

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[Table of Contents](#)

---

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

---

**FORM 10-Q**

(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

---

**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**

---

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.



**TABLE OF CONTENTS**

	<u>Page</u>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1.</u> <u>Financial Statements (Unaudited)</u>	<u>1</u>
<u>Condensed Consolidated Statements of Comprehensive Income for the Three Months Ended March 31, 2012 and 2011</u>	<u>1</u>
<u>Condensed Consolidated Balance Sheets as of March 31, 2012 and December 31, 2011</u>	<u>2</u>
<u>Condensed Consolidated Statements of Stockholder's (Deficit) Equity for the Three Months Ended March 31, 2012 and the year ended December 31, 2011</u>	<u>3</u>
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2012 and 2011</u>	<u>4</u>
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	<u>5</u>
<u>Item 2.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>27</u>
<u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>42</u>
<u>Item 4.</u> <u>Controls and Procedures</u>	<u>43</u>
<b><u>PART II. OTHER INFORMATION</u></b>	
<u>Item 1.</u> <u>Legal Proceedings</u>	<u>45</u>
<u>Item 1A.</u> <u>Risk Factors</u>	<u>45</u>
<u>Item 6.</u> <u>Exhibits</u>	<u>46</u>
<u>Signatures</u>	<u>47</u>
<u>Exhibit Index</u>	<u>48</u>

---

## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

## Lantheus MI Intermediate, Inc. and subsidiaries

## Condensed Consolidated Statements of Comprehensive Income

(unaudited, in thousands)

	For the Three Months Ended March 31,	
	2012	2011
Revenues		
Net product revenues	\$ 82,631	\$ 95,956
License and other revenues	2,720	2,163
Total revenues	85,351	98,119
Cost of goods sold	52,535	52,051
Gross profit	32,816	46,068
Operating expenses		
General and administrative expenses	9,199	8,132
Sales and marketing expenses	9,993	9,395
Research and development expenses	10,362	10,505
Proceeds from manufacturer	(29,914)	—
Total operating expenses	(360)	28,032
Operating income	33,176	18,036
Interest expense, net	(10,346)	(6,937)
Other income, net	305	498
Income before income taxes	23,135	11,597
Provision for income taxes	2,237	5,250
Net income	20,898	6,347
Foreign currency translation, net of taxes	867	395
Total comprehensive income	\$ 21,765	\$ 6,742

See notes to unaudited condensed consolidated financial statements.

**Lantheus MI Intermediate, Inc. and subsidiaries**

**Condensed Consolidated Balance Sheets**

**(unaudited, in thousands except share data)**

	March 31, 2012	December 31, 2011
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 73,335	\$ 40,607
Accounts receivable, net of allowance of \$460 and \$462	46,481	40,000
Inventory	12,125	14,765
Deferred tax assets	124	93
Other current assets	5,135	2,662
Total current assets	137,200	98,127
Property, plant and equipment, net	110,872	112,452
Capitalized software development costs	3,206	3,582
Intangibles, net	78,847	82,749
Goodwill	15,714	15,714
Deferred tax assets	—	—
Deferred financing costs	12,808	13,141
Due from parent	1,242	1,286
Other long-term assets	32,500	31,753
Total assets	<u>\$ 392,389</u>	<u>\$ 358,804</u>
<b>Liabilities and Stockholder's (Deficit) Equity</b>		
Current liabilities		
Note payable	\$ 1,073	\$ —
Accounts payable	17,279	22,010
Accrued expenses	32,196	20,949
Income tax payable	2,636	1,482
Deferred tax liability	—	—
Deferred revenue	5,824	3,918
Total current liabilities	59,008	48,359
Asset retirement obligations	5,007	4,868
Long-term debt, net	398,678	398,629
Deferred tax liability	1,017	931
Other long-term liabilities	39,641	39,220
Total liabilities	<u>503,351</u>	<u>492,007</u>
Commitments and contingencies (see Note 13)		
Stockholder's (deficit) equity		
Common stock (\$0.001 par value, 10,000 shares authorized; 1 share issued and outstanding)	—	—
Additional paid-in capital	1,561	1,085
Accumulated deficit	(113,761)	(134,659)
Accumulated other comprehensive income	1,238	371
Total stockholder's (deficit) equity	<u>(110,962)</u>	<u>(133,203)</u>
Total liabilities and stockholder's (deficit) equity	<u>\$ 392,389</u>	<u>\$ 358,804</u>

See notes to unaudited condensed consolidated financial statements.

**Lantheus MI Intermediate, Inc. and subsidiaries****Condensed Consolidated Statements of Stockholder's (Deficit) Equity****(unaudited, in thousands except share data)**

	Common Stock		Additional Paid-In Capital	(Accumulated Deficit) Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total Stockholder's (Deficit) Equity
	Shares	Amount				
Balance at January 1, 2011	1	\$ —	\$ 150,316	\$ 2,410	\$ 708	\$ 153,434
Dividend paid to Holdings (see Note 10)	—	—	(149,400)	(600)	—	(150,000)
Net loss	—	—	—	(136,469)	—	(136,469)
Other comprehensive loss	—	—	—	—	(337)	(337)
Stock-based compensation	—	—	169	—	—	169
Balance at December 31, 2011	1	—	1,085	(134,659)	371	(133,203)
Net income	—	—	—	20,898	—	20,898
Other comprehensive income	—	—	—	—	867	867
Stock-based compensation	—	—	476	—	—	476
Balance at March 31, 2012	1	\$ —	\$ 1,561	\$ (113,761)	\$ 1,238	\$ (110,962)

See notes to unaudited condensed consolidated financial statements.

**Lantheus MI Intermediate, Inc. and subsidiaries**  
**Condensed Consolidated Statements of Cash Flows**  
(unaudited, in thousands)

	For the Three Months	
	March 31,	
	2012	2011
<b>Cash flow from operating activities</b>		
Net income	\$ 20,898	\$ 6,347
Adjustments to reconcile net income to cash flow from operating activities		
Depreciation and amortization	7,450	9,322
Provision for excess and obsolete inventory	546	162
Stock-based compensation (credit) expense	574	(746)
Deferred income taxes	255	4,104
Other	85	461
Increase (decrease) in cash from operating assets and liabilities		
Accounts receivable	(6,442)	(5,749)
Prepaid expenses and other current assets	(845)	(435)
Inventory	1,891	(10,474)
Due from parent	44	—
Deferred revenue	1,906	(1,333)
Accounts payable	(3,312)	(92)
Income tax payable	1,154	340
Accrued expenses and other liabilities	11,000	12,334
Cash provided by operating activities	<u>35,204</u>	<u>14,241</u>
<b>Cash flows from investing activities</b>		
Purchase of certificate of deposit	(225)	—
Capital expenditures	(2,044)	(4,019)
Cash used in investing activities	<u>(2,269)</u>	<u>(4,019)</u>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of debt	—	152,250
Payments on note payable	(457)	—
Consent solicitation fee	—	(3,750)
Debt issuance costs	(198)	(4,211)
Payment of dividend to parent	—	(150,000)
Cash used in financing activities	<u>(655)</u>	<u>(5,711)</u>
Effect of foreign exchange rate on cash	448	447
Increase in cash and cash equivalents	32,728	4,958
Cash and cash equivalents, beginning of period	40,607	33,006
Cash and cash equivalents, end of period	<u>\$ 73,335</u>	<u>\$ 37,964</u>
<b>Supplemental disclosure of cash flow information</b>		
Interest paid	\$ 8	\$ —
Income taxes paid, net of refunds	\$ 533	\$ 212

See notes to unaudited condensed consolidated financial statements.

**Lantheus MI Intermediate, Inc. and subsidiaries**

**Notes to Unaudited Condensed Consolidated Statements**

Unless the context requires otherwise, references to the "Company," "Lantheus," "our company," "we," "us" and "our" refer to Lantheus MI Intermediate, Inc. and its direct and indirect subsidiaries, references to "Lantheus Intermediate" refer to only Lantheus MI Intermediate, Inc., the parent of Lantheus Medical Imaging, Inc., references to "Holdings" refer to Lantheus MI Holdings, Inc., the parent of Lantheus Intermediate and references to "LMI" refer to Lantheus Medical Imaging, Inc., the subsidiary of Lantheus Intermediate. Solely for convenience, we refer to trademarks, service marks and trade names without the TM, SM and ® symbols. Such references are not intended to indicate, in any way, that we will not assert, to the fullest extent permitted under applicable law, our rights to our trademarks, service marks and trade names.

**1. Description of Business**

*Overview*

The Company manufactures, markets, sells and distributes medical imaging products globally with operations in the United States (U.S.), Puerto Rico, Canada and Australia and distribution relationships in Europe, Asia Pacific and Latin America. The Company provides medical imaging products, primarily focused on cardiovascular diagnostic imaging, to nuclear physicians, cardiologists, radiologists, internal medicine physicians, independent delivery networks, group purchasing organizations and technologists/sonographers working in a variety of clinical settings.

The Company's principal products include:

- DEFINITY—an ultrasound contrast agent;
- Cardiolite—a myocardial perfusion imaging agent;
- TechnoLite—a generator that provides the radioisotope used to radiolabel Cardiolite and other radiopharmaceuticals.

In the U.S., the Company's nuclear imaging products are primarily distributed through radiopharmacy chains, with a small portion of the sales of these products also made through the Company's direct sales force to hospitals and clinics that maintain their own in-house radiopharmacies. In the U.S., sales of the Company's contrast agents are made through a direct sales force. Outside of the U.S., the Company owns five radiopharmacies in Canada and two radiopharmacies in each of Puerto Rico and Australia. The Company also maintains a direct sales force in each of these countries. In the rest of the world, the Company relies on third-party distributors to sell both nuclear imaging and contrast agent products.

*Basis of Consolidation and Presentation*

The financial statements have been prepared in United States dollars, in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

In the opinion of the Company's management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the Company's financial statements for interim periods in accordance with U.S. GAAP. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant



**Lantheus MI Intermediate, Inc. and subsidiaries**

**Notes to Unaudited Condensed Consolidated Statements (Continued)**

**1. Description of Business (Continued)**

to the rules and regulations of the Securities and Exchange Commission ("SEC"). The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the Company's consolidated financial statements and the accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2011 ("2011 Form 10-K"). The Company's accounting policies are described in the "Notes to Consolidated Financial Statements" in the 2011 Form 10-K and updated, as necessary, in this Form 10-Q. The year-end condensed consolidated balance sheet data presented for comparative purposes was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. The results of operations for the three months ended March 31, 2012 are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

*Recent Events*

The Company generated net income of \$20.9 million during the three months ended March 31, 2012 and had an accumulated deficit of \$113.8 million at March 31, 2012. The Company currently relies on Ben Venue Laboratories ("BVL") as its sole source manufacturer for DEFINITY and Neurolite and as the primary manufacturer for the Cardiolite product supply. In July 2010, BVL temporarily shutdown the facility where it manufactures products for a number of customers, including the Company, in order to upgrade the facility to meet certain regulatory requirements. In anticipation of this shutdown, BVL manufactured for the Company additional inventory of these products to meet the Company's expected needs during the shutdown period which was initially anticipated to end in March 2011. As the shutdown and re-inspection periods have been longer than anticipated by either BVL or the Company, the Company could not meet all of the demand for certain products during the second half of 2011 and the first quarter of 2012, resulting in an overall revenue decline in comparison to the prior periods. The continued delay of BVL in resuming full production of the Company's products represents a supply uncertainty to the Company's business, and the Company can give no assurance as to when BVL will be able to successfully manufacture and distribute the products. The inventory of DEFINITY, Cardiolite and Neurolite previously supplied to us by BVL has now been exhausted. The Company has expedited a number of technology transfer programs to secure and qualify production of its BVL-manufactured products to alternate contract manufacturer sites. Currently, the Company is utilizing an alternate manufacturer for Cardiolite and has entered into separate manufacturing and supply agreements with Jubilant HollisterStier ("JHS") for the manufacture of each of DEFINITY, Cardiolite and Neurolite. The Company is also pursuing new manufacturing relationships to establish and secure additional long-term or alternative suppliers of Cardiolite, Neurolite and DEFINITY but is uncertain of the timing as to when the new arrangements with JHS and any other supply arrangements would provide meaningful quantities of products to the Company. During the first quarter of 2012, the Company implemented a reduction in force and other cost cutting measures in conjunction with business pressures resulting from the continuing BVL outage. Also during the first quarter of 2012, the Company received \$30.0 million from BVL to compensate the Company for its business losses, and BVL and LMI terminated their original manufacturing agreement and entered into (i) a Settlement and Mutual Release Agreement (the "Settlement Agreement"), (ii) a Transition Services Agreement (the "Transition Services Agreement"), and (iii) a Manufacturing and Service Contract (the "Manufacturing and Service Contract").

**Lantheus MI Intermediate, Inc. and subsidiaries**

**Notes to Unaudited Condensed Consolidated Statements (Continued)**

**1. Description of Business (Continued)**

- In the Settlement Agreement, LMI and BVL agreed to a broad mutual waiver and release for all matters that occurred prior to the date of the Settlement Agreement, a covenant not to sue and a payment in the amount of \$30.0 million from BVL to compensate LMI for business losses.
- Under the Transition Services Agreement, BVL agreed to manufacture for LMI an initial supply of DEFINITY, Cardiolute, Neurolite and certain TechneLite accessories, and agreed to make weekly payments to LMI, up to an aggregate of \$5.0 million as further compensation for business losses until an agreed-upon supply of LMI's products has been restored.
- Under the Manufacturing and Service Contract, BVL agreed to manufacture for LMI certain amounts of DEFINITY, Cardiolute, Neurolite and certain TechneLite accessories following the initial supply provided under the Transition Services Agreement. The agreement expires on December 31, 2013.

The \$30.0 million received upon termination of the Company's original manufacturing agreement and the weekly payments for additional delays under the Transition Services Agreement are compensation to the Company for business losses associated with the lack of product supply. As the Company has no remaining obligations associated with the original manufacturing agreement and the price to be paid upon delivery of product under the Transition Services Agreement and Manufacturing and Service Contract are at prices the Company believes are at market prices, the Company has recognized the proceeds as gains within the Company's results of operations. These payments are included within operating income as proceeds from manufacturer. The net proceeds totaled \$29.9 million in the condensed consolidated statement of comprehensive income for the quarter ended March 31, 2012.

If BVL is not able to provide the Company adequate product supply for a further prolonged period of time, or the Company is not successful with its JHS technology transfer programs in 2012 and cannot obtain adequate supply from JHS, the Company will need to implement additional expense reductions, such as a delay of discretionary spending, and other operating and strategic initiatives.

*Use of Estimates*

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. The more significant estimates reflected in the Company's condensed consolidated financial statements include certain judgments regarding revenue recognition, goodwill and intangible asset valuation, inventory valuation, asset retirement obligations, income tax liabilities, deferred tax assets and liabilities, accrued expenses and stock-based compensation. Actual results could materially differ from those estimates or assumptions.

**2. Summary of Significant Accounting Policies**

*Revenue Recognition*

The Company recognizes revenue when evidence of an arrangement exists, title has passed, the risks and rewards of ownership have transferred to the customer, the selling price is fixed or determinable, and collectability is reasonably assured. For transactions for which revenue recognition

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

criteria have not yet been met, the respective amounts are recorded as deferred revenue until such point in time the criteria are met and revenue can be recognized. Revenue is recognized net of reserves, which consist of allowances for returns and allowances for rebates.

Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. Supply or service transactions may involve the charge of a nonrefundable initial fee with subsequent periodic payments for future products or services. The up-front fees, even if nonrefundable, are earned (and revenue is recognized) as the products and/or services are delivered and performed over the term of the arrangement.

3. Fair Value of Financial Instruments

The tables below present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2012 and December 31, 2011, and indicate the fair value hierarchy of the valuation techniques utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points from active markets that are observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability.

(in thousands)	Total fair value at March 31, 2012	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Money market	\$ 6,254	\$ 6,254	\$ —	\$ —
Certificate of deposit—restricted	327	—	327	—
	<u>\$ 6,581</u>	<u>\$ 6,254</u>	<u>\$ 327</u>	<u>\$ —</u>

(in thousands)	Total fair value at December 31, 2011	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Money market	\$ 6,024	\$ 6,024	\$ —	\$ —
	<u>\$ 6,024</u>	<u>\$ 6,024</u>	<u>\$ —</u>	<u>\$ —</u>

In the first quarter of 2012, the Company invested \$0.2 million in a certificate of deposit, and, as a result, the Company's use of such cash is restricted. As a result, this investment is classified in other current assets on the condensed consolidated balance sheet. The remaining \$0.1 million in the line item "Certificate of deposits—restricted" represents a certificate of deposit that is collateral for a long-term lease.

At March 31, 2012, the Company had total cash and cash equivalents of \$73.3 million, which included approximately \$6.3 million of money market accounts and \$67.0 million of cash on-hand. At December 31, 2011, the Company had total cash and cash equivalents of \$40.6 million, which included approximately \$6.0 million of money market accounts and \$34.6 million of cash on-hand.

**Lantheus MI Intermediate, Inc. and subsidiaries**

**Notes to Unaudited Condensed Consolidated Statements (Continued)**

**3. Fair Value of Financial Instruments (Continued)**

The estimated fair values of the Company's financial instruments, including its cash and cash equivalents, receivables, accounts payable and accrued expenses approximate the carrying values of these instruments due to their short term nature. The estimated fair value of the debt at March 31, 2012, based on Level 2 inputs of recent market activity available to the Company, was \$359.5 million compared to the face value of \$400.0 million, and at December 31, 2011 the estimated fair value of the debt was \$320.0 million compared to the face value of \$400.0 million.

**4. Income Taxes**

The Company provides for income taxes at the end of each interim period based on the estimated effective tax rate for the full fiscal year in addition to discrete events which impact the interim period. The Company's effective tax rate differs from the U.S. statutory rate principally due to the rate impact of uncertain tax positions, recording of certain discrete tax items, valuation allowance changes and state taxes. For the three months ended March 31, 2012, the Company decreased its valuation allowance by \$(6.8) million relating to taxable income earned in the period. Cumulative adjustments to the tax provision are recorded in the interim period in which a change in the estimated annual effective rate is determined. The Company's tax provision was \$2.2 million for the three months ended March 31, 2012 on pre-tax income of \$23.1 million compared to \$5.2 million for the three months ended March 31, 2011 on pre-tax income of \$11.6 million.

The Company has a tax indemnification agreement with Bristol-Myers Squibb Company ("BMS") related to certain tax obligations arising prior to the acquisition of the Company, for which the Company has the primary legal obligation. The tax indemnification receivable is recognized within other long-term assets. The changes in the tax indemnification asset are recognized within other income, net in the statement of comprehensive income. In accordance with the Company's accounting policy, the change in the tax liability and penalties and interest associated with these obligations (net of any offsetting federal or state benefit) is recognized within the tax provision. Accordingly, as these reserves change, adjustments are included in the tax provision while the offsetting adjustment is included in other income. Effective December 31, 2011, the Company has a valuation allowance against all of its domestic net deferred tax assets. Assuming that the receivable from BMS continues to be considered recoverable by the Company, there is no net effect on earnings related to these liabilities and no net cash outflows.

**5. Inventory**

The Company includes within current assets the amount of inventory that is estimated to be utilized within twelve months. Inventory that will be utilized after twelve months is classified within other long-term assets.

**Lantheus MI Intermediate, Inc. and subsidiaries****Notes to Unaudited Condensed Consolidated Statements (Continued)****5. Inventory (Continued)**

Inventory, classified in inventory or other long-term assets, consisted of the following:

<u>(in thousands)</u>	<u>March 31,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
Raw materials	\$ 7,546	\$ 7,755
Work in process	608	2,615
Finished goods	3,971	4,395
Inventory	12,125	14,765
Other long-term assets	11,455	11,249
Total	<u>\$ 23,580</u>	<u>\$ 26,014</u>

At March 31, 2012, inventories reported as other long-term assets included \$11.2 million of raw materials and \$0.3 million of finished goods. At December 31, 2011, inventories reported as other long-term assets included \$10.7 million of raw materials and \$0.5 million of finished goods.

The Company's Ablavar product was commercially launched in January 2010 and the Company is continuing the process of educating radiologists on optimizing the use of the product within their patient populations. The revenues for this product through March 31, 2012 have not been significant. At March 31, 2012 and December 31, 2011, the balances of inventory on-hand reflected approximately \$12.6 million and \$12.2 million, respectively, of finished products, work-in-process and raw materials related to Ablavar. At March 31, 2012 and December 31, 2011, approximately \$11.5 million and \$11.2 million, respectively, of Ablavar inventory was included in long-term assets. LMI has an agreement with a supplier to provide Active Pharmaceutical Ingredient ("API") and finished products for Ablavar under which LMI is required to purchase future minimum quantities. At March 31, 2012, the remaining purchase commitment under the agreement was approximately \$11.1 million. The Company records the inventory when it takes delivery, at which time the Company assumes title and risk of loss.

**6. Property, Plant and Equipment, net**

Property, plant and equipment consisted of the following:

<u>(in thousands)</u>	<u>March 31,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
Land	\$ 22,450	\$ 22,450
Buildings	64,053	64,029
Machinery, equipment and fixtures	64,136	65,648
Construction in progress	4,658	4,383
Accumulated depreciation	(44,425)	(44,058)
Property, plant and equipment, net	<u>\$ 110,872</u>	<u>\$ 112,452</u>

For the three months ended March 31, 2012, depreciation expense related to property, plant and equipment was \$2.4 million compared to \$3.0 million for the three months ended March 31, 2011.

Included within property, plant and equipment are spare parts of approximately \$2.8 million as of both March 31, 2012 and December 31, 2011. Spare parts include replacement parts relating to plant

**Lantheus MI Intermediate, Inc. and subsidiaries****Notes to Unaudited Condensed Consolidated Statements (Continued)****6. Property, Plant and Equipment, net (Continued)**

and equipment and are either recognized as an expense when consumed or re-classified and capitalized as part of the related plant and equipment and depreciated over a time period not exceeding the useful life of the related asset. In addition, the Company had included \$0.4 million and \$1.6 million in accounts payable related to its property, plant and equipment at March 31, 2012 and December 31, 2011, respectively.

**7. Asset Retirement Obligations**

The Company considers the legal obligation to remediate its facilities upon a decommissioning of its radioactive related operations as an asset retirement obligation. The operations of the Company have radioactive production facilities at its North Billerica, Massachusetts and San Juan, Puerto Rico sites.

The fair value of a liability for asset retirement obligations is recognized in the period in which the liability is incurred. The liability is measured at the present value of the obligation when incurred and is adjusted in subsequent periods as accretion expense is recorded. The corresponding asset retirement costs are capitalized as part of the carrying value of the related long-lived assets and depreciated over the asset's useful life.

The following is a reconciliation of the Company's asset retirement obligations for the three months ended March 31, 2012:

<u>(in thousands)</u>	
Balance at January 1, 2012	\$ 4,868
Capitalization	—
Accretion expense	139
Balance at March 31, 2012	<u>\$ 5,007</u>

**8. Intangibles, net**

Intangibles, net consisted of the following:

<u>(in thousands)</u>	<u>March 31, 2012</u>				
	<u>Cost</u>	<u>Accumulated amortization</u>	<u>Net</u>	<u>Weighted Average Useful Life</u>	<u>Amortization Method</u>
Trademarks	\$ 53,390	\$ 15,520	\$ 37,870	8 years	Straight-line
Customer relationships	113,981	77,000	36,981	19 years	Accelerated
Other patents	42,780	38,784	3,996	2 years	Straight-line
	<u>\$ 210,151</u>	<u>\$ 131,304</u>	<u>\$ 78,847</u>		

## Lantheus MI Intermediate, Inc. and subsidiaries

## Notes to Unaudited Condensed Consolidated Statements (Continued)

## 8. Intangibles, net (Continued)

(in thousands)	December 31, 2011				
	Cost	Accumulated amortization	Net	Weighted Average Useful Life	Amortization Method
Trademarks	\$ 53,390	\$ 13,779	\$ 39,611	16 years	Straight-line
Customer relationships	113,480	74,575	38,905	19 years	Accelerated
Other patents	42,780	38,547	4,233	2 years	Straight-line
	<u>\$ 209,650</u>	<u>\$ 126,901</u>	<u>\$ 82,749</u>		

For the three months ended March 31, 2012, the Company recorded amortization expense for its intangible assets of \$4.1 million as compared to \$5.5 million for the prior year comparative period.

In the first quarter of 2012, the Company reviewed the estimated useful life of certain of its trademarks. As a result of utilizing the most recent forecasted data, the Company revised its estimate of the remaining useful life of one of its trademarks to five years. Expected future amortization expense related to the intangible assets is as follows:

(in thousands)	
Remainder of 2012	\$ 12,045
2013	14,470
2014	13,182
2015	11,505
2016	10,749
2017 and thereafter	16,896
	<u>\$ 78,847</u>

## 9. Accrued Expenses

Accrued expenses are comprised of the following:

(in thousands)	March 31, 2012	December 31, 2011
Compensation and benefits	\$ 5,128	\$ 5,501
Accrued interest	14,635	4,886
Accrued professional fees	1,964	1,927
Research and development services	2,907	2,100
Freight, distribution and operations	4,587	3,416
Marketing expense	922	1,104
Accrued rebates, discounts and chargebacks	1,450	1,356
Other	603	659
	<u>\$ 32,196</u>	<u>\$ 20,949</u>

**Lantheus MI Intermediate, Inc. and subsidiaries**

**Notes to Unaudited Condensed Consolidated Statements (Continued)**

**9. Accrued Expenses (Continued)**

As of March 31, 2012 and December 31, 2011, the Company had accrued a \$5.6 million loss associated with the portion of the committed purchases of Ablavar product that the Company did not believe it would sell prior to expiry, of which \$1.0 million was included in accrued expenses and \$4.6 million was included in other long-term liabilities.

On March 1, 2012, the Company took action to reduce its workforce in an effort to reduce costs and increase operating efficiency, which resulted in approximately \$0.5 million charge to the statement of comprehensive income during the three month period ended March 31, 2012. The remaining balance in accrued expenses at March 31, 2012 associated with this action was approximately \$0.4 million.

On June 30, 2011, the Company also implemented a reduction in workforce, which resulted in a \$1.6 million charge to the statement of comprehensive income during three month period ended June 30, 2011. The remaining balance in accrued expenses at December 31, 2011 associated with this action was approximately \$37,000.

**10. Financing Arrangements**

*Notes*

On March 21, 2011, LMI issued \$150.0 million of 9.750% Senior Notes due 2017. The new notes were issued at a price of 101.50% and were issued as additional debt securities under the Indenture pursuant to which LMI previously issued \$250.0 million in aggregate principal amount of 9.750% Senior Notes due 2017. The new notes and the existing 9.750% Senior Notes due 2017 (collectively, the "Notes") vote as one class under the Indenture. As a result, LMI has \$400.0 million in aggregate principal amount of Notes outstanding. The Notes bear interest at a rate of 9.750% per year, payable on May 15 and November 15 of each year, beginning May 15, 2011 with respect to the new notes. Interest on the new notes accrues from November 15, 2010. The Notes mature on May 15, 2017.

*Redemption*

LMI can redeem the Notes at 100% of the principal amount on May 15, 2016 or thereafter. LMI may also redeem the Notes prior to May 15, 2016 depending on the timing of the redemption during the twelve month period beginning May 15 of each of the years indicated below:

<u>Year</u>	<u>Percentage</u>
2014	104.875%
2015	102.438%
2016	100.000%

In addition, at any time prior to May 15, 2013, LMI may, at its option, redeem up to 35% of the aggregate principal amount of Notes issued at 109.750% of the principal amount thereof, plus accrued and unpaid interest, if any, to, but not including, the redemption date, subject to the right of holders of record on such date to receive any interest due, using proceeds of an equity offering, provided that at least 65% of the aggregate principal amount of the Notes remains outstanding immediately after such redemption and that such redemption occurs within 90 days of each equity offering (as defined in the Indenture).



**Lantheus MI Intermediate, Inc. and subsidiaries**

**Notes to Unaudited Condensed Consolidated Statements (Continued)**

**10. Financing Arrangements (Continued)**

At any time prior to May 15, 2014, LMI may also redeem all or a part of the Notes, with notice, at a redemption price equal to 100% of the principal amount thereof of the Notes redeemed plus the applicable premium (as defined in the Indenture) as of, and accrued and unpaid interest and additional interest (as defined in the Indenture), if any, to, but not including, the redemption date, subject to the rights of holders of record on the relevant record date to receive interest due on the relevant interest payment date.

Upon a change of control (as defined in the Indenture), LMI will be required to make an offer to purchase each holder's Note at a price of 101% of the principal amount thereof, plus accrued and unpaid interest, if any, to the date of purchase.

The Notes are unsecured and are equal in right of payment to all of the existing and future senior debt, including borrowings under its secured credit facilities, subject to the security interest thereof. LMI's obligations under the Notes are fully and unconditionally guaranteed, jointly and severally, on an unsecured senior basis by Lantheus Intermediate and by certain of LMI's subsidiaries, and the obligations of such guarantors under their guarantees are equal in right of payment to all of their existing and future senior debt.

*Revolving Line of Credit*

In connection with the issuance of the additional Notes on March 21, 2011, certain covenants and interest rates under LMI's existing \$42.5 million revolving facility (the "Facility") were modified as described below. The other terms of the Facility were unchanged, including LMI's ability to request the lenders to increase the Facility by an additional amount of up to \$15.0 million at the discretion of the Lenders. Interest on the Facility will be at either LIBOR plus 3.75% or the Reference Rate (as defined in the Facility) plus 2.75%. The Facility expires on May 10, 2014, at which time all outstanding borrowings are due and payable.

At March 31, 2012 and December 31, 2011, there was no outstanding balance under the Facility and the aggregate borrowing capacity was \$38.1 million and \$42.5 million, respectively. The availability under the Facility decreased in the quarter ended March 31, 2012 due to the Company entering in to an unfunded Standby Letter of Credit of \$4.4 million, which expires February 2, 2013. On April 11, 2012, this unfunded Standby Letter of Credit was increased to \$8.8 million.

*Covenants*

The Notes and the Facility contain affirmative and negative covenants, as well as restrictions on the ability of Lantheus Intermediate (in the case of the Facility), LMI and LMI's subsidiaries (in the case of the Notes and the Facility), to: (i) incur additional indebtedness or issue preferred stock; (ii) repay subordinated indebtedness prior to its stated maturity; (iii) pay dividends on, repurchase or make distributions in respect of its capital stock or make other restricted payments; (iv) make certain investments; (v) sell certain assets; (vi) create liens; (vii) consolidate, merge, sell or otherwise dispose of all or substantially all of the Company's assets; and (viii) enter into certain transactions with the Company's affiliates. The Notes contain customary events of default provisions, including payment default and cross-acceleration for non-payment of any outstanding indebtedness, where such indebtedness exceeds \$10.0 million. The Facility also contains customary default provisions and the Company is required to comply with financial covenants in the Facility including a total leverage ratio and interest coverage ratio, beginning with the quarter ended September 30, 2010, as well as limitations

**Lantheus MI Intermediate, Inc. and subsidiaries****Notes to Unaudited Condensed Consolidated Statements (Continued)****10. Financing Arrangements (Continued)**

on the amount of capital expenditures. The financial ratios are driven by the Company's earnings before interest, taxes, depreciation and amortization ("EBITDA") as defined in the Facility ("Facility EBITDA"). The total leverage ratio is considered by the Company to be the financial covenant that is currently the most restrictive. The financial covenants, as amended, are displayed in the table below:

**Revolving Credit Facility Financial Covenants**

<u>Period</u>	<u>Total Leverage Ratio</u>	<u>Interest Coverage Ratio</u>
Q1 2012	6.80 to 1.00	1.40 to 1.00
Q2 2012	7.55 to 1.00	1.30 to 1.00
Q3 2012	6.70 to 1.00	1.40 to 1.00
Q4 2012	5.50 to 1.00	1.80 to 1.00
Q1 2013	4.60 to 1.00	2.00 to 1.00
Q2 2013	4.60 to 1.00	2.10 to 1.00
Q3 2013	4.25 to 1.00	2.15 to 1.00
Q4 2013	4.25 to 1.00	2.15 to 1.00
Q1 2014	3.75 to 1.00	2.25 to 1.00
Thereafter	3.75 to 1.00	2.25 to 1.00

As of March 31, 2012 and the date hereof, other than the unfunded standby letter of credit in the amount of \$4.4 million (increased to \$8.8 million as of April 11, 2012), there were no amounts outstanding under the Facility.

*Financing Costs*

LMI incurred and capitalized approximately \$15.6 million in direct financing fees including \$5.2 million associated with the additional Notes issued in March 2011, consisting primarily of underwriting fees and expenses, consent solicitation fee, legal fees, accounting fees and printing costs in connection with the issuance of the Notes and the Facility. Deferred financing costs are being amortized over the life of the Notes and the Facility, as appropriate, using the effective interest method and are included in interest expense in the accompanying condensed consolidated statements of comprehensive income.

On January 26, 2012, LMI executed an amendment to the Facility which changed the financial covenant ratios as noted in the above table. LMI incurred approximately \$0.2 million in fees associated with this amendment, which is being amortized over the remaining life of the Facility using the straight-line method and is included in interest expense in the accompanying condensed consolidated statements of comprehensive income.

**11. Stock-Based Compensation**

The Company's employees are eligible to receive awards from Holdings' 2008 Equity Incentive Plan (the "2008 Plan"). The 2008 Plan is administered by the Holdings Board of Directors. The 2008 Plan permits the granting of nonqualified stock options, stock appreciation rights (or SARs), restricted stock and restricted stock units to employees, officers, directors and consultants of Holdings or any subsidiary of Holdings (including Intermediate and LMI). The maximum number of shares that may be issued pursuant to awards under the 2008 Plan at March 31, 2012 is 4,995,450. Option awards are granted with an exercise price equal to the fair value of Holdings' stock at the date of grant, as

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

11. Stock-Based Compensation (Continued)

determined by the Board of Directors of Holdings. Time based option awards vest based on time, either four or five years, and performance based option awards vest based on the performance criteria specified in the grant. All option awards have a ten year contractual term. The Company recognizes compensation costs for its time based awards on a straight-line basis equal to the vesting period. The compensation cost for performance based awards is recognized on a graded vesting basis, based on the probability of achieving the performance targets over the requisite service period for the entire award. The fair value of each option award is estimated on the date of grant using a Black-Scholes valuation model that uses the assumptions noted in the following table. Expected volatilities are based on the historic volatility of a selected peer group. Expected dividends represent the dividends expected to be issued at the date of grant. The expected term of options represents the period of time that options granted are expected to be outstanding. The risk-free interest rate assumption is the seven-year U.S. Treasury rate at the date of the grant which most closely resembles the expected life of the options.

The Company uses the following Black-Scholes inputs to determine the fair value of new stock option grants.

	Three Months Ended	
	March 31,	
	2012	2011
Expected volatility	41%	33%
Expected dividends	—	—
Expected term (in years)	6.5	6.5
Risk-free interest rate	1.4%	2.9%

A summary of option activity for 2012 is presented below:

	Time Based	Performance Based	Total	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2012	2,287,600	1,307,538	3,595,138	\$ 2.90	6.4	\$ 22,787,000
Options granted	7,500	7,500	15,000	9.28		
Options cancelled	9,000	5,790	14,790	2.00		
Options exercised	—	—	—	—		
Options forfeited or expired	15,450	11,650	27,100	6.08		
Outstanding at March 31, 2012	<u>2,270,650</u>	<u>1,297,598</u>	<u>3,568,248</u>	2.91	6.0	\$ 19,515,000
Vested and expected to vest at March 31, 2012	<u>2,258,277</u>	<u>940,547</u>	<u>3,198,824</u>	2.89	6.0	\$ 17,542,000
Exercisable at March 31, 2012	<u>1,749,600</u>	<u>832,547</u>	<u>2,582,147</u>	\$ 2.24	5.9	\$ 15,461,000

The weighted average grant-date fair value of options granted during the three months ended March 31, 2012 was \$3.99 as compared to \$4.01 for the three months ended March 31, 2011. There were 15,000 options granted during the three months ended March 31, 2012. There were no options exercised during the three months ended March 31, 2012 and 2011. During the three months ended March 31, 2012, 499,939 options vested, with an aggregate fair value of approximately \$0.8 million.

**Lantheus MI Intermediate, Inc. and subsidiaries****Notes to Unaudited Condensed Consolidated Statements (Continued)****11. Stock-Based Compensation (Continued)**

During the three months ended March 31, 2011, 266,258 options vested, with an aggregate fair value of approximately \$0.3 million. Stock-based compensation expense (credit) for both time based and performance based awards was recognized in the condensed consolidated statements of comprehensive income as follows:

<u>(in thousands)</u>	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
Cost of goods sold	\$ 17	\$ 16
General and administrative	471	128
Sales and marketing	47	(957)
Research and development	39	67
<b>Total stock-based compensation expense</b>	<b>\$ 574</b>	<b>\$ (746)</b>

Stock-based compensation expense recognized in the condensed consolidated statement of comprehensive income for the three months ended March 31, 2012 and 2011 was based on awards ultimately expected to vest as well as any changes in the probability of achieving certain performance features as required. In the first quarter of 2012, the Company recognized approximately \$0.4 million of stock-based compensation expense associated with the modification of two option agreements. The modifications of both awards affected the vesting ability of the awards, allowing vesting to continue beyond the last day of employment, so long as the option holder continues to provide service as a consultant to the Company.

The Company used the following Black-Scholes inputs to determine the fair value of stock options that were modified during the quarter ended March 31, 2012. There were no stock option modifications during the quarter ended March 31, 2011.

Expected volatility	30 - 36%
Expected dividends	—
Expected term (in years)	0.3 - 3.5
Risk-free interest rate	0.3 - 0.8%

As part of the 2008 Plan, the Company has the right to call options upon notice of exercise and to settle the exercise in cash in lieu of issuing shares. As a result of this right, upon termination of service, stock-based awards are reclassified to liability based awards until the period of probable exercise has lapsed. As of March 31, 2012, the Company had recorded a liability and stock-based compensation expense of approximately \$97,000 representing 13,343 options relating to stock-based liabilities that could be settled in part or in whole, in cash in the following period. The Company did not have any awards classified as liabilities as of March 30, 2011. There were no stock-based liability awards paid out in the first three months of 2012 or 2011. The Company recorded a benefit of approximately \$1.0 million in the three month period ended March 30, 2011 related to liability awards which expired during the period.

The Company did not recognize an income tax benefit for the three months ended March 31, 2012 or March 31, 2011 associated with option awards. As of March 31, 2012, there were approximately \$1.4 million of total unrecognized compensation costs related to non-vested stock options granted under the

**Lantheus MI Intermediate, Inc. and subsidiaries****Notes to Unaudited Condensed Consolidated Statements (Continued)****11. Stock-Based Compensation (Continued)**

2008 Plan. These costs are expected to be recognized over a weighted-average remaining period of 0.9 years. In addition, performance based awards contain certain contingent features, such as change in control provisions, which allow for the vesting of awards which did not previously meet performance criteria. As of March 31, 2012, there was approximately \$1.3 million of unrecognized compensation expense relating to these features, which could be recognized through 2018 or longer.

**12. Other Income, net**

Other income, net consisted of the following:

<u>(in thousands)</u>	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
Foreign currency (losses) gains	\$ (157)	\$ 89
Tax indemnification income	415	380
Other income	47	29
Total other income, net	<u>\$ 305</u>	<u>\$ 498</u>

**13. Legal Proceedings**

From time to time, the Company is a party to various legal proceedings arising in the ordinary course of business. In addition, the Company has in the past been, and may in the future be, subject to investigations by regulatory authorities which expose it to greater risks associated with litigation, regulatory or other proceedings, as a result of which the Company could be required to pay significant fines or penalties. The outcome of litigation, regulatory or other proceedings cannot be predicted with certainty and some lawsuits, claims, actions or proceedings may be disposed of unfavorably to the Company. In addition, intellectual property disputes often have a risk of injunctive relief which, if imposed against the Company, could materially and adversely affect its financial condition or results of operations.

On December 16, 2010, LMI filed suit against one of its insurance carriers seeking to recover business interruption losses associated with the NRU reactor shutdown and the ensuing global Moly supply challenge (*Lantheus Medical Imaging, Inc., Plaintiff v. Zurich American Insurance Company, Defendant*, United States District Court, Southern District of New York, Case No. 10 Civ 9371). The claim is the result of the shutdown of the NRU reactor in Chalk River, Ontario. The NRU reactor was off-line from May 2009 until August 2010 due to a "heavy water" leak in the reactor vessel. The defendant answered the complaint on January 21, 2011, denying substantially all of the allegations, presenting certain defenses and requesting dismissal of the case with costs and disbursements. On April 4, 2011, the parties had their first pre-trial conference in United States District Court for the Southern District of New York, and discovery has commenced and is continuing. Non-binding mediation of the case is currently scheduled to take place in the summer of 2012. The Company cannot be certain what amount, if any, or when, if ever, it will be able to recover for business interruption losses related to this matter.

**Lantheus MI Intermediate, Inc. and subsidiaries****Notes to Unaudited Condensed Consolidated Statements (Continued)****14. Segment Information**

The Company reports two operating segments, U.S. and International, based on geographic customer base. The results of these operating segments are regularly reviewed by the chief operating decision maker, the President and Chief Executive Officer. The Company's segments derive revenues through the manufacturing, marketing, selling and distribution of medical imaging products, focused primarily on cardiovascular diagnostic imaging. The U.S. segment comprised 73.8% and 76.3% of consolidated revenues for the three months ended March 31, 2012 and 2011, respectively, and 87.3% and 85.5% of consolidated assets at March 31, 2012 and December 31, 2011, respectively. All goodwill has been allocated to the U.S. operating segment.

Selected information for each business segment are as follows (in thousands):

	Three Months Ended March 31,	
	2012	2011
<b>Revenues</b>		
U.S.	\$ 68,338	\$ 80,625
International	22,371	23,243
Total revenue, including inter-segment	90,709	103,868
Less inter-segment revenue	(5,358)	(5,749)
	<u>\$ 85,351</u>	<u>\$ 98,119</u>
<b>Revenues from external customers</b>		
U.S.	\$ 62,980	\$ 74,876
International	22,371	23,243
	<u>\$ 85,351</u>	<u>\$ 98,119</u>
<b>Operating income</b>		
U.S.	\$ 27,872	\$ 13,055
International	4,998	3,607
Total operating income, including inter-segment income	32,870	16,662
Inter-segment operating income	306	1,374
	<u>\$ 33,176</u>	<u>\$ 18,036</u>
	March 31, 2012	December 31, 2011
<b>Assets</b>		
U.S.	\$ 342,667	\$ 306,615
International	49,722	52,189
	<u>\$ 392,389</u>	<u>\$ 358,804</u>

**Lantheus MI Intermediate, Inc. and subsidiaries****Notes to Unaudited Condensed Consolidated Statements (Continued)****14. Segment Information (Continued)**

	<u>March 31, 2012</u>	<u>December 31, 2011</u>
<b><i>Long-lived Assets</i></b>		
U.S.	\$ 192,292	\$ 197,565
International	16,347	16,932
	<u>\$ 208,639</u>	<u>\$ 214,497</u>

**15. Guarantor Financial Information**

The Notes are guaranteed by Lantheus Intermediate and Lantheus MI Real Estate, LLC, one of Lantheus Intermediate's consolidated subsidiaries (the "Guarantor Subsidiary"). The guarantees are full and unconditional and joint and several. The following supplemental financial information sets forth, on a condensed consolidating basis, balance sheet information as of March 31, 2012 and December 31, 2011, comprehensive (loss) income information for the three months ended March 31, 2012 and 2011 and cash flow information for the three months ended March 31, 2012 and 2011 for Lantheus Intermediate, LMI, the Guarantor Subsidiary and Lantheus Intermediate's other subsidiaries (the "Non-Guarantor Subsidiaries"). The supplemental financial information reflects the investments of Lantheus Intermediate in LMI and Lantheus Intermediate's investment in the Guarantor Subsidiary and Non-Guarantor Subsidiaries using the equity method of accounting.

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

15. Guarantor Financial Information (Continued)

Consolidating Balance Sheet Information

March 31, 2012

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
Assets:						
Cash and cash equivalents	\$ —	\$ 55,159	\$ —	\$ 18,176	\$ —	\$ 73,335
Accounts receivable, net	—	34,787	—	11,694	—	46,481
Intercompany accounts receivable	—	2,503	—	—	(2,503)	—
Inventory	—	9,325	—	2,800	—	12,125
Deferred tax assets	—	—	—	124	—	124
Other current assets	—	4,775	—	360	—	5,135
Total current assets	—	106,549	—	33,154	(2,503)	137,200
Property, plant and equipment, net	—	79,013	23,255	8,604	—	110,872
Capitalized software development costs	—	3,200	—	6	—	3,206
Goodwill	—	15,714	—	—	—	15,714
Intangibles, net	—	71,111	—	7,736	—	78,847
Deferred financing costs	—	12,808	—	—	—	12,808
Investment in subsidiaries	(110,962)	63,140	—	—	47,822	—
Due from parent	—	1,242	—	—	—	1,242
Other long-term assets	—	32,280	—	220	—	32,500
Total assets	\$ (110,962)	\$ 385,057	\$ 23,255	\$ 49,720	\$ 45,319	\$ 392,389
Liabilities and (deficit) equity:						
Note payable	\$ —	\$ 1,073	\$ —	\$ —	\$ —	\$ 1,073
Accounts payable	—	14,553	—	2,726	—	17,279
Intercompany accounts payable	—	—	—	2,503	(2,503)	—
Accrued expenses	—	29,322	—	2,874	—	32,196
Deferred revenue	—	5,614	—	210	—	5,824
Income tax payable	—	2,522	—	114	—	2,636
Total current liabilities	—	53,084	—	8,427	(2,503)	59,008
Asset retirement obligation	—	4,871	—	136	—	5,007
Long-term debt, net of current portion	—	398,678	—	—	—	398,678
Deferred tax liability	—	—	—	1,017	—	1,017
Other long-term liabilities	—	39,386	—	255	—	39,641
Total liabilities	—	496,019	—	9,835	(2,503)	503,351
(Deficit) equity	(110,962)	(110,962)	23,255	39,885	47,822	(110,962)
Total liabilities and (deficit) equity	\$ (110,962)	\$ 385,057	\$ 23,255	\$ 49,720	\$ 45,319	\$ 392,389



Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

15. Guarantor Financial Information (Continued)

Consolidating Balance Sheet Information

December 31, 2011

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
<b>Assets:</b>						
Current assets						
Cash and cash equivalents	\$ —	\$ 20,474	\$ —	\$ 20,133	\$ —	\$ 40,607
Accounts receivable, net	—	27,872	—	12,128	—	40,000
Intercompany accounts receivable	—	1,414	—	—	(1,414)	—
Inventory	—	12,269	—	2,496	—	14,765
Deferred tax assets	—	—	—	93	—	93
Other current assets	—	2,349	—	313	—	2,662
Total current assets	—	64,378	—	35,163	(1,414)	98,127
Property, plant and equipment, net	—	80,225	23,275	8,952	—	112,452
Capitalized software development costs	—	3,575	—	7	—	3,582
Intangibles, net	—	74,775	—	7,974	—	82,749
Goodwill	—	15,714	—	—	—	15,714
Deferred financing costs	—	13,141	—	—	—	13,141
Investment in subsidiaries	(133,203)	66,983	—	—	66,220	—
Due from parent	—	1,286	—	—	—	1,286
Other long-term assets	—	31,659	—	94	—	31,753
Total assets	<u>\$ (133,203)</u>	<u>\$ 351,736</u>	<u>\$ 23,275</u>	<u>\$ 52,190</u>	<u>\$ 64,806</u>	<u>\$ 358,804</u>
<b>Liabilities and (deficit) equity:</b>						
Current liabilities						
Accounts payable	\$ —	\$ 19,738	\$ —	\$ 2,272	\$ —	\$ 22,010
Intercompany accounts payable	—	—	—	1,414	(1,414)	—
Accrued expenses	—	17,780	—	3,169	—	20,949
Income tax payable	—	1,595	—	(113)	—	1,482
Deferred tax liability	—	—	—	—	—	—
Deferred revenue	—	3,712	—	206	—	3,918
Total current liabilities	—	42,825	—	6,948	(1,414)	48,359
Asset retirement obligations	—	4,737	—	131	—	4,868
Long-term debt, net	—	398,629	—	—	—	398,629
Deferred tax liability	—	—	—	931	—	931
Other long-term liabilities	—	38,748	—	472	—	39,220
Total liabilities	—	484,939	—	8,482	(1,414)	492,007
(Deficit) equity	(133,203)	(133,203)	23,275	43,708	66,220	(133,203)
Total liabilities and (deficit) equity	<u>\$ (133,203)</u>	<u>\$ 351,736</u>	<u>\$ 23,275</u>	<u>\$ 52,190</u>	<u>\$ 64,806</u>	<u>\$ 358,804</u>

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

15. Guarantor Financial Information (Continued)

Consolidating Statement of Comprehensive Income (Loss)

Three Months Ended March 31, 2012

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
Net product revenues	\$ —	\$ 71,049	\$ —	\$ 16,940	\$ (5,358)	\$ 82,631
License and other revenues	—	2,720	—	—	—	2,720
Total revenues	—	73,769	—	16,940	(5,358)	85,351
Cost of goods sold	—	42,960	—	14,933	(5,358)	52,535
Gross profit	—	30,809	—	2,007	—	32,816
Operating expenses						
General and administrative expenses	—	8,545	20	634	—	9,199
Sales and marketing expenses	—	9,013	—	980	—	9,993
Research and development expenses	—	10,319	—	43	—	10,362
Proceeds from manufacturer	—	(29,914)	—	—	—	(29,914)
Operating income (loss)	—	32,846	(20)	350	—	33,176
Interest expense, net	—	(10,447)	—	101	—	(10,346)
Other income, net	—	263	—	42	—	305
Equity in earnings (losses) of affiliates	20,898	220	—	—	(21,118)	—
Income (loss) before income taxes	20,898	22,882	(20)	493	(21,118)	23,135
Provision (benefit) for income taxes	—	1,984	(7)	260	—	2,237
Net income (loss)	20,898	20,898	(13)	233	(21,118)	20,898
Foreign currency translation, net of taxes	—	200	—	667	—	667
Total comprehensive (loss) income	\$ 20,898	\$ 21,098	\$ (13)	\$ 900	\$ (21,118)	\$ 21,765

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

15. Guarantor Financial Information (Continued)

Consolidating Statement of Comprehensive Income (Loss)

Three Months Ended March 31, 2011

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
Net product revenues	\$ —	\$ 81,696	\$ —	\$ 20,009	\$ (5,749)	\$ 95,956
License and other revenues	—	2,163	—	—	—	2,163
Total revenues	—	83,859	—	20,009	(5,749)	98,119
Cost of goods sold	—	41,066	—	16,734	(5,749)	52,051
Gross profit	—	42,793	—	3,275	—	46,068
Operating expenses						
General and administrative expenses	—	7,416	20	696	—	8,132
Sales and marketing expenses	—	8,338	—	1,057	—	9,395
Research and development expenses	—	10,393	—	112	—	10,505
Operating income (loss)	—	16,646	(20)	1,410	—	18,036
Interest expense, net	—	(7,006)	—	69	—	(6,937)
Other income, net	—	415	—	83	—	498
Equity in earnings (losses) of affiliates	6,347	1,283	—	—	(7,630)	—
Income (loss) before income taxes	6,347	11,338	(20)	1,562	(7,630)	11,597
Provision (benefit) for income taxes	—	(4,991)	7	(266)	—	(5,250)
Net income (loss)	6,347	6,347	(13)	1,296	(7,630)	6,347
Foreign currency translation, net of taxes	—	—	—	395	—	395
Total comprehensive (loss) income	\$ 6,347	\$ 6,347	\$ (13)	\$ 1,691	\$ (7,630)	\$ 6,742

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

15. Guarantor Financial Information (Continued)

Condensed Consolidating Cash Flow Information

Three Months Ended March 31, 2012

	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
<b>Cash provided by operating activities</b>	\$ —	\$ 32,846	\$ —	\$ 2,358	\$ —	\$ 35,204
<b>Cash flows from investing activities</b>						
Purchase of certificate of deposit	—	(225)	—	—	—	(225)
Capital expenditures	—	(2,004)	—	(40)	—	(2,044)
Proceeds from dividend	—	4,723	—	—	(4,723)	—
Cash provided by (used in) investing activities	—	2,494	—	(40)	(4,723)	(2,269)
<b>Cash flows from financing activities</b>						
Payments on note payable	—	(457)	—	—	—	(457)
Debt issuance costs	—	(198)	—	—	—	(198)
Payment of dividend	—	—	—	(4,723)	4,723	—
Cash provided by (used in) financing activities	—	(655)	—	(4,723)	4,723	(655)
Effect of foreign exchange rate on cash	—	—	—	448	—	448
Increase (decrease) in cash and cash equivalents	—	34,685	—	(1,957)	—	32,728
Cash and cash equivalents, beginning of period	—	20,474	—	20,133	—	40,607
Cash and cash equivalents, end of period	\$ —	\$ 55,159	\$ —	\$ 18,176	\$ —	\$ 73,335

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

15. Guarantor Financial Information (Continued)

Condensed Consolidating Cash Flow Information

Three Months Ended March 31, 2011

	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
<b>Cash provided by (used in) operating activities</b>	\$ 600	\$ 11,454	\$ —	\$ 2,787	\$ (600)	\$ 14,241
<b>Cash flows from investing activities</b>						
Capital expenditures	—	(3,987)	—	(32)	—	(4,019)
Proceeds from dividend	149,400	—	—	—	(149,400)	—
Cash provided by (used in) investing activities	149,400	(3,987)	—	(32)	(149,400)	(4,019)
<b>Cash flows from financing activities</b>						
Proceeds from issuance of debt	—	152,250	—	—	—	152,250
Consent solicitation fee	—	(3,750)	—	—	—	(3,750)
Debt issuance costs	—	(4,211)	—	—	—	(4,211)
Payment of dividend to parent	(150,000)	(150,000)	—	—	150,000	(150,000)
Cash provided by (used in) financing activities	(150,000)	(5,711)	—	—	150,000	(5,711)
Effect of foreign exchange rate on cash	—	—	—	447	—	447
Increase in cash and cash equivalents	—	1,756	—	3,202	—	4,958
Cash and cash equivalents, beginning of period	—	19,079	—	13,927	—	33,006
Cash and cash equivalents, end of period	\$ —	\$ 20,835	\$ —	\$ 17,129	\$ —	\$ 37,964

16. Subsequent Events

On April 11, 2012, LMI entered in to a revised unfunded Standby Letter of Credit, which increased the existing \$4.4 million to \$8.8 million and decreased the net borrowing capacity on the Facility to \$33.7 million.

On May 3, 2012, LMI entered into separate Manufacturing and Supply Agreements with JHS for the manufacture of Cardiolite and Neurolite, each with an initial five-year term with automatic renewals for additional one-year periods thereafter. Each agreement allows for termination upon the occurrence of specified events, including material breach or bankruptcy by either party. Each agreement requires LMI to place orders for a minimum percentage of its Cardiolite or Neurolite requirements during such term.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

### Cautionary Note Regarding Forward-Looking Statements

Some of the statements contained in this quarterly report are forward-looking statements. Such forward-looking statements are subject to risks and uncertainties, including, in particular, statements about our plans, strategies, prospects and industry estimates. These statements identify prospective information and include words such as "anticipates," "intends," "plans," "seeks," "believes," "estimates," "expects," "should," "predicts," "hopes" and similar expressions. Examples of forward-looking statements include, but are not limited to, statements we make regarding: (i) our liquidity, including our belief that our existing cash, cash equivalents and anticipated revenues are sufficient to fund our existing operating expenses, capital expenditures and liquidity requirements for at least the next twelve months; (ii) our outlook and expectations including, without limitation, in connection with continued market expansion and penetration for our commercial products, including DEFINITY, Ablavar and TechneLite; (iii) expected new product launch dates and market exclusivity periods; (iv) outlook and expectations related to supply challenges following the Ben Venue Laboratories, Inc., or BVL, shutdown; and (v) supply availability from new manufacturers. The foregoing is not an exclusive list of all forward-looking statements we make. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. The matters referred to in the forward-looking statements contained in this annual report may not in fact occur. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions and the following:

- our dependence upon third parties for the manufacture and supply of a substantial portion of our non-radioactive products, including our current dependence on BVL, as the sole source manufacturer for DEFINITY and NeuroLite and as our primary manufacturer for Cardiolite products;
- risks associated with BVL's manufacturing of our products and the regulatory requirements related thereto;
- risks associated with the technology transfer programs to secure production of our BVL-manufactured products from alternate contract manufacturer sites;
- our dependence on a limited number of third-party suppliers and the instability of global molybdenum-99 (or Moly) supply;
- a sustained decrease in TechneLite generator demand following the end of the global Moly shortage;
- our dependence on key customers, primarily Cardinal Health, Inc., or Cardinal, United Pharmacy Partners, Inc., or UPPI, and GE Healthcare, for our nuclear imaging products;
- our inability to compete effectively;
- ongoing generic competition to Cardiolite products;
- our dependence upon third-party healthcare payors and the uncertainty of third-party coverage and reimbursement rates;
- uncertainties regarding the impact of U.S. healthcare reform on our business, including related reimbursements of our products;

## [Table of Contents](#)

- our being subject to extensive government regulation and our potential inability to comply with such regulations;
- the extensive costs, time and uncertainty associated with new product development, including further product development in cooperation with a development partner or partners;
- liability associated with our marketing and sales practices;
- the occurrence of side effects with our products;
- our inability to introduce new products and adapt to an evolving technology and diagnostic landscape, such as the much slower than anticipated market acceptance of Ablavar;
- our exposure to product liability claims and environmental liability;
- our inability to protect our intellectual property and the risk of claims that we have infringed on the intellectual property of others;
- risks associated with the current economic environment, including the U.S. credit markets;
- risks associated with our international operations;
- our inability to adequately protect our technology infrastructure;
- our inability to hire or retain skilled employees and the loss of any of our key personnel;
- costs and other risks associated with the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010; and
- risks related to our outstanding indebtedness and our ability to satisfy such obligations, including in the event BVL is unable to provide us adequate product supply.

Factors that could cause or contribute to such differences include, but are not limited to, those that are discussed in other documents we file with the Securities and Exchange Commission, including our Annual Report on Form 10-K. Any forward-looking statement made by us in this quarterly report speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

*The following discussion and analysis of our financial condition and results of operations should be read together with the consolidated financial statements and the related notes included in Item 1 of this Quarterly Report on Form 10-Q as well as the other factors described in "Risk Factors" under Part II—Item 1A of this report and the information provided in our Annual Report on Form 10-K.*

### **Overview**

We are a global leader in developing, manufacturing and distributing innovative diagnostic medical imaging agents and products that assist clinicians in the diagnosis of cardiovascular diseases such as coronary artery disease, congestive heart failure and stroke, peripheral vascular disease and other diseases.

Our current marketed products are used by nuclear physicians, cardiologists, radiologists, internal medicine physicians, technologists and sonographers working in a variety of clinical settings. We sell our products to radiopharmacies, hospitals, clinics, group practices, integrated delivery networks, group purchasing organizations and, in certain circumstances, wholesalers. In addition to our marketed products, we have three products in clinical and pre-clinical development including our lead Phase 3 product, flurpiridaz F 18, a myocardial perfusion imaging agent, or MPI agent, 18F LMI1195, a cardiac neuronal imaging agent, and BMS 753951, for the identification of vascular plaque. We expect ongoing

[Table of Contents](#)

investment in our clinical programs and research and development to remain an important component of our business strategy.

We market our products globally and have operations in the United States, Puerto Rico, Canada and Australia and distribution relationships in Europe, Asia Pacific and Latin America.

#### *Our Products*

Our principal products include DEFINITY, an ultrasound contrast agent, Cardiolite, a myocardial perfusion imaging agent, and TechneLite, a generator used to provide the radioisotope to radiolabel Cardiolite and other radiopharmaceuticals. We launched DEFINITY in 2001 and it is currently patent protected in the United States until 2021 and in numerous foreign jurisdictions with protection until 2019. Cardiolite was approved by the FDA in 1990 and its market exclusivity expired in July 2008.

In the United States, our nuclear imaging products, including Cardiolite and TechneLite, are primarily distributed through over 350 radiopharmacies that are controlled by or associated with Cardinal, UPPI, Triad Isotopes, Inc., or Triad, and GE Healthcare. A small portion of our sales in the United States of nuclear imaging products are made through our direct sales force to hospitals and clinics that maintain their own in-house radiopharmaceutical capabilities. Sales of our contrast agents, including DEFINITY, are made through our direct sales force of approximately 85 people in the United States. Outside the United States, we own five radiopharmacies in Canada and two radiopharmacies in each of Puerto Rico and Australia. We also maintain a direct sales force in each of these countries. In the rest of the world, we rely on third-party distributors to market, distribute and sell our nuclear imaging and contrast agent products, either on a country-by-country basis or on a multi-country regional basis.

The following table sets forth our revenue derived from our principal products:

(dollars in thousands)	Three Months Ended March 31,			
	2012	%	2011	%
Cardiolite	\$ 8,991	11	\$ 22,707	23
TechneLite	31,372	37	35,944	37
DEFINITY	20,169	24	16,161	16
Other	24,819	28	23,307	24
Total revenues	<u>\$ 85,351</u>	<u>100</u>	<u>\$ 98,119</u>	<u>100</u>

#### **Key Factors Affecting Our Results**

Our business and financial performance have been, and continue to be, affected by the following:

##### ***Inventory Supply***

We currently rely on BVL for sole source manufacturing of DEFINITY and Neurolite. We also rely on BVL as our primary manufacturer of our Cardiolite product supply. In July 2010, BVL implemented a planned shutdown of the facility where it manufactures products for a number of customers, including us, in order to upgrade the facility to meet certain regulatory requirements. In anticipation of this shutdown, BVL manufactured for us additional inventory of these products to meet our expected needs during the shutdown period which was anticipated to end in March 2011. As the shutdown and re-inspection periods have been longer than anticipated by either BVL or ourselves, we could not meet all of the demand for certain products during the second half of 2011 and the first quarter of 2012, resulting in an overall revenue decline compared to the prior periods. We can give no assurance as to when BVL will be able to successfully manufacture and distribute products to us. The inventory of DEFINITY, Cardiolite and Neurolite previously supplied to us by BVL has now been



## [Table of Contents](#)

exhausted, which will negatively impact our second quarter financial results. We have expedited a number of technology transfer programs to secure and qualify production of our BVL-manufactured products to alternate contract manufacturing sites. Currently, we are utilizing an alternate manufacturer for Cardiolite and have entered into separate manufacturing and supply agreements with JHS for the manufacture of each of DEFINITY, Cardiolite and Neurolite. We are also pursuing new manufacturing relationships to establish and secure additional long-term or alternative suppliers of Cardiolite, Neurolite and DEFINITY, but we are uncertain of the timing as to when the new arrangements with JHS and any other supply arrangement would provide meaningful quantities of product to us. If BVL is not able to provide us adequate product supply for a further prolonged period of time and we are not able to obtain adequate amounts of such products from alternate suppliers (including DEFINITY, Cardiolite and Neurolite from JHS), our financial results will be negatively impacted and we will need to implement additional expense reduction such as further delays of discretionary spending and other operating and strategic initiatives such as entering into potential partnering arrangements.

### ***Global Moly Supply***

Historically, our largest supplier of Moly, our highest volume raw material, has been Nordion, which has relied on the NRU reactor in Chalk River, Ontario. This reactor was off-line from May 2009 until August 2010 due to a heavy water leak in the reactor vessel. As part of the conditions for the recent relicensing of the NRU reactor from 2011 to 2016, the Canadian government has asked Atomic Energy of Canada Limited, or AECL, to shut down the reactor for at least four weeks at least once a year for inspection and maintenance. The scheduled 2012 shutdown period is currently running from mid-April 2012 until mid-May 2012 and we believe that we will be able to source substantially all of our customer demand for Moly during this period from our other suppliers.

During the 2009-10 period when the NRU reactor was off-line, instability in the global supply of Moly and supply shortages resulted in substantial volatility in the cost of Moly in comparison to historical costs. We were able to pass some of these Moly cost increases on to our customers through our customer contracts. Additionally, the instability in the global supply of Moly during such period resulted in Moly producers requiring, in exchange for fixed Moly prices, supply minimums in the form of take-or-pay obligations. With less Moly, we manufactured fewer TechnoLite generators for radiopharmacies and hospitals to make up unit doses of Cardiolite, resulting in decreased sales of TechnoLite and Cardiolite in favor of other diagnostic modalities that did not use Moly during the 2009-10 period when the NRU reactor was off-line.

### ***Growth of DEFINITY***

We believe the market opportunity for our contrast agent, DEFINITY, remains quite significant. As we better educate the physician and healthcare provider community about the benefits and risks of this product, we believe we will experience further penetration of suboptimal echocardiograms. Sales of DEFINITY have continually increased quarter over quarter since June 2008, when we were able to modify the boxed warning on DEFINITY. Unit sales of DEFINITY had decreased substantially in late 2007 and early 2008 as a result of an FDA request in October 2007 that all manufacturers of ultrasound contrast agents add a boxed warning to their products to notify physicians and patients about potentially serious safety concerns or risks posed by the products. However, in May 2008, the boxed warning was modified by the FDA in response to the substantial advocacy efforts of prescribing physicians. Since then, DEFINITY sales have continually increased quarter over quarter. In October 2011, we received FDA approval of further modifications to the DEFINITY label, including: further relaxing the boxed warning; eliminating the sentence in the Indication and Use section "The safety and efficacy of DEFINITY with exercise stress or pharmacologic stress testing have not been established" (previously added in October 2007 in connection with the imposition of the box warning); and including summary data from the post-approval CaRES (Contrast echocardiography Registry for Safety

## [Table of Contents](#)

Surveillance) safety registry and the post-approval pulmonary hypertension study. DEFINITY is currently the only echocardiography contrast agent able to benefit from these label modifications. However, as discussed above under "Inventory Supply", until we resume obtaining adequate supply of DEFINITY, the continued growth of our DEFINITY sales will be negatively impacted by the BVL manufacturing shutdown and our current lack of DEFINITY inventory.

### ***Demand for TechnoLite***

Following the global Moly supply challenge in 2009-10, we have experienced reduced demand for TechnoLite generators from pre-shortage levels even though volume has increased in absolute terms from shortage levels following the return of our normal Moly supply in August 2010. Although, we do not know if Technetium demand will ever return to pre-shortage levels, we believe we will experience some increase in sales of TechnoLite generators.

We believe that TechnoLite unit volume has not returned to pre-shortage levels for a number of reasons, including: (i) changing staffing and utilization practices in radiopharmacies, which have resulted in increased efficiencies in the preparation of unit doses of Technetium-based radiopharmaceuticals; (ii) shifts to alternative diagnostic imaging modalities during the 2009-10 Moly supply shortage, which have not returned to Technetium-based procedures; and (iii) decreased amounts of Technetium being used in unit-doses of Technetium-based radiopharmaceuticals due to increased concerns about patient radiation dose exposure. We also believe that there has been an overall decline in the MPI study market because of decreased levels of patient studies during the Moly shortage period that have not returned to pre-shortage levels and industry-wide cost-containment initiatives that have resulted in a transition of where imaging procedures are performed from free standing imaging centers to the hospital setting. We expect these factors will continue to affect Technetium demand in the future.

### ***Cardiolite Competitive Pressures***

Cardiolite's market exclusivity expired in July 2008. In September 2008, the first of several competing generic products to Cardiolite was launched. With continued pricing pressure from generic competitors, we also sell our Cardiolite product in the form of a generic sestamibi while at the same time continuing to sell branded Cardiolite throughout the MPI segment. We believe this strategy of selling branded as well as generic sestamibi allows us to maintain total segment share by having multiple sestamibi offerings that are attractive in terms of brand, as well as price.

In addition to pricing pressure due to generics, our Cardiolite products have also faced a share decline in the MPI segment due to a change in professional society appropriateness guidelines, on-going reimbursement pressures, the limited availability of Moly during the NRU reactor shutdown, the limited availability of Cardiolite products to us during BVL outage, and the increase in use of other diagnostic modalities as a result of a shift to more available imaging agents and modalities. With the continued pressure of generic competition, we believe our share of the MPI segment decreased from approximately one-half to approximately one-third, prior to the BVL-related supply challenges. During 2011, we saw our share of the MPI segment decline further to just over one-quarter. We believe these decreases were mitigated by continued brand awareness, loyalty to the agent within the cardiology community and our strong relationships with our distribution partners.

### ***Increases in Research and Development Expenses***

To compete successfully in the marketplace, we must make substantial investments in new product development. As a result, research and development expenses are a key factor that has historically affected our results and will continue to do so in the future. We expect that research and development expenses will fluctuate depending primarily on the timing and outcomes of clinical trials, related

[Table of Contents](#)

manufacturing initiatives and the results of our decisions based on these outcomes. We expect to incur substantial additional expenses over the next several years for clinical trials related to our product development candidates, including flurpiridaz F 18, 18F LMI1195 and BMS 753951. We also expect manufacturing expenses for some programs included in research and development expenses to increase as we support our manufacturing infrastructure for later stages of clinical development.

**Results of Operations**

The following have impacted our results in the three months ended March 31, 2012:

- limited supply of Neurolite and Cardiolite product inventory as a result of the BVL shutdown, and a higher cost of goods sold for Cardiolite because of more expensive sourcing from our current back-up manufacturer of Cardiolite;
- DEFINITY's continued sales growth as a result of the product's relaunch in June 2008;
- continued generic competition to Cardiolite;
- limited Ablavar revenues to offset costs related to the launch and commercialization of the product;
- underabsorption of manufacturing overhead due to BVL outage;
- action taken on March 1, 2012 to reduce our workforce in an effort to reduce costs and increase operating efficiency; and
- Receipt of \$30.0 million from BVL to compensate us for business losses in exchange for a broad mutual waiver and release for all matters that occurred prior to March 20, 2012 and a covenant not to sue.

For the remainder of 2012, until we are able to obtain renewed supply of DEFINITY from BVL or obtain adequate supply from JHS, our results of operations will be negatively impacted with our DEFINITY inventory supply currently exhausted. We believe this will be partially mitigated following the return of a sustained DEFINITY supply and the expected continuation of DEFINITY sales growth.

[Table of Contents](#)

(dollars in thousands)	For the Three Months Ended March 31,	
	2012	2011
<b>Revenues</b>		
Net product revenues	\$ 82,631	\$ 95,956
License and other revenues	2,720	2,163
Total revenues	85,351	98,119
Cost of goods sold	52,535	52,051
Gross profit	32,816	46,068
<b>Operating expenses</b>		
General and administrative expenses	9,199	8,132
Sales and marketing expenses	9,993	9,395
Research and development expenses	10,362	10,505
Proceeds from manufacturer	(29,914)	—
Total operating expenses	(360)	28,032
Operating income	33,176	18,036
Interest expense	(10,447)	(7,007)
Interest income	101	70
Other income, net	305	498
Income before income taxes	23,135	11,597
Provision for income taxes	2,237	5,250
Net income	\$ 20,898	\$ 6,347

**Revenues**

Revenues are summarized as follows:

(dollars in thousands)	Three Months Ended	
	March 31,	
	2012	2011
<b>U.S.</b>		
Cardiolite	\$ 3,980	\$ 15,389
TechneLite	27,937	31,188
DEFINITY	19,765	15,881
Other currently marketed products	8,578	10,255
Total U.S. product revenues	60,260	72,713
License and other revenues	2,720	2,163
Total U.S. revenues	\$ 62,980	\$ 74,876
<b>International</b>		
Cardiolite	\$ 5,011	\$ 7,318
TechneLite	3,436	4,756
DEFINITY	404	280
Other currently marketed products	13,520	10,889
Total International product revenues	\$ 22,371	\$ 23,243
Product revenues	\$ 82,631	\$ 95,956
License and other revenues	2,720	2,163
Total revenues	\$ 85,351	\$ 98,119

Total revenues decreased \$12.8 million, or 13%, to \$85.4 million in the three months ended March 31, 2012 as compared to \$98.1 million in the three months ended March 31, 2011. U.S. segment revenue decreased \$11.9 million, or 16%, to \$63.0 million in the same period, as compared to \$74.9 million in the prior year. The decrease in revenue was primarily due to the BVL shutdown impacting our supply of Cardiolite and NeuroLite. See "Key Factors Affecting Our Results—Inventory Supply." TechneLite sales decreased in the current period as compared to the same period in the prior year given lower volume. Offsetting these decreases were increases of DEFINITY, due to an increase in the number of contrast studies performed, and Xenon, as a result of price increases.

The International segment revenues decreased \$0.9 million, or 4%, to \$22.4 million in the three months ended March 31, 2012 as compared to \$23.2 million in the three months ended March 31, 2011. The International segment was affected by our Cardiolite and NeuroLite product shortage resulting from the BVL shutdown in certain international markets and experienced lower sales of TechneLite in the first quarter of 2012 over the same period in 2011 due to lower volume. These decreases were partially offset by an increase in ligand revenue, an Active Pharmaceutical Ingredient ("API") for NeuroLite.

*Rebates, Discounts and Allowances*

Estimates for rebates, discounts and allowances represent our estimated obligations under contractual arrangements with third parties. Rebate accruals and allowances are recorded in the same period the related revenue is recognized, resulting in a reduction to product revenue and the establishment of a liability which is included in accrued expenses in the accompanying condensed consolidated balance sheets. These rebates result from performance-based offers that are primarily based on attaining contractually specified sales volumes and growth, Medicaid rebate programs for certain products, administration fees of group purchasing organizations and certain distributor related

[Table of Contents](#)

commissions. The calculation of the accrual for these rebates and allowances is based on an estimate of the third party's buying patterns and the resulting applicable contractual rebate or commission rate(s) to be earned over a contractual period.

Revenue reserves are categorized as rebates or allowances. An analysis of the amount of, and change in, reserves is summarized as follows:

<u>(dollars in thousands)</u>	<u>Rebates</u>	<u>Allowances</u>	<u>Total</u>
Balance, as of January 1, 2011	\$ 910	\$ 101	\$ 1,011
Current provisions relating to revenues in current year	3,672	474	4,146
Payments/credits relating to revenues in current year	(2,617)	(441)	(3,058)
Payments/credits and other adjustments relating to revenues in prior years	(609)	(101)	(710)
Balance, as of December 31, 2011	1,356	33	1,389
Current provisions relating to revenues in current year	898	79	977
Payments/credits relating to revenues in current year	(357)	(49)	(406)
Payments/credits and other adjustments relating to revenues in prior years	(447)	(35)	(482)
Balance, as of March 31, 2012	<u>\$ 1,450</u>	<u>\$ 28</u>	<u>\$ 1,478</u>

Sales rebates and other accruals were approximately \$1.5 million and \$1.4 million at March 31, 2012 and December 31, 2011, respectively. The increase in the accrual resulted principally from the full year impact in 2011 of the addition of contracts with rebate rights in the second half of 2010. In October 2010, we entered into a Medicaid Drug Rebate Agreement for certain of our products which did not have a material impact on our results of operations. If the demand for these products through the Medicaid program increases in the future, our rebates associated with this program could increase and could have a material impact on future results of operations.

### Costs of Goods Sold

Cost of goods sold consists of manufacturing, distribution, definite lived intangible asset amortization and other costs related to our commercial products. In addition, it includes the write off of excess and obsolete inventory.

Cost of goods sold is summarized as follows:

<u>(dollars in thousands)</u>	<u>Three Months Ended</u>	
	<u>March 31,</u>	
	<u>2012</u>	<u>2011</u>
United States	\$ 38,650	\$ 38,156
International	13,885	13,895
Total Cost of Goods Sold	<u>\$ 52,535</u>	<u>\$ 52,051</u>

Total cost of goods sold increased \$0.5 million, or 1%, to \$52.5 million in the three months ended March 31, 2012, as compared to \$52.1 million in the three months ended March 31, 2011. U.S. segment cost of goods sold increased \$0.5 million to \$38.7 million in the same period, as compared to \$38.1 million in the prior period. International segment cost of goods sold remained level at \$13.9 million for the reporting periods.

For the three months ended March 31, 2012 compared to the same period for 2011, the primary contributing factor to the increase in the U.S. segment was an increase in DEFINITY cost due to higher volumes and technology transfer costs. We also experienced an increase in Cardiolite cost due to

[Table of Contents](#)

higher material expense as we sourced material from an alternate higher cost manufacturer because of the BVL shutdown.

These increases were partially offset by a decrease in TechneLite cost driven by lower volumes. We also incurred lower intangible amortization expense.

**Gross Profit**

(dollars in thousands)	Three Months Ended March 31,	
	2012	2011
United States	\$ 24,330	\$ 36,720
International	8,486	9,348
<b>Total Gross Profit</b>	<b>\$ 32,816</b>	<b>\$ 46,068</b>

Total gross profit decreased \$13.3 million, or 29%, to \$32.8 million in the three months ended March 31, 2012, as compared to \$46.1 million in the three months ended March 31, 2011. U.S. segment gross profit decreased \$12.4 million, or 34%, to \$24.3 million in the same period, as compared to \$36.7 million in the prior period. International segment gross profit decreased \$0.9 million, or 9%, to \$8.5 million for the same period, as compared to \$9.3 million in the prior period.

Gross profit in the U.S. segment decreased due to lower profit from Cardiolite and Neurolite sales because of the supply issues resulting from the BVL shutdown and lower profit from TechneLite due to lower volume. In the case of Cardiolite, we incurred higher manufacturing costs due to the need to source higher cost material from our back-up supplier. In the case of Neurolite, we had no sales because finished product manufactured at BVL was unavailable. These decreases were partially offset by an increase in profit contributed by DEFINITY due to higher volume, higher profit from Xenon due to price increases and lower intangible amortization expense.

Gross profit in our International segment decreased \$0.9 million due to lower Cardiolite and Neurolite volumes related to the product shortage in certain markets and lower TechneLite volume. These decreases were partially offset by favorable foreign exchange rates. We also experienced higher profits from higher volumes of Neurolite ligand (which we sell internationally but not in the U.S. segment), which is unaffected by the BVL shutdown.

**General and Administrative**

(dollars in thousands)	Three Months Ended March 31,	
	2012	2011
United States	\$ 8,564	\$ 7,436
International	635	696
<b>Total General and Administrative</b>	<b>\$ 9,199</b>	<b>\$ 8,132</b>

General and administrative expenses consist of salaries and related costs for personnel in executive, finance, legal, information technology and human resource functions. Other costs in general and administrative include professional fees for information technology services, external legal fees, consulting and accounting services as well as bad debt expense, and certain facility and insurance costs, including director and officer liability insurance.

Total general and administrative expense increased \$1.1 million, or 13%, to \$9.2 million in the three months ended March 31, 2012 as compared to \$8.1 million in the three months ended March 31, 2011. U.S. segment general and administrative expense increased \$1.1 million, or 15%, to \$8.6 million in the same period, as compared to \$7.4 million in the prior year. The increase in expense was due to

[Table of Contents](#)

external legal fees in connection with our suit seeking to recover business interruption losses, modifications to stock option agreements, contractor support, and severance costs related to a reduction in workforce in the first quarter of 2012. Offsetting these increases was a decrease in variable compensation.

### Sales and Marketing

(dollars in thousands)	Three Months Ended March 31,	
	2012	2011
United States	\$ 8,908	\$ 8,143
International	1,085	1,252
Total Sales and Marketing	<u>\$ 9,993</u>	<u>\$ 9,395</u>

Sales and marketing expenses consist primarily of salaries and related costs for personnel in field sales, marketing, business development, and customer service functions. Other costs in sales and marketing expense include the development and printing of advertising and promotional material, professional services, market research, and sales meetings.

For the three months ended March 31, 2012 compared to the three months ended March 31, 2011, sales and marketing expense increased \$0.6 million, or 6%. In the U.S. segment, the increase related primarily to the reversal of stock-based compensation in the first quarter of 2011, offset by lower salary and other personnel cost related to a workforce reduction during the second quarter of 2011. In the International segment, sales and marketing expense decreased by \$0.2 million, or 13%, to \$1.1 million in the three months ended March 31, 2012 as compared to the three months ended March 31, 2011. The decrease was primarily due to a reduction in headcount, in addition to lower overall expense on sales and marketing activities.

### Research and Development

(dollars in thousands)	Three Months Ended March 31,	
	2012	2011
United States	\$ 10,320	\$ 10,393
International	42	112
Total Research and Development	<u>\$ 10,362</u>	<u>\$ 10,505</u>

Total research and development expense decreased \$0.1 million, or 1%, to \$10.4 million in the three months ended March 31, 2012 as compared to \$10.5 million in the three months ended March 31, 2011. U.S. segment research and development expense decreased \$0.1 million, or 1%, to \$10.3 million, as compared to \$10.4 million in the prior year. The decrease in research and development expense in the U.S. segment was primarily due to our reduction in workforce in the second quarter of 2011, offset by the timing of clinical activity related to our flurpiridaz F 18 program as we continued to actively enroll patients and activate sites for our Phase III trial. During the same period in 2011 we were primarily in the planning and preparation stage for our flurpiridaz F 18 Phase III trial. This increase of clinical activity in 2012 resulted in increased costs of external expenses related to Clinical Research Organization (CRO), investigator expense, drug products, lab supplies, and consultants.

In the International segment, research and development expense decreased \$0.1 million, or 63%, in the three months ended March 31, 2012 as compared to the three months ended March 31, 2011. The decrease was primarily due to our reduction in workforce in the second quarter of 2011.



[Table of Contents](#)

We anticipate that our research and development expenses for the balance of 2012 will primarily relate to the support of our flurpiridaz F-18 Phase III trial.

**Proceeds from Manufacturer**

For the three months ended March 31, 2012 compared to the same period in 2011, proceeds from manufacturer increased by \$29.9 million as a result of the receipt of the \$30.0 million from BVL to compensate us for business losses. During the first quarter of 2012, BVL and LMI terminated their original manufacturing agreement and entered into the Settlement Agreement, the Transition Services Agreement and the Manufacturing and Services Contract.

- In the Settlement Agreement, LMI and BVL agreed to a broad mutual waiver and release for all matters that occurred prior to the date of the Settlement Agreement, a covenant not to sue and a payment in the amount of \$30.0 million from BVL to compensate us for our business losses.
- Under the Transition Services Agreement, BVL agreed to manufacture for LMI an initial supply of DEFINITY, Cardiolite, Neurolite and certain TechnLite accessories, and agreed to make weekly payments to LMI, up to an aggregate of \$5.0 million as further compensation for business losses until an agreed-upon supply of LMI's products has been restored.
- Under the Manufacturing and Service Contract, BVL agreed to manufacture for LMI certain amounts of DEFINITY, Cardiolite, Neurolite and certain TechnLite accessories following the initial supply provided under the Transition Services Agreement. The agreement expires on December 31, 2013.

**Other Income (Expense), Net**

(dollars in thousands)	Three Months Ended	
	March 31,	
	2012	2011
Interest expense	\$ (10,447)	\$ (7,007)
Interest income	101	70
Other income, net	305	498
Total Other Expense, net	<u>\$ (10,041)</u>	<u>\$ (6,439)</u>

*Interest Expense*

For the three months ended March 31, 2012 compared to the same period in 2011, interest expense increased by \$3.4 million as a result of the issuance of the Notes in March 2011. See Note 10, "Financing Arrangements" to our unaudited condensed consolidated financial statements.

*Interest Income*

For the three months ended March 31, 2012 compared to the same period in 2011, interest income increased by \$31,000 as a result of an increase in cash in interest bearing accounts.

*Other Income, net*

For the three months ended March 31, 2012 compared to the same period in 2011, other income decreased by \$0.2 million primarily due to the change in foreign currency exchange rates.

**Provision for Income Taxes**

(dollars in thousands)	Three Months Ended	
	March 31,	
	2012	2011
Provision for income taxes	\$ 2,237	\$ 5,250

[Table of Contents](#)

For the three months ended March 31, 2012, compared to the same period in 2011, income tax expense decreased due primarily to the generation of higher pretax income which was offset by the releasing of a portion of our valuation allowance recorded at the end of 2011. Our full year effective tax rate for 2012 is estimated to be 5.04%. Our tax provision for the period ending March 31, 2012 consisted of \$1.2 million associated with current year earnings and \$1.0 million associated with discrete events relating primarily to uncertain tax positions and the settlement of certain tax audits.

**Liquidity and Capital Resources**

*Cash Flows*

The following table provides information regarding our cash flows:

(dollars in thousands)	Three Months Ended March 31,		
	2012	2011	\$ Change
Cash provided by (used in):			
Operating activities	\$ 35,204	\$ 14,241	\$ 20,963
Investing activities	\$ (2,269)	\$ (4,019)	\$ 1,750
Financing activities	\$ (655)	\$ (5,711)	\$ 5,056

*Net Cash from Operating Activities*

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. Cash provided by operating activities is primarily driven by our earnings and changes in working capital. The increase in cash provided by operating activities for the three months ended March 31, 2012 as compared to 2011 was primarily driven by the receipt of the \$30 million from BVL to compensate us for business losses from the BVL shutdown, less the impact of decreased unit sales associated with the BVL shutdown.

*Net Cash from Investing Activities*

Net cash used in investing activities in the three months ended March 31, 2012 and 2011 primarily reflected the purchase of property and equipment.

*Net Cash from Financing Activities*

Our primary historical uses of cash in financing activities are principal payments on our term loan and line of credit as well as dividends to Holdings, our parent. On March 21, 2011, we issued an additional \$150.0 million of Notes at 9.750% per annum.

*Internal Sources of Liquidity*

Our internal sources of liquidity are derived from cash and cash equivalents of \$73.3 million as of March 31, 2012, as well as revenues primarily from the sale of TechneLite, DEFINITY and Cardiolute.

*External Sources of Liquidity*

Since 2010, in addition to revenues provided by the sales of our products, our primary source of external liquidity has been the proceeds from the issuance of the \$400.0 million 9.750% Senior Notes due in May of 2017. In addition to the Notes, we have an outstanding \$42.5 million credit facility that bears interest at either LIBOR plus 3.75% or the Reference Rate (as defined in the agreement) plus 2.75%. The Facility expires on May 10, 2014, at which time all outstanding borrowings are due and payable.

## [Table of Contents](#)

As of March 31, 2012, we were in compliance with all applicable financial covenants. As of March 31, 2012 and the date hereof, there were no amounts outstanding under the Facility (other than a \$4.4 million unfunded standby letter of credit) and the aggregate borrowing capacity was \$38.1 million. The availability under the Facility decreased in the quarter ended March 31, 2012 due to the Company entering into an unfunded Standby Letter of Credit of \$4.4 million to support a surety bond related to a statutory decommissioning obligation we have in connection with our Billerica facility. On April 11, 2012, this unfunded Standby Letter of Credit was increased to \$8.8 million, which expires on February 2, 2013.

If BVL is not able to provide us adequate supply of DEFINITY, Cardiolite and Neurolite for a further prolonged period of time and we are not able to obtain adequate supply of such products from alternative suppliers, we will need to implement certain expense reductions such as a delay of discretionary spending and other operating and strategic initiatives. Despite these initiatives, because our prior inventory of DEFINITY, Cardiolite and Neurolite from BVL is exhausted, our second quarter 2012 results will be negatively impacted and we could be in default with one or more of the financial ratio covenants in the Facility at some point during the life of the Facility. If this were to occur, we would seek either an additional amendment to the Facility or a waiver or consent in connection with the appropriate financial covenants to eliminate such potential default. There can be no assurance that we would be able to obtain an amendment, waiver or consent from our lenders. Any financial covenant default under the Facility will not result in a cross-default under the Indenture that governs the Notes unless the amount outstanding under the Facility is greater than \$10 million and the lenders accelerate the repayment of such debt. Currently there is \$8.8 million outstanding under the Facility in the form of issued but undrawn letters of credit. Consequently, based on amounts outstanding as of the date of this report, a financial ratio covenant default under the Facility would only impact our ability to borrow under the Facility and, as a result of our available cash on hand, we believe there would be no need to borrow under the Facility for at least the next 12 months.

We may from time to time repurchase or otherwise retire our debt and take other steps to reduce our debt or otherwise improve our balance sheet. These actions may include open market repurchases of any notes outstanding, prepayments of our term loans or other retirements or refinancing of outstanding debt. The amount of debt that may be repurchased or otherwise retired, if any, would be decided upon at the sole discretion of our Board of Directors and will depend on market conditions, trading levels of our debt from time to time, our cash position and other considerations.

### *Funding Requirements*

Our future capital requirements will depend on many factors, including:

- the effect of the BVL shutdown and our ability to have product manufactured at alternative manufacturing sites;
- the level of product sales of our currently marketed products and any additional products that we may market in the future;
- the scope, progress, results and costs of development activities for our current product candidates and whether we obtain one or more partners to help share such development costs;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, additional product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution and whether we obtain one or more partners to help share such commercialization costs;
- the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates and products;

[Table of Contents](#)

- the extent to which we acquire or invest in products, businesses and technologies;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products and product candidates;
- the legal costs relating to maintaining, expanding and enforcing our intellectual property portfolio, pursuing insurance or other claims and defending against product liability, regulatory compliance or other claims; and
- the cost of interest on any additional borrowings which we may incur under our financing arrangements.

If our capital resources become insufficient to meet our future capital requirements, we would need to finance our cash needs through public or private equity offerings, debt financings, sale/leasebacks or other financing or strategic alternatives, to the extent such transactions are permissible under the covenants of the Facility and the Indenture. Additional equity or debt financing, or other transactions, may not be available on acceptable terms, if at all. If any of these transactions require an amendment or waiver under the covenants in the Facility and under the Indenture, which could result in additional expenses associated with obtaining the amendment or waiver, we will seek to obtain such a waiver to remain in compliance with the covenants of the Facility and the Indenture. However, we cannot be assured that such an amendment or waiver would be granted, or that additional capital will be available on acceptable terms, if at all.

Our only current committed external source of funds is borrowing availability under the Facility. Based on our current operating plans, we believe that our existing cash and cash equivalents and results of operations will be sufficient to continue to fund our liquidity requirements for at least the next twelve months. As of March 31, 2012, we had \$73.3 million of cash and cash equivalents.

### Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, certain suppliers, contingent royalty payments and/or scientific, regulatory, or commercial milestone payments under development agreements. The following table summarizes our contractual obligations as of March 31, 2012:

	Payments Due by Period				
	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
	(dollars in thousands)				
Debt obligations (principal)	\$ 401,073	\$ 1,073	\$ —	\$ —	\$ 400,000
Interest on debt obligations	214,513	39,013	78,000	78,000	19,500
Operating leases(1)	4,079	957	1,691	715	716
Purchase obligations(2)	99,849	55,688	44,161	—	—
Asset retirement obligation	5,007	—	—	—	5,007
Other long-term liabilities(3)	34,730	—	—	—	34,730
<b>Total contractual obligations</b>	<b>\$ 759,251</b>	<b>\$ 96,731</b>	<b>\$ 123,852</b>	<b>\$ 78,715</b>	<b>\$ 459,953</b>

- (1) Operating leases include minimum payments under leases for our facilities and certain equipment.
- (2) Purchase obligations include fixed or minimum payments under manufacturing and service agreements with Covidien (for Ablavar supply) and other third-parties.

[Table of Contents](#)

- (3) Due to the uncertainty related to the timing of the reversal of uncertain tax positions, the liability is not subject to fixed payment terms and the amount and timing of payments, if any, which we will make related to this liability, are not known.

**Critical Accounting Estimates**

The discussion and analysis of our financial position and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements in accordance with U.S. GAAP requires us to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition and related allowances, inventory, impairments of long-lived assets including intangible assets, impairments of goodwill, income taxes including the valuation allowance for deferred tax assets, valuation of investments, research and development expenses, contingencies and litigation, and share-based payments. For the quarter ended March 31, 2012, our critical estimates included estimates related to what we believe to be our portion of the fee payable to the Federal Government by Pharmaceutical Manufacturers pursuant to ASU 2010-027. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

Please read Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2011 for a discussion of our critical accounting estimates. There have been no material changes to our critical accounting policies in the three months ended March 31, 2012.

**Off-Balance Sheet Arrangements**

Since inception, we have not engaged in any off-balance sheet arrangements, including structured finance, special purpose entities or variable interest entities.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risk from changes in interest rates and foreign currency exchange rates. We do not hold or issue financial instruments to reduce these risks or for trading purposes.

**Interest Rate Risk**

We are subject to interest rate risk in connection with the Facility, which is variable rate indebtedness. Interest rate changes could increase the amount of our interest payments and thus negatively impact our future earnings and cash flows. As of March 31, 2012, there was no amount outstanding under the Facility (other than a \$4.4 million unfunded standby letter of credit which reduces availability to \$38.1 million and increased to \$8.8 million as of April 11, 2012 which further reduced current availability to \$33.7 million). Any increase in the interest rate under the Facility may have a negative impact on our future earnings.

**Foreign Currency Risk**

We face exposure to movements in foreign currency exchange rates whenever we, or any of our subsidiaries, enter into transactions with third parties that are denominated in currencies other than our, or its, functional currency. Intercompany transactions between entities that use different functional currencies also expose us to foreign currency risk. During the three months ended March 31, 2012 and 2011, the net impact of foreign currency changes on transactions was a loss of \$0.2 million and a gain

[Table of Contents](#)

of \$89,000, respectively. Historically, we have not used derivative financial instruments or other financial instruments to hedge such economic exposures.

Gross margins of products we manufacture at our U.S. plants and sell in currencies other than the U.S. Dollar are also affected by foreign currency exchange rate movements. Our gross margin on total revenue for each of the three month periods ended March 31, 2012 and 2011 was 38.4% and 47.0%, respectively. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during the three months ended March 31, 2012, we estimate our gross margin on total sales would have been 38.5%, 38.7% and 38.9%, respectively. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during the three months ended March 31, 2011, we estimate our gross margin on total net product sales would have been 47.0%, 47.2% and 47.5%, respectively.

In addition, a portion of our earnings is generated by our foreign subsidiaries, whose functional currencies are other than the U.S. Dollar (in which we report our consolidated financial results); our earnings could be materially impacted by movements in foreign currency exchange rates upon the translation of the earnings of such subsidiaries into the U.S. Dollar.

If the U.S. Dollar had been uniformly stronger by 1%, 5% or 10%, compared to the actual average exchange rates used to translate the financial results of our foreign subsidiaries, our net product sales and net income for the three months ended March 31, 2012 would have been impacted by approximately the following amounts:

	<u>Approximate Decrease in Net Revenue</u>	<u>Approximate Increase in Net Income</u>
	(dollars in thousands)	
1%	\$ (133)	\$ —
5%	(665)	1
10%	(1,329)	3

If the U.S. Dollar had been uniformly stronger by 1%, 5% or 10%, compared to the actual average exchange rates used to translate the financial results of our foreign subsidiaries, our net product sales and net income for the three months ended March 31, 2011 would have been impacted by approximately the following amounts:

	<u>Approximate Decrease in Net Revenue</u>	<u>Approximate Decrease in Net Income</u>
	(dollars in thousands)	
1%	\$ (166)	\$ (9)
5%	(832)	(47)
10%	(1,663)	(94)

#### Item 4. Controls and Procedures

##### Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) or 15d-15(e) promulgated under the Exchange Act. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report.

**Changes in Internal Control Over Financial Reporting**

There have been no changes during the quarter ended March 31, 2012 in our internal control over financial reporting (as defined in Rule 13a-15(f) promulgated under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

From time to time, we are a party to various legal proceedings arising in the ordinary course of business. In addition, we have in the past been, and may in the future be, subject to investigations by regulatory authorities which expose it to greater risks associated with litigation, regulatory or other proceedings, as a result of which we could be required to pay significant fines or penalties. The outcome of litigation, regulatory or other proceedings cannot be predicted with certainty and some lawsuits, claims, actions or proceedings may be disposed of unfavorably to us. In addition, intellectual property disputes often have a risk of injunctive relief which, if imposed against us, could materially and adversely affect its financial condition or results of operations.

On December 16, 2010, we filed suit against one of our insurance carriers seeking to recover business interruption losses associated with the NRU reactor shutdown and the ensuing global Moly supply challenge (*Lantheus Medical Imaging, Inc., Plaintiff v. Zurich American Insurance Company, Defendant*, United States District Court, Southern District of New York, Case No. 10 Civ 9371). The claim is the result of the shutdown of the NRU reactor in Chalk River, Ontario. The NRU reactor was off-line from May 2009 until August 2010 due to a "heavy water" leak in the reactor vessel. The defendant answered the complaint on January 21, 2011, denying substantially all of the allegations, presenting certain defenses and requesting dismissal of the case with costs and disbursements. On April 4, 2011, the parties had their first pre-trial conference in United States District Court for the Southern District of New York, and discovery has commenced and is continuing. Non-binding mediation of the case is currently scheduled to take place in the summer of 2012. We cannot be certain what amount, if any, or when, if ever, we will be able to recover for business interruption losses related to this matter.

Except as noted above, as of March 31, 2012, we had no material ongoing litigation, regulatory or other proceeding and had no knowledge of any investigations by governmental or regulatory authorities in which we are a target that could have a material adverse effect on our current business.

### Item 1A. Risk Factors

There have been no changes in the risk factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011. For further information, refer to Part I—Item IA. "Risk Factors," in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.



**Item 6. Exhibits**

- 10.1<sup>†</sup> 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<sup>†</sup> 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<sup>†</sup> 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<sup>†</sup> 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<sup>†</sup> Transition Services Agreement, effective as of March 20, 2012, by and between Ben Venue Laboratories, Inc. and Lantheus Medical Imaging, Inc.
- 10.6<sup>†</sup> 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.
- 101.INS\* XBRL Instance Document
- 101.SCH\* XBRL Taxonomy Extension Schema Document
- 101.CAL\* XBRL Taxonomy Calculation Linkbase Document
- 101.LAB\* XBRL Taxonomy Extension Labels Linkbase Document
- 101.PRE\* XBRL Taxonomy Extension Presentation Linkbase Document
- 101.DEF\* XBRL Taxonomy Extension Definition Linkbase Document

\* Furnished herewith.

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

**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

---

Name: Donald R. Kiepert  
Title: *President and Chief Executive Officer*  
Date: May 15, 2012

LANTHEUS MEDICAL IMAGING, INC.

By: /s/ JEFFREY E. YOUNG

---

Name: Jeffrey E. Young  
Title: *Chief Financial Officer*  
Date: May 15, 2012

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
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.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Calculation Linkbase Document
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document

\* Furnished herewith.

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



**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.**

## SECOND AMENDMENT TO DISTRIBUTION AGREEMENT

This Second Amendment to Distribution Agreement (this "Amendment") is made by and between Lantheus Medical Imaging, Inc., formerly known as Bristol-Myers Squibb Medical Imaging, Inc. ("LMI"), and Medi-Physics, Inc., doing business as G.E. Healthcare Inc. ("G.E. Healthcare") (referred to individually as "Party" and collectively as "Parties"), and shall be effective as of January 1, 2012.

## WITNESSETH:

WHEREAS, LMI and G.E. Healthcare are Parties to that certain Distribution Agreement dated as of October 31, 2001, as amended by the First Amendment to Distribution Agreement effective as of January 1, 2005 (as amended, the "Agreement");

WHEREAS, the Parties desire to amend the Agreement all in accordance with, and subject to the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained herein, the Parties agree as follows:

1. **Defined Terms.** Capitalized terms used, but not defined, herein shall have the meanings ascribed to them in the Agreement. All references to "NA" in the Agreement shall be read to mean "G.E. Healthcare." All references to BMS in the Agreement shall be read to mean "Lantheus Medical Imaging, Inc. ("LMI")."

2. **Amendments.** Subject to the terms and conditions of this Amendment, the Agreement is hereby amended as follows:

(a) **Article 1.** Article 1, **Appointment as Distributor**, is hereby deleted in its entirety with the following substituted therefor:

*ARTICLE 1. Appointment as Distributor*

*LMI hereby grants to G.E. Healthcare, under the terms and conditions of this Agreement, the non-exclusive right to market, distribute and sell the terminally sterilized Technetium (Tc-99m) generators (brand name "TechneLite®"), Gallium Citrate Ga-67 Injection and Xe-133 gas products and accessory products hereinafter identified on Exhibit A attached hereto ("Products") in the \*\*\*\*\* to the list of unaffiliated customers currently being supplied by G.E. Healthcare, a copy of which has been provided to*

---

*LMI and which may be modified from time to time by mutual consent of the Parties. In addition, LMI agrees to supply to G.E. Healthcare Radiopharmacies in the Territory, solely for unit dose preparation in the Territory, the TechneLite®, Ga-67 and Xe-133 Products listed on Exhibit A. G.E. Healthcare Radiopharmacies in the Territory are defined as those free-standing radiopharmacies in which G.E. Healthcare has at least a \*\*\*\* percent (\*\*\*\*%) ownership interest. Hereinafter, the term "Territory" shall refer to both \*\*\*\* and \*\*\*\*, including all \*\*\*\* and \*\*\*\*, and specifically excluding \*\*\*\*.*

(b) Section 2.1. Section 2.1(a) and (b) are hereby deleted in their entirety with the following substituted therefor:

*2.1 G.E. Healthcare guarantees, subject to LMI's ability to supply, a minimum purchase requirement of Products as set forth in this Section 2.1. LMI agrees to use commercially reasonable efforts to manufacture and sell to G.E. Healthcare, and G.E. Healthcare agrees to purchase from LMI, the following requirements (collectively, the "Minimum Purchase Requirements"):*

*(a) \*\*\*\* percent (\*\*\*\*%) of G.E. Healthcare's requirements for Gallium Citrate Ga-67 Injection and Xe-133 gas Products from the Effective Date through \*\*\*\*;*

*\*\*\*\*; (b) \*\*\*\* percent (\*\*\*\*%) of G.E. Healthcare's requirements for TechneLite® Products from the Effective Date through*

*\*\*\*\*; (c) \*\*\*\* percent (\*\*\*\*%) of G.E. Healthcare's requirements for TechneLite® Products during the period from \*\*\*\* through*

*\*\*\*\*; and (d) \*\*\*\* percent (\*\*\*\*%) of G.E. Healthcare's requirements for TechneLite® Products from the period of \*\*\*\* through*

*\*\*\*\*. (e) \*\*\*\* percent (\*\*\*\*%) of G.E. Healthcare's requirements for TechneLite® Products during the period from \*\*\*\* through*

*Compliance with the Minimum Purchase Requirements set forth in this Section 2.1 will be determined as of \*\*\*\* and as of the end of each \*\*\*\* thereafter (as evidenced by reasonable documentation made available to LMI or its representatives). Not later than five (5) days after the end of each \*\*\*\*, G.E. Healthcare shall provide to LMI a timely and accurate report that sets forth G.E. Healthcare's total requirements for each Product and certifies that G.E. Healthcare has complied or failed to comply with its obligation to purchase the Minimum Purchase Requirements for such period. In any \*\*\*\* in which G.E. Healthcare does not purchase at least the applicable Minimum Purchase Requirements*

from LMI, G.E. Healthcare shall promptly pay to LMI the Shortfall Payment (as hereinafter defined). For purposes of calculating such payments, G.E. Healthcare will make a good faith estimate of the Product orders for the final \*\*\*\* (\*\*\*\*) weeks of each \*\*\*\* and will use commercially reasonable efforts to place purchase orders for such additional amounts or make any necessary payments prior to the end of such \*\*\*\*. By the end of the \*\*\*\* week of the month immediately succeeding such \*\*\*\*, G.E. Healthcare shall make any necessary true-up payments to comply with the requirements of this Section 2.1.

“Shortfall Payment” shall mean the \*\*\*\* payment for any portion of the Minimum Purchase Requirements not purchased by G.E. Healthcare from LMI during such \*\*\*\* (subject to LMI’s ability to supply). Such payments will be calculated using the shortfall in the Minimum Purchase Requirements for such \*\*\*\* (i.e., the remaining portion of the applicable Minimum Purchase Requirements for which purchase orders were not received) multiplied by the price of the applicable Products hereunder (based on the average per curie price for such Products during the period).

For purposes of clarity, the Parties acknowledge and agree that the Minimum Purchase Requirements set forth herein shall include all of G.E. Healthcare’s requirements for similar products. For example, the Minimum Purchase Requirements for TechnneLite® Products shall include all of G.E. Healthcare’s requirements for Technetium-99m products.

(c) Section 2.6. Section 2.6 is hereby deleted in its entirety with the following substituted therefor:

2.6 LMI shall use commercially reasonable efforts to ship Products pursuant to G.E. Healthcare’s Firm Orders. Tc-99m generators shall be made available for shipment \*\*\*\* each day of manufacture. Days of manufacture of Tc-99m generators are currently \*\*\*\* and \*\*\*\*. Xe-133 gas products shall be made available for shipment \*\*\*\* each \*\*\*\* calibrated for the following \*\*\*\*. Gallium Citrate Ga-67 Injection products shall be made available \*\*\*\*, calibrated for the following \*\*\*\*. LMI will provide G.E. Healthcare with \*\*\*\* (\*\*\*\*) days prior notice of any LMI initiated, permanent changes in the manufacturing schedule for the Products, provided, however, that LMI will make a \*\*\*\* that, based on G.E. Healthcare’s standing orders at the time of any such change, are adversely affected by the new manufacturing schedule. Any \*\*\*\* to G.E. Healthcare that can reasonably be linked to the LMI manufacturing schedule change will be reimbursed by LMI to G.E. Healthcare via a corresponding \*\*\*\*. For purposes of the foregoing, G.E. Healthcare’s \*\*\*\* will be measured by the \*\*\*\* that LMI is required to provide G.E. Healthcare on \*\*\*\* as a direct result of the change to the manufacturing

*schedule (e.g., \*\*\*\*). In the event LMI is unable to deliver all product requirements on a given day, LMI will make a fair allocation of the available Product, such fair allocation to be determined by LMI in its sole discretion acting reasonably after due consideration of \*\*\*\*, other percentage supply requirements, and the available amount of Product for LMI's customers, including G.E. Healthcare, affected by such supply disruption. In the event that delivery of a Product is delayed more than \*\*\*\* hours past the agreed upon local delivery time, LMI will reduce the price G.E. Healthcare pays for such Product up to \*\*\*\*%. However, after \*\*\*\* (\*\*\*\*) hours delay, G.E. Healthcare shall not be required to accept such Product and may make arrangements with LMI to return unopened Product for \*\*\*\* credit. The foregoing shall not apply to delays caused by force majeure events such as weather conditions, effecting transportation of components or Products, for which there will be no price reduction. Following the \*\*\*\* hour period outlined above, in the event that G.E. Healthcare is required to find an alternate source of Product, LMI shall pay the difference between LMI's price under this Agreement and the price G.E. Healthcare is required to pay to obtain such Product, up to a limit of \*\*\*\*% of LMI's then current price, provided that such obligation shall only apply if G.E. Healthcare has purchased all of its Minimum Purchase Requirements hereunder and G.E. Healthcare has used its reasonable best efforts to avoid or mitigate any such payments.*

(d) Section 2.9. Section 2.9 is hereby deleted in its entirety with the following substituted therefor:

*2.9 All payments for Products ordered by G.E. Healthcare prior to \*\*\*\* shall be made within \*\*\*\* (\*\*\*\*) days after receipt of invoice. All payment for Products ordered by G.E. Healthcare from and after \*\*\*\* during the term of this Agreement shall be made within \*\*\*\* (\*\*\*\*) days after receipt of invoice.*

(e) Section 3.6. Section 3.6 is hereby deleted in its entirety.



(f) Section 6.6. The second paragraph of Section 6.6 is hereby deleted in its entirety with the following substituted therefor:

*Any communications to LMI under the terms of this Section 6.6 shall be directed to the attention of the following agent for global pharmacovigilance or to LMI's designee or successor:*

**United States**  
**Phone:** 1-800-343-7851

**Outside US/Canada**  
**Phone:** 978-667-9531

- Press Option 2 for Adverse Events or Special Situations
- Press Option 3 for Product Quality Complaints

- Press Option 2 for Adverse Events or Special Situations
- Press Option 3 for Product Quality Complaints

**Fax:** 1-866-880-9343

**Fax:** 734-929-6688

**E-Mail:** lantheussafety@i3global.com

*i3 Drug Safety is the pharmacovigilance partner of LMI*

(g) Section 9.1. Section 9.1 is hereby deleted in its entirety with the following substituted therefor:

*9.1 Unless earlier terminated as provided in this Agreement, the initial term of this Agreement shall commence as of October 31, 2001 (the "Effective Date") and conclude December 31, 2017. Notwithstanding the foregoing, this Agreement may be terminated at any time by either party on (i) three (3) years' written notice relating to TechneLite® prior to December 31, 2013, (ii) two (2) years' written notice relating to TechneLite® on and after December 31, 2013, and (iii) six (6) months' written notice relating to the other Products.*

(h) Section 9.2(c). Section 9.2(c) is hereby amended by replacing "\*\*\*\*\* (\*\*\*\*) days" with "\*\*\*\*\* (\*\*\*\*) days."

(i) Section 9.3(b). Section 9.3(b) is hereby deleted in its entirety with the following substituted therefor:

*(b) any substantial increase in Seller's direct or indirect costs relating to radioactive waste or transportation costs relating to the supply of Mo-99 and other raw materials;*

(j) Section 9.3(c). Section 9.3(c) is hereby deleted in its entirety with the following substituted therefor:

*then the parties shall negotiate in good faith in an effort to modify this Agreement in accordance with any of the matters described above and such negotiations shall commence within \*\*\*\* (\*\*\*) days of one party's written notice to the other of (a) and/or (b) above. During any negotiation period, the pricing increments defined in Exhibit C will continue in effect.*

(k) Section 10.3. Section 10.3 is hereby added as follows:

*10.3 Notwithstanding the foregoing provisions, in the event there is a \*\*\*\*, G.E. Healthcare may, at its reasonable discretion, divert some or all of G.E. Healthcare's supply of Mo-99 ("GEH Mo-99") to LMI for the manufacture of Product by LMI (pursuant to the terms of this Agreement, without the option of toll manufacturing). LMI will use commercially reasonable efforts to accept such GEH Mo-99, provided that the acceptance of GEH Mo-99 will be subject to LMI's then current manufacturing schedule and LMI's other policies and procedures applicable to such volume, including, but not limited to, LMI's purchasing specifications for Mo-99. LMI will make a good faith effort to optimize the manufacturing schedule related to the GEH Mo-99, provided, however, that LMI will not be required to schedule a manufacturing run for batches of TechneLite® generators that would result in the sale by LMI of less than \*\*\*\* total curies of activity per manufacturing run (as measured in curies of TechneLite® generators purchased by G.E. Healthcare and other customers from the day of manufacture of such Product at LMI's facility). Notwithstanding anything herein to the contrary, LMI SHALL NOT BE LIABLE TO G.E. HEALTHCARE FOR, AND G.E. HEALTHCARE WAIVES ANY AND ALL CLAIMS AGAINST LMI FOR, DAMAGES RELATING TO THE DECAY OR LOSS OF GEH MO-99. GEH Mo-99 will be used exclusively for the manufacture of Product for G.E. Healthcare, except that LMI shall have the right to use any GEH Mo-99 not used in the manufacture of TechneLite® generators for G.E. Healthcare in connection with the manufacture and sale of TechneLite® generators for LMI's other customers. During the period of disruption, LMI will continue to provide G.E. Healthcare with a fair allocation of the available Product, such fair allocation to be determined by LMI in its sole discretion acting reasonably after due consideration of \*\*\*\*, other percentage supply requirements, and the available amount of Product for LMI's customers, including G.E. Healthcare, affected by such supply disruption, until previous production levels and LMI's supply of Mo-99 have been restored. The Parties hereby agree that, notwithstanding anything herein to the contrary, the foregoing provisions represent G.E. Healthcare's sole and exclusive remedies with respect to such events.*

(l) Article 11. Article 11, Assignment, is hereby deleted in its entirety with the following substituted therefor:

*ARTICLE 11. Assignment*

*Neither this Agreement, nor any right, interest or obligation hereunder, may be assigned, or otherwise transferred by either Party, whether by operation of law or otherwise, without the prior written consent of the other Party; provided, however that (a) either Party may assign or otherwise transfer any or all of its rights, or delegate any or all of its respective duties or obligations, under this Agreement without the prior written consent of the other Party to (i) an acquirer of, or successor to, all or substantially all of the assets of such Party, or (ii) the surviving entity in any merger, consolidation, equity exchange or reorganization to which such Party is a party, provided that, in each case contemplated by this clause (a), such acquirer, successor or surviving entity, as the case may be, agrees to be bound by all of the obligations of such Party under this Agreement; and (b) LMI may assign or otherwise transfer any or all of its rights, or delegate any or all of its duties or obligations, under this Agreement to an acquirer of, successor to, or other transferee with respect to all or substantially all of the assets used in or related to the manufacture, sale and distribution of the Products or otherwise to the business of LMI to which this Agreement relates, provided that, in each case contemplated by this clause (b), such acquirer, successor or transferee, as the case may be, agrees to be bound by all of the obligations of LMI under this Agreement. In the event of any such assignment or transfer in violation hereof, such assignment or transfer shall be null and void and have no force or effect. This Agreement shall be binding upon and inure to the benefit of the Parties, and their respective successors and assigns as permitted hereunder.*

*In addition, G.E. Healthcare shall be required to provide LMI at least \*\*\*\* (\*\*\*\*) days prior written notice of any transaction or series of related transactions, whether or not G.E. Healthcare is a party thereto, which, after giving effect to such transaction or transactions, would result in the sale, lease, transfer or other disposition of some or all of the assets or business of G.E. Healthcare to which this Agreement relates (including, without limitation, the radiopharmacies owned or controlled by G.E. Healthcare). Unless otherwise requested by LMI in writing prior to the effective date of such transaction, G.E. Healthcare shall assign and ensure that, as a condition of such transaction or transactions, such acquirer, successor or transferee, as the case may be, agrees to be bound by all of the obligations of G.E. Healthcare (or the applicable pro rata portion thereof) under this Agreement for a period of not less than \*\*\*\* (\*\*\*\*) \*\*\*\* after the completion of such transaction or transactions.*

(m) Section 12.2. The name and address for LMI in Section 12.2 is hereby amended to read as follows:

*Lantheus Medical Imaging, Inc.  
Attn: Cyrille Villeneuve, Chief Commercial Officer  
331 Treble Cove Road  
North Billerica, MA 01862*

*Copy to: General Counsel, Legal Department (at the same address)*

(n) Exhibit A. Exhibit A is hereby deleted in its entirety with the following substituted therefor:

**Exhibit A**

***Products***

***TechneLite®***

****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****
****	Calibrated @ noon Eastern Time, ****

***MHDLG***                      ***TechneLite® handling fee***

<b><i>A15</i></b>	<b><i>Set of **** ml saline eluent vials</i></b>
<b><i>A17</i></b>	<b><i>Set of **** ml saline eluent vials</i></b>
<b><i>A3</i></b>	<b><i>Set of **** ml evacuated collection vials</i></b>
<b><i>EV12</i></b>	<b><i>Set of **** ml evacuated collection vials</i></b>
<b><i>A14</i></b>	<b><i>Lead elution shield</i></b>
<b><i>A25</i></b>	<b><i>Molycoddle® radiation reducer</i></b>
<b><i>A2</i></b>	<b><i>Aluminum ion indicator kit</i></b>

*Xenon-133*  
 X110 Xe-133 \*\*\*\* mCi, \*\*\*\* vial tube  
 Calibrated @ noon Eastern Time, \*\*\*\*  
 X510 Xe-133 \*\*\*\* mCi, \*\*\*\* vial tube  
 Calibrated @ noon Eastern Time, \*\*\*\*  
 X120 Xe-133 \*\*\*\* mCi, \*\*\*\* vial tube  
 Calibrated @ noon Eastern Time, \*\*\*\*  
 X520 Xe-133 \*\*\*\* mCi, \*\*\*\* vial tube  
 Calibrated @ noon Eastern Time, \*\*\*\*  
 XGUN Xenon Gun  
 XHDLG Xenon handling fee

*Gallium-67*  
 Ga6 \*\*\*\* mCi vial  
 Calibrated @ noon Eastern Time, \*\*\*\*  
 Ga8 \*\*\*\* mCi vial  
 Calibrated @ noon Eastern Time, \*\*\*\*  
 Ga12 \*\*\*\* mCi vial  
 Calibrated @ noon Eastern Time, \*\*\*\*  
 Ga18 \*\*\*\* mCi vial  
 Calibrated @ noon Eastern Time, \*\*\*\*  
 GHDLG Gallium handling fee

Notes (Exhibit A)

- LMI reserves the right to add or delete specific items from its total product portfolio with \*\*\*\* days' prior written notice.
  - DOM = Day of Manufacture
- (p) Exhibit C1. Exhibit C1 is hereby deleted in its entirety with the following substituted therefor:

**Exhibit C**

\*\*\*\*

Notes (Exhibit C1)

- Handling fee schedule per order
  - Federal Express door to door \$\*\*\*\*
  - Ground carrier door to door \$\*\*\*\*
  - Dual leg, i.e., Air Express and ground carrier door to door \$\*\*\*\*

- When necessary to substitute requested items due to inventory shortfall, LMI will adjust prices for substituted items to reflect requested items total cost.
- Annual Price Adjustments will be calculated as follows:
  - Pricing for the periods of \*\*\*\* through \*\*\*\* and each \*\*\*\* thereafter will be adjusted by an amount equal to the cost of materials plus \*\*\*\*% of the \*\*\*\*, provided that no \*\*\*\*-related adjustment will be applied to the \*\*\*\* for the Technelite® pricing.
  - Pricing for each calendar year will be communicated to G.E. Healthcare by \*\*\*\* of the previous year.
  - Pricing will be in effect from \*\*\*\* through \*\*\*\* of the same year.
  - Notwithstanding the foregoing, at any time during the term of this Agreement, LMI may adjust the Technelite® pricing to reflect any material change in costs of molybdenum, accounting for increases or decreases. A change in such costs is considered material if the adjustment in the cost of molybdenum over any \*\*\*\* (\*\*\*\*) day period is more than \*\*\*\* percent (\*\*\*\*%). In the event of such a material adjustment, LMI shall adjust the Technelite® pricing to reflect the incremental change in such costs effective as of when such costs are actually incurred by LMI, provided that LMI provides G.E. Healthcare at least \*\*\*\* (\*\*\*\*) days written notice and reasonable documentation supporting such change in costs prior to implementing such effective cost adjustments.
- Weekday Unit = DOM on \*\*\*\*, as set forth in Section 2.6 of the Agreement.
- Weekend Unit = DOM on \*\*\*\*, as set forth in Section 2.6 of the Agreement.

3. Full Force and Effect. Except as expressly waived by this Amendment, the terms and conditions of the Agreement shall remain in full force and effect. In the event of a conflict between the terms of this Amendment and the Agreement, this Amendment shall control.

4. Successors. This Amendment shall be binding upon and inure to the benefit of each of the Parties and their respective successors and assigns.

5. Counterparts. This Amendment may be executed in separate counterparts, each of which when so executed, shall be considered an original, and which counterparts together shall constitute the entire agreement.

10

---

6. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware, excluding the conflict of law provisions thereof.

7. Severability. Wherever possible, each provision of this Amendment shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Amendment shall be prohibited by or invalid under such law, such provision shall be ineffective to the extent of such prohibition or invalidity without invalidating the remainder of such provision or the remaining provisions of this Amendment.

[Signature page follows.]

11

---

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as the effective date set forth above.

G.E. HEALTHCARE INC.

By: /s/ Aaron Bernstein  
Name: Aaron Bernstein  
Title: Global Sourcing Leader

LANTHEUS MEDICAL IMAGING, INC.

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

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

---



\*\*\*\*, 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.

20

---

(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,

21

---

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.

---

Exhibit 1.2

Territory

\*\*\*

---

Exhibit 1.3

Pricing

COMMERCIAL BATCH/LOT PRODUCTION PRICES:

\*\*\*

---

**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.**

**AMENDMENT NO. 1 TO AMENDED AND RESTATED CARDIOLITE LICENSE AND SUPPLY AGREEMENT**

This Amendment No. 1 (this “Amendment”) to the Amended and Restated Cardiolite License and Supply Agreement by and between Lantheus Medical Imaging, Inc. (“LMI”) and Cardinal Health 414, LLC (“Licensee”) entered into as of January 1, 2009 and effective as of January 1, 2004 (the “Agreement”) is made by and between LMI and Licensee as of this 9th day of February 2012 (“Amendment Date”).

WHEREAS, Licensee and LMI have determined that the Agreement should be modified as set forth in this Amendment;

NOW, THEREFORE, for good and valuable consideration, the sufficiency of which is hereby acknowledged, the parties hereto hereby agree as follows:

1. **Definitions.** Terms defined in the Agreement and not otherwise defined in this Amendment are used herein with the meanings ascribed to them in the Agreement.

2. **Minimum Purchase Obligation.** The Parties agree that in full replacement of the remaining purchase obligations set forth in Section 2.24, from and after \*\*\*\* and for the balance of the term of the Agreement (as amended hereby) Licensee shall purchase from LMI Sestamibi Products as follows:

2.1. In full replacement and complete satisfaction of any remaining minimum purchase obligation otherwise set forth in the Agreement for the Compliance Period ending \*\*\*\*, no later than \*\*\*\* (\*\*\*\*) \*\*\*\* following the Amendment Date, Licensee shall purchase from LMI \*\*\*\* at a price of \$\*\*\*\*.

2.2. In full replacement and complete satisfaction of any remaining minimum purchase obligation otherwise set forth in the Agreement for each Compliance Period set forth below, on or before the end of such respective Compliance Period, Licensee shall purchase from LMI the quantity of vials of Sestamibi Products for such Compliance Period specified below at a price of \$\*\*\*\*, provided that for the Compliance Period ending \*\*\*\*, the Sestamibi Products shall be \*\*\*\* and for the final \*\*\*\* Compliance Periods in \*\*\*\*, the Sestamibi Products shall be \*\*\*\* thereof as Licensee specifies to LMI with at least \*\*\*\* (\*\*\*\*) days written notice prior to each order:

<b>Compliance Period</b>	<b>Quantity</b>
Quarter ending ****	****
Quarter ending ****	****
Quarter ending ****	****
Quarter ending ****	****

In addition to the immediately preceding sentence in this Section 2.2, for the final \*\*\*\* Compliance Periods in \*\*\*\*, Licensee shall purchase from LMI an additional aggregate amount of \*\*\*\* of Sestamibi Products at a price of \$\*\*\*\*, such Sestamibi Products to be \*\*\*\* thereof as

Licensee specifies to LMI with at least \*\*\*\* (\*\*\*\*) days written notice prior to each order and which purchases may be spread across such final \*\*\*\* Compliance Periods at Licensee's reasonable discretion.

2.3. Licensee shall also purchase from LMI and LMI shall sell to Licensee an additional \*\*\*\* of Sestamibi Products at a price of \$\*\*\*\*, such additional purchase and sale to occur no earlier than \*\*\*\* and no later than \*\*\*\*, at LMI's reasonable discretion. Sestamibi Products purchased and sold under this Section 2.3 may include \*\*\*\* thereof, at Licensee's reasonable discretion.

2.4. From and after the date of this Amendment, Sections 2.06, 2.07, 2.08, 2.09, 2.11, 2.23 (except for the first and last sentences), 2.24 and 3.01(c)(A) of the Agreement, and any applicable Exhibits referenced in any of the foregoing Sections, shall be deleted in their entirety and have no force or effect. For the avoidance of doubt, no \*\*\*\* under any of the foregoing Sections shall apply after \*\*\*\*. From and after the date of this Amendment, Section 2.03 of the Agreement is hereby deleted in its entirety and replaced as follows:

"Supply of Vials: During the term of this Agreement, LMI shall supply vials of Sestamibi Products in accordance with Section 2.16 and 2.17 and the terms of the Amendment. Title and risk of loss to the Sestamibi Products shall pass to Licensee immediately upon \*\*\*\* pursuant to the terms of this Agreement. Licensee hereby represents and warrants that Licensee will properly dispose of such material in accordance with the rules and regulations promulgated by the U.S. Nuclear Regulatory Commission and all other applicable state and federal Government regulations, including those covering pollution, hazardous substances, or the protection of human health, the environment or natural resources."

3. \*\*\*\* Pricing. In connection with the remaining minimum purchase obligations set forth in Section 2 of this Amendment, from and after the date of the Amendment and through \*\*\*\*, Section 2.26 of the Agreement shall continue to apply; provided, however, that it shall be based upon the \*\*\*\* pricing as \*\*\*\* equivalent (based on a \*\*\*\* utilization) in effect under the Agreement immediately prior to the Amendment Date (i.e.: \$\*\*\*\* or \$\*\*\*\* for \*\*\*\*, and \$\*\*\*\* or \$\*\*\*\* for \*\*\*\*). From and after \*\*\*\*, Section 2.26 shall no longer apply and have no further force or effect.

4. Term and Termination. Section 3.01 of the Agreement shall be amended such that the date of "December 31, 2012" appearing in the first sentence thereof shall be deleted and replaced with "the later to occur of December 31, 2012 or the date on which the purchase obligation set forth in section 2.3 of Amendment No. 1 to the Agreement shall have been consummated".

5. Effect of Termination. Section 3.03 of the Agreement shall be deleted in its entirety and have no force or effect. For the avoidance of doubt, following the termination date of the Agreement, Licensee shall not be restricted in any way from selling unit doses of any Sestamibi Products purchased from LMI prior to the termination date other than as specified in Section 7 hereof and in accordance with the FDA labeling for such Sestamibi Products or as specified by applicable law.

6. No Further Changes. Except as specifically amended hereby, the Agreement shall remain in full force and effect and otherwise unmodified. All amendments in Sections 2 through 5 of this Amendment shall be deemed made as of the Amendment Date, and the Agreement shall not be deemed to have been modified until the Amendment Date.

7. Sestamibi Products Expiry. Without limitation to any other provision in the Agreement, LMI shall use commercially reasonable efforts to deliver Sestamibi Products to Licensee with useful life prior to product expiration (“Product Dating”) of an average of at least \*\*\*\* months and in accordance with the FDA labeling for such Sestamibi Products. Without limitation to any other rights or remedies under the Agreement, including Product Exchanges permitted below, Licensee may reject Sestamibi Products delivered with less than \*\*\*\* months Product Dating.

Notwithstanding the foregoing, if any Sestamibi Products purchased under Section 2.2 above during the Compliance Period ending \*\*\*\*, or purchased under Section 2.3 above (collectively, the “Final Sestamibi Products”), are delivered to Licensee with less than \*\*\*\* months Product Dating, Licensee shall have the right, at its sole option, to return such Final Sestamibi Products to LMI upon expiration of such Final Sestamibi Products, and LMI shall promptly replace such Final Sestamibi Products at no cost to Licensee, subject to the calculations below (“Product Exchange”). For the avoidance of doubt, the Product Exchange terms set forth in this Section shall survive termination of the Agreement. Eligible Product Exchange amounts shall be separately calculated for each delivery as follows:

- a. Baseline Amount: For Final Sestamibi Products delivered with less than \*\*\*\* months Product Dating, an estimated monthly vial usage baseline shall be calculated by evenly prorating the total number of vials of such Final Sestamibi Products across \*\*\*\* months (“Baseline Amount”). For the avoidance of doubt, the Baseline Amount applies only for purposes of establishing a Product Exchange amount, and shall in no way bind Licensee to any set monthly usage amount of Final Sestamibi Products.
- b. Net Product Dating: A net product dating amount shall be calculated for the Final Sestamibi Products delivered with less than \*\*\*\* months Product Dating, based upon the difference between \*\*\*\* months Product Dating and the actual number of months Product Dating applicable to such Final Sestamibi Products (“Net Product Dating”).
- c. Product Exchange Amount Calculation: The Product Exchange amount for each applicable delivery of Final Sestamibi Products shall equal the Baseline Amount multiplied by the Net Product Dating. In the event that Product Dating is not uniform throughout all Final Sestamibi Products included within a single delivery, separate Product Exchange calculations shall be made for each group of Final Sestamibi Products with the same Product Dating, using the formula above for each group; provided, that LMI shall use reasonable efforts to include Final Sestamibi Products with uniform Product Dating throughout each delivery.
- d. Example: By way of example only, if Licensee receives a delivery of Final Sestamibi Products on \*\*\*\*, including 20,000 vials with \*\*\*\* months Product Dating, 45,000 vials with \*\*\*\* months Product Dating, and 28,000 vials with \*\*\*\* months Product Dating, the following Product Exchange amounts shall apply: 1. For the 20,000 vials with \*\*\*\* months Product Dating, the Product Exchange amount shall equal \*\*\*\* vials (i.e. \*\*\*\*); 2. For the 45,000 vials with \*\*\*\* months Product Dating, the Product Exchange amount shall equal \*\*\*\* vials (i.e. \*\*\*\*); and 3. For the 28,000 vials with \*\*\*\* months Product Dating, no Product Exchange amount shall apply.
- e. Usage of Final Sestamibi Products: In connection with its usage of Final Sestamibi Products, Licensee will make commercially reasonable efforts to use Final Sestamibi Products having the shortest remaining Product Dating first so as to minimize the aggregate amount of Product Exchange otherwise due under this Section 7.



As of the Amendment Date, Licensee releases and forever discharges LMI from any claims, damages, liabilities or causes of action arising from or related to \*\*\*, and LMI releases and forever discharges Licensee from any claims, damages, liabilities or causes of action arising from or related to \*\*\*.

8. Gallium Purchase Obligation. For the period from July 1, 2012 through December 31, 2012, Licensee shall purchase at least \*\*\* percent (\*\*\*) of its requirements for Gallium-67 in vial sizes to be reasonably specified by Licensee (as evidenced by reasonable documentation made reasonably available to LMI or its representatives), in accordance with a delivery schedule reasonably requested by Licensee based upon its business needs, at a price of \$\*\*\* per millicurie. Such purchases of Gallium-67 specified in this Section 8 shall be made pursuant to the terms and provisions of the Amended and Restated Supply Agreement (Thallium and Generators), as amended, entered into as of January 1, 2009 and effective as of October 1, 2004, in a manner similar to the purchase of Thallium-201 otherwise contemplated thereunder.

9. General. This Amendment may be executed in two or more counterparts, each of which when executed shall be deemed to be an original but all of which when taken together shall constitute one and the same agreement. Signatures hereto may be delivered by facsimile or a "pdf" file through electronic mail, and such delivery will have the same effect as the delivery of the paper document bearing the actual handwritten signatures. This Amendment shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to the conflict of laws provisions thereof. LMI and Licensee understand and agree that each and every term and condition of this Amendment, have or has been mutually negotiated, prepared and drafted, and in connection with the interpretation or construction of such term or condition or this Amendment, no consideration will be given to the issue of which of LMI or Licensee prepared, drafted or requested any term or condition of this Amendment.

**IN WITNESS WHEREOF**, the parties hereto have executed this Amendment as of the Amendment Date.

Signed for and on behalf of Cardinal Health 414, LLC

Signature: /s/ Thomas J. Rafferty

By: Thomas J. Rafferty

Title: VP – Strategic Sourcing

Signed for and on behalf of Lantheus Medical Imaging, Inc.

Signature: /s/ Michael P. Duffy

By: Michael P. Duffy

Title: Vice President and Secretary

**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

---

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: (###) ###-####  
Facsimile: (###) ###-####

Ben Venue Laboratories, Inc.:

300 Northfield Road  
Bedford, OH 44146  
Attn: Vice President, Contract Manufacturing Services  
Telephone: (###) ###-####  
Facsimile: (###) ###-####

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

Division Legal Counsel  
Ben Venue Laboratories, Inc.  
300 Northfield Road  
Bedford, Ohio 44146  
Telephone: (###) ###-####  
Facsimile: (###) ###-####

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

**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.**

**Table of Contents**

	<u>Page</u>
ARTICLE 1 - DEFINITIONS	2
ARTICLE 2 - DESCRIPTION OF WORK	7
ARTICLE 3 - MANUFACTURE	10
ARTICLE 4 - VOLUMES	17
ARTICLE 5 - PURCHASE ORDERS	17
ARTICLE 6 - PRICE AND PAYMENT	18
ARTICLE 7 - QUALITY AGREEMENT	20
ARTICLE 8 - INDEMNIFICATION	20
ARTICLE 9 - CONFIDENTIALITY	23
ARTICLE 10 - REPRESENTATIONS AND WARRANTIES	25
ARTICLE 11 - INTELLECTUAL PROPERTY	27
ARTICLE 12 - TERM AND TERMINATION	28
ARTICLE 13 - NOTICES	31
ARTICLE 14 - WAIVER	32
ARTICLE 15 - ASSIGNMENT OF AGREEMENT	32
ARTICLE 16 - GOVERNING LAW	33
ARTICLE 17 - FORCE MAJEURE	33
ARTICLE 18 - TITLE OF GOODS	34
ARTICLE 19 - ENTIRE AGREEMENT	34
ARTICLE 20 - SEVERABILITY	35

**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.**

ARTICLE 21 -	INDEPENDENT CONTRACTORS	35
ARTICLE 22 -	AMENDMENTS	35
ARTICLE 23 -	HEADINGS	35
ARTICLE 24 -	REVIEW BY LEGAL COUNSEL	35
ARTICLE 25 -	RECALL	35
ARTICLE 26 -	ENGLISH LANGUAGE	36
ARTICLE 27 -	EXPORT PROVISION	36
ARTICLE 28 -	ACKNOWLEDGEMENT	36
ARTICLE 29 -	CHANGE NOTIFICATION	37
ARTICLE 30 -	BOOKS AND RECORDS	37
ARTICLE 31 -	BINDING EFFECT	37
ARTICLE 32 -	USE OF NAME AND RESERVATION OF RIGHTS	37
ARTICLE 33 -	COUNTERPARTS	37
ARTICLE 34 -	LIQUIDATED DAMAGES	37



## 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 “EMEA”); if Territory includes Japan, the Japanese Ministry of Health, Labor and Welfare; (b) any successor organization of any such entity; and (c) any other government regulatory authority with regulatory oversight of the Manufacturing, 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 Indemnitees” 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.

16

---

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, ###-###-####

**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 Indemnatee, 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,

---

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: ###-###-####  
Facsimile: ###-###-####

Division Legal Counsel



Ben Venue Laboratories, Inc.  
300 Northfield Road  
Bedford, Ohio 44146  
Telephone: ###-###-####  
Facsimile: ###-###-####

If to Customer:

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

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: ###-###-####  
Facsimile: ###-###-####

#### **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.

#### **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



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

## Table of Contents

	<u>Page</u>
ARTICLE 1 - DEFINITIONS	2
ARTICLE 2 - DESCRIPTION OF WORK	7
ARTICLE 3 - MANUFACTURE	10
ARTICLE 4 - VOLUMES	17
ARTICLE 5 - FORECASTS AND PURCHASE ORDERS	17
ARTICLE 6 - PRICE AND PAYMENT	19
ARTICLE 7 - QUALITY AGREEMENT	23
ARTICLE 8 - INDEMNIFICATION	23
ARTICLE 9 - CONFIDENTIALITY	25
ARTICLE 10 - REPRESENTATIONS AND WARRANTIES	28
ARTICLE 11 - INTELLECTUAL PROPERTY	29
ARTICLE 12 - TERM AND TERMINATION	31
ARTICLE 13 - NOTICES	35
ARTICLE 14 - WAIVER	35
ARTICLE 15 - ASSIGNMENT OF AGREEMENT	36
ARTICLE 16 - GOVERNING LAW	36
ARTICLE 17 - FORCE MAJEURE	36
ARTICLE 18 - TITLE OF GOODS	37
ARTICLE 19 - ENTIRE AGREEMENT	37
ARTICLE 20 - SEVERABILITY	38
ARTICLE 21 - INDEPENDENT CONTRACTORS	38
ARTICLE 22 - AMENDMENTS	38
ARTICLE 23 - HEADINGS	38
ARTICLE 24 - REVIEW BY LEGAL COUNSEL	39

ARTICLE 25 -	RECALL	39
ARTICLE 26 -	ENGLISH LANGUAGE	39
ARTICLE 27 -	EXPORT PROVISION	39
ARTICLE 28 -	ACKNOWLEDGEMENT	40
ARTICLE 29 -	CHANGE NOTIFICATION	40
ARTICLE 30 -	BOOKS AND RECORDS	40
ARTICLE 31 -	BINDING EFFECT	40
ARTICLE 32 -	USE OF NAME AND RESERVATION OF RIGHTS	40
ARTICLE 33 -	COUNTERPARTS	40
ARTICLE 34 -	LIQUIDATED DAMAGES	40

**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.**

**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

**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.**

**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

16

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

26

---

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

27

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 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: ###-###-####  
Facsimile: ###-###-####

Division Legal Counsel  
Ben Venue Laboratories, Inc.  
300 Northfield Road  
Bedford, Ohio 44146  
Telephone: ###-###-####  
Facsimile: ###-###-####

If to Customer:

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

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: ###-###-####  
Facsimile: ###-###-####

**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

36

---

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

**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 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;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 15, 2012

/s/ DONALD R. KIEPERT

Name: Donald R. Kiepert

Title: *President and Chief Executive Officer*

---

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](#)

**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 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;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 15, 2012

/s/ JEFFREY E. YOUNG

---

Name: Jeffrey E. Young  
Title: Chief Financial Officer

---



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 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: May 15, 2012

/s/ DONALD R. KIEPERT

\_\_\_\_\_  
Name: Donald R. Kiepert  
Title: *President and Chief Executive Officer*

Dated: May 15, 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.

---

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](#)

