	9999900738	****	\$ ****

**All other configurations/quantities/ packaging splits will be quoted separately upon request by CUSTOMER to BVL. The above prices are for full batch quantities packaged as described.**

**Attachment A1  
Sestamibi**

**A1.6.) Territory for Sestamibi, \*\*\*\* mg lyo in a \*\*\*\* mL vial**

**CARDIOLITE® kit for the Preparation of Technetium Tc99m Sestamibi for Injection**

<b>COUNTRY</b>	<b>APPROVAL DATE</b>	<b>REGISTRATION NUMBER</b>	<b>EU REGULATORY PROCEDURE</b>
United States	21-Dec-1990	19,785	NDA
Canada	02-Jan-90	RN- 8804	NDS
Austria	20-Oct-94	4-00001	National
Belgium	24-Sep-90	BE 152686	National
Denmark	22-Oct-90	DK R 4	National
Finland	9-Dec-92	10860	National
France	21-Sep-90	556 934 - 8 (2 vial) 557 102 - 6 (5 vial)	National
Germany	11-May-92	20930.00.00	National
Italy	14-Jun-93	028601019	National
Luxembourg	30-Nov-06	0457/06110019	National
Netherlands	16-May-95	RVG 16518	National
Norway	6-May-98	94.194	National
Portugal	30-Sep-03	4809182 (2 vial) 4809281 (5 vial)	National
Spain	20-Mar-97	61.239	National
Sweden	21-Jun-90	80076	National
Switzerland	9-Oct-91	50632 01	National
United Kingdom	15-Feb-93	PL 14207/0019	National
Australia	18-Oct-94	49688	Local
Bahrain	N/A	N/A	N/A
Brazil	15-Sept-00	126940019002-3	Local
Colombia	3-Dec-03	2003M-0002941	Local
Costa Rica	28-Jun-93	2705-ZF-13679	Local
Egypt	N/A	N/A	N/A
Hong Kong	98-99	HK-43085	Local
India	4-Oct-06	FF-193	Local
Israel	23-Jun-94	637727948	Local
Japan	2-Apr-93	20500AMY00127000	Local
Korea	25-Mar-00	1	Local
Kuwait	N/A	N/A	N/A
Lebanon	N/A	N/A	N/A
Malaysia	19-Jan-05	SIN12645P	Local
Malta	9-Mar-10	PL34258/0001	Local
Mexico	26-Jan-10	1203R87SSA	Local
New Zealand	N/A	N/A	N/A
Oman	N/A	N/A	N/A
Panama	N/A	N/A	N/A

Philippines	N/A	N/A	N/A
Saudi Arabia	N/A	N/A	N/A
Slovenia	N/A	N/A	N/A
South Africa	1-Apr-92	2/35/108	Local
Taiwan	9-Mar-93	R00075	Local
Thailand	N/A	N/A	N/A
UAE	N/A	N/A	N/A

**Attachment A2  
Neurolite ligand**

**A2.1.) PRODUCT Description:** Neurolite ligand, \*\*\*\*mg lyo in a \*\*\*\* mL vial

**BVL Project Code: 0229-00**

**CUSTOMER Project Code:**

<b>PRODUCT Description (INCLUDING PACKAGING DESCRIPTION FOR EACH END ITEM NUMBER FROM THE SAME NUDE VIAL)</b>	<b>BVL End Item Number</b>	<b>BVL Nude Vial Number</b>	<b>Batch Size/Order Quantity</b>
Neurolite ligand, **** mg lyo in a **** mL vial unlabeled, bulk pkg for Domestic	9999900768	0229-00	****

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**Attachment A2  
Neurolite ligand**

**A2.2.) PRODUCT Specifications - Neurolite ligand**

Per BVL Spec Number 22900FP effective 1/22/98 as may be amended, modified or supplemented from time to time in accordance with this Agreement.

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**Attachment A2  
Neurolite ligand**

**A2.3.) Materials supplied by CUSTOMER and BVL for Neurolite ligand**

\*\*\*

Attachment A2  
Neurolite ligand

A2.4.) [INTENTIONALLY OMITTED]

A2.4.1

A2.4.2 [INTENTIONALLY OMITTED]

**Attachment A2  
Neurolite ligand**

A2.5.) Pricing for Neurolite ligand, \*\*\*\* mg lyo in a \*\*\*\* mL vial

**PRICING**

<u>PRODUCT Description</u>	<u>BVL Nude Vial Number</u>	<u>BVL End Item Number</u>	<u>Batch Size/Order Quantity</u>	<u>Price Per Vial for End Item with No Split Pack-outs</u>
Neurolite ligand, **** mg lyo in a **** mL vial, US labeled, bulk pkg	0229-00	99999900768	****	\$ ****

All other configurations/quantities/ packaging splits will be quoted separately upon request by CUSTOMER to BVL. The above prices are for full batch quantities packaged as described.

**Attachment A2  
Neurolite ligand**

**A2.6.) Territory for Neurolite ligand, \*\*\*\* mg lyo in a \*\*\*\* mL vial**

**NEUROLITE® Kit for the Preparation of Technetium Tc99m Bicisate for Injection**

<b>COUNTRY</b>	<b>APPROVAL DATE</b>	<b>REGISTRATION</b>	<b>PROCEDURE</b>
United States	23-Nov-1994	20,256	NDA
Canada	17-Oct-94	RN-9204	NDS
Austria	2-Dec-97	4-00002	MRP
Belgium	16-Mar-95	BE 168567	MRP
Czech Republic	29-Nov-00	88/581/00-C	National
Denmark	10-Feb-04	DK R11	MRP
Finland	27-Feb-95	11679	MRP
France	25-Apr-94	558 376-2 (box of 5) 558 375-6 (box of 1)	MRP
Germany	13-Dec-93	29602.00.00	MRP
Italy	21-Sep-95	28847010	MRP
Luxembourg	7-Apr-95	0685/93/12/0747	MRP
Norway	11-Jan-95	8069	National
Portugal	7-Oct-97	2566883	MRP
Spain	28-Jun-96	60.882	MRP
Sweden	29-Dec-94	12505	MRP
Australia	24-Aug-00	AUSTR 73014	Local
Bahrain	N/A	N/A	N/A
Colombia	5-Feb-99	M 011934	Local
Costa Rica	20-Nov-97	—	Local
Hong Kong	20-May-98	HK-43086	Local
Israel	11-Sept-97	10734/28989	Local
Japan	19-Jan-94	20600AMY0000600	Local
Korea	2-Aug-00	2	Local
Lebanon	N/A	N/A	N/A
Malaysia	20-Jan-05	SIN12644P	Local
Mexico	8-Nov-95	1614R95SSA	Local
New Zealand	N/A	N/A	N/A
Oman	N/A	N/A	N/A
Panama	N/A	N/A	N/A
Philippines	N/A	N/A	N/A
Saudi Arabia	N/A	N/A	N/A
Slovenia	N/A	N/A	N/A
Switzerland	17-Oct-94	52441	National
Taiwan	7-Apr-99	R000081	Local
Thailand	N/A	N/A	N/A
UAE	N/A	N/A	N/A

**Attachment A3**  
**Eluant**

**A.3.1) PRODUCT Description** Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial

**BVL Project Code:** 0078-72

**CUSTOMER Project Code:**

**PRODUCT Description (INCLUDING  
PACKAGING DESCRIPTION FOR EACH  
END ITEM NUMBER FROM THE SAME  
NUDE VIAL)**

	<b>BVL End Item Number</b>	<b>BVL Nude Vial Number</b>	<b>Batch Size/Order Quantity</b>
Eluant, **** mg/mL liquid, **** mL in a **** mL vial labeled, bulk packaged	9999983530	0078-72	****

**Attachment A3**  
**Eluant**

**A3.2.) PRODUCT Specifications** - Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial

Per BVL Spec Number 07872FP effective 1/14/94 as may be amended, modified or supplemented from time to time in accordance with this Agreement.

Attachment A3  
Eluant

A3.3) Materials supplied by CUSTOMER and BVL for Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial

\*\*\*\*

**Attachment A3  
Eluant**

A3.4.) [INTENTIONALLY OMITTED]

A3.4.1 .

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**Attachment A3  
Eluant**

A3.4.2 [INTENTIONALLY OMITTED]

60

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**Attachment A3  
Eluant**

A3.5.) Pricing for Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial

**BATCH PRICING**

<b>PRODUCT Description</b>	<b>BVL Nude Vial Number</b>	<b>BVL End Item Number</b>	<b>Batch Size/Order Quantity</b>	<b>Price Per Vial for End Item with No Split Pack-outs</b>
Eluant, **** mg/mL liquid, **** mL in a **** mL vial, labeled, bulk packaged	0078-72	9999983530	****	\$ ****

All other configurations/quantities/ packaging splits will be quoted separately upon request by CUSTOMER to BVL. The above price is for full batch quantities packaged as described.

**Attachment A3**  
**Eluant**

**A3.6.) Territory for Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial**

**Attachment A4**  
**Eluant**

**A4.1.) PRODUCT Description:** Eluant, \*\*\*\* mg/mL liquid \*\*\*\* mL in a \*\*\*\* mL vial

**BVL Project Code:**

**CUSTOMER Project Code:**

**PRODUCT Description (INCLUDING  
PACKAGING DESCRIPTION FOR  
EACH END ITEM NUMBER FROM THE  
SAME NUDE VIAL)**

	<b>BVL End Item Number</b>	<b>BVL Nude Vial Number</b>	<b>Batch Size/Order Quantity</b>
Eluant, **** mg/mL liquid **** mL in a **** mL vial, labeled, bulk packaged	9999980530	0078-73	****

**Attachment A4**  
**Eluant**

**A4.2.) PRODUCT Specifications** - Eluant, \*\*\*\* mg/mL liquid \*\*\*\* mL in a \*\*\*\* mL vial

Per BVL Spec Number 07873FP effective 1/14/94 as may be amended, modified or supplemented from time to time in accordance with this Agreement.

Attachment A4  
Eluant

A4.3.) Materials supplied by CUSTOMER and BVL for Eluant, \*\*\*\* mg/mL liquid \*\*\*\* mL in a \*\*\*\* mL vial

\*\*\*\*

Attachment A4  
Eluant

A4.4.) [INTENTIONALLY OMITTED]

A4.4.1

Attachment A4  
Eluant

A4.4.2 [INTENTIONALLY OMITTED]

**Attachment A4  
Eluant**

A4.5.) Pricing for Eluant, \*\*\*\* mg/mL liquid \*\*\*\* mL in a \*\*\*\* mL vial

**BATCH PRICING**

<b>PRODUCT Description</b>	<b>BVL Nude Vial Number</b>	<b>BVL End Item Number</b>	<b>Batch Size/Order Quantity</b>	<b>Price Per Vial for End Item with No Split Pack-outs</b>
Eluant, **** mg/mL liquid **** mL in a **** mL vial, labeled, bulk packaged	0078-73	9999980530	****	\$ ****

All other configurations/quantities/ packaging splits will be quoted separately upon request by CUSTOMER to BVL. The above price is for full batch quantities packaged as described.

**Attachment A4  
Eluant**

**A4.6.) Territory for Eluant, \*\*\*\* mg/mL liquid \*\*\*\* mL in a \*\*\*\* mL vial**

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**Attachment A5  
Neurolite Buffer**

**A5.1.) PRODUCT Description: Neurolite buffer, liquid, \*\*\*\* mL in a \*\*\*\* mL vial**

**BVL Project Code: 0230-40**

**CUSTOMER Project Code:**

**PRODUCT Description (INCLUDING  
PACKAGING DESCRIPTION FOR EACH  
END ITEM NUMBER FROM THE SAME  
NUDE VIAL)**

**BVL End Item  
Number**

**BVL Nude  
Vial Number**

**Batch  
Size/Order  
Quantity**

Neurolite buffer, liquid, **** mL in a **** mL vial Canada labeled, bulk packaged	9999993401	0230-40	****
Neurolite buffer, liquid, **** mL in a **** mL vial US labeled, bulk packaged	9999993400	0230-40	****
Neurolite buffer, liquid, **** mL in a **** mL vial unlabeled, bulk packaged	9999900574	0230-40	****

70

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**Attachment A5**  
**Neurolite buffer**

**A5.2.) PRODUCT Specifications** - Neurolite buffer, liquid, \*\*\*\* mL in a \*\*\*\* mL vial

Per BVL Spec Number 023040FP as may be amended, modified or supplemented from time to time in accordance with this Agreement.

**Attachment A5**  
**Neurolite buffer**

**A5.3.) Materials supplied by CUSTOMER and BVL for Neurolite buffer, liquid, \*\*\*\* mL in a \*\*\*\* mL vial**

\*\*\*\*

**Attachment A5  
Neurolite Buffer**

A5.4.) [INTENTIONALLY OMITTED]

**Attachment A5  
Neurolite Buffer**

A5.4.2 [INTENTIONALLY OMITTED] .

**Attachment A5  
Neurolite buffer**

**A5.5.) Pricing for Neurolite buffer, liquid, \*\*\*\* mL in a \*\*\*\* mL vial**

**BATCH PRICING**

<b>PRODUCT Description</b>	<b>BVL Nude Vial Number</b>	<b>BVL End Item Number</b>	<b>Batch Size/Order Quantity</b>	<b>Price Per Vial for End Item with No Split Pack-outs</b>
Neurolite buffer, liquid, **** mL in a **** mL vial Canada labeled, bulk packaged	0230-40	9999993401	****	\$ ****
Neurolite buffer, liquid, **** mL in a **** mL vial US labeled, bulk packaged	0230-40	9999993400	****	\$ ****
Neurolite buffer, liquid, **** mL in a **** mL vial unlabeled, bulk packaged	0230-40	9999900574	****	\$ ****

**All other configurations/quantities/ packaging splits will be quoted separately upon request by CUSTOMER to BVL. The above prices are for full batch quantities packaged as described.**

**Attachment A5  
Neurolite buffer**

**A5.6.) Territory for Neurolite buffer, liquid, \*\*\*\* mL in a \*\*\*\* mL vial**

**NEUROLITE® Kit for the Preparation of Technetium Tc99m Bicisate for Injection**

<b>COUNTRY</b>	<b>APPROVAL DATE</b>	<b>REGISTRATION</b>	<b>PROCEDURE</b>
United States	23-Nov-1994	20,256	NDA
Canada	17-Oct-94	RN-9204	NDS
Austria	2-Dec-97	4-00002	MRP
Belgium	16-Mar-95	BE 168567	MRP
Czech Republic	29-Nov-00	88/581/00-C	National
Denmark	10-Feb-04	DK R11	MRP
Finland	27-Feb-95	11679	MRP
France	25-Apr-94	558 376-2 (box of 5) 558 375-6 (box of 1)	MRP
Germany	13-Dec-93	29602.00.00	MRP
Italy	21-Sep-95	28847010	MRP
Luxembourg	7-Apr-95	0685/93/12/0747	MRP
Norway	11-Jan-95	8069	National
Portugal	7-Oct-97	2566883	MRP
Spain	28-Jun-96	60.882	MRP
Sweden	29-Dec-94	12505	MRP
Australia	24-Aug-00	AUSTR 73014	Local
Bahrain	N/A	N/A	N/A
Colombia	5-Feb-99	M 011934	Local
Costa Rica	20-Nov-97	—	Local
Hong Kong	20-May-98	HK-43086	Local
Israel	11-Sept-97	10734/28989	Local
Japan	19-Jan-94	20600AMY0000600	Local
Korea	2-Aug-00	2	Local
Lebanon	N/A	N/A	N/A
Malaysia	20-Jan-05	SIN12644P	Local
Mexico	8-Nov-95	1614R95SSA	Local
New Zealand	N/A	N/A	N/A
Oman	N/A	N/A	N/A
Panama	N/A	N/A	N/A
Philippines	N/A	N/A	N/A

Saudi Arabia	N/A	N/A	N/A
Slovenia	N/A	N/A	N/A
Switzerland	17-Oct-94	52441	National
Taiwan	7-Apr-99	R000081	Local
Thailand	N/A	N/A	N/A
UAE	N/A	N/A	N/A

**Attachment A6  
Technelite**

**A6.1.) INTENTIONALLY OMITTED**

**Attachment A6  
Technelite**

A6.2.) [[INTENTIONALLY OMITTED]]

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**Attachment A6  
Technelite**

A6.3.) [[INTENTIONALLY OMITTED]]

80

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Attachment A6  
Technelite

A6.4.) [INTENTIONALLY OMITTED]

Attachment A6  
Technelite

A6.4.2 [INTENTIONALLY OMITTED].

**Attachment A6  
Technelite**

**A6.5) INTENTIONALLY OMITTED**

Attachment A6  
Technelite

A6.6.) [INTENTIONALLY OMITTED]

**Attachment A7**  
**Definity**

A7.1.) **PRODUCT Description** Definity \*\*\*\* mg lyo in a \*\*\*\* mL vial

**BVL Project Code:**

**CUSTOMER Project Code:**

**PRODUCT Description (INCLUDING  
PACKAGING DESCRIPTION FOR EACH  
END ITEM NUMBER FROM THE SAME  
NUDE VIAL)**

**BVL End Item  
Number**

**BVL Nude  
Vial Number**

**Batch  
Size/Order  
Quantity**

Definity \*\*\*\* mg lyo in a \*\*\*\* mL vial unlabeled, bulk  
packaged

9999900095

2128-71

\*\*\*\*

**Attachment A7**  
**Definity**

**A7.2.) PRODUCT Specifications - Definity, \*\*\*\* mg lyo in a \*\*\*\* mL vial**

Per BVL Spec Number 212871FP effective 1/22/98 as may be amended, modified or supplemented from time to time in accordance with this Agreement.

**Attachment A7**  
**Definity**

**A7.3.) Materials supplied by CUSTOMER and BVL for Definity, \*\*\*\* mg lyo in a \*\*\*\* mL vial**

\*\*\*\*

**Attachment A7**  
**Definity**

A7.4.) [INTENTIONALLY OMITTED]

A7.4.1 .

Attachment A7  
Definity

A7.4.2 [INTENTIONALLY OMITTED]

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Attachment A7  
Definity

A7.5.) Pricing for Definity \*\*\*\* mg lyo in a \*\*\*\* mL vial

BATCH PRICING

PRODUCT Description	BVL Nude Vial Number	BVL End Item Number	Batch Size/Order Quantity	Price Per Vial for End Item with No Split Pack-outs
Definity **** mg lyo in a **** mL vial unlabeled bulk packaged	2128-71	9999900095	****	\$ ****

All other configurations/quantities/ packaging splits will be quoted separately upon request by CUSTOMER to BVL. The above price is for full batch quantities packaged as described.

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**Attachment A7  
Definity**

A7.6.) Territory for Definity \*\*\*\* mg lyo in a \*\*\*\* mL vial

**DEFINITY®  
Vial for (Perflutren Lipid Microsphere) Injectable Suspension**

<b>COUNTRY</b>	<b>APPROVAL DATE</b>	<b>REGISTRATION NUMBER</b>	<b>PROCEDURE</b>
Australia	10-Jan-07	AUSTR 124808	Local
Canada	28-Dec-00	062005	NDS
Europe	20-Sep-06	EU/1/06/361/001	Centralized
India	11-Mar-10	FF-541-16510	Local
Israel	7-Jul-05	133 15 31138 10 (Distributor: LAVI Industrial and Medical)	Local
Korea	19-Jan-07	5001	Local
Mexico	24-Jul-04	0613R2004 SSA	Local
New Zealand	6-Dec-07	76-19-7	Local
Singapore	25-Jun-07	SIN 13309P (Distributor: Research Biolabs PTE Ltd.)	Local
UAE	11-Jul-07	5217-6417-1	Local
United States	31-Jul-01	21-064	NDA

## Attachment B

### Purchase Order Requirements

If any of the required items are not on the PO, note as missing on the PO confirmation form.

- BVL item number: Required
- BVL delivery date: Required  
(date by which BLV is to release/deliver the lot or batch record)
- BVL quotation number: Required
- Theoretical batch size per quotation: Required
- Delivery address: Required
- Ship on BVL release? (yes or no): Required
- Is overnight shipment required? (yes or no)
- Are there any temperature requirements? If yes, what are they?
- Are temperature monitors required? (yes or no). If yes, customer must provide monitors.
- Do you require the use of dedicated truck or is a common carrier acceptable?
- Do you have a specific carrier you want to use? If yes, please provide contact information.

#### Not required at time PO is entered:

- Customer Lot Number: Not required but customer must note when they can provide
- Product Expiration Date: Not required but customer must note when they can provide

Manufacturing and Service Contract (BVL and BMS-MI)

**Attachment "C"**  
**MONTHLY STORAGE FEES**

Effective through \*\*\*\*

BVL has limited storage capacity. Therefore, Customers are expected to have Product shipped to them no later than \*\*\*\* (\*\*\*\*) days after BVL Quality Operations has released their Product and has shipped the documents identified Attachment D to Customer. Should unforeseen events lead to a request by a Customer for storage beyond this \*\*\*\* (\*\*\*\*) day grace period, the Customer must request such storage by BVL in writing at least \*\*\*\* (\*\*\*\*) days before the initial \*\*\*\* (\*\*\*\*) day grace period has expired. The request will be granted only if BVL has sufficient storage capacity to accommodate the request. Then, the following terms will apply.

Monthly storage fees are assessed on a per lot basis, and begin to accrue \*\*\*\* (\*\*\*\*) days following the BVL release date of the Batch by BVL's Quality Operations Dept. BVL will request that a separate Purchase Order be issued for the storage charges. These charges listed below will be reviewed and updated annually.

Monthly Storage Charge - per square foot per month

Room Temperature Storage	\$	****
Refrigerated Storage	\$	****
Freezer Storage	\$	****

Minimum Storage Charge - per lot per month

Room Temperature Storage	\$	****
Refrigerated Storage	\$	****
Freezer Storage	\$	****

Transition Service Agreement (BVL and Lantheus)

**Attachment D**

**Documents To Be Supplied By BVL to CUSTOMER As Part Of Batch Release**

- 1.) BVL Certificate of Analysis (if required)
- 2.) BVL Certificate of Compliance
- 3.) Copies of the executed Batch Record
- 4.) Raw Material C of A's 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 audits by the customer.

Transition Service Agreement (BVL and Lantheus)

**Attachment "E"**  
**QUALITY AGREEMENT**

**QUALITY AGREEMENT – Pharmaceutical Product**

Print Name

Manufacturing and Service Contract (BVL and BMS-MI)

**APPENDIX A:**

**List of Products:**

Cardiolite / Sestamibi

Neurolite Ligand

Neurolite Buffer

Definity / Luminity / DMP115-e

Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial

Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial

Transition Service Agreement (BVL and Lantheus)

**Attachment "F"**  
**Customer Supplied Equipment**

**PFM CART**  
**Squarewave test equipment and associated spare parts**

**Attachment "G"**  
**Representation regarding Customer's Qualified Person**

**CUSTOMER LETTERHEAD**  
**Customer Address**

BEN VENUE LABORATORIES, INC.  
ATTN: COMPLIANCE MANAGER  
A Boehringer Ingelheim Company  
300 Northfield Road  
Bedford, Ohio 44146

Dear BVL COMPLIANCE MANAGER,

Please take notice that Lantheus Medical Imaging hereby confirms in writing to BVL that it has appointed one or more Qualified Person(s) in compliance with the requirements of Article 48 of Directive 2001/83/EC, with respect to the product(s) subject to the manufacturing and services contract for commercial and developmental products between Ben Venue Laboratories, Inc. and Lantheus Medical Imaging, Inc. dated . Said Qualified Person(s) shall be responsible for release of Product(s) into EU member states and shall comply with Article 51 of 2001/83/EC.

Sincerely,

Name  
Title

Attachment "H"  
Certificate of Compliance

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**Boehringer Ingelheim**  
**Ben Venue Laboratories**

Ben Venue Laboratories, Inc.  
300 Northfield Road  
P.O. Box 46568  
Bedford, Ohio 44146-0568

**CONTRACT CLIENT**

PRODUCT NAME:

BVL LOT NUMBER:

CUSTOMER:

CUSTOMER LOT  
NUMBER:

DOSAGE:

CONTAINER TYPE

MANUFACTURING  
SPECIFICATION:

MPR

TESTING  
SPECIFICATION:

REFER TO CoA  
 N/A

DATE OF  
MANUFACTURE:

PREP or  
 EXP DATE:

QUANTITY RELEASED:

**Regulatory statement:**

I hereby certify that the above information is authentic and accurate. This Product was manufactured in accordance with the Manufacturing Process approved mutually by the customer and BVL. In addition, all Product production and control records are reviewed and approved by BVL's Quality Assurance Department to determine compliance with all established, approved written procedures in determining that this Product could be released, in accordance with 21 C.F.R § 211.192 of cGMP regulations found in the Code of Federal Regulations of the U.S. Food and Drug Administration. Deviations were documented, reviewed, and approved prior to release. The batch/lot has been released by an authorized disposition individual.

**Released to Contract Client**

AUTHORIZED BY /  
DATE:

\_\_\_\_\_  
Authorized Disposition Personnel

\_\_\_\_\_  
(printed name)

CONFIDENTIAL TREATMENT REQUESTED

INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND NOTED WITH "\*\*\*\*\*". AN UNREDACTED VERSION OF THIS DOCUMENT HAS ALSO BEEN PROVIDED TO THE SECURITIES AND EXCHANGE COMMISSION.

CONFIDENTIAL  
EXECUTION VERSION

**Manufacturing and Service Contract  
For Commercial Products**

Lantheus Medical Imaging, Inc.  
03/20/2012

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## ATTACHMENTS

**Attachment “A”** — Product Supplements

- A x.1 Product Identification
- A x.2 Product Testing Specification
- A x.3 Materials Supplied By Customer and BVL
- A x.4 Forecasts
  - A1.4.1 Forecast Through \*\*\*\*
- A x.5 Pricing
- A x.6 Territory (for Products identified in A1.1)

**Attachment “B”** — Purchase Order Requirements

**Attachment “C”** — Monthly Storage Fees

**Attachment “D”** — Documents Supplied with Batch Release

**Attachment “E”** — Quality Agreement

**Attachment “F”** — Customer Supplied Equipment

*Additional Attachment for Use if “Territory” for any Product Includes the European Union:*

**Attachment “G”** — Representation regarding Customer’s Qualified Person

**Attachment “H”** — Certificate of Compliance

## MANUFACTURING AND SERVICE CONTRACT FOR COMMERCIAL PRODUCTS

This Manufacturing and Service Contract for Commercial Products (hereinafter this "Agreement") is entered into as of March 20, 2012 (the "Effective Date"), by Ben Venue Laboratories, Inc., a corporation organized and existing under the laws of Delaware, with its principal office at 300 Northfield Road, Bedford, Ohio, 44146 (hereinafter "BVL" and as further defined in Article I) and Lantheus Medical Imaging, Inc., a corporation organized and existing under the laws of Delaware, with its principal place of business at 331 Treble Cove Road, North Billerica, MA 01862 (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 the owner or licensee of all rights to certain proprietary technical information, patents and/or patent applications relating to Product(s) (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

WHEREAS, BVL possesses the personnel and Facilities (as defined below) for the development and Manufacturing (as defined below) of finished sterile dosage forms of Product and is willing to allocate and commit resources and Manufacture such Product(s) pursuant to the terms of this Agreement; and

WHEREAS, Customer acknowledges that it is aware that in May 2011 and November 2011, BVL's manufacturing facility was inspected by the United States Food and Drug Administration and by the European Medicines Agency in March 2011 and November 2011. Customer further acknowledges that each of these inspections resulted in observations from the regulatory authority citing deviations from current Good Manufacturing Practices ("GMP"). Customer acknowledges The European Medicines Agency and the Therapeutic Goods Administration have issued BVL short-dated, restricted GMP licenses. Customer further acknowledges that it is aware (i) BVL voluntarily suspended manufacturing at its site as of November 2011 and (ii) \*\*\*\*. Customer has reviewed the records of inspection from the above mentioned regulatory authorities as well as BVL's corrective action responses to the regulatory agencies and is satisfied that the corrective actions set forth in BVL's corrective action plan should rectify the cGMP issues at the manufacturing facility that directly or indirectly affect Customer's Products. Based on the foregoing, Customer acknowledges that the GMP issues set forth above, as well as any prior deviations from cGMP by BVL, shall not constitute grounds for a claim of any breach of this Agreement, and Customer specifically waives any right to claim any breach under this Agreement based on any such prior deviations from cGMP. For the avoidance of doubt, any reference in this Agreement to BVL's compliance and/or conformance with GMP or cGMP,

whether for facilities, manufacturing operations, personnel, products or otherwise, shall be deemed qualified by the terms of this paragraph.

WHEREAS, Customer and BVL are parties to that certain Manufacturing and Service Contract for Commercial and Developmental Goods dated as of July 1, 2008 (the "Manufacturing Agreement") which agreement was terminated pursuant to the terms of the certain Settlement and Release Agreement entered into between BVL and Customer as of March 20, 2012 (the "Settlement Agreement");

WHEREAS, Customer and BVL are parties to that certain Transition Services Agreement dated March 20, 2012 (the "Transition Services Agreement"); and

WHEREAS, the foregoing recitals constitute express terms of this Agreement.

NOW, THEREFORE, Customer and BVL agree as follows:

#### **ARTICLE 1 - DEFINITIONS**

In this Agreement, the following terms shall have the meanings set forth below:

1.1. "Act" means the US Federal Food, Drug and Cosmetic Act of 1938, the Public Health Service Act of 1944 and the regulations promulgated under that Act, as may be amended from time to time.

1.2. "Active Pharmaceutical Ingredient" or "API" shall mean bulk supplies of the pharmacologically active compound(s) comprising Product and listed in each Attachment "A#.3," (*i.e.*, A1.3) which Customer will provide to BVL in bulk form, from time to time, for the sole purpose of development and Manufacture of Product for Customer.

1.3. "Affiliate" shall mean, with respect to Customer: (a) any corporation or business entity, fifty percent (50%) or more of the voting stock or voting equity interests of which are owned directly or indirectly by a Party; or (b) any corporation or business entity which directly or indirectly owns fifty percent (50%) or more of the voting stock or voting equity interests of a Party; or (c) any corporation or business entity directly or indirectly controlling or under control of a corporation or business entity as described in (a) or (b). For the purposes of this Agreement, the "Affiliate" shall mean, with respect to BVL, Bedford Laboratories (along with its successors and assigns) ("Bedford"). For the avoidance of doubt, this Agreement will not be binding on affiliates of BVL other than (i) Bedford, (ii) BVL's Agents as authorized hereunder, and (iii) as set forth in Articles 9 and 11.

1.4. "Agent" or "Agents" shall mean any individual or entity that performs on behalf of a Party under this Agreement, and in the case of any such individuals, the term "Agent" shall be understood to include the entity employing such individual.

1.5. "Agency" and "Agencies" shall mean the regulatory entities for each respective country, states and/or territories as identified in and limited to each Product's definition of the Territory (as defined below) (*i.e.*, for Product A1 see Attachment A1.6); including: if Territory includes the United States, the FDA; if Territory includes Canada and its Provinces, the Canadian Health Protection Branch; if Territory includes any member state of the European Union, the European Agency for Evaluation of Medicinal Products (hereinafter the "EMA"); if

Territory includes Japan, the Japanese Ministry of Health, Labor and Welfare; (b) any successor organization of any such entity; and (c) any other government regulatory authority with regulatory oversight of the Manufacturing, the Facilities or use of Product in or for its Territory, as such other authorities are mutually agreed upon by the Parties in writing.

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, without limitation, the bodies of law, regulations (including without limitation, cGMP or its equivalent) and environmental, health and safety for each country of the Territory.

1.7. “Batch” shall mean a specific quantity of Product that is intended to be of uniform character and quality and is produced during the same cycle of Manufacture as defined by the applicable Batch Record (as defined below). 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 Indemnities” shall have the meaning ascribed thereto in Section 8.1.

1.10. “BVL Inventions” shall have the meaning ascribed thereto in Section 11.4.1.

1.11. “BVL Technology” shall mean the Technology (as defined below) 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, the Transition Services Agreement or the Manufacturing Agreement and without reliance upon Product, any API supplied by Customer, or Confidential Information or Composition of Customer; or (c) is a BVL Invention or BVL’s Other Invention (as defined herein).

1.12. “cGMP” shall mean, with respect to each Product, the current Good Manufacturing Practices in such Product’s Territory (Attachment “A#.6”, *i.e.*, A1.6) as may be amended or supplemented from time to time; including (i) if in the United States, then cGMP shall include without limitation, the current Good Manufacturing Practices set forth in 21 C.F.R. 210 and 21 C.F.R. 211 and relevant FDA guidance documents; and (ii) if in the European Union, then cGMP shall include, without limitation, the practices and standards described in the Guide to Good Manufacturing Practices for Medicinal Products as promulgated by the European Commission under European Directive 2003/94/EC, as may be amended or supplemented from time to time and the ICH Harmonised Tripartite Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients (ICH Q7), as each may be amended from time-to-time, or any successors thereto. In the event of any conflict among Applicable Laws pertaining to the Manufacture of Product, the most stringent among the conflicting Applicable Laws will govern unless the Parties agree otherwise in writing.

1.13. “Certificate of Analysis” shall mean a summary of the test results, including the test methods, specification parameters, and the pass/fail criteria, used in the determination of the quality and suitability of a specific Batch of Product, including review and approval by the appropriate quality assurance department at BVL

1.14. “Certificate of Compliance” shall mean, subject to the limitations set forth in the fourth Recital paragraph, a document, signed by an authorized representative of BVL,

attesting that a particular Batch was manufactured in accordance with cGMP, the Specifications (as defined below) and other Applicable Law. As Customer is aware, the European Medicines Agency and Therapeutic Goods Administration have issued BVL restricted, short-dated GMP licenses. In addition, BVL's GMP license in Canada has been restricted to medically necessary products. Based on these restricted GMP licenses, BVL has modified its Certificate of Compliance, a copy of which is included in Attachment "H").

1.15. "Claims" shall have the meaning ascribed thereto in Section 8.1.

1.16. "Composition" shall mean any components and/or raw materials other than API that are used in the Manufacturing of Product and listed in each Attachment "A#.3" (i.e., A1.3) hereto, which may be supplied by BVL or Customer as required pursuant to such 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. [Intentionally Omitted]

1.20. "Customer Indemnitees" shall have the meaning ascribed thereto in Section 8.2.

1.21. "Customer Inventions" shall have the meaning ascribed thereto in Section 11.3.1.

1.22. "Customer Technology" shall mean all: (a) API and Customer-supplied Composition; (b) Products and any intermediates or derivatives thereof; (c) Specifications; (d) the Technology of Customer owned, developed or obtained by or on behalf of Customer or Customer's Affiliates prior to the Effective Date, or owned, developed or obtained by or on behalf of Customer or its Affiliates independent of this Agreement and without reliance upon the Confidential Information, Improvements or BVL Technology; and (e) Customers' Improvement.

1.23. [Intentionally Omitted].

1.24. "Disclosing Party" shall mean the party that is directly or indirectly disclosing Confidential Information to the Receiving Party (as defined below) 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 relating to the API and Product and such other information as required by Applicable Laws, including 21 C.F.R. Section 314.420 and to the extent applicable any equivalent requirement in under Applicable Laws including as required by the Committee for Proprietary Medicinal Products Note for Guidance on the European Drug Master File Procedure for Active Ingredients.

1.26. "Equipment" shall mean the equipment described in the Master Batch Record (as defined below) which is: (a) owned or leased by BVL; or (b) if supplied by Customer, then

identified in Attachment “F” to this Agreement, and in each case will be used by BVL for the 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 300 Northfield Road, Bedford, Ohio, and 19200 Treat Road, Walton Hills, Ohio, 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 accordance with Section 3.2.

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. §§301 et seq., as amended from time to time.

1.30. “Firm Order” shall mean a binding commitment, as established by a Purchase Order (as defined below) issued by Customer, to have a Batch of Product Manufactured by BVL hereunder.

1.31. [Intentionally Omitted]

1.32. “Force Majeure” shall have the meaning set forth in Section 17.1.

1.33. “Forecasts” shall mean the collective reference to the Manufacturing 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 the Manufacture of Product or otherwise arise in the performance of any services related to the Product under this Agreement.

1.36. “Investigation” shall mean a detailed and thorough review of any Manufacturing deviation (or any other matter requiring review pursuant to the terms of this Agreement) that is documented in a written report and approved at a senior management level. Each such written report shall include, without limitation, a detailed description of the atypical event, deviation or other matter, all steps taken to review such 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, if applicable.

1.37. “Lot” shall have the same meaning as Batch.

1.38. “Losses” shall have the meaning ascribed thereto in Section 8.1.

1.39. “Manufacture,” “Manufacturing,” and “Manufactured” shall mean all operations of BVL in the scheduling, production, packaging, labeling, warehousing, quality control testing (including in-process, release and stability testing when applicable), release and shipping of Product to meet the Specifications for Products.

- 1.40. “Manufacturing Process” shall mean any and all processes (or any step in any process) used or planned to be used by BVL to Manufacture Product, as evidenced in the Batch Records.
- 1.41. “Manufacturing Date” shall mean the date on which BVL commences manufacture of a Batch.
- 1.42. “Manufacturing Forecast” shall have the meaning ascribed thereto in Section 5.1.1.
- 1.43. “Marketing Authorization” shall mean a New Drug Application (as defined below) filed with an Agency outside the United States.
- 1.44. “Master Batch Record” or “MBR” means the document containing the mutually agreed to Manufacturing Process including but not limited to the instructions for formulation, filling, lyophilization if applicable, packaging, labeling and specifications for components and raw materials to be used in the Manufacture of the Product. In-process and finished Product Specifications for the Product will be referenced in the Master Batch Record. It may also be referred to as the “Master Production Record” or “MPR”. The MBR may be amended from time to time by mutual written agreement of the Parties
- 1.45. “NDA” shall mean a New Drug Application filed with the FDA.
- 1.46. “Obsolete Materials” shall have the meaning set forth in Paragraph 6.4.2.
- 1.47. “Party” or “Parties” shall have that meaning as set first in the first unnumbered paragraph of this Agreement.
- 1.48. [Intentionally Omitted]
- 1.49. “Products” shall mean the final packaged dosage forms of the product(s) listed separately in each Attachment “A#.1” (e.g. A1.1) to this Agreement. If used in the singular rather than plural, “Product” shall apply to an individual product as listed in Attachment “A#.1”
- 1.50. “Promptly” shall mean within thirty calendar (30) days.
- 1.51. “Purchase Order” shall mean a written form submitted by Customer to BVL authorizing the Manufacture of Product or other services as specified on the document which references this Agreement or a quotation number provided by BVL or other document provided by BVL outlining the services to be performed, the price to be paid, and contains each of the requirements set forth on Attachment “B.”
- 1.52. “Qualified Person” shall have the meaning set forth in Article 48 of the European Directive 2001/83/EC, and as set forth elsewhere within the EU regulations, as may be amended from time to time.
- 1.53. “Quality Agreement” shall mean the separate quality agreement 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.

- 1.54. “Receiving Party” shall mean the party which is directly or indirectly in receipt of Confidential Information from the Disclosing Party pursuant to this Agreement. The Receiving Party may also act as the Disclosing Party of the other party’s Confidential Information.
- 1.55. “Records” shall have the meaning ascribed thereto in Section 3.8.
- 1.56. “Relevant Product” shall mean the Product; any product containing the same API as Customer’s Product, or any product developed or manufactured using the same API which competes in the same diagnostic class as the Product. For the avoidance of doubt, BVL shall not be prevented from manufacturing a product containing the same API which does not compete in the same diagnostic class as the Product.
- 1.57. “Representative” shall have the meaning ascribed thereto in Section 2.5.
- 1.58. [Intentionally Omitted]
- 1.59. “SOP’s” (of a Party) shall mean such Party’s standard operating procedures as defined in the controlled written documentation of such Party.
- 1.60. “Specification” or “Specifications” shall mean the quality standards, including tests, analytical procedures and acceptance criteria that are established to confirm the quality of Product which are mutually agreed to in writing and are contained or referenced in the Master Batch Record for Product or as otherwise mutually agreed to in writing by the Parties.
- 1.61. “Technology” shall mean all methods, techniques, trade secrets, copyrights, know-how, data, documentation, regulatory submissions, Product Specifications (which are solely owned by Customer, except for those portions of such Specifications that include routine BVL policies, procedures, etc. and that are not Product-specific) and other intellectual property of any kind (whether or not protectable under patent, trademark, copyright or similar laws).
- 1.62. “Temporary Storage Period” shall have that meaning ascribed in Section 6.5.
- 1.63. “Territory” shall mean those countries and territories set forth in each Attachment “A#.6” (i.e., A1.6) for the Product identified in each such Attachment “A,” it being understood that different Products may have different Territories for purposes of this Agreement.
- 1.64. “Third Party” shall mean any person or entity other than a Party to this Agreement or such Party’s Affiliate.
- 1.65. “United States” or “U.S.” shall mean the United States of America, its territories and possessions including Puerto Rico.

**ARTICLE 2 - DESCRIPTION OF WORK**

2.1. Equipment.

2.1.1. 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.

2.1.2. 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 purchased is identified on Attachment "F" (title to which shall at all times remain with Customer) and shall be solely dedicated to the production of Products hereunder. 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. BVL shall, at all times and at its sole cost, be responsible for all normal and routine maintenance to the Equipment identified on Attachment "F" in accordance with current BVL's SOP's, which procedures have been reviewed and approved by Customer. Customer shall, at all times and at its sole cost, be responsible for upgrades, repairs, replacement, non-routine maintenance and/or enhancements to the Equipment identified on Attachment "F" and BVL shall obtain Customer's prior written approval prior to incurring such costs. Risk of loss of all Equipment identified on Attachment "F" shall be retained by BVL to the extent that loss and/or damage of equipment is caused by BVL's act of negligence, breach, willful misconduct. For the avoidance of doubt, BVL shall not be liable or bear risk of loss for repairs or upgrades to the equipment except if caused by BVL's failure to perform maintenance as required pursuant to this Agreement.

2.2. API and Composition.

2.2.1. Customer Supply of API & Composition. Customer shall, at its own expense, supply BVL with sufficient quantities of API and Customer-supplied Composition, including API, needed for the Manufacture of Product, as specified in the supporting Purchase Orders, in order to meet Customer's requirements for commercial quantities of Product in finished dosage form. Customer shall provide API and any Customer supplied Composition to BVL at least \*\*\*\*\* (\*\*\*\*\* ) calendar days in advance of scheduled Manufacturing dates. BVL shall have no liability for quantities of API or Customer-Supplied Composition shipped in excess of the requirement to Manufacture the amount of Product required to fill open Purchase Orders, but shall use such API or Composition for future Purchase Orders.

2.2.2. Certification of Customer Supplied Composition & Equipment. Upon BVL's request, Customer shall provide written confirmation of the review and approval of the quality systems of its designated vendors for Customer-supplied Composition/Equipment.

2.2.3. Reports for Customer Supplied Composition. BVL shall: (i) provide Customer with standard inventory reports for all API and Customer-supplier Composition for the prior \*\*\*\*\* not later than the \*\*\*\*\* (\*\*\*\*\*) business day of each \*\*\*\*\*; (ii) notify Customer when the amount of API or Customer-supplied Composition available at BVL reaches the minimum quantity of materials as agreed by both Parties; (iii) not provide API or Customer-supplied Composition to any Third Party without the express prior written consent of Customer; (iv) not use API or Customer-supplied Composition for any purpose other than the Manufacture of Product or conducting other services under this Agreement, including, without limitation, not to analyze, characterize, modify or reverse engineer any API, or take any action to determine the structure or composition of any API, unless the foregoing is required under this Agreement; and (v) destroy or return to Customer or its designee all unused quantities of API and Customer-supplied Composition according to

Customer's written directions at Customer's cost. If no written directions are provided to BVL within thirty (30) days following termination of this Agreement, or any postponement or cancellation of a Purchase Order, then without BVL having any liability to Customer, BVL may dispose of such API or Composition upon not less than ten (10) days prior written notification to Customer of BVL's intent to dispose of such API or Composition per cGMP(s). Customer shall be financially liable for the cost or expense associated with any such disposal.

2.2.4. Annual Physical Audit. In addition to Customer's annual GMP audit, Customer will be entitled to perform an annual physical audit of Customer-supplied Composition, at a date and time to be agreed upon by both Parties. If the scope of the audit warrants (e.g., significant number of materials, number of personnel in attendance, BVL's involvement, etc.) a quotation will be provided to Customer.

2.2.5. ID Only Verification. Customer must give written permission to BVL to do ID-only, by-label verification of any API or active drug substance if no identification test is requested by Customer to be performed by BVL.

2.2.6. Release of Materials. BVL will release all materials provided by BVL. In the event the Territory (Attachment "A#.6") includes the European Union, then Customer's Qualified Person shall be responsible to certify compliance of the Customer-supplied API and for the release of Product within the European Union and for EU Directives, standards and rules, including without limitation, Article 51(3) of Directive 2001/83/EC, with respect to the Product(s).

2.2.7. Quality Control Testing Requirements. Customer will provide, or cause BVL to develop at mutually agreed upon fees, written quality control testing requirements, methods, specifications and reference standards for the API and Product, which shall be performed by BVL in accordance with the Specifications. Customer will approve in writing initial testing documents, the Master Production Record and any revisions of the documents thereafter. Revisions of approved testing documents requested within eight (8) weeks prior to the Manufacturing Date or other services related to the subject Product may cause a delay or postponement of such 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. Upon mutual agreement between the Parties which shall not be unreasonably or untimely withheld, BVL shall make revisions to the testing documents or MBR for a Product that are requested by Customer. Further, BVL shall be entitled to reasonable reimbursement for any and all additional costs and expenses incurred by BVL in connection with any such revision or delay as agreed upon by the Parties. The Parties shall cooperate in good faith to reach agreement for the changes and the associated costs.

2.2.8. Disposition of Tailings/Rejects. Customer is responsible for notifying BVL with instruction for disposition of tailings and rejects, which will be incorporated into the Master Batch Record and include a shipment address for tailing and rejects if Customer requests return of tailings and rejects.

2.2.9. Customer Liable for Changes to BVL Composition. BVL shall procure, at its cost, all BVL-supplied Composition listed as BVL's responsibility in Attachment A#.3 for a Product in order for BVL to meet Customer's Purchase Orders made

pursuant to this Agreement. In the event that Customer makes changes to the vendor and/or specifications of any BVL-supplied Composition, any additional expense due to such change shall be borne by the Customer as agreed upon, and the Parties shall negotiate, in good faith, an appropriate adjustment to the purchase price of the Product to reflect any increase or decrease in costs due to such changes. If Customer requires BVL utilize a specific vendor for any BVL supplied Composition and BVL is reasonably unable to utilize such vendor, then if Customer requires such vendor to be utilized, Customer shall have the responsibility to source such Composition and provide to BVL pursuant to the terms of this Agreement, which shall thereafter be deemed a Customer-supplied Composition under this Agreement.

2.3. Product Manufacture. Pursuant to the provisions of this Agreement, BVL shall Manufacture Customer's Purchase Order quantities of Product in finished packaged dosage form as defined in each Attachment "A#.1" (i.e., A1.1) For the avoidance of doubt, notwithstanding anything in this Agreement to the contrary, such Product shall meet the Specification, the requirements of cGMP and all Applicable Law. BVL, its Agents and Bedford (and any business, operations, personnel or assets owned or controlled by BVL and such Agents and any successors thereto, as the same may be reorganized from time to time) shall not during the term Manufacture for any Third Party, directly or through any Third Party any Relevant Product or provide or cause to be or assist in providing any products or services (including in manufacturing, development, or procurement) any Relevant Product, only in each case with the prior written consent of Customer (which may be given at its sole discretion).

2.4. [Intentionally Omitted].

2.5. Representatives. Each Party shall appoint a representative having primary responsibility for day-to-day interactions with the other Party for the services under this Agreement (each, a "Representative"). Both Parties shall use reasonable efforts to provide the other with at least forty-five (45) days prior written notice of any change in its Representative. Except for notices or communications required or permitted under this Agreement, which shall be subject to Article 13, or unless otherwise mutually agreed by the Parties in writing, all communications between BVL and Customer regarding the conduct of the services under this Agreement shall be addressed to, or routed directly through, the respective Representatives of each Party, as appropriate.

### **ARTICLE 3 - MANUFACTURE**

3.1. BVL Compliance. BVL has obtained, and will maintain at its sole cost and expense throughout the term of this Agreement, all licenses, permits, certifications and approvals required under Applicable Law for its Manufacturing Facilities and for its performance under this Agreement; BVL's Facilities conform, and will throughout the term of this Agreement conform to cGMP and other Applicable Law. Customer acknowledges that it is aware that in May 2011 and November 2011, BVL's manufacturing facility was inspected by the United States Food and Drug Administration and by the European Medicines Agency in March 2011 and November 2011. Customer further acknowledges that each of these inspections resulted in observations from the regulatory authority citing deviations from current Good Manufacturing Practices. Customer also acknowledges The European Medicines Agency and the Therapeutic Goods Administration have issued BVL short-dated, restricted GMP licenses. Customer further acknowledges that it is aware BVL voluntarily suspended manufacturing at its site as of November 2011. Customer has reviewed the records of inspection from the above mentioned regulatory authorities as well as BVL's corrective action

responses to the regulatory agencies and is satisfied that the corrective actions set forth in BVL's corrective action plan should rectify the cGMP issues at the manufacturing facility that directly or indirectly affect Customer's Products.

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 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 completion of a quality assurance audit and/or regulatory impact assessment satisfactory to it including without limitation an environmental, health and safety audit of the new location or additional facility, as the case may be); provided, that the Parties will meet and confer to discuss allocation of any applicable costs and expenses in connection with any change of location of the Facility or use of any additional facility for BVL's convenience. BVL will be responsible for all applicable costs and expenses in connection with any change of location of the Facility or use of any additional facility for BVL's convenience (including costs for qualification and validation batches). For the avoidance of doubt, it is the Parties' intent that changes to the Facility made by or on behalf of Customer, or for the convenience of Customer shall be borne by Customer; changes to the Facility made by or on behalf, or for the convenience of BVL shall be borne by BVL. In the event that a change to the Facility is initiated by BVL, the Parties shall meet and confer on the scope of reasonable regulatory requirements to be provided by BVL. In the event the Parties cannot in good faith reasonably agree to such filing requirements, then the Parties shall mutually agree upon a qualified, neutral regulatory expert who shall fully and finally allocate the costs after reviewing and hearing each Parties arguments. The costs of the expert shall be borne equally by the Parties. BVL shall maintain, at its own expense, the Facility and all Equipment required for the Manufacture of Product in a state of repair and operating efficiency consistent with the requirements of the cGMP and all other Applicable Law.

3.3. Change Control. Any changes to the Specification, Manufacturing Process, Equipment utilized to Manufacture such Product, its testing procedures, validation, suppliers of raw materials and components, or documentation systems that are specific or related to Product would likely impact any government submission or approval pending, received and/or required for such Product, either foreign or domestic as applicable for the Territory, shall be made only with the prior written consent of the Parties and in accordance with change control provisions of the Quality Agreement. In the event any such changes are required by an Agency, BVL will Promptly notify Customer. Customer may, from time to time, propose to change Specification which shall require mutual written consent of the Parties, and BVL will not unreasonably or untimely withhold its consent to such change and will use commercially reasonable efforts to implement such change. For the avoidance of doubt, it is the Parties' intent that the costs of any changes made pursuant to this Section 3.3 at Customer's request shall be borne by Customer, and the costs of any changes made pursuant to this Section 3.3 made for the convenience of BVL shall be borne by BVL. In the event that a change made pursuant to this Section 3.3 is initiated by BVL, the Parties shall meet and confer on the scope of reasonable regulatory requirements to be provided by BVL. In the event the Parties cannot in good faith reasonable agree to such filing requirements, then the Parties shall mutually agree upon a qualified, neutral regulatory expert who shall fully and finally allocate the costs after reviewing and hearing each Parties arguments. The costs of the expert shall be borne equally by the Parties.

3.4. Product Compliance. Product delivered to Customer pursuant to this Agreement shall conform to the Specification and be in compliance with all Applicable Law, including but not limited to the requirements of cGMP. Customer acknowledges that it is aware that in May 2011 and November 2011, BVL's manufacturing facility was inspected by the United States Food and Drug Administration and by the European Medicines Agency in March 2011 and November 2011. Customer further acknowledges that each of these inspections resulted in observations from the regulatory authority citing deviations from current Good Manufacturing Practices. Customer acknowledges The European Medicines Agency and the Therapeutic Goods Administration have issued BVL short-dated, restricted GMP licenses. Customer further acknowledges that it is aware BVL voluntarily suspended manufacturing at its site as of November 2011. Customer has reviewed the records of inspection from the above mentioned regulatory authorities as well as BVL's corrective action responses to the regulatory agencies and is satisfied that the corrective actions set forth in BVL's corrective action plan should rectify the cGMP issues at the manufacturing facility that directly or indirectly affect Customer's Products. Based on the foregoing, Customer acknowledges that the GMP issues set forth above, as well as any prior deviations from cGMP by BVL, shall not constitute grounds for a claim of any breach of this Agreement, and Customer specifically waives any right to claim any breach under this Agreement based on any such prior deviations from cGMP. In the event of conflicting Applicable Law, Product will comply with the most stringent from the conflicting 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 and/or the Facilities directly relevant to the manufacture of the Product which are required by any Agency shall be provided by BVL in a timely manner, and BVL shall submit to all inquiries and inspections by any such Agency. All documents directly related to Product and a summary of all information provided by BVL to any Agency shall be provided to Customer in advance of submission to such Agency if feasible, and in no case shall such documents be provided to Customer later than five (5) business days after such documents and information are provided to any Agency. The foregoing obligation of disclosure excludes any information which BVL is prohibited from disclosing and/or requested or directed by a regulatory authority not to disclose, including without limitation, drafts of any potential consent decrees. BVL shall notify Customer Immediately (or, if during a weekend, upon the next business day) of all scheduled Product-specific Agency inspections, and Customer shall have the right to be present for all scheduled inspections relating to the Manufacture of Product. Any and all written communications or notices of inspection directly related to Product received from any Agency shall be provided by Customer and BVL to the other Party no later than five (5) business days after such communications or notices are received by such Party; provided, however, that if such document is from BVL, it may redact the confidential information of Third Parties from such communications prior to providing same to Customer.

3.5.1. BVL shall also notify Customer Immediately of any notices, observations or other written, formal communications from such Agency provided to BVL after the Effective Date regarding any deficiencies that have or may have an adverse effect on the Product or BVL's ability to perform its obligations under this Agreement. For the avoidance of doubt, the foregoing obligation of disclosure excludes any information which BVL is prohibited from disclosing, and/or directed or requested by a regulatory agency not to disclose, including without limitation, drafts of any potential consent decrees. Notwithstanding anything to the contrary hereunder, Customer shall have the right to postpone all pending and future Purchase Orders hereunder (and adjust all forecasts accordingly) in the event of (i) any such notices, observations or

communications newly provided to Customer following the Effective Date; (ii) any regulatory or other concerns under Applicable Law newly discovered following the Effective Date; (iii) any material issues with the supply of Products hereunder (including atypical Manufacturing deviations of the sort requiring investigation hereunder); (iv) any consent decree; or (v) violations of any of the Product quality provisions of this Agreement.

3.5.2. To the extent BVL does not already have copies, 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 (2) 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 Files (DMFs) and authorization for FDA to access the DMFs. This may be used by the Customer only to prepare any required Regulatory filing. Any other use of the DMF shall require BVL's prior written approval.

3.6. Health, Safety and Environmental Compliance.

3.6.1. Dispensing and other Manufacturing operations are to be performed by BVL 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. Notwithstanding the foregoing, Customer shall be solely responsible for the disposal of any waste generated by Customer disposition of Customer-supplied Composition or finished Product.

3.6.2. Customer has established a program for systematic assessment of its suppliers' EHS programs ("TPM EHS Assessment Program") and BVL agrees to participate and reasonably cooperate with Customer in effectively implementing this TPM EHS Assessment Program.

3.6.3. BVL will review Customer's TPM EHS Assessment Program and, if applicable, provide quotations for additional resources required to address the program. BVL policies will govern except in the event that Customer is willing to bear the cost of compliance. Specifically, BVL agrees to:

3.6.3.1. Promptly respond to reasonable Customer requests for non-confidential information made as part of TPM EHS Assessment Program. Customer will provide a questionnaire to BVL and BVL is expected to provide the complete response within thirty (30) calendar days;

3.6.3.2. Reasonably cooperate with Customer to clarify and supplement any information related to its facilities and operations;  
and

3.6.3.3. Provide to Customer, upon request, copies of BVL's environmental, health and safety permits required by any governmental authority which are associated with the Products and all facility operations related thereto.

3.6.4. BVL agrees that Customer or its appointed Agent(s) (which Agent shall be disclosed to BVL not less than 30-days in advance of an audit and which shall not be rejected by BVL in the absence of good cause shown) shall be entitled to conduct inspections and audits upon reasonable notice (at Customer's cost) and mutually convenient times of any areas or facilities used to produce the Products or required for production of the Products, including for the following reasons:

3.6.4.1. to assist in completion of TPM EHS Assessment Program described in this Section 3.6.2; and

3.6.4.2. to allow for a loss prevention inspection of the Facility by Customer's fire insurance underwriting company as necessary for Customer to obtain contingent business interruption insurance.

3.6.5. BVL shall take reasonable and appropriate precautions to ensure that its personnel (including its employees, contractors, and Agents) are protected from Product and/or the Product's Manufacturing process exposures through either engineering infrastructure, personnel protective equipment or a combination of both. Upon request, within ninety (90) days, BVL shall provide workplace monitoring data which demonstrates the effectiveness of controls. For testing of Customer-supplied Composition or API, Customer will provide sampling method and media to allow samples to be collected at Customer's cost. If testing methods for the API or Customer-supplied Composition in question are unavailable, surrogates may be used. Workplace monitoring data will be performed in accordance with proposals provided to Customer.

3.7. Subcontractors. Neither Party may subcontract with any Third Party or use Agents to perform any of its obligations hereunder without the prior written consent of the other Party, provided that for the avoidance of doubt: (i) any rights of Customer to perform audits as authorized hereunder (and subject to the requirements of Section 3.6.4) are not subject to the foregoing, provided in any event that such auditor shall be required to enter into a reasonable and appropriate confidentiality agreement with BVL; and (ii) BVL shall have the right to subcontract nominal, non-Manufacturing Process tasks (such as pest control, cleaning, etc.). In the event that a Party does subcontract with a permitted Third Party or Agent pursuant to this Section 3.7, it shall be solely responsible for the performance of any permitted subcontractor, and for costs, expenses, damages, or losses of any nature arising out of such performance as if such performance had been provided by itself under this Agreement. Each Party shall cause any such permitted subcontractor and Agent to be bound by, and to comply

with, all confidentiality, quality assurance, regulatory and other obligations and requirements as set forth in this Agreement.

3.8. Records. BVL shall keep complete and accurate 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 and on notice to Customer pursuant to Section 3.5, without the prior written approval of Customer. While in the possession or control of BVL, Records shall be available during annual audits or as otherwise mutually agreed to times for inspection, examination and review by or on behalf of Customer and its Agents (which Agent shall be subject to the requirements set forth in Section 3.6.4 as well as a reasonable and appropriate confidentiality agreement). All original Records of the Manufacture of Product hereunder shall be retained and archived by BVL in accordance with cGMP and Applicable Law, but in no case for less than a period of\*\*\*\* (\*\*\*\*) 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. \*\*\*\* (\*\*\*\*) years after completion of the applicable work or project or such longer period in accordance with cGMP and Applicable Law unless otherwise agreed to in advance by the Parties in writing all of the aforementioned records shall be destroyed unless Customer instructs BVL in writing as to a contrary disposition for such files.

3.9. Product and Process Failure.

3.9.1. Product shall be Manufactured in accordance with cGMP and the Manufacturing Process approved mutually by Customer and BVL. Customer acknowledges that it is aware that in May 2011 and November 2011, BVL's manufacturing facility was inspected by the United States Food and Drug Administration and by the European Medicines Agency in March 2011 and November 2011. Customer further acknowledges that each of these inspections resulted in observations from the regulatory authority citing deviations from current Good Manufacturing Practices. Customer acknowledges The European Medicines Agency and the Therapeutic Goods Administration have issued BVL short-dated, restricted GMP licenses. Customer further acknowledges that it is aware BVL voluntarily suspended manufacturing at its site as of November 2011. Customer has reviewed the records of inspection from the above mentioned regulatory authorities as well as BVL's corrective action responses to the regulatory agencies and is satisfied that the corrective actions set forth in BVL's corrective action plan should rectify the cGMP issues at the manufacturing facility that directly or indirectly affect Customer's Products. Each Batch of Product will be sampled and tested by BVL against the Specification. The Quality Assurance Department of BVL will review the Records relating to the Manufacture of the Batch and will assess if the Manufacture has taken place in compliance with cGMP and the Manufacturing Process.

3.9.2. If, based upon such tests and/or review, a Batch of Product conforms to the Specification and was Manufactured according to cGMP and the Manufacturing Process, then a Certificate of Compliance will be generated and approved by the Quality Assurance Department of BVL. This Certificate of Compliance, a Certificate of Analysis, if required, and a complete and accurate copy of the executed Batch records (collectively, the "Batch Records") for each Batch of Product (including all the Batch documentation described in Attachment "D" to this Agreement) will be delivered

to Customer in advance of Product shipment by a reputable overnight courier or by registered or certified mail, postage prepaid, return receipt requested to verify delivery date. As Customer is aware, the European Medicines Agency and Therapeutic Goods Administration have issued BVL restricted, short-dated GMP licenses. In addition, BVL's GMP license in Canada has been restricted to medically necessary products. Based on these restricted GMP licenses, BVL has modified its Certificate of Compliance, a copy of which is included in Attachment "H". Unless the Batch is shipped under Quarantine (as defined in Section 6.3 below), in the event that Customer has not received all such Batch Records at the time of receipt of BVL's invoice for such Batch, Customer will notify BVL in writing, and unless the Batch (or a partial Batch) is shipped under Quarantine, Customer shall be entitled to withhold payment until Customer receives the Batch Record. 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 lot disposition of such Batch within \*\*\*\* (\*\*\*\*) calendar days of receipt of the complete Batch Records relating to such Batch. If no acceptance or rejection in writing is received by BVL within \*\*\*\* (\*\*\*\*) days, the Batch will be conclusively deemed accepted. During this review period, the Parties agree to respond punctually, and shall endeavor in good faith to comply in the typical circumstance within five (5) calendar days, to any reasonable inquiry by the other Party with respect to such Batch Records. Customer has no obligation to accept a Batch to the extent such Batch does not comply with the Specification, Applicable Law (for purposes solely due to BVL or BVL's Manufacturing or services hereunder), and/or was not Manufactured in compliance with cGMP and the Manufacturing Process.

3.9.4. In case of any disagreement between the Parties as to whether Product conforms to the applicable Specification, a representative sample of such Product shall be submitted to an independent testing laboratory mutually agreed upon by the Parties for tests and final determination of whether such Product conforms to such Specification. The laboratory must meet cGMP requirements, be of recognized standing in the pharmaceutical industry, and consent to the appointment of such laboratory shall not be unreasonably withheld or delayed by either Party. Such laboratory shall use the validated test methods contained in the applicable Specification. The determination of conformance or not by such laboratory with respect to all or part of such Product shall be final and binding on the Parties. The fees and expenses of the laboratory incurred in making such determination shall be paid by the Party against whom the determination is made.

3.9.5. Subject to Section 6.4 and Article 8, if BVL does not manufacture any Batch of Products according to cGMP or the Manufacturing Process and the Product does not meet the requirements of this Agreement then BVL shall, after consultation with and written agreement from Customer:

3.9.5.1. refund any Manufacturing fees and expenses paid by Customer to BVL on a *pro rata* basis over the usable portion for such Batch; or

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3.9.5.2. at BVL's cost and expense produce a new Batch of Product as soon as reasonably possible; and

3.9.5.3. reimburse Customer for any loss of API or Customer-supplied Composition pursuant to the terms set forth in Section 8.5 to the extent the reimbursement is not provided in Section 3.9.5.1 or Section 3.9.5.2.

3.9.6. BVL or Customer may postpone all scheduled Manufacture of the affected Product until such time as final disposition of rejected Batch(s) has been determined and complete Investigations have been finalized with root cause analysis and corrective actions determined to prevent further Batch rejections. BVL shall without any undue delay perform all Investigations (including for such rejected Batches) diligently and expeditiously. The Parties will use good faith efforts to Investigate and perform corrective actions to address Batches for which any Batch Record indicates an out-of-profile condition as defined by generally accepted practice and mutually agreed upon by the Parties. Customer may request, in writing, that BVL continue to Manufacture Product pending its Investigation, and in the event that BVL elects to Manufacture Customer's Product prior to the conclusion of an Investigation, then Customer shall assume financial responsibility in the event of further Batch rejection for similar reasons. If Customer requests postponement until completion of the Investigation, the postponement fees in Section 6.5 do not apply.

3.9.7. Moreover, the Parties shall meet to discuss, evaluate and analyze the reasons for and implications of the failure to meet the Specification or comply with the cGMP and/or the Manufacturing Process.

#### ARTICLE 4 - VOLUMES

4.1. Product Purchase and Supply Obligations. BVL shall supply Customer no more than \*\*\*\* percent (\*\*\*\*%) of Customer's Product as identified in Attachment "A#.1" in accordance with the terms of this Agreement for the Territory. 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 meet the requested delivery date, the Manufacturing of any Batch of Product or any other services under this Agreement, BVL shall promptly notify Customer thereof, but in any event, within \*\*\*\* (\*\*\*\*) business days.

#### ARTICLE 5 - FORECASTS AND PURCHASE ORDERS

##### 5.1. Forecasts.

5.1.1. Manufacturing Forecast. Attached hereto as part of each Attachment "A#.4.1" (i.e., A1.4.1) is Customer's forecast of its requirements for Manufacture by BVL of Products through \*\*\*\* (the "Manufacturing Forecast"). Such Manufacturing Forecast represents Customer's good faith projection of its requirement of Product(s) from BVL through \*\*\*\*. The Manufacturing Forecast is non-binding on either of the Parties and is used for planning purposes only, except that the initial Manufacturing Forecast and the minimum number of Batches set forth in Attachment A8 shall be binding on BVL.

5.1.2. Updates to Manufacturing Forecast. Customer shall supply updates to the Manufacturing Forecast as follows: \*\*\*\*.



5.2. [Intentionally Omitted]

5.3. Purchase Orders.

5.3.1. Customer shall provide BVL with Purchase Orders for its Product requirements not less than \*\*\*\* (\*\*\*\*) days prior to its anticipated delivery date. Customer may increase the quantity or accelerate the scheduled Manufacturing Date of any Firm Order with the written consent of BVL, such consent not to be unreasonably withheld or delayed, provided however, that: (i) BVL shall not be required to implement such alteration if it cannot reasonably or practicably do so; and/or (ii) BVL shall provide a quotation for the additional fee, if any, required to implement such increase or acceleration and Customer shall provide authorization for such fee. Such Purchase Orders shall be subject to acceptance by BVL. BVL will respond to Customer's Purchase Order with either a confirmation or proposed modification as to delivery date within \*\*\*\* (\*\*\*\*) business days of receipt by BVL. Customer may, in its sole discretion, decrease, postpone or cancel any Firm Order, subject to the provisions of Paragraph 6.5. Any terms or conditions of a Purchase Order, acknowledgement or similar standardized form given or received pursuant to this Agreement that are additional or inconsistent with this Agreement shall have no effect and are hereby excluded, unless this Section is expressly referenced by the Parties.

5.3.2. Unless mutually agreed, no later than \*\*\*\* days prior to the date of manufacture, BVL will notify Customer of said date of manufacture.

5.3.3. Notwithstanding the foregoing, in the event that either (i) Customer, in its good faith judgment, determines that a Product, if Manufactured, will not be marketable in the Territory and that the cause for such non-marketability is solely and proximately the responsibility of BVL, (ii) the Products or Manufacture are subject to any consent decree or any of the remedial actions, investigations or adverse events described in Article 3 hereof or (iii) BVL has breached its representations, warranties, or other obligations under of this Agreement, then Customer shall have the right, at its discretion, to postpone without penalty to either Party any future Purchase Orders of Product until such time as the cause giving rise to the non-marketability of the Product is abated. The Parties shall cooperate in good faith to schedule Manufacturing of such affected Products as soon as reasonably practicable.

5.4. Obligation of Supply. BVL shall use commercially reasonable efforts to Manufacture Product and supply Product to Customer in accordance with the Purchase Orders and pursuant to Attachment A8. At Customer's request, BVL agrees to cooperate with Customer and work in good faith to achieve an increase in the number of Batches from those set forth in Attachment A8.

5.5. Inventory. Regarding additional Customer inventory to exist prior to the expiration or termination of this Agreement, BVL and Customer shall discuss in good faith any Customer request to increase Product inventory, and BVL shall use commercially reasonable efforts to (a) accommodate Customer with respect to increasing Product inventory in accordance with Attachment A8, (b) provide levels of Customer inventory as of \*\*\*\* of each of \*\*\*\*, so that BVL Manufactures up to the number of additional Batches of Product set forth in Attachment A8 under the heading "Terminal Supply", which is expected to cover the manufacture of at least \*\*\*\* (\*\*\*\*) months of additional inventory of each Product based upon

then current quarterly Product unit sales, and (c) Manufacture such inventory no earlier than the \*\*\*\*, provided that the Parties will negotiate reasonable adjustments to the Manufacturing Dates for such Product in good faith based on BVL's then current manufacturing schedule and operating capacity for the Facility and any then applicable regulatory restrictions.

5.6. Additional Services.

5.6.1. [Intentionally Omitted].

5.6.2. In the event that Customer requests or an Agency requires additional services in support of Product, 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: (a) maintain at all times a quantity of BVL-supplied Composition from mutually approved vendors sufficient to meet Purchase Orders, (b) notify Customer of its requirements of API and Customer-supplied Composition needed in order to fulfill its obligations hereunder and meet the requirements of scheduled Manufacturing dates. If Customer would like BVL to maintain additional quantities of BVL-supplied Composition above that required for Firm Orders, Customer will inform BVL in writing. Upon Customer's written request and BVL's acceptance, BVL will maintain additional stock of API and Composition in excess of the amounts needed for Firm Order quantities for which Customer shall be liable as provided in Section 6.4.1. API and Customer-supplied Composition shall be delivered to BVL not less than \*\*\*\* (\*\*\*\*) days in advance of the scheduled Manufacturing Date. Customer will provide adequate supply of reference standards for the foregoing upon request by BVL. Customer will coordinate with BVL's Materials Management Department on the specifics related to each shipment of Customer-supplied Composition. 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.

**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 for other services in applicable quotations or proposals provided to Customer and confirmed by Customer's Purchase Orders. .

6.1.2. Delivery terms for Products shall be \*\*\*\* (Incoterms 2000). Customer shall assume title and risk of loss of the finished Product upon delivery to \*\*\*\*. BVL shall ensure that each Batch shall be delivered to Customer, or Customer's designee: (i) within \*\*\*\* (\*\*\*\*) days in advance or \*\*\*\* (\*\*\*\*) days after the requested delivery date or as otherwise mutually agreed to and to the destination designated by Customer on the Purchase Order; and (ii) in accordance with the instructions for shipping included on the Purchase Order and packaging specified in the Master Batch Record or as otherwise agreed to by the Parties in writing. A bill of lading shall be furnished to Customer with respect to each shipment. Customer is responsible for all shipment costs and shipping charges will be paid directly by Customer.

6.2. Pricing

6.2.1. Annual Price Adjustments The Parties agree that the prices listed in Attachment A#.5 will be held for \*\*\*\*. Annual Price adjustments will automatically be made starting on \*\*\*\*. The automatic price adjustment starting on \*\*\*\* will be a \*\*\*\* percent (\*\*\*\*%) increase from the prices listed on Attachment A#.5.

6.2.2. Price Adjustment on Product or Process Specification Changes. BVL reserves the right to adjust prices as mutually agreed based on changes to the Specifications or Manufacturing Process for a Product regardless of the event or action causing the Specification or Manufacturing Process change taking into account process efficiencies from such changes other than: (1) a change required as a result of BVL's negligence action, willful misconduct or breach of this Agreement; or (2) for BVL's convenience or request pursuant to Section 3.3.

6.2.3. [Intentionally Omitted].

6.2.4. Continuous improvements. Customer in concert with BVL is resolved to fostering perpetual value-added activity and continuous improvement. Therefore, Customer and BVL acknowledge and agree with the importance of pursuing process, quality, and cost improvement goals.

6.3. Payment of Invoices.

6.3.1. The purchase price for Product or services in an undisputed invoice shall be paid to BVL through an electronic funds transfer no later than \*\*\*\* (\*\*\*\*) days after the date of BVL's invoice to Customer. BVL will issue an invoice for: (i) Product Manufacture at such time that BVL's quality control department has completed its testing, found Product suitable to be shipped and has shipped the Products, Batch Records and other documents identified in Attachment "D;" and (ii) 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 \*\*\*\* (\*\*\*\*) days from the date of any disputed invoice, Customer must provide a written notice that conforms to the requirements of this Agreement of the disputed invoices and the reason such invoice is disputed. The Parties will negotiate in good faith to resolve such dispute within \*\*\*\* (\*\*\*\*) days following notice of such dispute. If a disputed invoice is resolved in Customer's favor, BVL shall either reimburse Customer or issue Customer a trade credit, as mutually agreed between BVL and Customer. If the Parties are unable to reach an agreement, either party may pursue any remedies available to it under this Agreement, at law, or in equity.

6.3.2. In the event of nonpayment of balances without written notice by Customer and reasonable cause within \*\*\*\* (\*\*\*\*) days of the invoice date, BVL has the option to assess and Customer agrees to pay a monthly late payment charge equal to \*\*\*\* percent (\*\*\*\*%) of the unpaid balance. Should unpaid balances on undisputed invoices extend beyond \*\*\*\* (\*\*\*\*) days after an invoice has been issued, BVL reserves the right to require Customer to pay \*\*\*\* (\*\*\*\*%) of the full price for each Batch at the time of Purchase Order issuance or may cancel all scheduled

Manufacture until such time as all unpaid overdue invoices, together with any and all late fees, have been paid.

6.4. Payment for Non-Validated Services or Production; Obsolete Materials.

6.4.1. Customer will be required to pay BVL for all Product Manufactured during any period when any Manufacturing Process and material testing procedures have not been fully developed and validated, regardless of whether Product is accepted or rejected by the Customer, unless such rejection is due to BVL's negligence, willful misconduct or breach of this Agreement by BVL.

6.4.2. Customer will be required to pay BVL for all packaging components and Composition which were purchased by BVL to fulfill open purchase orders or at Customer request for use specifically in the Manufacture of Product covered by this Agreement, should any of the BVL-supplied Composition become obsolete for any reason other than BVL's negligence, willful misconduct or breach of this Agreement (the "Obsolete Materials"). Notwithstanding the foregoing, Customer's liability for Obsolete Material shall be limited to the amount of packaging components and Composition necessary for Manufacture in accordance with Section 5.4. Customer shall provide BVL with shipping instructions for disposition of any Obsolete Materials within \*\*\*\* (\*\*\*\*) days from notification by BVL. If BVL does not receive notification of where to ship Obsolete Materials within such \*\*\*\* (\*\*\*\*) day period, BVL has the right to dispose of such materials per governing cGMP(s) without BVL having any liability to Customer and BVL shall invoice Customer the amounts listed on the written notice for reasonable direct, out-of-pocket expenses incurred by BVL for such disposal.

6.5. Fee for Postponement / Cancellation.

6.5.1. Customer and BVL wish to allocate risk of loss fairly and equitably in the event that a scheduled Manufacturing does not occur due to Customer's request to cancel and/or postpone any Batch. Accordingly, as a policy consideration, BVL and Customer agree to certain fees as set forth below based upon the length of prior notice that Customer is able to provide BVL. Such prior written notice determines BVL's likelihood of being able to fill the capacity reserved by Customer and to reduce the likelihood of BVL's loss due to Customer's cancellation. In the event that Customer cancels or gives notice of its intent to postpone a scheduled Manufacturing of a Batch of Product, then the following fees shall apply:

6.5.1.1. Notice of \*\*\*\* (\*\*\*\*) days or less: As the equipment, preparations, and materials associated with the Batch have been allocated and prepared and can no longer be re-used, Customer shall pay \*\*\*\* percent (\*\*\*\*%) of the Purchase Order price.

6.5.1.2. Notice of \*\*\*\* (\*\*\*\*) to \*\*\*\* (\*\*\*\*) Days: If notice of such postponement/cancellation is delivered not less than \*\*\*\* (\*\*\*\*) days and not more than \*\*\*\* (\*\*\*\*) days from the scheduled Manufacturing Date, Customer shall pay \*\*\*\* percent (\*\*\*\*%) of the Purchase Order price.

6.5.1.3. Notice greater than \*\*\*\* (\*\*\*\*) Days: As BVL may have the opportunity to avoid certain costs associated with the Manufacturing of the Batch pursuant to the Purchase Order but may not be able to mitigate its losses by

utilizing the Manufacturing suites allocated pursuant to Customer's Purchase Order, Customer and BVL agree to allocate and share the potential risk and BVL may charge, in its discretion, an administrative fee to cover the cost of rescheduling Manufacturing. In no event shall such administrative fee exceed \*\*\*\* dollars (\$\*\*\*\*).

6.5.2. BVL will use commercially reasonable efforts to use the capacity created by any postponement or cancellation under this Paragraph 6.5 to manufacture product for its other customers, including Bedford Laboratories. To the extent the capacity is able to be used fees as applied in Paragraphs 6.5.1.1 and 6.5.1.2 will be reduced commensurately.

6.5.3. Within \*\*\*\* (\*\*\*\*) days of receipt of an invoice for a cancellation/postponement fee, Customer shall be entitled to request an audit (through Agents) at a mutually agreed upon timeframe, of the Equipment and BVL's books and records regarding the use of such Equipment following any cancellation/postponement, the use of the operating capacity of any applicable Facility at the time of a postponement/cancellation, and the calculation of any and all personnel and associated expenses incurred by BVL and charged to Customer. Any such audit shall be conducted by a mutually agreed third-party auditor, and the costs of any such audit shall be born by Customer.

6.6. Storage Fees. Customer is responsible for storage charges as specified in Attachment "C" for Product stored for more than \*\*\*\* (\*\*\*\*) calendar days beyond BVL's release of such Product the "Temporary Storage Period". Storage beyond the Temporary Storage Period of Product in BVL's warehousing Facilities must receive prior written approval from BVL. Such approval will be granted only on a space-available basis. 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 applicable Purchase Order. Notwithstanding anything in this Agreement to the contrary, at no time shall Customer incur or be responsible to pay any storage charges if the reason for such storage is an investigation pursuant to Paragraphs 3.5 or 3.6.

6.7. Stability Program. During the term of this Agreement and upon Customer's request and BVL's written agreement, BVL will conduct and support, at Customer's reasonable expense, all stability studies in progress or planned (e.g., NDA annual stability studies) as of the Effective Date until such studies are concluded. Customer shall be responsible for all costs of conducting any stability studies. Stability program costs will be covered in a separate quotation provided by BVL to Customer based on the agreed upon protocol. Customer may also make arrangements for stability work to be performed at a facility other than BVL at Customer's expense.

6.8. Inspection, Packaging and Labeling. Customer shall be responsible for and bear all costs associated with the design, 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 irreconcilably inconsistent with the terms of this Agreement, the terms of this Agreement shall prevail with respect to commercial issues, and the Quality Agreement shall prevail with respect to cGMP issues.

## ARTICLE 8 - INDEMNIFICATION

8.1. Customer Indemnity. Customer hereby holds harmless and indemnifies BVL, its Affiliates and its and their directors, officers, employees and agents (the "BVL Indemnitees") against any and all losses, liabilities, damages, reasonable costs and expenses whatsoever, including, without limitation, reasonable attorneys' fees, and the cost of recalls and any and all amounts reasonably paid in settlement of any claim or litigation, any settlement payments subject Section 8.3 below, (collectively, "Losses") incurred by any BVL Indemnitee in investigating, preparing, or defending against any litigation, commenced or threatened by a Third Party, or any other claim, demand or proceeding of a Third Party (collectively, "Claims"), based on, resulting from, arising out of or in connection with any actual or alleged: (a) personal injuries and/or death resulting from, arising out of or in connection with any distribution or sale of a Product by Customer, its Affiliates or its distributors, including, without limitation, Claims based on negligence, warranty, strict liability or any other theory of liability or violation of any Applicable Law; (b) breach by Customer of its representations, warranties or covenants hereunder; or (c) negligent act or the willful misconduct of any Customer Indemnitees in performing Customer's obligations under this Agreement; (d) Customer's API and any Customer supplied Composition, materials, Equipment, Specifications, formulations, marketing, labeling, design, instructions, handling and/or storage; except, in each case, to the comparative extent such Claim arose out of or resulted from a matter for which BVL is responsible pursuant to Section 8.2.

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 Losses incurred by any Customer Indemnitee in preparing, or defending against any Claims based on, resulting from, arising out of or in connection with any actual or alleged: (a) personal injuries and/or death that are proximately caused (as defined under Delaware law) by a Manufacturing Defect (as hereinafter defined); (b) breach by BVL of its representations, warranties or covenants hereunder, including personal injuries and/or death claims; (c) any recall pursuant to Article 25 of this Agreement due to BVL's negligence, willful misconduct, or breach of any covenant, representation or warranty in this Agreement; or (d) negligent act or the willful misconduct of any BVL Indemnitees in performing BVL's obligations under this Agreement except, in each case, to the comparative extent such Claim arose out of or resulted from a matter for which Customer is responsible therefore pursuant to Section 8.1. For the purposes of this Section 8.2, "Manufacturing Defect" means the negligence, recklessness (having a baseline not less than negligence), wrongful intentional acts or negligent omissions, or strict liability of or by BVL or its Affiliates or its Agents resulting from, or arising out of or in connection with the Manufacture of a Product by BVL.

8.3. Indemnification Procedures. Any BVL Indemnitees or Customer Indemnitees (collectively, "Indemnitees") seeking indemnification under Section 8.1 or 8.2, agrees to notify the indemnifying Party within ten (10) business days of receipt of any Claims, demands or threats of suit for which such Party may be liable under Section 8.1 or 8.2 as the case may be;

provided, however, that failure to give such notification shall not affect the indemnification to be provided hereunder except to the extent the indemnifying Party shall have been actually prejudiced as a result of such failure (except that the indemnifying Party shall not be liable for any expenses incurred during the period in which the Indemnitee(s) failed to give such notice). 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 Indemnitee(s) shall be entitled to participate in the defense of such matter and to employ counsel at its expense to assist therein. The Indemnitee(s) shall provide the indemnifying Party with such information and assistance as the indemnifying Party may reasonably request, at the expense of the indemnifying Party. The Parties understand that no insurance deductible shall be credited against losses for which a Party is responsible under this Article 8. No indemnifying Party under Section 8.1 or 8.2 may compromise or settle any Claim or pay any settlement amount in the connection with the compromise or settlement of any Claim without the prior written consent of Indemnitee, such written consent not to be unreasonably withheld or delayed.

8.4. Insurance. Customer and BVL will each, at its own cost and expense, obtain and maintain in full force and effect, during the term of this Agreement and for a period of one year following the expiration or other termination of this Agreement, Commercial General Liability insurance, written on the standard approved Policy Form, and Blanket Contractual Liability, with limits of liability of not less than \*\*\*\* dollars (\$\*\*\*\*) Combined Single Limit Bodily Injury and Property Damage covering its duties and obligations under the Agreement. The coverage limits may be provided, individually or jointly, through a combination of Primary, Excess/Umbrella or Self-Insured Retention. The Parties further understand and agree that the insurance limits identified herein shall not act as a bar to any recovery.

8.5. Specific Limitation of Liability for Process-Related (i.e., during Manufacturing) Losses.

8.5.1. Notwithstanding anything to the contrary set forth herein or in any collateral documents hereunder (invoices, purchase orders, etc.), the Parties acknowledge and agree that BVL's sole liability to Customer for in-process Manufacturing losses (i.e. loss of API, or Customer-supplied Composition) is set forth exclusively in this section 8.5. Except for Batches of Definity (where the maximum liability shall be \$\*\*\*\*), BVL agrees to reimburse Customer up to a maximum of \$\*\*\*\* per Batch pro-rated over the usable portion of the Batch, if applicable, for any loss of API or Customer-supplied Composition for each Batch that does not meet Specification or was not Manufactured in accordance with the Manufacturing Process or cGMP and therefore can not be released; provided that the loss of such materials can be shown after Investigation to be caused solely and directly by: (a) the failure of BVL to follow its SOP's; or (b) BVL's negligence, willful misconduct or breach of this Agreement; or (c) BVL's willful misconduct, where, solely for purposes of this Section 8.5.1, such "willful misconduct" shall have the meaning set forth under Delaware law. In the absence of a showing of (a), (b) or (c), above, then BVL shall have no liability to Customer for such Batch of Product. 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. Notwithstanding the foregoing, or any declared value of API costs in excess of \$\*\*\*\* or \$\*\*\*\*, as applicable, or the insurance levels identified in Section 8.4 or elsewhere, in no event shall BVL's liability to Customer for in-process loss of API or Customer-supplied Composition be in excess of \$\*\*\*\* or \$\*\*\*\*, as applicable, per Batch.

8.6. **LIABILITY LIMITATION.**

8.6.1. **ELECTION OF REMEDIES.** SECTION 3.9.4, 3.9.5, 8.2, 8.5, 25.1 AND 34 ARE CUSTOMER'S SOLE AND EXCLUSIVE 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.

8.6.2. **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").

8.6.3. **AGGREGATE CAP ON COSTS, LOSSES, EXPENSES AND DAMAGES.** THE PARTIES RECOGNIZE AND ACKNOWLEDGE THAT THIS ARTICLE 8 ATTEMPTS TO EQUITABLY ALLOCATE RISK WITH RESPECT TO EACH PARTIES' RESPECTIVE INTEREST IN THE AGREEMENT AND THAT THE LIMITATIONS OF LIABILITY SET FORTH HEREIN ARE COMPROMISES. NOTWITHSTANDING ANYTHING TO THE CONTRARY SET FORTH HEREIN. A PARTY'S TOTAL MAXIMUM AGGREGATE LIABILITY FOR COSTS, LOSSES, EXPENSES, DAMAGES, LIABILITY AND INDEMNIFICATION OBLIGATIONS UNDER THIS AGREEMENT SHALL NOT EXCEED \*\*\*\* DOLLARS (\$\*\*\*\*) (THE "BVL CAP"). THE BVL CAP ON DAMAGES AND LIABILITY IS INTEGRAL TO THIS AGREEMENT AND THE AGREEMENT WOULD NOT HAVE BEEN EXECUTED IN ITS ABSENCE.

8.6.4. **EXCEPTIONS TO LIABILITY CAP.** THE BVL CAP SHALL NOT APPLY TO DAMAGES RESULTING FROM: BREACHES BY A PARTY OF A DUTY IMPOSED UNDER ARTICLE 9 (CONFIDENTIALITY), ARTICLE 11 (INTELLECTUAL PROPERTY), OR DUE TO A PARTY'S WILLFUL MISCONDUCT OR FRAUD. FOR THE AVOIDANCE OF DOUBT, THE PARTIES EXPLICITLY ACKNOWLEDGE AND AGREE THAT BVL'S OFFERING TO ENTER INTO THIS AGREEMENT AND ENTERING INTO THIS AGREEMENT GIVEN BVL'S CURRENT AND POTENTIAL REGULATORY SITUATION AND THE POTENTIAL IMPACT OF THAT ON BVL'S ABILITY TO MANUFACTURE AND DELIVER PRODUCT UNDER THIS AGREEMENT SHALL NOT SERVE AS THE BASIS OF ANY CLAIM FOR WILLFUL MISCONDUCT, FRAUD OR FRAUD IN THE INDUCEMENT.

8.6.5. **INTEGRAL PROVISIONS.** THE LIMITATIONS SET FORTH IN THIS SECTION 8.6 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, business or proprietary information related to the subject of the Agreement, irrespective of whether in human or machine-readable form, tangible or

intangible, (a) which is or has been 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 was developed by BVL for Customer under the terms of the Manufacturing Agreement, Transition Services agreement or is developed by BVL for Customer under the terms of this Agreement. Confidential Information does not include information that: (a) is lawfully in the possession of the Receiving Party, without restriction as to confidentiality or use, at the time of disclosure by the Disclosing Party, as demonstrated by competent written records of the Receiving Party; (b) is or later becomes part of the public domain through no fault of the Receiving Party (i.e., other than by breach of this Agreement by the Receiving Party); (c) is received, without restriction as to confidentiality or use, by the Receiving Party from a Third Party lawfully entitled to possession of such Confidential Information and who does not violate any contractual, legal or fiduciary obligation to the Disclosing Party by providing such Confidential Information to the Receiving Party; or (d) is developed independently by the Receiving Party without any use of, or access or reference to, or reliance on, the Disclosing Party's Confidential Information, in whole or in part. Disclosing Party is not obligated to mark information as "CONFIDENTIAL" for such information to be deemed Confidential Information under this Agreement. Confidential Information of BVL includes, but is not limited to, BVL Technology, BVL Improvements, BVL pricing information and capabilities/capacities. Confidential Information of Customer includes, but is not limited to, Customer Technology, Customer Inventions and Customer Improvements. This Agreement shall not be construed as a grant of any right or license to the Receiving Party with respect to Confidential Information of the Disclosing Party or as a requirement of either Party to enter into any further arrangement with respect to Confidential Information of the Disclosing Party.

9.2. Disclosure and Use. The Receiving Party shall: (a) maintain the confidentiality of the Disclosing Party's Confidential Information; (b) not disclose the Disclosing Party's Confidential Information to any Third Party without the prior written consent of the Disclosing Party; and (c) use the Disclosing Party's Confidential Information only as necessary to fulfill its obligations or in the reasonable exercise of rights granted to it hereunder. Notwithstanding the foregoing, a Receiving Party may disclose: (i) Confidential Information of the Disclosing Party to its Affiliates, and to its and their directors, employees, consultants, and Agents provided, that in each case such individuals and entities have a specific need to know such Confidential Information and are previously bound by written obligation of confidentiality and restriction at least as rigorous as those set forth herein; (ii) Improvements or Inventions owned by the Receiving Party to the extent required to exploit the grant of its rights under Article 11 of this Agreement; and (iii) Confidential Information of the Disclosing Party to the extent such disclosure is required to comply with Applicable Law or to defend or prosecute litigation; provided, however, that prior to any such use or disclosure in accordance with Applicable Law, the Receiving Party shall provide written notice of such potential disclosure to the Disclosing Party (which shall include a copy of any applicable subpoena or order), and cooperate with Disclosing Party's requests and 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 confidential treatment or 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

9.3. Protection of Customer Information. BVL understands and acknowledges that Customer's Confidential Information, Customer Technology, and Customer Inventions (collectively, "Customer Information") related to the Product have been developed or obtained by the investment of significant time, effort and expense by Customer, and that such Customer Information is a valuable, special and unique asset of Customer which provides Customer with

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a significant commercial advantage, and needs to be protected from improper use and disclosure (including, but not limited to, any improper use by BVL and its Affiliates). Except as provided in this Agreement, BVL will not disclose the Customer Information to its Affiliates or otherwise use the Customer Information for the benefit of such Affiliates. BVL further recognizes that the Manufacture, supply, or development of a Relevant Product for itself, its Affiliates, or any third party could result in the improper use or disclosure of Customer Information, and, as a result, BVL agrees not to undertake, in any manner, directly or indirectly, the manufacture, supply or development of a Relevant Product until \*\*\*\*. BVL further agrees to avoid any reliance on or use of Customer Information for the production of the Relevant Product. BVL agrees that there may be no adequate remedy at law for any such breach and, upon any such breach or any threat thereof, Customer shall be entitled to appropriate equitable relief in courts located in Delaware, including injunctive relief, in addition to whatever other remedies it might be entitled.

9.4. Publicity. Neither Party will issue any press release or other public announcement concerning this Agreement or the transactions contemplated by this Agreement without the prior written consent of the other Party, except where such announcements are required by Applicable Law or the rules of any stock exchange or NASDAQ provided, however, that prior to any announcement in accordance with Applicable Law or rules, the disclosing Party shall provide written notice of such potential announcement to the other Party, and cooperate with the other Party's requests and lawful decision to avoid or minimize the degree of such disclosure. Such other Party shall permit the disclosing Party the opportunity, if desired, to seek an appropriate protective order or other confidential treatment or remedy with respect to narrowing the scope of such announcement. Product labeling (primary, secondary, and any insert) and government filings may indicate that Product has been Manufactured for Customer by BVL.

9.5. Customer's Agents. In the event that Customer desires for its Agents to perform an audit at the Facility and/or otherwise enter upon the Facility, then prior to any such visit, such Agent shall either be required to enter into an agreement with BVL in which it agrees to comply with the confidentiality obligations, restrictions and responsibilities imposed upon Customer in this Section. In BVL's discretion, such agreement shall be acknowledged by Customer denoting that the individual identified thereon is Customer's Agent.

9.5 Non-Disclosure of Customer's Confidential Information to Third Parties or Bedford Laboratories. The Parties acknowledge that the actual Manufacturing Process may be performed by employees that perform routine and normal manufacturing services (e.g., in filling, packaging, sterile rooms, shipping, etc.) and who also perform similar services for BVL's other third-party customers and for Bedford Laboratories. Notwithstanding the foregoing, BVL agrees that it shall not disclose Customer's Confidential Information or Customer Technology to any Third Party or Affiliate of BVL, including any personnel of Bedford (except for those manufacturing employees referenced in the preceding sentence that require the use of such Customer Confidential Information or Customer Technology in order to Manufacture Product).

9.6 Notice to Senior Scientists and Manufacturing Personnel who Separate Employment with BVL. For senior members of BVL's Product and Process Development (PPD) Department and Manufacturing Department who separate employment from BVL, BVL shall, when it determines appropriate in its sole discretion, send a copy of such individual's "Invention & Secrecy Agreement" agreement to both the individual and his/her new company (if known). The cover letter enclosing the Invention & Secrecy Agreement shall remind the former employee and

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his/her new employer of the confidentiality, non-use and non-disclosure obligations pertaining to BVL and its customer's confidential and proprietary information.

#### **ARTICLE 10 - REPRESENTATIONS, WARRANTIES AND COVENANTS**

10.1. Representations of BVL. Subject to the qualifications set forth in the Recitals, BVL represents, warrants and covenants to Customer that:

10.1.1. (a) it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind held by other parties, private or public, materially inconsistent or conflict with the provisions of this Agreement; and (b) the execution and delivery of this Agreement and the performance of such Party's obligations hereunder: and (c), other than the previously referenced findings of deviations by the United States Food and Drug Administration and by the European Medicines Agency at BVL's manufacturing facility and the issuance by the European Medicines Agency and the Therapeutic Goods Administration of short-dated, restricted GMP licenses to BVL, there are no, and shall be no, liens, conveyances, mortgages, assignments, encumbrances, or other contacts or agreements that would prevent or materially impair such Party's full and complete exercise of the terms and conditions of this Agreement.

10.1.2. the services provided by BVL shall be performed with requisite care, skill and diligence, in accordance with the terms of this Agreement (including 2.2.6, 3.3, 3.6, 7.1 (and Attachment "E")), Applicable Laws and industry standards, and by individuals who are appropriately trained and qualified;

10.1.3. the services provided by BVL, and the use, practice or exploitation of the BVL Technology, Customer Improvements, Customer Inventions and BVL Confidential Information, will not infringe, misappropriate, or otherwise violate any patents, trademarks, copyrights, trade secrets, or any other intellectual property rights of any Third Party in the Territory and it will promptly notify Customer in writing should it become aware of any claims asserting such infringement, misappropriation or violation; and

10.1.4. 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 the Specifications, and shall be free of any manufacturing defects, (ii) will not be adulterated or misbranded under the FDCA or other Applicable Law; and (iii) will be provided free and clear of any liens and encumbrances of any kind; (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(b)(1)(B) of the FDCA (or who is the subject of a conviction described in such section) and will provide a certification that it has not, does not and will not use in any capacity the services of any person debarred under Section 306(b) of the FDCA in connection with the Manufacture of the Products. 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(b), 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, warrants and covenants to BVL that:

10.2.1. (a) it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights held by other parties, private or public, inconsistent with the provisions of this Agreement; and (b) the execution and delivery of this Agreement and the performance of such Party's obligations hereunder: (i) do not conflict with or violate any requirement of Applicable Law; (ii) do not, and will not conflict with or otherwise interfere with resulting in a violation, breach, or default under, or require any consent that has not been obtained under any contact or agreement between such Party or any of its Affiliates, Agents and any third party; and (iii) there are no, and shall be no, liens, conveyances, mortgages, assignments, encumbrances, or other contacts or agreements that would prevent or impair such Party's full and complete exercise of the terms and conditions of this Agreement;

10.2.2. the use, practice or exploitation of Customer Technology, Customer Improvements, and Customer Confidential Information in the performance of services under this Agreement will not infringe, misappropriate or otherwise violate the patents, trademarks, copyrights, trade secrets, or other 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, misappropriation or violation;

10.2.3. that the API and Customer-supplied Composition shall be free of defects of any kind, shall not be adulterated, shall conform to applicable Specifications and will be provided to BVL free and clear of any liens and encumbrances; and

10.2.4. Customer's further distribution of the Product will not cause the Product to be adulterated or misbranded under the FDCA or other Applicable Law.

10.3. Additional Representations of Customer in the event that Product(s) will be Offered for Sale, Sold, Marketed within the Member States of the European Union. In the event that the Territory includes the European Union ("EU") or any member states thereof, then in addition to all other warranties and representations set forth herein, Customer also represents and warrants that Customer shall be responsible for the release of the Products in the European Union in compliance with all applicable EU Directives and Standards. It is Customer's obligation to notify BVL as to whether the Territory for any Product includes an EU member nation, or if a country within the Territory subsequently becomes a member of, or subject to, the European Union.

#### **ARTICLE 11 - INTELLECTUAL PROPERTY**

11.1. Customer Technology. All rights, title and interests in and to Customer Technology and Customer's Other Inventions (as defined below) shall remain solely in Customer and no right, title or interest therein or thereunder is transferred or granted to BVL, except as set forth in the following sentence. 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-sublicensable, non-transferable license shall (i) expire upon the completion of such duties and obligations or the termination or expiration of this Agreement, whichever is the first to occur, and (ii) does not require disclosure of any Customer Technology to any other

persons or entities. Except as provided in Section 3.7 or Section 9.4, under no circumstances shall BVL share, convey, license, or otherwise transfer any Customer Technology or Customer's Other Inventions to any BVL Affiliate or BVL Agent

11.2. BVL Technology. All rights, title, and interests in and to BVL Technology shall remain solely in BVL and no right, title or interest therein is transferred or granted to Customer, except as set forth in the following two sentences. 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. BVL shall not incorporate any BVL Technology into any Inventions hereunder without the prior written consent of Customer, and, if BVL does incorporate any BVL Technology into any Inventions, absent an agreement to the Parties to the contrary, Customer is granted a royalty-free, fully paid-up, sublicensable (solely for the Product), license to freely use (solely for the Product), practice and otherwise exploit the BVL Technology (solely for the Product). For the avoidance of doubt, to the extent that BVL incorporates BVL Technology into the Product, the foregoing grant shall be for the benefit of Customer and solely for the benefit of the Product, and shall not be utilized for any other product, whether by Customer or any of Customer's Agents.

11.3. Customer Improvements.

11.3.1. Customer shall own all right, title and interest in and to all inventions, discoveries, developments, improvements, new uses, processes, know-how, compounds, compositions, or syntheses that are conceived, reduced to practice or first demonstrated to have utility in the course of activities under this Agreement, the Transition Services Agreement or the Manufacturing Agreement and that are API or Product-specific or are specific to the use of the API for use in the same therapeutic class, including but not limited to any process for making any Product, any use of any Product, any method of analyzing or characterizing any Product or any Product formulation, and any analysis or characterization of any Product or any Product formulation (collectively, "Customer Inventions"). As used in this Agreement, "Product-specific" shall mean relating to the Products, any intermediates or derivatives thereof, and the Manufacturing thereof but not routine manufacturing processes which are not specific to the Manufacturing of Product.

11.4. BVL Improvements.

11.4.1. BVL shall own all right, title and interest in and to all inventions, discoveries, developments, improvements, new uses, processes, know-how, compounds, compositions, or syntheses that are conceived, reduced to practice or first demonstrated to have utility in the course of activities under this Agreement, the Transition Services Agreement or the Manufacturing Agreement and that are conceived, reduced to practice or first demonstrated to have utility in the course of activities under this Agreement, the Transition Services Agreement or the Manufacturing Agreement and that relate to BVL's Technology, BVL Confidential Information or BVL Improvements but are not Product-specific (collectively, "BVL Inventions"). For the avoidance of doubt, where an invention relates to both the BVL's technology, equipment or equipment processes and to a Product or a Product formulation (e.g., a complex between a Product and a proprietary complexing agent of BVL), such invention to the extent it is "Product-specific" shall be a Customer Invention.

11.4.2. Ownership of any Invention which is not a Customer Invention or a BVL Invention (“Other Invention”) shall be as follows: (x) where such Other Invention is jointly conceived, reduced to practice or first demonstrated to have utility under this Agreement, the Transition Services Agreement or the Manufacturing Agreement by: (i) one or more employees, consultants or Agents of a Party or an Affiliate of such Party; and (ii) one or more employees, consultants or Agents of the other Party or an Affiliate of such other Party, such Other Invention shall be jointly owned by the Parties, and (y) where such Other Invention is conceived, reduced to practice or first demonstrated to have utility solely by an employee, consultant or Agent of a Party or an Affiliate of that Party, such Other Invention shall be owned by such Party.

11.4.3. The inventorship of all Inventions conceived, reduced to practice or first demonstrated to have utility in the course of activities under this Agreement will be determined in accordance with United States laws for inventorship. Each party hereby agrees to disclose to the other Party promptly and in writing all Inventions conceived or reduced to practice or first demonstrated to have utility in the course of activities under this Agreement by any employee, consultant or Agent of a Party or its Agents. BVL hereby assigns to Customer all right, title and interest of BVL in or to any Customer Inventions. Customer hereby assigns to BVL all right, title and interest of Customer in or to any BVL Inventions. Each Party shall cooperate (and cause its Agents and all employees to cooperate) with the other Party in taking all steps and actions (including but not limited to maintaining in confidence any Inventions that constitute trade-secrets, and executing appropriate documentation in connection with the filing of any patent application(s) on any Invention of the other Party) which such Party believes reasonably necessary or desirable to apply for and/or maintain intellectual property protection for the benefit of Customer or BVL as the case may be in any country, or to perfect or enforce such Party’s ownership and right in the Inventions; provided, however, that the costs and expenses for taking such steps and actions are borne by the Party seeking to obtain IP registration or protection.

## ARTICLE 12 - TERM AND TERMINATION

12.1. Term. This Agreement shall become effective on the Effective Date. This Agreement shall expire on December 31, 2013.

12.1.1. [Intentionally Omitted]

12.2. [Intentionally Omitted]

12.3. Termination for Breach. Either Party may terminate this Agreement for a material breach or default by the other Party by giving the breaching Party written notice, specifying the breach or default, and giving the breaching Party thirty (30) days to cure such breach or default. For the avoidance of doubt either Party may terminate with respect to any individual Product which termination shall not affect the viability of the Agreement with respect to any remaining Products. If the breach or default has not been cured within thirty (30) days after the receipt of such notice the non-defaulting Party shall be entitled, without prejudice, to terminate this Agreement; provided, however, that if such breach or default reasonably cannot be cured within such 30 day period, then upon the mutual agreement of the Parties the defaulting Party may be granted an additional period of time during which it shall exercise reasonably diligent efforts to cure such breach, and the non-defaulting Party shall not be permitted to terminate this Agreement under this Section during any such mutually agreed extended cure period.

Termination for breach or default will have no effect on performance obligations or amounts to be paid which have accrued up to the effective date of such termination. Customer's failure to make timely payments hereunder following notice of non-payment as required in this section 12.3 shall constitute a breach. Customer acknowledges that it is aware that in May 2011 and November 2011, BVL's manufacturing facility was inspected by the United States Food and Drug Administration and by the European Medicines Agency in March 2011 and November 2011. Customer further acknowledges that each of these inspections resulted in observations from the regulatory authority citing deviations from current Good Manufacturing Practices. Customer acknowledges The European Medicines Agency and the Therapeutic Goods Administration have issued BVL short-dated, restricted GMP licenses. Customer further acknowledges that it is aware BVL voluntarily suspended manufacturing at its site as of November 2011. Customer has reviewed the records of inspection from the above mentioned regulatory authorities as well as BVL's corrective action responses to the regulatory agencies and is satisfied that the corrective actions set forth in BVL's corrective action plan should rectify the cGMP issues at the manufacturing facility that directly or indirectly affect Customer's Products. Based on the foregoing, Customer acknowledges that the cGMP issues set forth above, as well as any prior deviations from cGMP by BVL, shall not constitute grounds for a claim of any breach of this Agreement, and Customer specifically waives any right to claim any breach under this Agreement based on any such prior deviations from cGMP.

12.4. Termination for Bankruptcy. In the event of any proceedings, voluntary or involuntary, in bankruptcy or insolvency, by or against Customer or BVL, or the appointment with or without the Parties' consent of a receiver for either Party, the other Party immediately shall be entitled to terminate this Agreement upon written notice to the other Party without any liability whatsoever, subject to the payments of liquidated damages, if any, set forth in Article 34 if BVL is the party in bankruptcy. Such termination shall not affect any claim for damages available to the terminating Party or for costs or fees accrued to date.

12.5. Termination for Regulatory or Governmental Action. In the event the Products or any Product, Manufacture, or BVL's Facility are subject to an injunction, consent decree, administrative order or findings or any other regulatory or remedial action that prohibits or otherwise prevents BVL from manufacturing or distributing the Products or any Product for the term of this Agreement, then BVL may terminate this Agreement with respect to the affected Products or Product by providing at least \*\*\*\* (\*\*\*\*) days prior written notice to Customer; provided, however, that, to the extent BVL can Manufacture or distribute only part of the Products or any Product hereunder as a result of such prohibition or prevention because there is less than six (6) months remaining in the term of this Agreement when BVL returns to the production of the Products or any Product, then the Parties will work in good faith to prioritize the Manufacture and distribution of such portion of the Products or Product that can be Manufactured and distributed hereunder during the balance of the term of this Agreement. In the event of a termination pursuant to this Section 12.5, then BVL shall pay Customer the liquidated damages, if any, set forth in Article 34.

12.6. Termination for Force Majeure. In the case of a Force Majeure (as defined herein) 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 \*\*\*\* (\*\*\*\*) months, the other Party shall be entitled to terminate this Agreement upon prior written notice to the affected Party without any liability whatsoever.

12.7. Termination based upon Wind-Down or Cessation of the Business. In the event that BVL sells all or substantially all of the company's assets, or otherwise ceases operations

or takes material steps to wind-down its business, then, subject to the obligations set forth in Section 15.1, BVL may terminate this Agreement by providing \*\*\*\* (\*\*\*) days prior written notice to Customer. In the event of a termination pursuant to this Section 12.7, then BVL shall pay Customer the liquidated damages, if any, set forth in Article 34.

12.8. Consequences of Expiration/Termination. In the event of any expiration or termination of this Agreement, BVL shall perform such functions requested by Customer that are reasonably necessary or required in connection with the orderly conclusion of any active project as required by the terms of this Agreement and Applicable Law.

12.8.1. Promptly upon expiration or 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. Furthermore, BVL shall promptly return all Customer-supplied Composition, Customer-supplied Equipment, API, retained samples, reference standards, data, reports and other property, information and/or know-how in recorded form that was provided by Customer, or developed in the performance of the services under this Agreement, that are owned by or licensed to Customer, excepting that required to be retained by Applicable Law, litigation holds or for regulatory compliance.

12.8.2. In the event of any termination by BVL pursuant to Section 12.3, Customer shall pay BVL for Manufacturing, Development and other services completed up to the effective date of such termination of this Agreement, the Parties shall meet and confer in good faith in an effort to address disposition of any existing API, inventory, or supplies. Customer: (i) shall purchase from BVL any existing inventories of Product conforming to the Specification and Manufactured in accordance with cGMP and the Manufacturing Process, at the then-current price for such Product; and (ii) may either: (1) purchase any Product in process held by BVL as of the date of the termination, at a price to be mutually agreed (it being understood that such price shall reflect, on a pro rata basis, work performed and non-cancelable, out-of-pocket expenses actually incurred by BVL with respect to the Manufacture of such in-process Product), (2) reimburse BVL for all work performed and non-cancelable costs, and out-of-pocket expenses incurred by BVL and direct BVL to dispose of such material at Customer's cost.

12.8.3. BVL shall provide all reasonably requested assistance for technology transfer and otherwise to ensure the orderly transition of the Manufacturing and other services provided hereunder to an alternate source, which shall be provided at no cost to Customer provided, that no Confidential Information of BVL shall be disclosed to such alternate source, it being understood that any Product-specific information contained in the Master Batch Record for Product is not Confidential Information of BVL and may be disclosed to the alternate source;

12.8.4. Notwithstanding anything to the contrary herein, if there is a termination event pursuant to Section 12.3 (Termination for Breach), Section 12.4 (Termination for Bankruptcy), Section 12.5 (Termination for Regulatory Action or Governmental Actions), or Section 12.7 (Termination based upon Wind-Down or Cessation of the Business), then Customer's sole and exclusive remedy shall be the payment of liquidated damages pursuant to Article 34. Customer shall not be entitled to seek any other damages under Applicable Law.

12.8.5. Upon the effective date of termination of this Agreement, Customer shall have no further obligation to BVL with respect to any Purchase Orders with delivery dates beyond such date and BVL will have no further obligations to Manufacture Product, provided that termination or expiration shall have no effect on payment obligations that have accrued up to the effective date of termination.

12.9. Effect of Termination Under Section 12.3. In addition to Section 12.8, in the event of any termination by Customer pursuant to Section 12.3:

12.9.1. Customer shall pay BVL for its costs of Manufacturing, and other services completed up to the effective date of such termination within \*\*\*\* (\*\*\*\*) days of Customer's receipt of all Product, 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 \*\*\*\* (\*\*\*\*) days after the effective date of termination.

12.9.2. Customer shall reimburse BVL for the costs of any BVL-supplied Composition that cannot be canceled, unless these materials can be utilized by BVL on other projects. This reimbursement shall be made within \*\*\*\* (\*\*\*\*) days after receipt by Customer of an invoice itemizing the material costs. Notwithstanding the foregoing, Customer's liability for BVL supplied Composition shall be limited to the amount of BVL supplied Composition outlined in section 5.4. 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.

12.10. Injunctive Relief for Certain Breach or Threatened Breach. The Parties agree that should this Agreement be breached for reasons other than provided under Section 12.4 (Termination for Bankruptcy), Section 12.5 (Termination for Regulatory Action or Governmental Actions), Section 12.6 (Force Majeure) or Section 12.7 (Termination based upon Wind-Down or Cessation of the Business) that 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 (up to the BVL Cap), available to a non-breaching Party at law or in equity.

12.11. Survival. Expiration or termination of this Agreement for any reason shall not relieve either Party of any obligation arising under this Agreement that accrues prior to such expiration or termination or of any rights and obligations of the Parties that by their terms survive termination or expiration of this Agreement, including, without limitation, duties of confidentiality (Article 9), indemnification (Article 8), intellectual property rights (Article 11), consequences of termination (Sections 12.8 and 12.9), notices (Article 13), governing law and jurisdiction (Article 16) and under the Quality Agreement (Attachment "E") of this Agreement. Notwithstanding anything to the contrary set forth herein, the obligations identified in this Paragraph 12.11 shall survive for a period of ten (10) years from any termination or expiration of this Agreement, unless specified otherwise in the applicable Articles and Sections.

### ARTICLE 13 - NOTICES

13.1. All notices concerning this Agreement shall be given in writing, as follows: (a) 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; (b) by Federal Express, UPS, DHL or any other overnight carrier, in which case the notice shall be deemed given two (2) business days from the date of delivery to such carrier or (c) by confirmed facsimile (followed by delivery of an original via overnight carrier), in which case the notice shall be deemed given on confirmation of transmission. All notices which concern this Agreement shall be addressed as follows (or at such other address for a Party as shall be specified in a notice given in accordance with this Section):

If to BVL:

Ben Venue Laboratories, Inc.  
300 Northfield Road  
Bedford, Ohio 44146  
Attn: Vice President, Contract Manufacturing Services  
Telephone: 440-232-3320  
Facsimile: 440-439-6398

Division Legal Counsel  
Ben Venue Laboratories, Inc.  
300 Northfield Road  
Bedford, Ohio 44146  
Telephone: 440-703-7899  
Facsimile: 440-232-6264

If to Customer:

Lantheus Medical Imaging, Inc.  
331 Treble Cove Road  
North Billerica, MA 08162  
Attn: General Counsel  
Telephone: 978-671-8408  
Facsimile: 978-671-8724

With a copy (that shall not constitute legal notice) to:

Lantheus Medical Imaging, Inc.  
331 Treble Cove Road  
North Billerica, MA 08162  
Attn: General Manager of Manufacturing  
Telephone: 978-671-8853  
Facsimile: 978-671-9577

### 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. The waiver of any term, condition, or provision of this Agreement must be in writing and signed by an authorized representative of the waiving Party. Any such waiver shall not be construed as a waiver of any other term, condition, or provision, nor as a waiver of any subsequent breach of the same term, condition, or provision, except as provided in a signed writing.

#### **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 or unreasonably delayed; except that either Party may assign this Agreement, without the other Party's prior written consent, to an entity that acquires all or substantially all of the business or assets of such Party to which this Agreement pertains (whether by merger, reorganization, acquisition, sale or otherwise); provided that, in the event of the acquisition or sale of BVL's business or assets to which this Agreement pertains, and prior to such acquisition or sale, the successor party shall agree in writing to be bound by the terms and conditions of this Agreement specifically pertaining to the duties with respect to confidentiality (Article 9) and intellectual property rights (Article 11) set forth herein. For the avoidance of doubt, it is the Parties' specific intent to protect the Customer Technology and Customer's Confidential Information in the event of an acquisition, sale or similar transaction with a third party. Any assignment not permitted by this Section 15.1 shall be void and of no effect whatsoever.

#### **ARTICLE 16 - GOVERNING LAW**

16.1. This Agreement and the rights and obligations of the Parties hereunder shall be governed by Delaware law and, to the extent the laws of the State of Delaware are preempted or otherwise made inapplicable by federal law, the laws of the United States of America. Each of the Parties irrevocably and unconditionally:

16.1.1. agrees that any suit, action or legal proceeding arising out of or relating to this Agreement shall be instituted in the United States District Court for Delaware, or if such court does not possess subject matter jurisdiction, of any type, or will not accept jurisdiction, in any court of general jurisdiction in Wilmington, Delaware;

16.1.2. consents and submits to the exclusive jurisdiction of such foregoing courts in any such suit, action or proceeding;

16.1.3. consents to personal jurisdiction in such courts;

16.1.4. waives any objection which it may have to laying of venue of any such suit, action or proceeding in said courts; and

16.1.5. waives any claim or defense of inconvenient forum.

#### **ARTICLE 17 - FORCE MAJEURE**

17.1. No Party shall be liable for a failure or delay in performing any of its obligations under this Agreement (but, for the avoidance of doubt, shall be liable for any performance actually rendered) if, and only to the extent that, such failure or delay (directly or indirectly) is

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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 or regulations by any Agency or Government, conflict of laws or regulations by any Agency or government with the exception of enactments, changes or conflicts where notice of such enactments, changes or conflicts and a corresponding CAPA remediation plan cannot be satisfactorily agreed upon by BVL, Customer and the agency or government who enacted the change, orders, restrictions, actions, embargoes or blockages; (v) national or regional emergency; injunctions, strikes, lockouts, labor trouble or other industrial disturbances (regardless of the reasonableness of the demands of labor); or (vi) acts of terrorism ("Force Majeure"). For the avoidance of doubt, the Parties agree that an event shall only rise to the level of "Force Majeure" under section 17.1 (iv) when, following reasonable consultation with the other Party: (a) the Party claiming Force Majeure is substantially and materially prejudiced in its ability to comply with the requirements of this Agreement; (b) the claimed Force Majeure is due to an enactment or change of laws or regulations, and (c) performance is rendered impossible in the short-term or so manifestly burdensome that no reasonable pharmaceutical manufacturing facility of like size and circumstances to BVL would perform under such circumstances. For the avoidance of doubt, termination for regulatory action pursuant to Section 12.5 is not considered a Force Majeure event.

17.2. The Party whose performance of this Agreement is affected or potentially affected by a Force Majeure shall promptly notify the other Party of the Force Majeure condition, explaining the nature, details and expected duration thereof, and shall exert reasonable efforts to eliminate, cure or overcome any such condition and to resume performance of its obligations under this Agreement as soon as possible. Upon termination of the event of Force Majeure, the performance of any suspended obligation or duty shall promptly recommence.

#### **ARTICLE 18 - TITLE OF GOODS**

18.1. Title to API and Customer-supplied Composition shall remain with Customer at all stages of the Manufacturing Process and the foregoing shall be held in bailment by BVL. 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 Specifications and cGMP, and in such a way as to be able at all times to clearly distinguish the same from products and materials belonging to BVL, or held by it for a Third Party's account.

18.2. BVL shall at all times take such measures as are required to protect the API, Customer-supplied Composition, Product, and any work in process from risk of loss or damage at all stages of the Manufacturing Process. BVL shall ensure that the API, Customer-supplied Composition, Product, and any work in process are free and clear of any liens or encumbrances. BVL shall Immediately notify Customer if at any time it believes any API, Customer-supplied Composition, Product or work in process have been damaged, lost or stolen.

#### **ARTICLE 19 - ENTIRE AGREEMENT**

19.1. This Agreement, together with the Attachments identified herein embody the entire agreement and understanding between BVL and Customer relating to the Products. This Agreement is intended as a final expression of their agreement and as a complete

statement of the Parties' agreement regarding the Products subject to this Agreement. For the avoidance of doubt, the parties acknowledge the existence of two separate documents, the Settlement Agreement, which is a settlement agreement of the prior Manufacturing Agreement, and the Transition Services Agreement, which is a similar manufacturing agreement for a discrete number of batches. This Agreement is mutually exclusive from these other two agreements, and each of these agreements' terms and conditions are independent and do not impact the other agreement in any manner. In the event of any inconsistency between this Agreement and any other writings relating to the Products (other than the Settlement Agreement and the Transition Services Agreement), the terms and conditions of this Agreement shall take precedence in any contract construction. 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 in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible.

#### **ARTICLE 21 - INDEPENDENT CONTRACTORS**

21.1. Neither Party shall have the right to control the activities of the other in the performance of this Agreement and each shall perform as an independent contractor, and nothing herein shall be construed to be inconsistent with that relationship or status. Under no circumstances shall the employees or Agents of one Party be considered employees or Agents of the other. This Agreement shall not constitute, create, or in any way be interpreted as a joint venture, partnership, or formal business organization of any kind.

#### **ARTICLE 22 - AMENDMENTS**

22.1. No provision of this Agreement or the Attachments attached hereto may be modified or supplemented, except by an instrument in writing signed by both BVL and Customer.

#### **ARTICLE 23 - HEADINGS AND CONSTRUCTION**

23.1. The Article and Section 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. As used herein, "including", "includes" and derivatives thereof shall be deemed to be followed by "without limitation".

#### **ARTICLE 24 - REVIEW BY LEGAL COUNSEL**

24.1. Each Party has carefully reviewed this Agreement, and understands its terms. Each Party has been given sufficient opportunity to seek legal advice prior to signing this Agreement, and has either sought legal advice with counsel experienced in issues of confidentiality in regards to this Agreement, or has relied wholly upon that Party's own judgment and knowledge in executing this Agreement. Each Party fully understands and voluntarily accepts each and every provision contained in this Agreement. Failure to seek

legal advice prior to signing this Agreement does not excuse either Party from failure to understand the terms and conditions set forth in this Agreement. This Agreement has been prepared on the basis of the mutual understanding of the Parties and in the event of an ambiguity, such ambiguity shall not be strictly construed against either Party as a drafter of this Agreement.

#### **ARTICLE 25 - RECALL**

25.1. In the event: (a) any Agency or governmental authority issues a request, directive, or order that Product be recalled; or (b) a court of competent jurisdiction orders such a recall; or (c) the Customer determines that the Product should be recalled or withdrawn, Customer, in cooperation with BVL, shall take all appropriate corrective action. Customer shall also retain the right to conduct a Product recall for any safety reasons Customer deems significant. In the event 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. Customer shall consult with BVL prior to making any determination to recall Product if practicable. BVL will be financially responsible for the costs of any recall or withdrawal (including but not limited to the actual cost of manufacturing the Product, through final packaging, pro-rated over the usable portion of the batch, if any) to the extent its negligence, willful misconduct, or breach of any covenant, representation or warranty hereunder is responsible for such recall, provided, that, to the extent any recall or withdrawal includes any Batch(es) not yet released to Customer that are subject to Section 8.5, BVL's liability for such un-released Batch(es) shall be subject to the limitations set forth in Section 8.5 until such release. For the avoidance of doubt, the costs of recall shall be limited to direct costs and expenses associated with the recall (i.e., notices, collection, shipping, destruction) but shall specifically exclude lost profits, lost market share, interruption of business, harm to reputation, or any other indirect collateral cost, such as unrelated marketing, advertising, or any other cost, fee or charge not directly related the recall of Product. For purposes of clarity, the Parties acknowledge that all potential claims under this Section 25.1 are subject to the BVL Cap.

#### **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. Each Party agrees and understands that the information and any materials provided by the other Party under this Agreement are subject to United States laws and regulations, which may restrict certain exports, re-exports or other transfers to other countries and parties. Each Party agrees that no materials or information provided to it under this Agreement by the other Party 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**

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 and Section 2.3, 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 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 - CHANGE NOTIFICATION.**

29.1. BVL shall notify Customer promptly of any change in ownership of BVL, and in no event later than three (3) days of such change being made public.

## **ARTICLE 30 - BOOKS AND RECORDS.**

30.1. Any books and records to be maintained under this Agreement by a Party or its Affiliates shall be maintained in accordance with U.S. generally accepted accounting principles, consistently applied; *except* that the same need not be audited (but if any audits are conducted by a Party, the results of such audits shall be maintained along with such books and records).

## **ARTICLE 31 - BINDING EFFECT.**

31.1. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

## **ARTICLE 32 - USE OF NAME AND RESERVATION OF RIGHTS.**

32.1. Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation or intellectual property of the other Party or its Affiliates or any other trade name or trademark of the other Party or its Affiliates for any purpose in connection with the performance of this Agreement or otherwise.

## **ARTICLE 33 - COUNTERPARTS.**

33.1. This Agreement may be executed in several counterparts, each of which is an original notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers.

## **ARTICLE 34 - LIQUIDATED DAMAGES.**

34.1. Liquidated Damages. As set forth in Section 8.6.3, the parties recognize and acknowledge that each is seeking by this Agreement to equitably allocate risk with respect to each party's respective interest in the Agreement. For purposes of interpretation and to aid in any contract construction, the parties have elected to allocate a total BVL Cap on liability which serves to limit BVL's aggregate liability but also serves to compel performance so as to

avoid forfeiture should BVL inexcusably not perform its obligations under this Agreement. As such, the limitations of liability and BVL Cap are highly negotiated and represent compromises between the parties, which the parties acknowledge are fair and reasonable under the present circumstances. In light of the fact that breach and/or non-performance by BVL may cause Customer to incur economic damages and losses of types and in amounts which are difficult to ascertain with any certainty as a basis for recovery of actual damages, the parties have agreed for the payment of liquidated damages which each believes to represent a fair, reasonable and appropriate estimate thereof, as set forth herein. Such liquidated damages are intended to represent estimated actual damages as contemplated by the parties at the time of entering into this Agreement and are not intended as a penalty.

34.2. Calculation of Liquidated Damages. In the event that BVL is unable to perform its obligations under this Agreement due to Section 12.3, 12.4, 12.5, or 12.7, then as Customer's sole and exclusive remedy, it shall be entitled to seek, and BVL shall be obligated to pay, liquidated damages calculated as the difference between the BVL Cap and any payments or claims made under it. For the avoidance of doubt, and solely for purposes of illustration, if BVL was not able to deliver any Product to Customer and there were no other claims against the BVL Cap, then the liquidated damages payable to Customer would be \*\*\*\* Dollars (\$\*\*\*\*). By way of a second example, if Customer had received reimbursement of \$150,000 for API costs for failed batches, then the BVL Cap of \$\*\*\*\* would be reduced by \$150,000, thereby leaving \$\*\*\*\* available for liquidated damages. In the event that the BVL Cap is reduced to zero (\$0) for any reason, then the parties acknowledge and agree that the liquidated damages shall likewise be zero (\$0). The parties further acknowledge and agree that the liquidated damages provision shall not be deemed to have failed for any essential purpose or deprived Customer of any remedy because it was depleted, in whole or in part, by payments which reduced the BVL Cap.

\*\_\*\_\*\_\*

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement by their duly authorized representatives as of the dates set forth below:

**BEN VENUE LABORATORIES, INC.**

**LANTHEUS MEDICAL IMAGING, INC.**

By: /s/ George Doyle  
Print: George Doyle  
Title: President, CEO  
Date Signed: 3/20/12

By: /s/ Michael P. Duffy  
Print: Michael P. Duffy  
Title: Vice President and Secretary  
Dated Signed: 3/20/2012

By: /s/ William A. Owen  
Print: William A. Owen  
Title: VP Finance  
Date Signed: 3/20/12

**Attachment A**

**PRODUCT SUPPLEMENTS**

<b>Attachment A-1 –</b>	<b>See Attached</b>
<b>Attachment A-2 –</b>	<b>See Attached</b>
<b>Attachment A-3 –</b>	<b>See Attached</b>
<b>Attachment A-4 –</b>	<b>See Attached</b>
<b>Attachment A-5 –</b>	<b>See Attached</b>
<b>Attachment A-6 –</b>	<b>See Attached</b>
<b>Attachment A-7 –</b>	<b>See Attached</b>

Manufacturing and Service Contract (BVL and Lantheus)

**Attachment "A1"**  
**Sestamibi**

**A1.1) PRODUCT Description:** Sestamibi, \*\*\*\* mg lyo in a \*\*\*\* mL vial

**BVL Project Code:** 0077-00

**CUSTOMER Project Code:**

<b>PRODUCT Description (INCLUDING PACKAGING DESCRIPTION FOR EACH END ITEM NUMBER FROM THE SAME NUDE VIAL)</b>	<b>BVL End Item Number</b>	<b>BVL Nude Vial Number</b>	<b>Batch Size/Order Quantity</b>
Sestamibi, **** mg lyo in a **** mL vial, unlabeled vial, bulk pack with foam partition	9999900573	0077-00	****
Sestamibi, **** mg lyo in a **** mL vial, US labeled vial, 5 pk shelf carton with foam partition	9999993801	0077-00	****
Sestamibi, **** mg lyo in a **** mL vial, CAN labeled vial, 2 pk shelf carton with foam partition	9999993802	0077-00	****
Sestamibi, **** mg lyo in a **** mL vial, CAN labeled vial, 5 pk shelf carton with foam partition	9999993807	0077-00	****
Sestamibi, **** mg lyo in a **** mL vial, unlabeled vial, bulk pack with foam partition	9999900738	0077-00	****

**Attachment A1**  
**Sestamibi**

**A1.2) PRODUCT Specifications - Sestamibi**

Per BVL Spec Number 0770FP effective 6/27/94 as may be amended, modified or supplemented from time to time in accordance with this Agreement.

**Attachment A1  
Sestamibi**

**A1.3) Materials supplied by CUSTOMER and BVL for Sestamibi**

\*\*\*

Attachment A1  
Sestamibi

A1.4) [INTENTIONALLY OMITTED]

A1.4.2 [INTENTIONALLY OMITTED]

**Attachment A1  
Sestamibi**

A1.5.) Pricing for Sestamibi, \*\*\*\* mg lyo in a \*\*\*\* mL vial

**BATCH PRICING**      **Effective From \*\*\*\* Through \*\*\*\***

<b>PRODUCT Description</b>	<b>BVL Nude Vial Number</b>	<b>BVL End Item Number</b>	<b>Batch Size/Order Quantity</b>	<b>Price Per Vial for End Item with No Split Pack-outs</b>
Sestamibi, CAN labeled vial, 2 pk carton with foam partition	0077-00	9999993802	****	\$ ****
Sestamibi, CAN labeled vial 5 pk shelf carton with foam partition	0077-00	9999993807	****	\$ ****
Sestamibi, unlabeled vial bulk pk with foam partition	0077-00	9999900573	****	\$ ****
Sestamibi, US labeled vial, 5 pk shelf carton with foam partition	0077-00	9999993801	****	\$ ****
Sestamibi, unlabeled vial bulk pk with foam partition	0077-00	9999900738	****	\$ ****

**\$\*\*\*\* is assessed per packaging change over for each split batch.**

**\$\*\*\*\* is assessed per label proof generation.**

**All other configurations/quantities/ packaging splits will be quoted separately upon request by CUSTOMER to BVL. The above prices are for full batch quantities packaged as described.**

**Attachment A1  
Sestamibi**

**A1.6.) Territory for Sestamibi, \*\*\*\* mg lyo in a \*\*\*\* mL vial**

**CARDIOLITE® kit for the Preparation of Technetium Tc99m Sestamibi for Injection**

<b>COUNTRY</b>	<b>APPROVAL DATE</b>	<b>REGISTRATION NUMBER</b>	<b>EU REGULATORY PROCEDURE</b>
United States	21-Dec-1990	19,785	NDA
Canada	02-Jan-90	RN- 8804	NDS
Austria	20-Oct-94	4-00001	National
Belgium	24-Sep-90	BE 152686	National
Denmark	22-Oct-90	DK R 4	National
Finland	9-Dec-92	10860	National
France	21-Sep-90	556 934 - 8 (2 vial) 557 102 - 6 (5 vial)	National
Germany	11-May-92	20930.00.00	National
Italy	14-Jun-93	028601019	National
Luxembourg	30-Nov-06	0457/06110019	National
Netherlands	16-May-95	RVG 16518	National
Norway	6-May-98	94.194	National
Portugal	30-Sep-03	4809182 (2 vial) 4809281 (5 vial)	National
Spain	20-Mar-97	61.239	National
Sweden	21-Jun-90	80076	National
Switzerland	9-Oct-91	50632 01	National
United Kingdom	15-Feb-93	PL 14207/0019	National
Australia	18-Oct-94	AUSTR 49688	Local
Bahrain	N/A	N/A	N/A
Brazil	15-Sept-00	126940019002-3	Local
Colombia	3-Dec-03	2003M-0002941	Local
Costa Rica	28-Jun-93	2705-ZF-13679	Local
Egypt	N/A	N/A	N/A
Hong Kong	98-99	HK-43085	Local
India	4-Oct-06	FF-193	Local
Israel	23-Jun-94	637727948	Local
Japan	2-Apr-93	20500AMY00127000	Local
Korea	25-Mar-00	1	Local
Kuwait	N/A	N/A	N/A
Lebanon	N/A	N/A	N/A
Malaysia	19-Jan-05	SIN12645P	Local
Malta	9-Mar-10	PL34258/0001	Local
Mexico	26-Jan-10	1203R87SSA	Local
New Zealand	N/A	N/A	N/A

Oman	N/A	N/A	N/A
Panama	N/A	N/A	N/A
Philippines	N/A	N/A	N/A
Saudi Arabia	N/A	N/A	N/A
Slovenia	N/A	N/A	N/A
South Africa	1-Apr-92	2/35/108	Local
Taiwan	9-Mar-93	R00075	Local
Thailand	N/A	N/A	N/A
UAE	N/A	N/A	N/A

**Attachment A2  
Neurolite ligand**

**A2.1.) PRODUCT Description:** Neurolite ligand, \*\*\*\* mg lyo in a \*\*\*\* mL vial

**BVL Project Code: 0229-00**

**CUSTOMER Project Code:**

**PRODUCT Description (INCLUDING  
PACKAGING DESCRIPTION FOR EACH  
END ITEM NUMBER FROM THE SAME  
NUDE VIAL)**

**BVL End Item  
Number**

**BVL Nude Vial  
Number**

**Batch  
Size/Order  
Quantity**

Neurolite ligand, \*\*\*\* mg lyo in a \*\*\*\* mL vial unlabeled, bulk  
pkg for Domestic

9999900768

0229-00

\*\*\*\*

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**Attachment A2  
Neurolite ligand**

**A2.2.) PRODUCT Specifications - Neurolite ligand**

Per BVL Spec Number 22900FP effective 1/22/98 as may be amended, modified or supplemented from time to time in accordance with this Agreement.

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**Attachment A2  
Neurolite ligand**

**A2.3.) Materials supplied by CUSTOMER and BVL for Neurolite ligand**

\*\*\*

Attachment A2  
Neurolite ligand

A2.4.) [INTENTIONALLY OMITTED]

A2.4.1

A2.4.2 INTENTIONALLY OMITTED

**Attachment A2  
Neurolite ligand**

A2.5.) Pricing for Neurolite ligand, \*\*\*\* mg lyo in a \*\*\*\* mL vial

**PRICING**

**Effective From \*\*\*\* Through \*\*\*\***

<b>PRODUCT Description</b>	<b>BVL Nude Vial Number</b>	<b>BVL End Item Number</b>	<b>Batch Size/Order Quantity</b>	<b>Price Per Vial for End Item with No Split Pack-outs</b>
Neurolite ligand, **** mg lyo in a **** mL vial, US labeled, bulk pkg	0229-00	99999900768	****	\$ ****

\*\*\*\* is assessed per packaging change over for each split batch.

\*\*\*\* is assessed per label proof generation.

All other configurations/quantities/ packaging splits will be quoted separately upon request by CUSTOMER to BVL. The above prices are for full batch quantities packaged as described.

**Attachment A2  
Neurolite ligand**

**A2.6.) Territory for Neurolite ligand, \*\*\*\* mg lyo in a \*\*\*\* mL vial**

**NEUROLITE® Kit for the Preparation of Technetium Tc99m Bicisate for Injection**

<b>COUNTRY</b>	<b>APPROVAL DATE</b>	<b>REGISTRATION</b>	<b>PROCEDURE</b>
United States	23-Nov-1994	20,256	NDA
Canada	17-Oct-94	RN-9204	NDS
Austria	2-Dec-97	4-00002	MRP
Belgium	16-Mar-95	BE 168567	MRP
Czech Republic	29-Nov-00	88/581/00-C	National
Denmark	10-Feb-04	DK R11	MRP
Finland	27-Feb-95	11679	MRP
France	25-Apr-94	558 376-2 (box of 5) 558 375-6 (box of 1)	MRP
Germany	13-Dec-93	29602.00.00	MRP
Italy	21-Sep-95	28847010	MRP
Luxembourg	7-Apr-95	0685/93/12/0747	MRP
Norway	11-Jan-95	8069	National
Portugal	7-Oct-97	2566883	MRP
Spain	28-Jun-96	60.882	MRP
Sweden	29-Dec-94	12505	MRP
Australia	24-Aug-00	AUSTR 73014	Local
Bahrain	N/A	N/A	N/A
Colombia	5-Feb-99	M 011934	Local
Costa Rica	20-Nov-97	—	Local
Hong Kong	20-May-98	HK-43086	Local
Israel	11-Sept-97	10734/28989	Local
Japan	19-Jan-94	20600AMY0000600	Local
Korea	2-Aug-00	2	Local
Lebanon	N/A	N/A	N/A
Malaysia	20-Jan-05	SIN12644P	Local
Mexico	8-Nov-95	1614R95SSA	Local
New Zealand	N/A	N/A	N/A
Oman	N/A	N/A	N/A
Panama	N/A	N/A	N/A
Philippines	N/A	N/A	N/A
Saudi Arabia	N/A	N/A	N/A
Slovenia	N/A	N/A	N/A
Switzerland	17-Oct-94	52441	National
Taiwan	7-Apr-99	R000081	Local
Thailand	N/A	N/A	N/A
UAE	N/A	N/A	N/A

**Attachment A3  
Eluant**

**A.3.1) PRODUCT Description** Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial

**BVL Project Code: 0078-72**

**CUSTOMER Project Code:**

**PRODUCT Description (INCLUDING  
PACKAGING DESCRIPTION FOR EACH  
END ITEM NUMBER FROM THE SAME  
NUDE VIAL)**

**BVL End Item  
Number**

**BVL Nude Vial  
Number**

**Batch  
Size/Order  
Quantity**

Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial labeled,  
bulk packaged

9999983530

0078-72

\*\*\*\*

**Attachment A3**  
**Eluant**

**A3.2.) PRODUCT Specifications** - Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial

Per BVL Spec Number 07872FP effective 1/14/94 as may be amended, modified or supplemented from time to time in accordance with this Agreement.

**Attachment A3  
Eluant**

**A3.3) Materials supplied by CUSTOMER and BVL for Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial**

\*\*\*\*

**Attachment A3  
Eluant**

A3.4.) INTENTIONALLY OMITTED

A3.4.1 .

62

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**Attachment A3  
Eluant**

A3.4.2 INTENTIONALLY OMITTED

63

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**Attachment A3  
Eluant**

A3.5.) Pricing for Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial

**BATCH PRICING**

**Effective From \*\*\*\* Through \*\*\*\***

<b>PRODUCT Description</b>	<b>BVL Nude Vial Number</b>	<b>BVL End Item Number</b>	<b>Batch Size/Order Quantity</b>	<b>Price Per Vial for End Item with No Split Pack-outs</b>
Eluant, **** mg/mL liquid, **** mL in a **** mL vial, labeled, bulk packaged	0078-72	9999983530	****	\$ ****

All other configurations/quantities/ packaging splits will be quoted separately upon request by CUSTOMER to BVL. The above price is for full batch quantities packaged as described.

**Attachment A3**  
**Eluant**

**A3.6.) Territory for Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial**

**Attachment A4  
Eluant**

**A4.1.) PRODUCT Description:** Eluant, \*\*\*\* mg/mL liquid \*\*\*\* mL in a \*\*\*\* mL vial

**BVL Project Code:**

**CUSTOMER Project Code:**

**PRODUCT Description (INCLUDING  
PACKAGING DESCRIPTION FOR  
EACH END ITEM NUMBER FROM THE  
SAME NUDE VIAL)**

**BVL End Item  
Number**

**BVL Nude Vial  
Number**

**Batch  
Size/Order  
Quantity**

Eluant, \*\*\* mg/mL liquid \*\*\*\* mL in a \*\*\*\* mL vial,  
labeled, bulk packaged

9999980530

0078-73

\*\*\*

**Attachment A4**  
**Eluant**

**A4.2.) PRODUCT Specifications** - Eluant, \*\*\*\* mg/mL liquid \*\*\*\* mL in a \*\*\*\* mL vial

Per BVL Spec Number 07873FP effective 1/14/94 as may be amended, modified or supplemented from time to time in accordance with this Agreement.

Attachment A4  
Eluant

A4.3.) Materials supplied by CUSTOMER and BVL for Eluant, \*\*\*\* mg/mL liquid \*\*\*\* mL in a \*\*\*\* mL vial

\*\*\*\*

Attachment A4  
Eluant

A4.4.) [INTENTIONALLY OMITTED]

A4.4.1

Attachment A4  
Eluant

A4.4.2 INTENTIONALLY OMITTED

**Attachment A4  
Eluant**

A4.5.) Pricing for Eluant, \*\*\*\* mg/mL liquid \*\*\*\* mL in a \*\*\*\* mL vial

**BATCH PRICING**

**Effective From \*\*\*\* Through \*\*\*\***

<b>PRODUCT Description</b>	<b>BVL Nude Vial Number</b>	<b>BVL End Item Number</b>	<b>Batch Size/Order Quantity</b>	<b>Price Per Vial for End Item with No Split Pack-outs</b>
Eluant, **** mg/mL liquid **** mL in a **** mL vial, labeled, bulk packaged	0078-73	9999980530	****	\$ ****

All other configurations/quantities/ packaging splits will be quoted separately upon request by CUSTOMER to BVL. The above price is for full batch quantities packaged as described.

**Attachment A4  
Eluant**

A4.6.) Territory for Eluant, \*\*\*\* mg/mL liquid \*\*\*\* mL in a \*\*\*\* mL vial

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**Attachment A5  
Neurolite Buffer**

A5.1.) **PRODUCT Description:** Neurolite buffer, liquid, \*\*\*\* mL in a \*\*\*\* mL vial

**BVL Project Code: 0230-40**

**CUSTOMER Project Code:**

**PRODUCT Description (INCLUDING  
PACKAGING DESCRIPTION FOR EACH  
END ITEM NUMBER FROM THE SAME  
NUDE VIAL)**

**BVL End Item  
Number**

**BVL Nude  
Vial Number**

**Batch  
Size/Order  
Quantity**

Neurolite buffer, liquid, **** mL in a **** mL vial Canada labeled, bulk packaged	9999993401	0230-40	****
Neurolite buffer, liquid, **** mL in a **** mL vial US labeled, bulk packaged	9999993400	0230-40	****
Neurolite buffer, liquid, **** mL in a **** mL vial unlabeled, bulk packaged	9999900574	0230-40	****

73

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**Attachment A5**  
**Neurolite buffer**

**A5.2.) PRODUCT Specifications** - Neurolite buffer, liquid, \*\*\*\* mL in a \*\*\*\* mL vial

Per BVL Spec Number 023040FP as may be amended, modified or supplemented from time to time in accordance with this Agreement.

**Attachment A5**  
**Neurolite buffer**

**A5.3.) Materials supplied by CUSTOMER and BVL for Neurolite buffer, liquid, \*\*\*\* mL in a \*\*\*\* mL vial**

\*\*\*\*

**Attachment A5  
Neurolite Buffer**

A5.4.) [INTENTIONALLY OMITTED]

**Attachment A5  
Neurolite Buffer**

A5.4.2 [INTENTIONALLY OMITTED] .

**Attachment A5  
Neurolite buffer**

A5.5.) Pricing for Neurolite buffer, liquid, \*\*\*\* mL in a \*\*\*\* mL vial

**BATCH PRICING**

**Effective From \*\*\*\* Through \*\*\*\***

<b>PRODUCT Description</b>	<b>BVL Nude Vial Number</b>	<b>BVL End Item Number</b>	<b>Batch Size/Order Quantity</b>	<b>Price Per Vial for End Item with No Split Pack-outs</b>
Neurolite buffer, liquid, **** mL in a **** mL vial Canada labeled, bulk packaged	0230-40	9999993401	****	\$ ****
Neurolite buffer, liquid, **** mL in a **** mL vial US labeled, bulk packaged	0230-40	9999993400	****	\$ ****
Neurolite buffer, liquid, **** mL in a **** mL vial unlabeled, bulk packaged	0230-40	9999900574	****	\$ ****

\*\*\*\* is assessed per packaging change over for each split batch.

\*\*\*\* is assessed per label proof generation.

All other configurations/quantities/ packaging splits will be quoted separately upon request by CUSTOMER to BVL. The above prices are for full batch quantities packaged as described.

**Attachment A5  
Neurolite buffer**

**A5.6.) Territory for Neurolite buffer, liquid, \*\*\*\* mL in a \*\*\*\* mL vial**

**NEUROLITE® Kit for the Preparation of Technetium Tc99m Bicisate for Injection**

<b>COUNTRY</b>	<b>APPROVAL DATE</b>	<b>REGISTRATION</b>	<b>PROCEDURE</b>
United States	23-Nov-1994	20,256	NDA
Canada	17-Oct-94	RN-9204	NDS
Austria	2-Dec-97	4-00002	MRP
Belgium	16-Mar-95	BE 168567	MRP
Czech Republic	29-Nov-00	88/581/00-C	National
Denmark	10-Feb-04	DK R11	MRP
Finland	27-Feb-95	11679	MRP
France	25-Apr-94	558 376-2 (box of 5) 558 375-6 (box of 1)	MRP
Germany	13-Dec-93	29602.00.00	MRP
Italy	21-Sep-95	28847010	MRP
Luxembourg	7-Apr-95	0685/93/12/0747	MRP
Norway	11-Jan-95	8069	National
Portugal	7-Oct-97	2566883	MRP
Spain	28-Jun-96	60.882	MRP
Sweden	29-Dec-94	12505	MRP
Australia	24-Aug-00	AUSTR 73014	Local
Bahrain	N/A	N/A	N/A
Colombia	5-Feb-99	M 011934	Local
Costa Rica	20-Nov-97	—	Local
Hong Kong	20-May-98	HK-43086	Local
Israel	11-Sept-97	10734/28989	Local
Japan	19-Jan-94	20600AMY0000600	Local
Korea	2-Aug-00	2	Local
Lebanon	N/A	N/A	N/A
Malaysia	20-Jan-05	SIN12644P	Local
Mexico	8-Nov-95	1614R95SSA	Local
New Zealand	N/A	N/A	N/A
Oman	N/A	N/A	N/A
Panama	N/A	N/A	N/A
Philippines	N/A	N/A	N/A
Saudi Arabia	N/A	N/A	N/A
Slovenia	N/A	N/A	N/A
Switzerland	17-Oct-94	52441	National
Taiwan	7-Apr-99	R000081	Local
Thailand	N/A	N/A	N/A
UAE	N/A	N/A	N/A

**Attachment A6  
Technelite**

**A6.1.) INTENTIONALLY OMITTED**

Attachment A6  
Technelite

A6.2.) [INTENTIONALLY OMITTED]

**Attachment A6  
Technelite**

A6.3.) [INTENTIONALLY OMITTED]

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**Attachment A6  
Technelite**

A6.4.) [INTENTIONALLY OMITTED]

83

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Attachment A6  
Technelite

A6.4.2 [INTENTIONALLY OMITTED].

**Attachment A6  
Technelite**

**A6.5) INTENTIONALLY OMITTED**

Attachment A6  
Technelite

A6.6.) [INTENTIONALLY OMITTED]

**Attachment A7**  
**Definity**

A7.1.) **PRODUCT Description** Definity \*\*\*\* mg lyo in a \*\*\*\* mL vial

**BVL Project Code:**

**CUSTOMER Project Code:**

**PRODUCT Description (INCLUDING  
PACKAGING DESCRIPTION FOR EACH  
END ITEM NUMBER FROM THE SAME  
NUDE VIAL)**

**BVL End Item  
Number**

**BVL Nude  
Vial Number**

**Batch  
Size/Order  
Quantity**

Definity \*\*\*\* mg lyo in a \*\*\*\* mL vial unlabeled, bulk  
packaged

9999900095

2128-71

\*\*\*\*

**Attachment A7**  
**Definity**

**A7.2.) PRODUCT Specifications - Definity, \*\*\*\* mg lyo in a \*\*\*\* mL vial**

Per BVL Spec Number 212871FP effective 1/22/98 as may be amended, modified or supplemented from time to time in accordance with this Agreement.

**Attachment A7**  
**Definity**

**A7.3.) Materials supplied by CUSTOMER and BVL for Definity, \*\*\*\* mg lyo in a \*\*\*\* mL vial**

\*\*\*\*

**Attachment A7**  
**Definity**

A7.4.) [INTENTIONALLY OMITTED]

A7.4.1 .

**Attachment A7**  
**Definity**

A7.4.2 [INTENTIONALLY OMITTED]

**Attachment A7  
Definity**

**A7.5.) Pricing for Definity \*\*\*\* mg lyo in a \*\*\*\* mL vial**

**BATCH PRICING**

**Effective From \*\*\*\* Through \*\*\*\***

<b>PRODUCT Description</b>	<b>BVL Nude Vial Number</b>	<b>BVL End Item Number</b>	<b>Batch Size/Order Quantity</b>	<b>Price Per Vial for End Item with No Split Pack-outs</b>
Definity **** mg lyo in a **** mL vial unlabeled bulk packaged	2128-71	9999900095	****	\$ ****

All other configurations/quantities/ packaging splits will be quoted separately upon request by CUSTOMER to BVL. The above price is for full batch quantities packaged as described.

**Attachment A7  
Definity**

**A7.6.) Territory for Definity \*\*\*\* mg lyo in a \*\*\*\* mL vial**

**DEFINITY®**

**Vial for (Perflutren Lipid Microsphere) Injectable Suspension**

<b>COUNTRY</b>	<b>APPROVAL DATE</b>	<b>REGISTRATION NUMBER</b>	<b>PROCEDURE</b>
Australia	10-Jan-07	AUSTR 124808	Local
Canada	28-Dec-00	062005	NDS
Europe	20-Sep-06	EU/1/06/361/001	Centralized
India	11-Mar-10	FF-541-16510	Local
Israel	7-Jul-05	133 15 31138 10 (Distributor: LAVI Industrial and Medical)	Local
Korea	19-Jan-07	5001	Local
Mexico	24-Jul-04	0613R2004 SSA	Local
New Zealand	6-Dec-07	76-19-7	Local
Singapore	25-Jun-07	SIN 13309P (Distributor: Research Biolabs PTE Ltd.)	Local
UAE	11-Jul-07	5217-6417-1	Local
United States	31-Jul-01	21-064	NDA

**Attachment A8  
Inventory**

**A8.1.) Firm Supply Obligations (pursuant to Section 5.4).**

**BVL's \*\*\*\* Firm Obligations (if requested by Customer)**

<b>PRODUCT</b>	<b>Minimum Number of Batches</b>
Definity	****
Cardiolite	****
Neurolite ligand and buffer eluant (saline)	****

**BVL's \*\*\*\* Firm Obligations (if requested by Customer)**

<b>PRODUCT</b>	<b>Minimum Number of Batches</b>
Definity	****
Cardiolite	****
Neurolite ligand and buffer	****

**Terminal Supply (if requested by Customer)**

<b>PRODUCT</b>	<b>Maximum Number of Batches</b>
Definity	****
Cardiolite	****
Neurolite ligand and buffer	****

## Attachment B

### Purchase Order Requirements

If any of the required items are not on the PO, note as missing on the PO confirmation form.

- BVL item number: Required
- BVL delivery date: Required  
(date by which BLV is to release/deliver the lot or batch record)
- BVL quotation number: Required
- Theoretical batch size per quotation: Required
- Delivery address: Required
- Ship on BVL release? (yes or no): Required
- Is overnight shipment required? (yes or no)
- Are there any temperature requirements? If yes, what are they?
- Are temperature monitors required? (yes or no). If yes, customer must provide monitors.
- Do you require the use of dedicated truck or is a common carrier acceptable?
- Do you have a specific carrier you want to use? If yes, please provide contact information.

#### Not required at time PO is entered:

- Customer Lot Number: Not required but customer must note when they can provide
- Product Expiration Date: Not required but customer must note when they can provide

**Attachment "C"**  
**MONTHLY STORAGE FEES**

Effective through \*\*\*\*

BVL has limited storage capacity. Therefore, Customers are expected to have Product shipped to them no later than \*\*\*\* (\*\*\*\*) days after BVL Quality Operations has released their Product and has shipped the documents identified Attachment D to Customer. Should unforeseen events lead to a request by a Customer for storage beyond this \*\*\*\* (\*\*\*\*) day grace period, the Customer must request such storage by BVL in writing at least \*\*\*\* (\*\*\*\*) days before the initial \*\*\*\* (\*\*\*\*) day grace period has expired. The request will be granted only if BVL has sufficient storage capacity to accommodate the request. Then, the following terms will apply.

Monthly storage fees are assessed on a per lot basis, and begin to accrue \*\*\*\* (\*\*\*\*) days following the BVL release date of the Batch by BVL's Quality Operations Dept. BVL will request that a separate Purchase Order be issued for the storage charges. These charges listed below will be reviewed and updated annually.

Monthly Storage Charge - per square foot per month

Room Temperature Storage	\$	****
Refrigerated Storage	\$	****
Freezer Storage	\$	****

Minimum Storage Charge - per lot per month

Room Temperature Storage	\$	****
Refrigerated Storage	\$	****
Freezer Storage	\$	****

**Attachment D**

**Documents To Be Supplied By BVL to CUSTOMER As Part Of Batch Release**

- 1.) BVL Certificate of Analysis (if required)
- 2.) BVL Certificate of Compliance
- 3.) Copies of the executed Batch Record
- 4.) Raw Material C of A's 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 audits by the customer.

**Attachment "E"**  
**QUALITY AGREEMENT**

**QUALITY AGREEMENT — Pharmaceutical Product**

Print Name

E-1

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**APPENDIX A:**

**List of Products:**

Cardiolite / Sestamibi

Neurolite Ligand

Neurolite Buffer

Definity / Luminity / DMP115-e

Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial

Eluant, \*\*\*\* mg/mL liquid, \*\*\*\* mL in a \*\*\*\* mL vial

**Attachment "F"**  
**Customer Supplied Equipment**

**PFM CART**  
**Squarewave test equipment and associated spare parts**

**Attachment "G"**  
**Representation regarding Customer's Qualified Person**

**CUSTOMER LETTERHEAD**  
**Customer Address**

BEN VENUE LABORATORIES, INC.  
ATTN: COMPLIANCE MANAGER  
A Boehringer Ingelheim Company  
300 Northfield Road  
Bedford, Ohio 44146

Dear BVL COMPLIANCE MANAGER,

Please take notice that Lantheus Medical Imaging hereby confirms in writing to BVL that it has appointed one or more Qualified Person(s) in compliance with the requirements of Article 48 of Directive 2001/83/EC, with respect to the product(s) subject to the manufacturing and services contract for commercial and developmental products between Ben Venue Laboratories, Inc. and Lantheus Medical Imaging, Inc. dated . Said Qualified Person(s) shall be responsible for release of Product(s) into EU member states and shall comply with Article 51 of 2001/83/EC.

Sincerely,

Name  
Title

---



[QuickLinks](#) -- Click here to rapidly navigate through this document

**Exhibit 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO  
SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a), AS ADOPTED  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Donald R. Kiepert, certify that:

1. I have reviewed this quarterly report on Form 10-Q/A of Lantheus Medical Imaging, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Dated: September 27, 2012

/s/ Donald R. Kiepert

\_\_\_\_\_  
Name: Donald R. Kiepert

Title: *President and Chief Executive Officer*

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QuickLinks

[Exhibit 31.1](#)

[CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14\(a\) AND 15d-14\(a\), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002](#)

[QuickLinks](#) -- Click here to rapidly navigate through this document

Exhibit 31.2

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO  
SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a), AS ADOPTED  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jeffrey E. Young, certify that:

1. I have reviewed this quarterly report on Form 10-Q/A of Lantheus Medical Imaging, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Dated: September 27, 2012

/s/ Jeffrey E. Young

\_\_\_\_\_  
Name: Jeffrey E. Young  
Title: *Chief Financial Officer*

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QuickLinks

[Exhibit 31.2](#)

[CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14\(a\) AND 15d-14\(a\), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002](#)

[QuickLinks](#) -- Click here to rapidly navigate through this document

Exhibit 32.1

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED  
BY SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned hereby certifies that to his knowledge the Quarterly Report on Form 10-Q/A for the fiscal quarter ended March 31, 2012 of Lantheus Medical Imaging, Inc. (the "Company") filed with the Securities and Exchange Commission on the date hereof fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: September 27, 2012

/s/ Donald R. Kiepert

\_\_\_\_\_  
Name: Donald R. Kiepert  
Title: *President and Chief Executive Officer*

Dated: September 27, 2012

/s/ Jeffrey E. Young

\_\_\_\_\_  
Name: Jeffrey E. Young  
Title: *Chief Financial Officer*

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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QuickLinks

[Exhibit 32.1](#)

[CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED BY SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002](#)