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

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**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 June 30, 2012

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

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

Commission File Number 333-169785

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**LANTHEUS MEDICAL IMAGING, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State of incorporation)

51-0396366  
(IRS Employer Identification No.)

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

01862  
(Zip Code)

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

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

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

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

The registrant had 1,000 shares of common stock, \$0.01 par value per share, issued and outstanding as of August 13, 2012.



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**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements**

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2012	2011	2012	2011
<b>Revenues</b>				
Net product revenues	\$ 54,045	\$ 88,278	\$ 136,676	\$ 184,234
License and other revenues	2,716	2,141	5,436	4,304
Total revenues	56,761	90,419	142,112	188,538
Cost of goods sold	48,626	87,445	101,161	139,496
Loss on firm purchase commitment	—	1,879	—	1,879
Total cost of goods sold	48,626	89,324	101,161	141,375
Gross profit	8,135	1,095	40,951	47,163
<b>Operating expenses</b>				
General and administrative expenses	7,760	7,122	16,959	15,254
Sales and marketing expenses	8,915	10,702	18,908	20,097
Research and development expenses	10,409	10,342	20,771	20,847
Proceeds from manufacturer	(3,900)	—	(33,814)	—
Total operating expenses	23,184	28,166	22,824	56,198
Operating (loss) income	(15,049)	(27,071)	18,127	(9,035)
Interest expense, net	(10,467)	(10,433)	(20,813)	(17,370)
Other income, net	281	445	586	943
Loss before income taxes	(25,235)	(37,059)	(2,100)	(25,462)
Provision (benefit) for income taxes	(607)	(14,746)	1,630	(9,496)
Net loss	\$ (24,628)	\$ (22,313)	\$ (3,730)	\$ (15,966)
Foreign currency translation, net of taxes	(689)	232	178	627
Total comprehensive loss	\$ (25,317)	\$ (22,081)	\$ (3,552)	\$ (15,339)

See notes to unaudited condensed consolidated financial statements.

**Lantheus MI Intermediate, Inc. and subsidiaries****Condensed Consolidated Balance Sheets****(unaudited, in thousands except share data)**

	June 30, 2012	December 31, 2011
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 56,873	\$ 40,607
Accounts receivable, net of allowance of \$329 and \$462	33,532	40,000
Inventory	14,951	14,765
Deferred tax assets	131	93
Other current assets	4,714	2,662
Total current assets	110,201	98,127
Property, plant and equipment, net	109,670	112,452
Capitalized software development costs	2,854	3,582
Intangibles, net	74,710	82,749
Goodwill	15,714	15,714
Deferred financing costs	12,253	13,141
Due from parent	1,256	1,286
Other long-term assets	32,121	31,753
Total assets	<u>\$ 358,779</u>	<u>\$ 358,804</u>
<b>Liabilities and Stockholder's Deficit</b>		
Current liabilities		
Note payable	\$ 616	\$ —
Accounts payable	18,417	22,010
Accrued expenses	28,699	20,949
Income tax payable	1,274	1,482
Deferred revenue	4,693	3,918
Total current liabilities	53,699	48,359
Asset retirement obligation	5,145	4,868
Long-term debt, net	398,726	398,629
Deferred tax liability	625	931
Other long-term liabilities	36,566	39,220
Total liabilities	494,761	492,007
Commitments and contingencies (see Note 13)	—	—
<b>Stockholder's deficit</b>		
Common stock (\$0.001 par value, 10,000 shares authorized; 1 share issued and outstanding)	—	—
Additional paid-in capital	1,858	1,085
Accumulated deficit	(138,389)	(134,659)
Accumulated other comprehensive income	549	371
Total stockholder's deficit	(135,982)	(133,203)
Total liabilities and stockholder's deficit	<u>\$ 358,779</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)
Foreign currency translation	—	—	—	—	(337)	(337)
Stock-based compensation	—	—	169	—	—	169
Balance at December 31, 2011	1	—	1,085	(134,659)	371	(133,203)
Net loss	—	—	—	(3,730)	—	(3,730)
Foreign currency translation	—	—	—	—	178	178
Stock-based compensation	—	—	773	—	—	773
Balance at June 30, 2012	1	\$ —	\$ 1,858	\$ (138,389)	\$ 549	\$ (135,982)

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 Six Months Ended June 30,	
	2012	2011
<b>Cash flow from operating activities</b>		
Net loss	\$ (3,730)	\$ (15,966)
Adjustments to reconcile net loss to cash flow from operating activities		
Depreciation and amortization	14,861	18,831
Impairment of intangible asset	—	23,474
Provision for excess and obsolete inventory	1,145	14,660
Stock-based compensation	790	(1,272)
Deferred income taxes	(146)	(11,692)
Other	416	1,025
Increase (decrease) in cash from operating assets and liabilities		
Accounts receivable	6,573	(1,677)
Prepaid expenses and other assets	(463)	(804)
Inventory	(1,030)	(14,838)
Due from parent	30	—
Deferred revenue	1,234	(2,911)
Accounts payable	(2,582)	(8,400)
Income tax payable	(207)	(340)
Accrued expenses and other liabilities	3,947	5,985
Cash provided by operating activities	<u>20,838</u>	<u>6,075</u>
<b>Cash flows from investing activities</b>		
Purchase of certificate of deposit	(225)	—
Capital expenditures	(3,192)	(5,206)
Cash used in investing activities	<u>(3,417)</u>	<u>(5,206)</u>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of debt	—	152,250
Payments on note payable	(914)	—
Consent solicitation fee	—	(3,750)
Debt issuance costs	(198)	(5,368)
Payment of dividend to parent	—	(150,000)
Cash used in financing activities	<u>(1,112)</u>	<u>(6,868)</u>
Effect of foreign exchange rate on cash	(43)	781
Increase (decrease) in cash and cash equivalents	16,266	(5,218)
Cash and cash equivalents, beginning of period	40,607	33,006
Cash and cash equivalents, end of period	<u>\$ 56,873</u>	<u>\$ 27,788</u>
<b>Supplemental disclosure of cash flow information</b>		
Interest paid	\$ 19,516	\$ 19,500
Income taxes paid, net of refunds	\$ 1,014	\$ 1,132
<b>Noncash investing and financing activities</b>		
Property, plant and equipment included in accounts payable and accrued expenses	\$ 630	\$ 284

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. Business Overview**

*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 condensed 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 to the rules and regulations of the Securities and Exchange Commission ("SEC"). The information



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

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

**1. Business Overview (Continued)**

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. There were no changes to the Company's accounting policies since December 31, 2011. 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 and six months ended June 30, 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 a net loss of \$3.7 million during the six months ended June 30, 2012 and had an accumulated deficit of \$138.4 million at June 30, 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 shut down 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. Because the shutdown and restart activities took substantially 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 half of 2012, resulting in an overall revenue decline in comparison to the prior periods. BVL resumed manufacturing certain of the Company's products in May 2012. After BVL released the first lot of newly-manufactured DEFINITY in June 2012, the Company shipped product to its customers in late June and early July. The Company is currently working closely with BVL to complete the quality review and commercial release process for the remaining lots BVL has recently manufactured for the Company, a process the Company believes should be completed in the next several weeks. The Company continues to work to restore full and normal production of all of its BVL-manufactured products as well as to build a sufficient inventory to appropriately serve all of its customers. The Company can give no assurances that the remaining product that BVL has recently manufactured for the Company will successfully complete the quality review and commercial release process, or that BVL will be able to manufacture product for the Company on a timely and consistent basis in the future.

The Company has also expedited a number of technology transfer programs to secure and qualify production of its BVL-manufactured products with alternate contract manufacturer sites. Currently, the Company is utilizing an alternate manufacturer for a portion of its Cardiolite sales demand 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 other suppliers would provide meaningful quantities of products to the Company.

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

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

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

**1. Business Overview (Continued)**

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").

- 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, 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.

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, which totaled approximately \$34.2 million in the six months ended June 30, 2012, 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 \$3.9 million and \$33.8 million in the condensed consolidated statement of comprehensive loss for the three and six months ended June 30, 2012, respectively.

If BVL is not able to provide the Company adequate product supply for a further prolonged period of time, we are unable to regain sufficient market share, 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 potential delay of discretionary spending including possible reductions in sales and marketing and research and development activities, as well as 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.

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

*Recent Accounting Pronouncement*

In July 2012, the Financial Accounting Standards Board (the "FASB"), issued Accounting Standards Update ("ASU"), No. 2012-02, "Intangibles—Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment," ("ASU 2012-02"). ASU 2012-02 allows a company the option to first assess qualitative factors to determine whether it is necessary to perform a quantitative impairment test. Under that option, a company would no longer be required to calculate the fair value of an indefinite-lived intangible asset unless the company determines, based on that qualitative assessment, that it is more likely than not that the fair value of the indefinite-lived intangible asset is less than its carrying amount. ASU 2012-02 is effective for annual and interim indefinite-lived intangible asset impairment tests performed for fiscal years beginning after September 15, 2012. Early adoption is permitted. The adoption of ASU 2012-02 is not expected to have a material impact on the Company's financial position or results of operations.

**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 June 30, 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.

<u>(in thousands)</u>	<u>Total fair value at June 30, 2012</u>	<u>Quoted prices in active markets (Level 1)</u>	<u>Significant other observable inputs (Level 2)</u>	<u>Significant unobservable inputs (Level 3)</u>
Money market	\$ 6,952	\$ 6,952	\$ —	\$ —
Certificates of deposit—restricted	324	—	324	—
	<u>\$ 7,276</u>	<u>\$ 6,952</u>	<u>\$ 324</u>	<u>\$ —</u>

**Lantheus MI Intermediate, Inc. and subsidiaries****Notes to Unaudited Condensed Consolidated Statements (Continued)****3. Fair Value of Financial Instruments (Continued)**

<u>(in thousands)</u>	<u>Total fair value at December 31, 2011</u>	<u>Quoted prices in active markets (Level 1)</u>	<u>Significant other observable inputs (Level 2)</u>	<u>Significant unobservable inputs (Level 3)</u>
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 and is included in the line item "Certificates of deposit—restricted". This investment is classified in other current assets on the condensed consolidated balance sheet. The remaining \$0.1 million represents a certificate of deposit that is collateral for a long-term lease and is included in other long-term assets on the condensed consolidated balance sheet. Certificates of deposit are classified within Level 2 of the fair value hierarchy as these are not traded on the open market.

At June 30, 2012, the Company had total cash and cash equivalents of \$56.9 million, which included approximately \$7.0 million of money market funds and \$49.9 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 funds and \$34.6 million of cash on-hand.

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 June 30, 2012, based on Level 2 inputs of recent market activity available to the Company, was \$366.0 million compared to the face value of \$400.0 million. 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, valuation allowance changes and state taxes. 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 (benefit) was \$(0.6) million and \$1.6 million for the three and six months ended June 30, 2012, respectively, on pre-tax losses of \$25.2 million and \$2.1 million for the respective periods compared to tax provisions (benefit) of \$(14.7) million and \$(9.5) million for the three and six months ended June 30, 2011, respectively, on pre-tax losses of \$37.1 million and \$25.5 million for the respective periods.

Within the next twelve months, unrecognized tax benefits of \$1.3 million associated with federal research credits may be recognized due to the closing of the statute of limitations.

The Company has a tax indemnification agreement with 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 loss. In accordance with the Company's accounting policy, the change in the tax liability

**Lantheus MI Intermediate, Inc. and subsidiaries****Notes to Unaudited Condensed Consolidated Statements (Continued)****4. Income Taxes (Continued)**

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. 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.

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

<u>(in thousands)</u>	<u>June 30,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
Raw materials	\$ 8,267	\$ 7,755
Work in process	1,219	2,615
Finished goods	5,465	4,395
Inventory	14,951	14,765
Other long-term assets	11,009	11,249
Total	<u>\$ 25,960</u>	<u>\$ 26,014</u>

At June 30, 2012, inventories reported as other long-term assets included \$11.0 million of raw materials. 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 June 30, 2012 have not been significant. At both June 30, 2012 and December 31, 2011, the balances of inventory on-hand reflected approximately \$12.2 million of finished products and raw materials related to Ablavar. At June 30, 2012 and December 31, 2011, approximately \$11.0 million and \$11.2 million, respectively, of Ablavar inventory was included in other 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 June 30, 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.

Prior to the issuance of the June 30, 2011 financial statements, the Company performed analyses of its expected future sales of its Ablavar product and recorded an inventory write-down to cost of goods sold of \$13.5 million, which represented the cost of Ablavar finished good product and API that the Company did not believe it will be able to sell prior to its expiration. Prior to the issuance of the Company's June 30, 2011 financial statements, the Company completed an updated sales forecast for Ablavar based on actual sales through June 30, 2011 in consideration of its supply agreement for API. Based on the updated sales forecast, coupled with the aggregate six-year shelf life of API and finished goods, the Company recorded in cost of goods sold a reserve of \$1.9 million for the loss associated

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

with the portion of the committed purchases of Ablavar product that the Company did not believe it would be able to sell prior to its expiration. Also, the Company determined that its write-down of Ablavar inventory represented an event that warranted assessment of the intellectual property associated with Ablavar for its recoverability and concluded that the intellectual property was not recoverable and in the second quarter of 2011, recorded in cost of goods sold an impairment of this intangible asset of \$23.5 million. See Note 8, "Intangibles, net."

In the event that the Company does not meet its sales expectations for Ablavar or cannot sell the product it has committed to purchase prior to its expiration, the Company could incur additional inventory write-downs and/or losses on its purchase commitments.

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

Property, plant and equipment consisted of the following:

<u>(in thousands)</u>	<u>June 30,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
Land	\$ 22,450	\$ 22,450
Buildings	64,292	64,029
Machinery, equipment and fixtures	63,138	65,648
Construction in progress	4,816	4,383
Accumulated depreciation	(45,026)	(44,058)
Property, plant and equipment, net	<u>\$ 109,670</u>	<u>\$ 112,452</u>

For the three and six months ended June 30, 2012, depreciation expense related to property, plant and equipment was \$2.4 million and \$4.8 million, respectively, as compared to \$3.0 million and \$6.0 million for the three and six months ended June 30, 2011.

Included within property, plant and equipment are spare parts of approximately \$2.8 million at both June 30, 2012 and December 31, 2011. Spare parts include replacement parts relating to plant 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.

**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.

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

7. Asset Retirement Obligations (Continued)

The following is a reconciliation of the Company's asset retirement obligations for the six months ended June 30, 2012:

<u>(in thousands)</u>	
Balance at January 1, 2012	\$ 4,868
Capitalization	—
Accretion expense	277
Balance at June 30, 2012	<u>\$ 5,145</u>

8. Intangibles, net

Intangibles, net consisted of the following:

<u>(in thousands)</u>	<u>June 30, 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	\$ 17,261	\$ 36,129	8 years	Straight-line
Customer relationships	113,643	78,906	34,737	19 years	Accelerated
Other patents	42,780	38,936	3,844	2 years	Straight-line
	<u>\$ 209,813</u>	<u>\$ 135,103</u>	<u>\$ 74,710</u>		

<u>(in thousands)</u>	<u>December 31, 2011</u>				
	<u>Cost</u>	<u>Accumulated amortization</u>	<u>Net</u>	<u>Weighted Average Useful Life</u>	<u>Amortization Method</u>
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>		

Prior to the issuance of the Company's June 30, 2011 financial statements, the Company completed an update of its sales forecast based on actual sales results through June 30, 2011 and its forecasted Ablavar sales activity. The Company, using its revised sales forecast, conducted an impairment analysis of its Ablavar patent portfolio as of June 30, 2011 and concluded that the estimate of future undiscounted cash flows associated with the Ablavar product did not exceed the carrying amount of the asset and therefore, the asset would need to be written down to its fair value. In order to calculate the fair value of the Ablavar patent portfolio asset, the Company estimated the future discounted cash flows associated with the Ablavar product and as a result of this analysis, recorded an impairment charge of \$23.5 million to adjust the carrying value to its fair value of zero. This expense was recorded within cost of goods sold in the accompanying condensed statement of comprehensive loss.

**Lantheus MI Intermediate, Inc. and subsidiaries****Notes to Unaudited Condensed Consolidated Statements (Continued)****8. Intangibles, net (Continued)**

For the three and six months ended June 30, 2012, the Company recorded amortization expense for its intangible assets of \$4.0 million and \$8.1 million, respectively, as compared to \$5.5 million and \$11.0 million for the prior year comparative periods.

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:

<u>(in thousands)</u>	
Remainder of 2012	\$ 8,010
2013	14,447
2014	13,164
2015	11,491
2016	10,737
2017 and thereafter	16,861
	<u>\$ 74,710</u>

**9. Accrued Expenses**

Accrued expenses are comprised of the following:

<u>(in thousands)</u>	<u>June 30,</u>	<u>December 31,</u>
	<u>2012</u>	<u>2011</u>
Compensation and benefits	6,538	\$ 5,501
Accrued interest	4,886	4,886
Accrued professional fees	1,749	1,927
Research and development services	3,943	2,100
Freight, distribution and operations	3,732	2,462
Accrued loss on firm purchase commitment	4,742	954
Marketing expense	1,367	1,104
Accrued rebates, discounts and chargebacks	1,285	1,356
Other	457	659
	<u>\$ 28,699</u>	<u>\$ 20,949</u>

As of June 30, 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 from the Company's supplier that the Company did not believe it would sell prior to expiry. At June 30, 2012, \$4.7 million was included in accrued expenses and \$0.9 million was included in other long-term liabilities. At December 31, 2011, \$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 loss during the three month period ended March 31, 2012. The remaining balance in accrued expenses at June 30, 2012 associated with this action was approximately \$0.2 million.



**Lantheus MI Intermediate, Inc. and subsidiaries****Notes to Unaudited Condensed Consolidated Statements (Continued)****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. 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 based on a premium percentage on the principal:

<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).

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.

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

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

**10. Financing Arrangements (Continued)**

*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 June 30, 2012 and December 31, 2011, there was no outstanding balance under the Facility and the aggregate borrowing capacity was \$33.7 million and \$42.5 million, respectively. The availability under the Facility decreased in the period ended June 30, 2012 due to an unfunded Standby Letter of Credit of \$8.8 million. The Standby Letter of Credit expires February 2, 2013.

*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 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").

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

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 June 30, 2012 and the date hereof, other than the unfunded Standby Letter of Credit in the amount of \$8.8 million, 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 loss.

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 loss.

**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 June 30, 2012 is 4,977,020. Option awards are granted with an exercise price equal to the fair value of Holdings' stock at the date of grant, as 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

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

11. Stock-Based Compensation (Continued)

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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Expected volatility	39 - 41%	33%	39 - 41%	33%
Expected dividends	—	—	—	—
Expected life (in years)	5.5 - 6.5	6.5	5.5 - 6.5	6.5
Risk-free interest rate	0.7 - 1.4%	2.9%	0.7 - 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	135,500	103,000	238,500	8.27		
Options cancelled	11,300	8,203	19,503	2.34		
Options exercised	7,500	1,930	9,430	2.00		
Options forfeited or expired	22,950	18,650	41,600	6.42		
Outstanding at June 30, 2012	2,381,350	1,381,755	3,763,105	3.21	6.02	\$ 20,069,000
Vested and expected to vest at June 30, 2012	2,367,857	1,009,105	3,376,962	3.20	6.02	\$ 18,036,000
Exercisable at June 30, 2012	1,758,300	828,205	2,586,505	\$ 2.29	5.61	\$ 15,873,000

The weighted average grant-date fair value of options granted during the three and six months ended June 30, 2012 was \$3.43 and \$3.47, as compared to \$4.01 for both the three and six months ended June 30, 2011, respectively. There were 223,500 and 238,500 options granted during the three and six months ended June 30, 2012, respectively. There were no options granted during the three months ended June 30, 2011 and there were 242,000 options granted during the six months ended June 30, 2011. During the six months ended June 30, 2012, 515,389 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 six months ended June 30, 2012, 9,430 stock options were exercised on a cashless basis for which 7,130 shares of common stock were issued. The intrinsic value for the options exercised during the six months ended June 30, 2012 was approximately \$59,000. There were no options exercised during the six months ended June 30, 2011.

Stock-based compensation expense (income) for both time based and performance based awards was recognized in the condensed consolidated statements of comprehensive loss as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Cost of goods sold	\$ —	\$ (48)	\$ 17	\$ (32)
General and administrative	165	(323)	636	(198)
Sales and marketing	9	(61)	56	(1,018)
Research and development	42	(91)	81	(24)
Total stock-based compensation expense (income)	\$ 216	\$ (523)	\$ 790	\$ (1,272)

Stock-based compensation expense (income) recognized in the condensed consolidated statement of comprehensive loss for the three and six months ended June 30, 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 three and six months ended June 30, 2012, the Company recognized approximately \$0.1 million and \$0.5 million, respectively, of stock-based compensation expense associated with the modification of two option agreements that were effected in the first quarter of 2012. The modifications of both awards affected the vesting terms of the awards, allowing vesting to continue beyond the last day of employment, so long as the option holders, whom are no longer employees, continue to provide consulting services to the Company. The Company will remeasure the fair value of these options at each reporting period until the consulting services are completed, which is the measurement date.

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 three months ended June 30, 2012 nor the six months ended June 30, 2011.

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

The Company used the following Black-Scholes inputs to remeasure the fair value of stock options that were modified during 2012 as of June 30, 2012.

Expected volatility	29%
Expected dividends	—
Expected term (in years)	3.0
Risk-free interest rate	0.4%

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

Upon termination of employee services, the Company has the right to call shares held by employees, that were purchased or acquired through option exercise. As a result of this right, upon termination of service, vested stock-based awards are reclassified to liability based awards until the period of probable exercise has lapsed. As of June 30, 2012, the Company had recorded a liability and stock-based compensation expense of approximately \$17,000 representing 13,300 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 June 30, 2011. There were no stock-based liability awards paid out in the first six months of 2012 or 2011. The Company recorded a benefit of approximately \$1.0 million in the three month period ended March 31, 2011 related to liability awards which expired during the period.

The Company did not recognize an income tax benefit for the six months ended June 30, 2012 or June 30, 2011 associated with option awards. As of June 30, 2012, there were approximately \$1.8 million of total unrecognized compensation costs related to non-vested stock options granted under the 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 the performance criteria. As of June 30, 2012, there was approximately \$1.4 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:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Foreign currency (losses) gains	\$ (175)	\$ 13	\$ (332)	\$ 102
Tax indemnification income	415	390	830	770
Other income	41	42	88	71
Total other income, net	<u>\$ 281</u>	<u>\$ 445</u>	<u>\$ 586</u>	<u>\$ 943</u>

**13. Legal Proceedings and Contingencies**

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

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

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

**13. Legal Proceedings and Contingencies (Continued)**

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. 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.

**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 our 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 comprises 65.0% and 70.3% of consolidated revenues for the three and six months ended June 30, 2012 as compared to 74.9% and 75.6% for the prior year comparative periods and 86.7% and 85.5% of consolidated assets at June 30, 2012 and December 31, 2011, respectively. All goodwill has been allocated to the U.S. operating segment.

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

14. Segment Information (Continued)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
<b>Revenues</b>				
U.S.	\$ 40,851	\$ 75,503	\$ 109,189	\$ 156,128
International	19,875	22,704	42,246	45,947
Total revenue, including inter-segment	60,726	98,207	151,435	202,075
Less inter-segment revenue	(3,965)	(7,788)	(9,323)	(13,537)
	<u>\$ 56,761</u>	<u>\$ 90,419</u>	<u>\$ 142,112</u>	<u>\$ 188,538</u>
<b>Revenues from external customers</b>				
U.S.	\$ 36,886	\$ 67,715	\$ 99,866	\$ 142,591
International	19,875	22,704	42,246	45,947
	<u>\$ 56,761</u>	<u>\$ 90,419</u>	<u>\$ 142,112</u>	<u>\$ 188,538</u>
<b>Operating (loss) income</b>				
U.S.	\$ (18,583)	\$ (30,098)	\$ 9,289	\$ (17,043)
International	2,788	3,525	7,786	7,132
Total operating income (loss), including inter-segment	(15,795)	(26,573)	17,075	(9,911)
Inter-segment operating income (loss)	746	(498)	1,052	876
Operating (loss) income	(15,049)	(27,071)	18,127	(9,035)
Interest expense, net	(10,467)	(10,433)	(20,813)	(17,370)
Other income, net	281	445	586	943
Loss before income taxes	<u>\$ (25,235)</u>	<u>\$ (37,059)</u>	<u>\$ (2,100)</u>	<u>\$ (25,462)</u>

	June 30, 2012	December 31, 2011
<b>Assets</b>		
U.S.	\$ 310,907	\$ 306,615
International	47,872	52,189
	<u>\$ 358,779</u>	<u>\$ 358,804</u>

15. Guarantor Financial Information

The 9.750% Senior Notes due 2017 (see Note 10) are guaranteed by Lantheus Intermediate and Lantheus MI Real Estate, LLC, one of the Company'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 June 30, 2012 and December 31, 2011, comprehensive (loss) income information for the three and six months ended June 30, 2012 and 2011 and cash flow information for the six months ended June 30, 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

June 30, 2012

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
<b>Assets</b>						
Cash and cash equivalents	\$ —	\$ 39,318	\$ —	\$ 17,555	\$ —	\$ 56,873
Accounts receivable, net	—	21,537	—	11,995	—	33,532
Intercompany accounts receivable	—	1,068	—	—	(1,068)	—
Inventory	—	12,585	—	2,366	—	14,951
Deferred tax assets	—	—	—	131	—	131
Other current assets	—	4,412	—	302	—	4,714
Total current assets	—	78,920	—	32,349	(1,068)	110,201
Property, plant and equipment, net	—	78,312	23,235	8,123	—	109,670
Capitalized software development costs	—	2,848	—	6	—	2,854
Intangibles, net	—	67,530	—	7,180	—	74,710
Goodwill	—	15,714	—	—	—	15,714
Deferred financing costs	—	12,253	—	—	—	12,253
Investment in subsidiaries	(135,982)	63,108	—	—	72,874	—
Due from parent	—	1,256	—	—	—	1,256
Other long-term assets	—	31,907	—	214	—	32,121
<b>Total assets</b>	<b>\$ (135,982)</b>	<b>\$ 351,848</b>	<b>\$ 23,235</b>	<b>\$ 47,872</b>	<b>\$ 71,806</b>	<b>\$ 358,779</b>
<b>Liabilities and (deficit) equity</b>						
Current portion of long-term debt	\$ —	\$ 616	\$ —	\$ —	\$ —	\$ 616
Accounts payable	—	16,375	—	2,042	—	18,417
Intercompany accounts payable	—	—	—	1,068	(1,068)	—
Accrued expenses	—	25,039	—	3,660	—	28,699
Income tax payable	—	1,324	—	(50)	—	1,274
Deferred revenue	—	4,430	—	263	—	4,693
<b>Total current liabilities</b>	<b>—</b>	<b>47,784</b>	<b>—</b>	<b>6,983</b>	<b>(1,068)</b>	<b>53,699</b>
Asset retirement obligation	—	5,003	—	142	—	5,145
Long-term debt, net	—	398,726	—	—	—	398,726
Deferred tax liability	—	—	—	625	—	625
Other long-term liabilities	—	36,317	—	249	—	36,566
<b>Total liabilities</b>	<b>—</b>	<b>487,830</b>	<b>—</b>	<b>7,999</b>	<b>(1,068)</b>	<b>494,761</b>
<b>(Deficit) equity</b>	<b>(135,982)</b>	<b>(135,982)</b>	<b>23,235</b>	<b>39,873</b>	<b>72,874</b>	<b>(135,982)</b>
<b>Total liabilities and (deficit) equity</b>	<b>\$ (135,982)</b>	<b>\$ 351,848</b>	<b>\$ 23,235</b>	<b>\$ 47,872</b>	<b>\$ 71,806</b>	<b>\$ 358,779</b>

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>						
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
<b>Total assets</b>	<b>\$ (133,203)</b>	<b>\$ 351,736</b>	<b>\$ 23,275</b>	<b>\$ 52,190</b>	<b>\$ 64,806</b>	<b>\$ 358,804</b>
<b>Liabilities and (deficit) equity</b>						
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 revenue	—	3,712	—	206	—	3,918
Total current liabilities	—	42,825	—	6,948	(1,414)	48,359
Asset retirement obligation	—	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
<b>Total liabilities</b>	<b>—</b>	<b>484,939</b>	<b>—</b>	<b>8,482</b>	<b>(1,414)</b>	<b>492,007</b>
(Deficit) equity	(133,203)	(133,203)	23,275	43,708	66,220	(133,203)
<b>Total liabilities and (deficit) equity</b>	<b>\$ (133,203)</b>	<b>\$ 351,736</b>	<b>\$ 23,275</b>	<b>\$ 52,190</b>	<b>\$ 64,806</b>	<b>\$ 358,804</b>

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

15. Guarantor Financial Information (Continued)

Condensed Consolidating Statement of Comprehensive (Loss) Income

Three Months Ended June 30, 2012

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
Net product revenues	\$ —	\$ 40,993	\$ —	\$ 17,018	\$ (3,966)	\$ 54,045
License and other revenues	—	2,716	—	—	—	2,716
Total revenues	—	43,709	—	17,018	(3,966)	56,761
Cost of goods sold	—	37,638	—	14,954	(3,966)	48,626
Gross profit	—	6,071	—	2,064	—	8,135
Operating expenses						
General and administrative expenses	—	7,241	20	499	—	7,760
Sales and marketing expenses	—	7,982	—	933	—	8,915
Research and development expenses	—	10,364	—	45	—	10,409
Proceeds from manufacturer	—	(3,900)	—	—	—	(3,900)
Operating income (loss)	—	(15,616)	(20)	587	—	(15,049)
Interest expense, net	—	(10,519)	—	52	—	(10,467)
Other income, net	—	392	—	(111)	—	281
Equity in earnings (losses) of affiliates	(24,628)	650	—	—	23,978	—
Income (loss) before income taxes	(24,628)	(25,093)	(20)	528	23,978	(25,235)
Provision (benefit) for income taxes	—	(465)	7	(149)	—	(607)
Net income (loss)	\$ (24,628)	\$ (24,628)	\$ (27)	\$ 677	\$ 23,978	\$ (24,628)
Foreign currency translation, net of taxes	—	—	—	(689)	—	(689)
Equity in other comprehensive income (loss) of subsidiaries	(689)	(689)	—	—	1,378	—
Total comprehensive (loss) income	\$ (25,317)	\$ (25,317)	\$ (27)	\$ (12)	\$ 25,356	\$ (25,317)

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

15. Guarantor Financial Information (Continued)

Condensed Consolidating Statement of Comprehensive (Loss) Income

Three Months Ended June 30, 2011

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
Net product revenues	\$ —	\$ 76,649	\$ —	\$ 19,417	\$ (7,788)	\$ 88,278
License and other revenues	—	2,141	—	—	—	2,141
Total revenues	—	78,790	—	19,417	(7,788)	90,419
Cost of goods sold	—	78,606	—	16,627	(7,788)	87,445
Loss on firm purchase commitment	—	1,879	—	—	—	1,879
Gross profit	—	(1,695)	—	2,790	—	1,095
Operating expenses						
General and administrative expenses	—	6,509	20	593	—	7,122
Sales and marketing expenses	—	9,444	—	1,258	—	10,702
Research and development expenses	—	10,061	—	281	—	10,342
Operating income (loss)	—	(27,709)	(20)	658	—	(27,071)
Interest expense, net	—	(10,511)	—	78	—	(10,433)
Other income, net	—	445	—	—	—	445
Equity in earnings (losses) of affiliates	(22,313)	914	—	—	21,399	—
Income (loss) before income taxes	(22,313)	(36,861)	(20)	736	21,399	(37,059)
Provision (benefit) for income taxes	—	(14,548)	(7)	(191)	—	(14,746)
Net income (loss)	\$ (22,313)	\$ (22,313)	\$ (13)	\$ 927	\$ 21,399	\$ (22,313)
Foreign currency translation, net of taxes	—	—	—	232	—	232
Total comprehensive (loss) income	\$ (22,313)	\$ (22,313)	\$ (13)	\$ 1,159	\$ 21,399	\$ (22,081)

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

15. Guarantor Financial Information (Continued)

Condensed Consolidating Statement of Comprehensive (Loss) Income

Six Months Ended June 30, 2012

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
Net product revenues	\$ —	\$ 112,042	\$ —	\$ 33,958	\$ (9,324)	\$ 136,676
License and other revenues	—	5,436	—	—	—	5,436
Total revenues	—	117,478	—	33,958	(9,324)	142,112
Cost of goods sold	—	80,598	—	29,887	(9,324)	101,161
Gross profit	—	36,880	—	4,071	—	40,951
Operating expenses						
General and administrative expenses	—	15,786	40	1,133	—	16,959
Sales and marketing expenses	—	16,995	—	1,913	—	18,908
Research and development expenses	—	20,683	—	88	—	20,771
Proceeds from manufacturer	—	(33,814)	—	—	—	(33,814)
Operating income (loss)	—	17,230	(40)	937	—	18,127
Interest expense, net	—	(20,966)	—	153	—	(20,813)
Other income, net	—	655	—	(69)	—	586
Equity in earnings (losses) of affiliates	(3,730)	870	—	—	2,860	—
Income (loss) before income taxes	(3,730)	(2,211)	(40)	1,021	2,860	(2,100)
Provision (benefit) for income taxes	—	1,519	—	111	—	1,630
Net income (loss)	\$ (3,730)	\$ (3,730)	\$ (40)	\$ 910	\$ 2,860	\$ (3,730)
Foreign currency translation, net of taxes	—	200	—	(22)	—	178
Equity in other comprehensive income (loss) of subsidiaries	178	(22)	—	—	(156)	—
Total comprehensive (loss) income	\$ (3,552)	\$ (3,552)	\$ (40)	\$ 888	\$ 2,704	\$ (3,552)

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

15. Guarantor Financial Information (Continued)

Condensed Consolidating Statement of Comprehensive (Loss) Income

Six Months Ended June 30, 2011

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
Net product revenues	\$ —	\$ 158,345	\$ —	\$ 39,426	\$ (13,537)	\$ 184,234
License and other revenues	—	4,304	—	—	—	4,304
Total revenues	—	162,649	—	39,426	(13,537)	188,538
Cost of goods sold	—	119,672	—	33,361	(13,537)	139,496
Loss on firm purchase commitment	—	1,879	—	—	—	1,879
Gross profit	—	41,098	—	6,065	—	47,163
Operating expenses						
General and administrative expenses	—	13,925	40	1,289	—	15,254
Sales and marketing expenses	—	17,782	—	2,315	—	20,097
Research and development expenses	—	20,454	—	393	—	20,847
Operating income (loss)	—	(11,063)	(40)	2,068	—	(9,035)
Interest expense, net	—	(17,517)	—	147	—	(17,370)
Other income, net	—	860	—	83	—	943
Equity in earnings (losses) of affiliates	(15,966)	2,197	—	—	13,769	—
Income (loss) before income taxes	(15,966)	(25,523)	(40)	2,298	13,769	(25,462)
Provision (benefit) for income taxes	—	(9,557)	(14)	75	—	(9,496)
Net income (loss)	\$ (15,966)	\$ (15,966)	\$ (26)	\$ 2,223	\$ 13,769	\$ (15,966)
Foreign currency translation, net of taxes	—	—	—	627	—	627
Total comprehensive (loss) income	\$ (15,966)	\$ (15,966)	\$ (26)	\$ 2,850	\$ 13,769	\$ (15,339)

## Lantheus MI Intermediate, Inc. and subsidiaries

## Notes to Unaudited Condensed Consolidated Statements (Continued)

## 15. Guarantor Financial Information (Continued)

## Condensed Consolidating Cash Flow Information

Six Months Ended June 30, 2012

	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
<b>Cash provided by operating activities</b>	\$ —	\$ 23,248	\$ —	\$ 2,313	\$ (4,723)	\$ 20,838
<b>Cash flows from investing activities</b>						
Purchase of certificate of deposit	—	(225)	—	—	—	(225)
Capital expenditures	—	(3,067)	—	(125)	—	(3,192)
Cash provided by (used in) investing activities	—	(3,292)	—	(125)	—	(3,417)
<b>Cash flows from financing activities</b>						
Payments on note payable	—	(914)	—	—	—	(914)
Payments of deferred financing costs	—	(198)	—	—	—	(198)
Payment of dividend	—	—	—	(4,723)	4,723	—
Cash used in financing activities	—	(1,112)	—	(4,723)	4,723	(1,112)
Effect of foreign exchange rate on cash	—	—	—	(43)	—	(43)
Increase (decrease) in cash and cash equivalents	—	18,844	—	(2,578)	—	16,266
Cash and cash equivalents, beginning of period	—	20,474	—	20,133	—	40,607
Cash and cash equivalents, end of period	\$ —	\$ 39,318	\$ —	\$ 17,555	\$ —	\$ 56,873

Lantheus MI Intermediate, Inc. and subsidiaries

Notes to Unaudited Condensed Consolidated Statements (Continued)

15. Guarantor Financial Information (Continued)

Condensed Consolidating Cash Flow Information

Six Months Ended June 30, 2011

	Company	Issuer	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
<b>Cash provided by operating activities</b>	\$ 600	\$ 4,447	\$ —	\$ 1,628	\$ (600)	\$ 6,075
<b>Cash flows from investing activities</b>						
Capital expenditures	—	(5,079)	—	(127)	—	(5,206)
Proceeds from dividend	149,400	—	—	—	(149,400)	—
Cash provided by (used in) investing activities	149,400	(5,079)	—	(127)	(149,400)	(5,206)
<b>Cash flows from financing activities</b>						
Proceeds from issuance of debt, net	—	152,250	—	—	—	152,250
Consent solicitation fee	—	(3,750)	—	—	—	(3,750)
Payments of deferred financing costs	—	(5,368)	—	—	—	(5,368)
Payment of dividend	(150,000)	(150,000)	—	—	150,000	(150,000)
Cash used in financing activities	(150,000)	(6,868)	—	—	150,000	(6,868)
Effect of foreign exchange rate on cash	—	—	—	781	—	781
Increase (decrease) in cash and cash equivalents	—	(7,500)	—	2,282	—	(5,218)
Cash and cash equivalents, beginning of period	—	19,079	—	13,927	—	33,006
Cash and cash equivalents, end of period	\$ —	\$ 11,579	\$ —	\$ 16,209	\$ —	\$ 27,788



## 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 for product manufactured at Ben Venue Laboratories, Inc., or BVL; 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 quarterly 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 Cardiolute 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 potential inability to compete effectively;
- ongoing generic competition to Cardiolute 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;

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- 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;
- potential liability associated with our marketing and sales practices;
- the occurrence of any 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 potential 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

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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 of nuclear imaging products in the United States 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 84 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 June 30,				Six Months Ended June 30,			
	2012	%	2011	%	2012	%	2011	%
Cardiolite	\$ 6,412	11.3	\$ 19,114	21.1	\$ 16,222	11.4	\$ 41,821	22.2
TechneLite	26,235	46.2	31,587	34.9	57,608	40.5	67,530	35.8
DEFINITY	2,678	4.7	17,305	19.2	22,847	16.1	33,466	17.8
Other	21,436	37.8	22,413	24.8	45,435	32.0	45,721	24.2
Total revenues	\$ 56,761	100.0	\$ 90,419	100.0	\$ 142,112	100.0	\$ 188,538	100.0

Included in Cardiolite is branded Cardiolite and generic sestamibi, some of which that we produce and some of which we procure from third parties.

#### **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. Because the shutdown and restart activities took substantially longer than anticipated by either BVL or us, we could not meet all of the demand for certain products during the second half of 2011 and the first half of 2012, resulting in overall revenue decline in comparison to the prior periods. BVL resumed

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manufacturing certain of our products in May 2012. After BVL released the first lot of newly-manufactured DEFINITY in June 2012, we shipped product to our customers in late June and early July. We are currently working closely with BVL to complete the quality review and commercial release process for the remaining lots BVL has recently manufactured for us, a process we believe should be completed in the next several weeks. We continue to work to restore full and normal production of all of our BVL-manufactured products as well as to build a sufficient inventory to appropriately serve all of our customers. We can give no assurances that the remaining product that BVL has recently manufactured for us will successfully complete the quality review and commercial release process, or that BVL will be able to manufacture product for us on a timely and consistent basis in the future.

We have also 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 Jubilant HollisterStier ("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, we are unable to regain sufficient market share, or 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 reductions such as a potential delay of discretionary spending including possible reductions in sales and marketing and research and development activities, as well as other operating and strategic initiatives.

### ***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 ran from mid-April 2012 until mid-May 2012, and during such period we were able to fulfill substantially all of our customer demand for Moly from our other suppliers.

During the 2009 to 2010 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 TechnLite generators for radiopharmacies and hospitals to make up unit doses of Cardiolite, resulting in decreased sales of TechnLite and Cardiolite in favor of other diagnostic modalities that did not use Moly during the 2009 to 2010 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. Prior to the supply issues with BVL, 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

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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 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 are able to restore full and normal production of all of our BVL-manufactured products with BVL or alternate suppliers, as well as to build sufficient inventory to appropriately serve all of our customers, the continued growth of our DEFINITY sales will be negatively impacted.

### ***Demand for TechnLite***

Following the global Moly supply challenge in 2009-2010, we have experienced reduced demand for TechnLite 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 TechnLite generators.

We believe that TechnLite 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 at the same time as we continue 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 the BVL outage, and the increase in use of other diagnostic modalities as a result of a shift to more available imaging agents and modalities. Prior

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to the BVL-related supply challenges, we believe we had been able to maintain share for our branded product in a generic segment, because of 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 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.

### **Executive Overview**

The following have impacted our results in the three and six months ended June 30, 2012:

- limited supply of DEFINITY, Cardiolite and Neurolite 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 alternate manufacturer of Cardiolite and from our third party manufacturers of generic sestamibi;
- 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 \$34.2 million from BVL to compensate us for business losses under (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").
  - 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.

For the remainder of 2012, until we are able to restore full and normal production of all of our BVL-manufactured products, as well as to build sufficient inventory to appropriately serve all of our customers, or obtain adequate supply from JHS, our results of operations will be negatively impacted. We believe this will be partially mitigated following the return of sustained DEFINITY supply and the expected continuation of DEFINITY sales growth.

**Results of Operations**

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2012	2011	2012	2011
<b>Revenues</b>				
Net product revenues	\$ 54,045	\$ 88,278	\$ 136,676	\$ 184,234
License and other revenues	2,716	2,141	5,436	4,304
Total revenues	56,761	90,419	142,112	188,538
Cost of goods sold	48,626	87,445	101,161	139,496
Loss on firm purchase commitment	—	1,879	—	1,879
Total cost of goods sold	48,626	89,324	101,161	141,375
Gross profit	8,135	1,095	40,951	47,163
<b>Operating expenses</b>				
General and administrative expenses	7,760	7,122	16,959	15,254
Sales and marketing expenses	8,915	10,702	18,908	20,097
Research and development expenses	10,409	10,342	20,771	20,847
Proceeds from manufacturer	(3,900)	—	(33,814)	—
Total operating expenses	23,184	28,166	22,824	56,198
Operating (loss) income	(15,049)	(27,071)	18,127	(9,035)
Interest expense, net	(10,467)	(10,433)	(20,813)	(17,370)
Other income, net	281	445	586	943
Loss before income taxes	(25,235)	(37,059)	(2,100)	(25,462)
Provision (benefit) for income taxes	(607)	(14,746)	1,630	(9,496)
Net loss	\$ (24,628)	\$ (22,313)	\$ (3,730)	\$ (15,966)
Foreign currency translation, net of taxes	(689)	232	178	627
Total comprehensive loss	\$ (25,317)	\$ (22,081)	\$ (3,552)	\$ (15,339)

**Revenues**

Revenues are summarized as follows:

(dollars in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
<b>United States</b>				
Cardiolite	\$ 511	\$ 11,770	\$ 4,491	\$ 27,158
TechneLite	22,758	27,215	50,695	58,403
DEFINITY	2,683	17,038	22,448	32,919
Other currently marketed products	8,225	9,551	16,803	19,807
Total U.S. product revenue	34,177	65,574	94,437	138,287
License and other revenues	2,709	2,141	5,429	4,304
Total U.S. revenues	\$ 36,886	\$ 67,715	\$ 99,866	\$ 142,591
<b>International</b>				
Cardiolite	\$ 5,901	\$ 7,344	\$ 11,731	\$ 14,663
TechneLite	3,477	4,372	6,913	9,127
DEFINITY	(5)	267	399	547
Other currently marketed products	10,495	10,721	23,196	21,610
Total International product revenue	19,868	22,704	42,239	45,947
License and other revenues	7	—	7	—
Total International revenues	19,875	22,704	42,246	45,947
Product revenue	54,045	88,278	136,676	184,234
License and other revenue	2,716	2,141	5,436	4,304
Total revenue	\$ 56,761	\$ 90,419	\$ 142,112	\$ 188,538

Total revenues decreased \$33.7 million, or 37.2%, to \$56.8 million in the three months ended June 30, 2012 as compared to \$90.4 million in the three months ended June 30, 2011. U.S. segment revenue decreased \$30.8 million, or 45.5%, to \$36.9 million in the same period, as compared to \$67.7 million in the prior year. International segment revenue decreased \$2.8 million, or 12.5%, to \$19.9 million in the same period, as compared to \$22.7 million in the prior year.

Total revenues decreased \$46.4 million, or 24.6%, to \$142.1 million in the six months ended June 30, 2012 as compared to \$188.5 million in the six months ended June 30, 2011. U.S. segment revenue decreased \$42.7 million, or 30.0%, to \$99.9 million in the same period, as compared to \$142.6 million in the prior year. International segment revenue decreased \$3.7 million, or 8.1%, to \$42.2 million in the same period, as compared to \$45.9 million in the prior year.

The decrease in revenue for the three and six months ended June 30, 2012 was primarily due to the BVL shutdown impacting our supply of DEFINITY, Cardiolite, and NeuroLite. See "Key Factors Affecting Our Results—Inventory Supply." TechneLite sales decreased given lower volume. Offsetting these decreases were increases in revenue for the U.S. segment of Xenon, as a result of price increases. Additional increases in revenue relating only to the six month period ended June 30, 2012 for the International segment related to 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



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period the related revenue is recognized, resulting in a reduction in product revenue and the establishment of a liability which is included in accrued expenses in the accompanying 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 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:

(dollars in thousands)	Rebates	Allowances	Total
Balance, as of January 1, 2011	\$ 910	\$ 101	\$ 1,011
Current provisions relating to revenues in current year	3,672	474	4,146
Adjustments relating to prior years' estimate	(116)	—	(116)
Payments/credits relating to revenues in current year	(2,617)	(441)	(3,058)
Payments/credits relating to revenues in prior years	(493)	(101)	(594)
Balance, as of December 31, 2011	1,356	33	1,389
Current provisions relating to revenues in current year	1,377	164	1,541
Adjustments relating to prior years' estimate	20	—	20
Payments/credits relating to revenues in current year	(902)	(128)	(1,030)
Payments/credits relating to revenues in prior years	(566)	(35)	(601)
Balance, as of June 30, 2012	<u>\$ 1,285</u>	<u>\$ 34</u>	<u>\$ 1,319</u>

Sales rebates and other accruals were approximately \$1.3 million and \$1.4 million at June 30, 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:

(dollars in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
United States	\$ 34,292	\$ 75,820	\$ 72,942	\$ 113,977
International	14,334	13,504	28,219	27,398
Total Cost of Goods Sold	<u>\$ 48,626</u>	<u>\$ 89,324</u>	<u>\$ 101,161</u>	<u>\$ 141,375</u>

Total costs of goods sold decreased \$40.7 million, or 45.6%, to \$48.6 million in the three months ended June 30, 2012 as compared to \$89.3 million in the three months ended June 30, 2011. U.S. segment costs of goods sold decreased \$41.5 million, or 54.8%, to \$34.3 million in the same period, as compared to \$75.8 million in the prior year. International segment costs of goods sold increased

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\$0.8 million, or 6.1%, to \$14.3 million in the same period, as compared to \$13.5 million in the prior year.

Total costs of goods sold decreased \$40.2 million, or 28.4%, to \$101.2 million in the six months ended June 30, 2012 as compared to \$141.4 million in the six months ended June 30, 2011. U.S. segment costs of goods sold decreased \$41.0 million, or 36.0%, to \$72.9 million in the same period, as compared to \$113.9 million in the prior year. International segment costs of goods sold increased \$0.8 million, or 3.0%, to \$28.2 million in the same period, as compared to \$27.4 million in the prior year.

The primary contributing factor to the decrease in cost of goods in the three and six months ended June 30, 2012 for the U.S. segment were prior period write-offs totaling \$38.9 million for Ablavar intangible property, inventory and recording of loss contract reserves, reduced product costs in 2012 as a result of lower TechneLite, DEFINITY and Cardiolite sales and lower intangible amortization expense. These decreases were offset in part, by increases of \$1.9 million and \$3.0 million in the three and six months, respectively, associated with technology transfer costs related to DEFINITY.

The increase in cost of goods in the three and six months ended June 30, 2012 for the International segment was primarily due to higher manufacturing costs in our radiopharmacies, as well as a temporary increase associated with third party sestamibi being utilized by radiopharmacies as a result of the lack of Cardiolite supply.

## Gross Profit

(dollars in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
United States	\$ 2,594	\$ (8,105)	\$ 26,924	\$ 28,614
International	5,541	9,200	14,027	18,549
<b>Total Gross Profit</b>	<b>\$ 8,135</b>	<b>\$ 1,095</b>	<b>\$ 40,951</b>	<b>\$ 47,163</b>

Total gross profit increased \$7.0 million, or 642.9%, to \$8.1 million in the three months ended June 30, 2012 as compared to \$1.1 million in the three months ended June 30, 2011. U.S. segment gross profit increased \$10.7 million, or 132.0%, to \$2.6 million in the same period, as compared to a loss of \$8.1 million in the prior year. International segment gross profit decreased \$3.7 million, or 39.8%, to \$5.5 million in the same period, as compared to \$9.2 million in the prior year.

Total gross profit decreased \$6.2 million, or 13.2%, to \$41.0 million in the six months ended June 30, 2012 as compared to \$47.2 million in the six months ended June 30, 2011. U.S. segment gross profit decreased \$1.7 million, or 5.9%, to \$26.9 million in the same period, as compared to \$28.6 million in the prior year. International segment gross profit decreased \$4.5 million, or 24.4%, to \$14 million in the same period, as compared to \$18.5 million in the prior year.

The increase in gross profit in the three months ended June 30, 2012 for the U.S. segment was due to prior period Ablavar write-offs noted above and lower intangible amortization expense. These lower expenses were partially offset by decreased profits from TechneLite due to lower volume. We also experienced lower profits from DEFINITY, Cardiolite and NeuroLite caused by supply issues resulting from the BVL shutdown.

The decrease in gross profit in the six months ended June 30, 2012 for the U.S. segment was due to lower profits from DEFINITY, Cardiolite and NeuroLite caused by supply issues resulting from the BVL shutdown. We also experienced decreased profits from TechneLite due to lower volume. These decreases were partially offset by prior period write-offs totaling \$38.9 million for Ablavar intangible property, inventory and the recording of a loss contract during the three and six months ended June 30,

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2011. We incurred less intangible amortization expense since a number of our intangibles are amortized on an accelerated method. In addition, we earned higher profits on Xenon due to price increases.

The decrease in gross profit in the three and six months ended June 30, 2012 for our International segment was a result of lower Cardiolite volumes related to the product shortage in certain markets and lower TechnLite volume. These decreases were partially offset by increases in gross profit due to generic sestamibi purchased from third parties as a temporary substitute for Cardiolite. Relating only to the six month period, we incurred higher profits in 2012 from NeuroLite ligand which is unaffected by the product shortage.

### General and Administrative

(dollars in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
United States	\$ 7,261	\$ 6,529	\$ 15,825	\$ 13,965
International	499	593	1,134	1,289
Total General and Administrative	<u>\$ 7,760</u>	<u>\$ 7,122</u>	<u>\$ 16,959</u>	<u>\$ 15,254</u>

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

Total general and administrative expense increased \$0.7 million, or 9.0%, to \$7.8 million in the three months ended June 30, 2012, as compared to \$7.1 million in the three months ended June 30, 2011. In the U.S. segment, general and administrative expense increased \$0.8 million, or 11.2%, to \$7.3 million, as compared to \$6.5 million in the prior year period. In the International segment, general and administrative expenses decreased \$0.1 million, or 15.9%, to \$0.5 million, as compared to \$0.6 million in the prior year period.

Total general and administrative expense increased \$1.7 million, or 11.2%, to \$17.0 million in the six months ended June 30, 2012, as compared to \$15.3 million in the six months ended June 30, 2011. In the U.S. segment, general and administrative expense increased \$1.9 million, or 13.3%, to \$15.8 million, as compared to \$13.9 million in the prior year period. In the International segment, general and administrative expenses decreased \$0.2 million, or 12.0%, to \$1.1 million, as compared to \$1.3 million in the prior year period.

The increase in general and administrative expense in the three and six months ended June 30, 2012 for the U.S. segment was primarily due to external legal fees in connection with our suit seeking to recover business interruption losses. In addition, we saw an increase in general and administrative expense due to modifications to stock option agreements, contractor support, recruitment expense and severance costs related to a reduction in workforce in the first quarter of 2012. Relating only to the three month period ended June 30, 2012, we saw a decrease in variable compensation during the second quarter of 2011. Offsetting these increases in the three and six month period was an overall lower external support for information technology and accounting services.

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The decrease in general and administrative expense in the three and six months ended June 30, 2012 for the International segment was primarily due to attrition in workforce during the second quarter of 2012 and a recovery of bad debt during the first half of 2012.

**Sales and Marketing**

(dollars in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
United States	\$ 7,789	\$ 9,307	\$ 16,697	\$ 17,450
International	\$ 1,126	1,395	\$ 2,211	2,647
Total Sales and Marketing	\$ 8,915	\$ 10,702	\$ 18,908	\$ 20,097

Sales and marketing expenses consist primarily of salaries and other 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.

Total sales and marketing expense decreased \$1.8 million, or 16.7%, to \$8.9 million in the three months ended June 30, 2012, as compared to \$10.7 million in the three months ended June 30, 2011. In the U.S. segment, sales and marketing expense decreased \$1.5 million, or 16.3%, to \$7.8 million, as compared to \$9.3 million in the prior year period. In the International segment, sales and marketing expenses decreased \$0.3 million, or 19.3%, to \$1.1 million, as compared to \$1.4 million in the prior year period.

Total sales and marketing expense decreased \$1.2 million, or 5.9%, to \$18.9 million in the six months ended June 30, 2012, as compared to \$20.1 million in the six months ended June 30, 2011. In the U.S. segment, sales and marketing expense decreased \$0.8 million, or 4.3%, to \$16.7 million, as compared to \$17.5 million in the prior year period. In the International segment, sales and marketing expenses decreased \$0.4 million, or 16.5%, to \$2.2 million, as compared to \$2.6 million in the prior year period.

The decrease in sales and marketing expense in the three and six months ended June 30, 2012 for the U.S. segment was primarily due to lower salary and other personnel cost in 2012 related to a workforce reduction during the second quarter of 2011 and overall lower expense on sales and marketing activities due to decreased inventory supply resulting from the prolonged BVL outage, which was offset by the reversal of stock-based compensation in the first quarter of 2011. In addition, relating only to the three month period ended June 30, 2012 was a decrease in variable compensation during the second quarter of 2011.

The decrease in sales and marketing expense in the three and six months ended June 30, 2012 for the International segment was primarily due to a transfer of workforce to the U.S. segment during 2012 and lower expense on sales and marketing activities due to decreased inventory supply resulting from the prolonged BVL outage.

**Research and Development**

(dollars in thousands)	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2012	2011	2012	2011
United States	\$ 10,362	\$ 10,061	\$ 20,682	\$ 20,454
International	47	281	89	393
<b>Total Research and Development</b>	<b>\$ 10,409</b>	<b>\$ 10,342</b>	<b>\$ 20,771</b>	<b>\$ 20,847</b>

Total research and development expense increased \$0.1 million, or 0.6%, to \$10.4 million in the three months ended June 30, 2012, as compared to \$10.3 million in the three months ended June 30, 2011. In the U.S. segment, research and development expense increased \$0.3 million, or 3.0%, to \$10.4 million, as compared to \$10.1 million in the prior year period. In the International segment, research and development expenses decreased \$0.2 million, or 83.3%, to \$47,000, as compared to \$0.3 million in the prior year period.

Total research and development expense decreased \$0.1 million, or 0.4%, to \$20.7 million in the six months ended June 30, 2012, as compared to \$20.8 million in the six months ended June 30, 2011. In the U.S. segment, research and development expense increased \$0.2 million, or 1.1%, to \$20.7 million, as compared to \$20.5 million in the prior year period. In the International segment, research and development expenses decreased \$0.3 million, or 77.4%, to \$0.1 million, as compared to \$0.4 million in the prior year period.

The increase in research and development expense in the three and six months ended June 30, 2012 for the U.S. segment was primarily due to 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 enrolling first patient during the second quarter of 2011. This increase in clinical activity in 2012 resulted in increased external costs related to our clinical research organization ("CRO"), investigator expense, drug products, lab supplies, and consultants. Offsetting these increases, were decreases caused by our reduction in workforce in the second quarter of 2011. In addition, relating only to the three month period ended June 30, 2012 was a decrease in variable compensation in the second quarter of 2011.

The decrease in research and development expense in the three and six months ended June 30, 2012 for the International segment was primarily due to our reduction in workforce in the second quarter of 2011.

During the second quarter of 2012, we reached an agreement with the U.S. Food and Drug Administration on a Special Protocol Assessment ("SPA") for the second flurpiridaz F 18 Phase III clinical trial and currently anticipate the program to start during the second half of 2012 as we continue our planning and preparation for the trial. 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 program.

**Proceeds from Manufacturer**

For the three and six months ended June 30, 2012 compared to the same period in 2011, proceeds from manufacturer increased by \$3.9 million and \$33.8 million, respectively, as a result of the receipt of the \$30.0 million from BVL to compensate us for business losses and an additional \$4.2 million under the Transition Services Agreement. 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.

**Other Income (Expense), Net**

(dollars in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Interest expense	\$ (10,519)	\$ (10,511)	\$ (20,966)	\$ (17,518)
Interest income	52	78	153	148
Other income, net	281	445	586	943
Total other income (expense), net	<u>\$ (10,186)</u>	<u>\$ (9,988)</u>	<u>\$ (20,227)</u>	<u>\$ (16,427)</u>

*Interest Expense*

For the three and six months ended June 30, 2012 compared to the same period in 2011, interest expense increased by \$8,000 and \$3.5 million, respectively, 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 and six months ended June 30, 2012, compared to the same period in 2011, interest income decreased by \$26,000 and increased by \$5,000, respectively, as a result of the change in balances in interest bearing accounts.

*Other Income, net*

For the three and six months ended June 30, 2012 compared to the same period in 2011, other income decreased by \$0.2 million and \$0.4 million, respectively, primarily due to the change in foreign currency exchange rates.

**(Benefit) Provision for Income Taxes**

(dollars in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
(Benefit) provision for income taxes	\$ (607)	\$ (14,746)	\$ 1,630	\$ (9,496)

For the three and six months ended June 30, 2012, compared to the same period in 2011, income tax expense increased due primarily to lower pretax losses. Our annualized effective tax rate for 2012 is estimated to be 16.68%. Our tax provision for the period ending June 30, 2012 consisted of \$0.2 million associated with current year earnings and \$1.4 million associated with discrete events. Of the discrete events, approximately \$1.0 million related to additional interest on uncertain tax positions.

## Liquidity and Capital Resources

### Cash Flows

The following table provides information regarding our cash flows:

(dollars in thousands)	Six Months Ended June 30,		
	2012	2011	\$ Change
Cash provided by (used in):			
Operating activities	\$ 20,838	\$ 6,075	\$ 14,763
Investing activities	\$ (3,417)	\$ (5,206)	\$ 1,789
Financing activities	\$ (1,112)	\$ (6,868)	\$ 5,756

#### Net Cash Provided by 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 six months ended June 30, 2012 as compared to 2011 was primarily driven by the receipt of the \$34.2 million BVL settlement less the impact of decreased unit sales associated with the BVL shutdown. Favorable operating cash was also driven by an amended purchase agreement for one of our products of which \$15.0 million of required purchases were made during the six months ended June 30, 2011, versus \$0 for the six months ended June 30, 2012.

#### Net Cash Used in Investing Activities

Net cash used in investing activities in the six months ended June 30, 2012 and 2011 primarily reflect the purchase of property and equipment.

#### Net Cash Used in 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 \$56.9 million as of June 30, 2012, as well as revenues primarily from the sale of Cardiolite, Technelite and DEFINITY.

#### 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 revolving credit facility (the "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.

As of June 30, 2012, we were in compliance with all applicable financial covenants. As of June 30, 2012 and the date hereof, there were no amounts outstanding under the Facility (other than an \$8.8 million unfunded Standby Letter of Credit) and the aggregate borrowing capacity was \$33.7 million. The availability under the Facility decreased in the quarter ended June 30, 2012 due to the Company increasing the unfunded Standby Letter of Credit from \$4.4 million to \$8.8 million to support a surety bond related to a statutory decommissioning obligation we have in connection with our Billerica facility, and expires on February 2, 2013.

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If BVL is not able to provide us adequate supply of DEFINITY, Cardiolute and Neurolite for a further prolonged period of time, we are unable to regain sufficient market share, or 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 including possible reductions in sales and marketing and research and development activities, as well as other operating and strategic initiatives. Despite these initiatives, because our prior inventory of DEFINITY, Cardiolute and Neurolite from BVL is exhausted, our third 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 in 2012. 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 an issued but undrawn letter 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.

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 full impact of the BVL shutdown and our ability to have product manufactured at alternative manufacturing sites in the future;
- 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;
- 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;
- the cost of interest on any additional borrowings which we may incur under our financing arrangements.



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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. We generated a net loss of \$3.7 million during the six months ended June 30, 2012 and had \$56.9 million of cash and cash equivalents at June 30, 2012. 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. However, if BVL is not able to provide us with an adequate product supply for a further prolonged period of time, we are unable to regain sufficient market share, or we are not successful with our JHS technology transfer programs in 2012 and we cannot obtain adequate supply from JHS, we will need to implement additional expense reductions, such as a potential delay of discretionary spending including possible reductions in sales and marketing and research and development activities, as well as other operating and strategic initiatives. Depending upon the status of our product supply, customer demand and expense management, we could be in default with one or more of the financial ratio covenants in the Facility in 2012 and, as a result, may not have access to funds under the Facility. In such event, we will seek to obtain an amendment or waiver to remain in compliance with the covenants of the Facility; however, we cannot be assured that such an amendment or waiver will be granted.

**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 June 30, 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)	\$ 400,616	\$ 616	\$ —	\$ 400,000	\$ —
Interest on debt obligations	195,004	39,004	78,000	78,000	—
Operating leases(1)	3,767	927	1,550	655	635
Purchase obligations(2)	83,375	59,861	23,514	—	—
Asset retirement obligation	5,145	—	—	—	5,145
Other long-term liabilities(3)	35,239	—	—	—	35,239
<b>Total contractual obligations</b>	<b>\$ 723,146</b>	<b>\$ 100,408</b>	<b>\$ 103,064</b>	<b>\$ 478,655</b>	<b>\$ 41,019</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.
- (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 condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed 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.

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 six months ended June 30, 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 currently 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 June 30, 2012, there was no amount outstanding under the Facility (other than a \$8.8 million unfunded Standby Letter of Credit, which reduces 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 six months ended June 30, 2012 and 2011, the net impact of foreign currency changes on transactions was a loss of \$0.3 million and a gain of \$0.1 million, 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 six month periods ended June 30, 2012 and 2011 was 28.8% and 25.0%, respectively. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during the six months ended June 30, 2012, we estimate our gross margin on total sales would have been 28.8%, 29.0% and 29.1%, respectively. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during the six months ended June 30, 2011, we estimate our gross margin on total net product sales would have been 25.0%, 25.1% and 25.2%, respectively.

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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 six months ended June 30, 2012 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%	\$ (264)	\$ (2)
5%	(1,322)	(11)
10%	(2,644)	(21)

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 six months ended June 30, 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%	\$ (324)	\$ (14)
5%	(1,618)	(70)
10%	(3,235)	(140)

#### 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 June 30, 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. 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 June 30, 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† First Amendment to Manufacturing and Supply Agreement, dated as of May 3, 2012, for the manufacture of DEFINITY® by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterStier LLC.
- 10.2† Manufacturing and Supply Agreement, dated as of May 3, 2012, for the manufacture of Cardiolite® by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterStier LLC.
- 10.3† Manufacturing and Supply Agreement, dated as of May 3, 2012, for the manufacture of Neurolite® by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterStier LLC.
- 10.4† Amendment No. 6 to the Agreement Concerning Cardiolite® and Technelite® Generator Supply, Pricing and Rebates, effective as of April 1, 2012, by and between Lantheus Medical Imaging, Inc. and United Pharmacy Partners, Inc.
- 31.1 Certification of Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), pursuant to section 302 of the Sarbanes-Oxley Act of 2002.

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31.2	Certification of Chief Financial Officer pursuant to 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: August 14, 2012

LANTHEUS MEDICAL IMAGING, INC.

By: /s/ JEFFREY E. YOUNG

Name: Jeffrey E. Young  
Title: *Chief Financial Officer*  
Date: August 14, 2012

**EXHIBIT INDEX**

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\* 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.

CONFIDENTIAL

Execution Version

**FIRST AMENDMENT TO MANUFACTURING AND SUPPLY AGREEMENT  
[DEFINITY® (Perflutren Lipid Microsphere) Injectable Suspension]**

This First Amendment to Manufacturing and Supply Agreement (this "Amendment"), dated as of May 3, 2012 (the "Amendment 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, LMI and HSL are Parties to that certain Manufacturing and Supply Agreement dated as of February 1, 2012 (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 covenants and agreements contained herein, the Parties, intending to be legally bound, hereby agree as follows:

1. Defined Terms. Capitalized terms used, but not defined, herein shall have the meanings ascribed to them in the Agreement.
2. Amendments.

(a) Section 2.2(a)(ii) of the Agreement is hereby amended by replacing the reference in the first sentence of Section 2.2(a)(ii) to "\*\*\*\*\* percent (\*\*\*\*%)" with "\*\*\*\*\* percent (\*\*\*\*%)." In addition, for purposes of clarity, the Parties hereby acknowledge the aggregate requirements for Product set forth in Section 2.2(a)(ii) of the Agreement include both LMI's and its Affiliates' requirements for such Product and that HSL's rights set forth in Section 2.2(a)(iv) of the Agreement extend to the books and records of both LMI and its Affiliates.

(b) Section 2.2 of the Agreement is hereby further amended by adding the following subsection after Section 2.2(a)(iv):

*"(v) LMI will establish performance parameters and weightings for the Product to determine a performance score ("Score") and communicate the same to HSL prior to*

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*each calendar year. For each calendar year from and after the calendar year in which HSL commences commercial manufacturing of the Product pursuant to Section 2.2(a)(ii) (each a "Subject Year") if in the immediately preceding calendar year or portion thereof (each a "Scoring Year") HSL achieved the highest Score with respect to the Product among LMI's qualified suppliers of such Product, then the minimum percentage requirement of Section 2.2(a)(ii) of this Agreement relating to such Product shall increase from \*\*\*\* percent (\*\*\*\*%) to \*\*\*\* percent (\*\*\*\*%) for the then current Subject Year, as if \*\*\*\* percent (\*\*\*\*%) was set forth in Section 2.2(a)(ii). Within \*\*\*\* (\*\*\*\*) days after the end of each Scoring Year, LMI shall send to HSL a written notice of HSL's Score for such Scoring Year (including the calculation of same) and a statement as to whether HSL had the highest Score. In the event HSL is determined not to have the highest Score, then, within \*\*\*\* (\*\*\*\*) days after the end of such Scoring Year, upon reasonable advance written notice and subject to a confidentiality agreement reasonably acceptable to LMI, LMI shall permit an independent industry expert selected by HSL and reasonably acceptable to LMI to confirm LMI's assessment of the highest Score for the immediately preceding Scoring Year, provided that such expert's report to HSL shall be limited to an indication from such expert that LMI is "in compliance" or "out of compliance" with the methodology for such Scoring Year."*

(c) Section 2.2(b) is amended by (I) replacing the sentence "LMI reserves the right to cancel any purchase order after acceptance by HSL" with "LMI reserves the right to cancel or postpone any purchase order after acceptance by HSL" and (II) by replacing the last two sentences of such Section with "LMI may not cancel or postpone 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 \*\*\*\*."

(d) Section 2.8 is amended by adding the words "(in no event less than \*\*\*\* (\*\*\*\*) days prior to the date of delivery)" after the reference to "purchase order" in the first sentence.

(e) Section 3.4(d) is amended by adding the words "pursuant to the terms of this Agreement (including, but not limited to, the pricing set forth herein) for delivery not later than \*\*\*\* (\*\*\*\*) months after the Term" after the reference to "terminal supply of Product" in the first sentence.

(f) Section 6.2(b) is amended by replacing the words: "The obligation not to disclose Information" with "The obligation not to disclose or use information".

(g) Section 7.2 is amended by replacing the words "HSL and its directors" with "HSL, its Affiliates, and its and their directors."

(h) Section 9.6 is amended by replacing the words "HSL'S WILLFUL MISCONDUCT" with "A PARTY'S WILLFUL MISCONDUCT."

3. Full Force and Effect. Except as specifically amended hereby, the Agreement shall remain in full force and effect and otherwise unmodified.

4. 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 exclusively interpreted in accordance with and governed by the laws of New York, without regard to the conflicts of law rules thereof.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their respective duly authorized representatives as of the Amendment Effective Date.

LANTHEUS MEDICAL IMAGING, INC.

By: /s/ Donald R. Kiepert  
Name: Donald R. Kiepert  
Title: President and Chief Executive Officer

JUBILANT HOLLISTERSTIER LLC

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

CONFIDENTIAL TREATMENT REQUESTED

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CONFIDENTIAL

Execution Version

**MANUFACTURING AND SUPPLY AGREEMENT**  
**[CARDIOLITE® Kit for the Preparation of Technetium Tc99m Sestamibi for Injection]**

This Manufacturing and Supply Agreement (this "Agreement"), dated as of May 3, 2012 (the "Effective Date"), is hereby entered into by and between **Lantheus Medical Imaging, Inc.**, a corporation organized and existing under the laws of Delaware with its principal place of business at 331 Treble Cove Road, North Billerica, MA 01862 ("LMI"), and **Jubilant HollisterStier LLC**, a limited liability company organized and existing under the laws of Delaware with a place of business at 3525 North Regal Street, Spokane, Washington, 99207 ("HSL"). LMI and HSL are referred to herein individually as a "Party" and collectively as the "Parties".

**RECITALS**

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

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

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

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

1. DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

or unbranded CARDIOLITE® products (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. For purposes of clarity, the Parties acknowledge that unbranded Product may include, without limitation, Product that will be labeled with a private label or generically.

(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: 973-8-20), 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 described in 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) *Forecasts; Orders.* (i) LMI shall send to HSL a \*\*\*\* (\*\*\*\*) 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 a country-by-country basis in the Territory on the \*\*\*\* (\*\*\*\*) day after HSL is qualified as a supplier of the Product under the applicable regulatory approval in such country and end on the earlier of the termination or expiration of this Agreement. 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. For purposes

of clarity, the Parties acknowledge that the aggregate requirements for Product set forth above include both LMI's and its Affiliates' requirements for such Product and that HSL's rights set forth in Section 2.2(a)(iv) of this Agreement extend to the books and records of both LMI and its Affiliates.

(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.

(v) LMI will establish performance parameters and weightings for the Product to determine a performance score ("Score") and communicate the same to HSL prior to each calendar year. For each calendar year from and after the calendar year in which HSL commences commercial manufacturing of the Product pursuant to Section 2.2(a)(ii) (each a "Subject Year") if in the immediately preceding calendar year or portion thereof (each a "Scoring Year") HSL achieved the highest Score with respect to the Product among LMI's qualified suppliers of such Product, then the minimum percentage requirement of Section 2.2(a)(ii) of this Agreement relating to such Product shall increase from \*\*\*\* percent (\*\*\*\*%) to \*\*\*\* percent (\*\*\*\*%) for the then current Subject Year, as if \*\*\*\* percent (\*\*\*\*%) was set forth in Section 2.2(a)(ii). Within \*\*\*\* (\*\*\*\*) days after the end of each Scoring Year, LMI shall send to HSL a written notice of HSL's Score for such Scoring Year (including the calculation of same) and a statement as to whether HSL had the highest Score. In the event HSL is determined not to have the highest Score, then, within \*\*\*\* (\*\*\*\*) days after the end of such Scoring Year, upon reasonable advance written notice and subject to a confidentiality agreement reasonably acceptable to LMI, LMI shall permit an independent industry expert selected by HSL and reasonably acceptable to LMI to confirm LMI's assessment of the highest Score for the immediately preceding Scoring Year, provided that such expert's report to HSL shall be limited to an indication from such expert that LMI is "in compliance" or "out of compliance" with the methodology for such Scoring 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. For purposes of clarity, the Parties acknowledge and agree that HSL shall use commercially reasonable efforts to schedule the date of manufacture not more than \*\*\*\* (\*\*\*\*) days prior to the delivery date. 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 or postpone any purchase order after acceptance by HSL subject to the fees payable as set forth below. 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 between \*\*\*\* (\*\*\*\*) 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 shall not cancel or postpone 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, e.g., if LMI orders 200% of the Forecasted amounts, and HSL is able to supply only 100% of the Forecasted amounts, LMI would receive credit for \*\*\*\*% of the 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 \*\*\*\* (in no event less than \*\*\*\* (\*\*\*\*) days prior to the \*\*\*\*) 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

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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 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, HSL 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

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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 pursuant to the terms of this Agreement (including, but not limited to, the pricing set forth herein) for delivery not later than \*\*\*\* (\*\*\*\*) months after the Term 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) *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. 973-8-20 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. 973-8-20. LMI recognizes that HSL does not currently produce Products for several countries in the Territory and there can be no assurance HSL will be qualified in those or other countries in the Territory.

#### 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 any \*\*\*\* 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 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.

(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,

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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 or use 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, 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 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

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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. LMI acknowledges that (i) this Agreement does not contain a non-compete provision; (ii) HSL and/or its Affiliates currently develop and manufacture generic equivalents of Cardiolite® for other customers and will continue to do so; and (iii) HSL and its Affiliates may in the future develop and manufacture generic equivalents of Cardiolite for any other customers (subject to Sections 6.1 and the other provisions of Section 6.2 of this Agreement).

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, its Affiliates, and its and their 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 (vi) 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 A PARTY'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/ Donald R. Kiepert  
Name: Donald R. Kiepert  
Title: President and Chief Executive Officer

JUBILANT HOLLISTERSTIER LLC

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

Exhibit 1.1

Specifications

The Specifications for the Product have been established by LMI based on the regulatory approvals for the Product in the Territory. The Specifications include, but are not limited to, the parameters approved by the FDA for the Product and have been separately acknowledged by the Parties in writing.

CONFIDENTIAL

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Exhibit 1.2

Territory

Australia  
Bahrain  
Brazil  
Costa Rica  
Finland  
Hong Kong  
Italy  
Korea  
Luxembourg  
Mexico  
Norway  
Philippines  
South Africa  
Switzerland  
Trinidad and Tobago  
United States

Austria  
Belgium  
Canada  
Denmark  
France  
India  
Jamaica  
Kuwait  
Malaysia  
Netherlands  
Oman  
Saudi Arabia  
Spain  
Taiwan  
United Arab Emirates

Bahamas  
Bermuda  
Colombia  
Egypt  
Germany  
Israel  
Japan  
Lebanon  
Malta  
New Zealand  
Panama  
Slovenia  
Sweden  
Thailand  
United Kingdom

CONFIDENTIAL

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Exhibit 1.3

Pricing

COMMERCIAL BATCH/LOT PRODUCTION PRICES:

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CONFIDENTIAL

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CONFIDENTIAL TREATMENT REQUESTED

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

CONFIDENTIAL

Execution Version

**MANUFACTURING AND SUPPLY AGREEMENT**  
**[NEUROLITE® Kit for the Preparation of Technetium Tc99m Bicisate for Injection]**

This Manufacturing and Supply Agreement (this "Agreement"), dated as of May 3, 2012 (the "Effective Date"), is hereby entered into by and between **Lantheus Medical Imaging, Inc.**, a corporation organized and existing under the laws of Delaware with its principal place of business at 331 Treble Cove Road, North Billerica, MA 01862 ("LMI"), and **Jubilant HollisterStier LLC**, a limited liability company organized and existing under the laws of Delaware with a place of business at 3525 North Regal Street, Spokane, Washington, 99207 ("HSL"). LMI and HSL are referred to herein individually as a "Party" and collectively as the "Parties".

**RECITALS**

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

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

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

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

1. DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(n) “Product” means the final finished dosage form of NEUROLITE® Kit for

the Preparation of Technetium Tc99m Bicisate for Injection (or such other name as LMI may choose to use in the Territory), which consists of both NEUROLITE® ligand and buffer, 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 Nos. 973-7-15 and 973-9-16), 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 described in 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) *Forecasts; Orders.* (i) LMI shall send to HSL a \*\*\*\* (\*\*\*\*) 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 a country-by-country basis in the Territory on the \*\*\*\* (\*\*\*\*) day after HSL is qualified as a supplier of the Product under the applicable regulatory approval in such country and end on the earlier of the termination or expiration of this Agreement. 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. For purposes of clarity, the Parties acknowledge that the aggregate requirements for Product set forth

above include both LMI's and its Affiliates' requirements for such Product and that HSL's rights set forth in Section 2.2(a)(iv) of this Agreement extend to the books and records of both LMI and its Affiliates.

(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.

(v) LMI will establish performance parameters and weightings for the Product to determine a performance score ("Score") and communicate the same to HSL prior to each calendar year. For each calendar year from and after the calendar year in which HSL commences commercial manufacturing of the Product pursuant to Section 2.2(a)(ii) (each a "Subject Year") if in the immediately preceding calendar year or portion thereof (each a "Scoring Year") HSL achieved the highest Score with respect to the Product among LMI's qualified suppliers of such Product, then the minimum percentage requirement of Section 2.2(a)(ii) of this Agreement relating to such Product shall increase from \*\*\*\* percent (\*\*\*\*%) to \*\*\*\* percent (\*\*\*\*%) for the then current Subject Year, as if \*\*\*\* percent (\*\*\*\*%) was set forth in Section 2.2(a)(ii). Within \*\*\*\* (\*\*\*\*) days after the end of each Scoring Year, LMI shall send to HSL a written notice of HSL's Score for such Scoring Year (including the calculation of same) and a statement as to whether HSL had the highest Score. In the event HSL is determined not to have the highest Score, then, within \*\*\*\* (\*\*\*\*) days after the end of such Scoring Year, upon reasonable advance written notice and subject to a confidentiality agreement reasonably acceptable to LMI, LMI shall permit an independent industry expert selected by HSL and reasonably acceptable to LMI to confirm LMI's assessment of the highest Score for the immediately preceding Scoring Year, provided that such expert's report to HSL shall be limited to an indication from such expert that LMI is "in compliance" or "out of compliance" with the methodology for such Scoring 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. For purposes of clarity, the Parties acknowledge and agree that HSL shall

use commercially reasonable efforts to schedule the date of manufacture not more than \*\*\*\* (\*\*\*\*) days prior to the delivery date. 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 or postpone any purchase order after acceptance by HSL subject to the fees payable as set forth below. 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 between \*\*\*\* (\*\*\*\*) 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 shall not cancel or postpone 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, e.g., if LMI orders 200% of the Forecasted amounts, and HSL is able to supply only 100% of the Forecasted amounts, LMI would receive credit for \*\*\*\*% of the 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 \*\*\*\* (in no event less than \*\*\*\* (\*\*\*\*) days prior to the \*\*\*\*) 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

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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 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, HSL 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

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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 pursuant to the terms of this Agreement (including, but not limited to, the pricing set forth herein) for delivery not later than \*\*\*\* (\*\*\*\*) months after the Term 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 for 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 Nos. 973-7-15 and 973-9-16 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. 973-7-15 and 973-9-16. LMI recognizes that HSL does not currently produce Products for several countries in the Territory and there can be no assurance HSL will be qualified in those or other countries in the Territory.

#### 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 any \*\*\*\* 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.

(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

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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 or use 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, 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

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recognizes that the \*\*\*\* and, as a result, HSL (excluding \*\*\*\*) agrees \*\*\*\* for \*\*\*\*; provided, however, that if LMI fails to order in the \*\*\*\* (\*\*\*\*) month period covered by the Initial Forecast, or in any \*\*\*\* (\*\*\*\*) month period beginning on the annual anniversary of the first day covered by the Initial Forecast thereafter during the first \*\*\*\* (\*\*\*\*) years of the Term, at least \*\*\*\* percent (\*\*\*\*%) of the Product set forth in the Initial Forecast, the Parties will agree in good faith on an appropriate remedy for the shortfall in such forecasted volume. Such remedies may include, by way of example, \*\*\*\*. If the Parties are unable to agree on a remedy that is reasonably acceptable to both Parties within a period of \*\*\*\* (\*\*\*\*) days, then, subject to the terms of this Agreement (including, but not limited to the other confidentiality and non-use obligations set forth herein), the restrictions set forth in third sentence of this Section 6.2(c) with respect to \*\*\*\* shall no longer apply. For purposes of clarity, an \*\*\*\* shall include \*\*\*\*. 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, its Affiliates, and its and their 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); (iv) 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 A PARTY'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/ Donald R. Kiepert  
Name: Donald R. Kiepert  
Title: President and Chief Executive Officer

JUBILANT HOLLISTERSTIER LLC

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

Exhibit 1.1

Specifications

The Specifications for the Product have been established by LMI based on the regulatory approvals for the Product in the Territory. The Specifications include, but are not limited to, the parameters approved by the FDA for the Product and have been separately acknowledged by the Parties in writing.

CONFIDENTIAL

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Exhibit 1.2

Territory

Australia  
Belgium  
Costa Rica  
Finland  
Hong Kong  
Japan  
Luxembourg  
New Zealand  
Panama  
Saudi Arabia  
Sweden  
Thailand  
United States

Austria  
Canada  
Czech Republic  
France  
Israel  
Korea  
Malaysia  
Norway  
Philippines  
Slovenia  
Switzerland  
Trinidad and Tobago

Bahrain  
Colombia  
Denmark  
Germany  
Italy  
Lebanon  
Mexico  
Oman  
Portugal  
Spain  
Taiwan  
United Arab Emirates

CONFIDENTIAL

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Exhibit 1.3

Pricing

COMMERCIAL BATCH/LOT PRODUCTION PRICES:

\*\*\*

CONFIDENTIAL

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**AMENDMENT NO. 6 TO THE AGREEMENT CONCERNING CARDIOLITE® AND TECHNELITE® GENERATOR SUPPLY, PRICING AND REBATES**

This Amendment No. 6 (“Amendment”) to the Agreement Concerning Cardiolite® and TechneLite® Generator Supply, Pricing and Rebates dated as of February 1, 2008 (as amended, the “Agreement”) is made by and between Lantheus Medical Imaging, Inc., with its principal place of business at 331 Treble Cove Road, North Billerica, Massachusetts 01862 (“Medical Imaging”), and United Pharmacy Partners, Inc., with its principal place of business at 5400 Laurel Springs Parkway, Suite 405, Suwanee, GA 30024 (“UPPI”), and is effective as of April 1, 2012 (the “Amendment Effective Date”).

**RECITALS**

WHEREAS, Medical Imaging and UPPI are parties to the Agreement and desire to further amend the Agreement, as provided herein;

NOW, THEREFORE, in consideration of the premises and agreements set forth in this Amendment and intending to be legally bound, Medical Imaging and UPPI hereby agree as follows:

**AMENDMENT**

1. Section I. - Section I. Defined Terms is amended by deleting such section in its entirety and replacing therewith the following:

“I. Defined Terms

- A. Capitalized terms not otherwise defined herein shall have the meanings specified in the Standard Cardiolite® Terms.
  - B. “Agreements” means collectively the Agreement, the Individual Pharmacy Agreements, and the Standard Cardiolite® Terms, each as in effect from time to time.
  - C. “Good Standing” means the status of having obtained and retained all federal, state and local licenses and other requirements necessary for the lawful conduct of business as a commercial radiopharmacy.
  - D. “Individual Pharmacy Agreements” means the Cardiolite® License and Supply Agreements between Medical Imaging and a Member or Member Radiopharmacy Family, each as in effect from time to time.
  - E. “Member” means a Member of UPPI in Good Standing.
  - F. “Member Radiopharmacy Family” means \*\*\*\* (\*\*\*\*) or more commercially established radiopharmacies in Good Standing and which are directly or indirectly Controlled by or under common Control with the same Member.
-



- G. “Month” means a calendar month.
  - H. “Radiopharmaceutical Reference Month” means for pricing and rebates, in any then-current Month, the immediately preceding Month.
  - I. “Radiopharmaceutical Reference Quarter” means for pricing and rebates, in any then-current calendar Quarter, the immediately preceding Quarter.
  - J. “Quarter” means a calendar quarter.
  - K. “TechneLite® Generators” means technetium Tc99m generators sold under the trademark TechneLite®.
  - L. “TechneLite® Generator Unshipped Curies” means the number of curies that are not shipped if a TechneLite® Generator order, accepted by Medical Imaging, is not filled as ordered resulting in no shipment or a shipment of fewer curies than originally specified on the order.
  - M. “\*\*\*\* Sestamibi Product” means \*\*\*\*.
2. Section IV Section IV. Rebates is amended by deleting such section in its entirety and replacing therewith the following:  
“*Section IV. Rebates. The Parties agree that UPPI and the Members will be eligible for rebates as set forth in Exhibit L.*”
3. Exhibit L. Exhibit L is amended by deleting such exhibit in its entirety and replacing therewith Exhibit L attached hereto.
4. General. Except as specifically modified hereby, the terms and provisions of the Agreement remain in full force and effect and otherwise unmodified. This Amendment shall be effective from and after the Amendment Effective Date and is 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. The Agreement, as amended hereby, constitutes the entire agreement between the parties with respect to the subject matter hereof, and supersedes any and all prior or contemporaneous agreements between the parties relating to the subject matter hereof (whether written or oral). This Amendment may be executed in one or more counterparts, and by the different parties in separate counterparts, each of which when executed is deemed to be an original but all of which when taken together shall constitute one and the same agreement.

[Signature page follows.]

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized officers as of the date first set forth above.

**UNITED PHARMACY PARTNERS, INC.**

By: /s/ Perry Polsinelli

Name: Perry Polsinelli

Title: President / CEO

Date: 4/18/2012

**LANTHEUS MEDICAL IMAGING, INC.**

By: /s/ Donald R. Kiepert

Name: Donald R. Kiepert

Title: President and CEO

Date: April 19, 2012

**Exhibit 1**

**NOTICE OF INCENTIVE PROGRAMS AND PRICING  
FOR SESTAMIBI PRODUCT AND TECHNELITE® GENERATORS**

Lantheus Medical Imaging, Inc. (“Medical Imaging”) is pleased to make the following Program for TechneLite® Generators, Sestamibi Product, and Thallium available to all Members (each, a “Member”) of United Pharmacy Partners, Inc. (“UPPI”). All capitalized terms used but not otherwise defined herein will have the meanings set forth in Schedule A. The terms of this notice are confidential and are subject to the confidentiality provisions of Section 5.11 of your Standard Cardiolite® Terms as in effect from time to time.

**I TechneLite® Generators**

- A. Except as otherwise set forth herein, pricing for TechneLite® Generators, effective as of \*\*\*\*, for the period from \*\*\*\* through the balance of the Term shall be the pricing set forth in Column A of the TechneLite® Pricing Grid attached hereto as Schedule B (the “TechneLite® Pricing Grid”).
- B. Medical Imaging shall have the right to increase pricing set forth in the TechneLite® Pricing Grid on \*\*\*\*, provided that such increases will be limited to no more than \*\*\*\* percent (\*\*\*\*%). In addition, if Members purchase less than a weekly average of \*\*\*\* curies of TechneLite®, as measured over the then applicable Radiopharmaceutical Reference Month, Medical Imaging shall have the right to increase pricing for \*\*\*\* for the then-current Month to the then-effective supply pricing for \*\*\*\* (the “Current Supply Pricing”). The \*\*\*\* for \*\*\*\* is attached hereto as Schedule C. Medical Imaging reserves the right to change such pricing upon \*\*\*\* (\*\*\*\*) days prior written notice.
- C. In calculating the monthly purchases of TechneLite® Generators, Medical Imaging will take into consideration the total number of curies purchased plus the number of TechneLite® Generator Unshipped Curies, provided, however, that curies of TechneLite® purchased from Medical Imaging during an industry shortfall or supply shortage which are incrementally greater than UPPI’s run rate during the last Radiopharmaceutical Reference Month in a period of normal supply conditions shall not be measured for purposes of determining the price reductions set forth herein.

**II Sestamibi Product**

- A. Members will purchase a minimum aggregate amount of \*\*\*\* of Sestamibi Product during each Quarter (the “Sestamibi Quarterly Minimum”) commencing \*\*\*\* and at all times thereafter. For purposes of clarity, the Parties acknowledge that all of the purchases of Sestamibi Product by UPPI’s Members from Medical Imaging in the applicable Radiopharmaceutical Reference Quarter will be included in the calculation to determine if the Sestamibi Quarterly Minimum has been achieved regardless of whether such purchases of Sestamibi Product are made as spot or standing orders.
- B. Pricing for Sestamibi Product effective as of \*\*\*\* will be as follows:

- a. \*\*\*\* will be \$\*\*\*\*; and
  - b. \*\*\*\* will be \$\*\*\*\*.
- C. If Members fail to purchase the Sestamibi Quarterly Minimum in the Radiopharmaceutical Reference Quarter, in addition to any other remedy it may have, Medical Imaging shall have the right to change each Member's \*\*\*\* pricing for the Quarter immediately following such Radiopharmaceutical Reference Quarter (the "then-current Quarter") to the \*\*\*\* for \*\*\*\*, effective as of the first day of the then-current Quarter, regardless of UPPI's then-current \*\*\*\* volume, unless UPPI purchases the shortfall in the Sestamibi Quarterly Minimum no later than \*\*\*\* (\*\*\*\*) days after the Radiopharmaceutical Reference Quarter.

### **III Thallium**

- A. Commencing as of \*\*\*\*, Members will pay a price for Thallium of \$\*\*\*\* per millicurie.
- B. Thereafter and for the balance of the Term, Members will pay a price of \$\*\*\*\* per millicurie for Thallium provided that the number of millicuries of Thallium purchased by Members, in aggregate, in the Radiopharmaceutical Reference Month is greater than \*\*\*\* millicuries (the "Thallium Monthly Minimum"). If in any Radiopharmaceutical Reference Month the number of Thallium millicuries purchased falls below the Thallium Monthly Minimum, the price per millicurie for Thallium will be changed to \$\*\*\*\* per millicurie in the then-current Month.

### **IV Combo Pack Pricing for Standing Orders**

- A. Notwithstanding the pricing described in Articles I and II of this Exhibit 1, each Member and Member Radiopharmacy Family (on behalf of each Member within such Member Radiopharmacy Family) that places a \*\*\*\* standing order for TechneLite® Generators on \*\*\*\* of each week, together with a \*\*\*\* standing order of at least \*\*\*\* (\*\*\*\*) \*\*\*\* of Sestamibi Product, for a period of at least \*\*\*\* (\*\*\*\*) \*\*\*\* shall be entitled to the following pricing for such standing orders effective as of May 1, 2012:
- a. the pricing for TechneLite® Generators for such orders shall be as set forth in Column B of the TechneLite® Pricing Grid attached hereto as Schedule B;
  - b. \*\*\*\* will be \$\*\*\*\*; and
  - c. \*\*\*\* will be \$\*\*\*\*.

Medical Imaging reserves the right, in its reasonable discretion, to change the number or size of TechneLite® Generators set forth in Column B of the TechneLite® Pricing Grid or change the manufacturing days available for such standing orders of TechneLite® Generators, upon \*\*\*\* (\*\*\*\*) days prior written notice.

- B. Members will be entitled to this pricing for standing orders in the then-current Month only if Members purchase a \*\*\*\* average of at least \*\*\*\* curies of TechneLite®, as measured over the then applicable Radiopharmaceutical Reference Month (i.e., the volumes required for Column B of the TechneLite® Pricing Grid). If Members purchase less than a \*\*\*\* average

of \*\*\*\* curies of TechneLite®, as measured over the then applicable Radiopharmaceutical Reference Month, the pricing for TechneLite® Generators and Sestamibi Product for the then-current Month (including standing orders) will be as described in Articles I and II of this Exhibit 1. Members will be able to participate in this pricing program for standing orders in the then-current Month only when the \*\*\*\* average volume of TechneLite® in the then applicable Radiopharmaceutical Reference Month is at least \*\*\*\* curies.

## V Rebates

For each Radiopharmaceutical Reference Quarter ending from and after \*\*\*\* (it being acknowledged and agreed that the initial Radiopharmaceutical Reference Quarter hereunder shall be measured on a Member by Member basis from and after the start date of the rebate program for such Member through \*\*\*\*), each Member or Member Radiopharmacy Family, as the case may be, in Good Standing that pays the invoices submitted by Medical Imaging on a timely basis may be entitled to a percentage rebate on the purchases of TechneLite® Generators invoiced and delivered to such Member or Member Radiopharmacy Family in the applicable Radiopharmaceutical Reference Quarter if such purchases of TechneLite® Generators meet the \*\*\*\* volume requirements set forth below. Such rebates will be calculated for each Member or Member Radiopharmacy Family as follows:

- a. **No Rebate** — if the \*\*\*\* purchases of TechneLite® Generators (in curies) invoiced and delivered to such Member or Member Radiopharmacy Family over the then applicable Radiopharmaceutical Reference Quarter is less than \*\*\*\* percent (\*\*\*\*%) of \*\*\*\* purchased by such Member or Member Radiopharmacy Family, as applicable, no rebate will be credited by Medical Imaging to such Member or Member Radiopharmacy Family;
- b. **Level 1 Rebate** — if the \*\*\*\* purchases of TechneLite® Generators (in curies) invoiced and delivered to such Member or Member Radiopharmacy Family over the then applicable Radiopharmaceutical Reference Quarter is equal to or greater than \*\*\*\* percent (\*\*\*\*%) of \*\*\*\* purchased by such Member or Member Radiopharmacy Family, but less than \*\*\*\* percent (\*\*\*\*%) of \*\*\*\* purchased by such Member or Member Radiopharmacy Family, as applicable, a rebate of \*\*\*\* percent (\*\*\*\*%) of such Member's or such Member Radiopharmacy Family's TechneLite® purchases in the applicable Radiopharmaceutical Reference Quarter will be credited by Medical Imaging to such Member or Member Radiopharmacy Family; or
- c. **Level 2 Rebate** — if the \*\*\*\* purchases of TechneLite® Generators (in curies) invoiced and delivered to such Member or Member Radiopharmacy Family over the then applicable Radiopharmaceutical Reference Quarter is equal to or greater than \*\*\*\* percent (\*\*\*\*%) of \*\*\*\* purchased by such Member or Member Radiopharmacy Family, as applicable, a rebate of \*\*\*\* percent (\*\*\*\*%) of such Member's or such Member Radiopharmacy Family's TechneLite® purchases in the applicable Radiopharmaceutical Reference Quarter will be credited by Medical Imaging to such Member or Member Radiopharmacy Family.

Not later than \*\*\*\* (\*\*\*\*) days after the end of each Radiopharmaceutical Reference Quarter, each Member or Member Radiopharmacy Family, as applicable, shall certify to Medical Imaging as to the rebate, if any, earned by such Member or Member Radiopharmacy Family for such period. Rebates will be determined as of \*\*\*\* and as of the end of each Quarter thereafter (as evidenced by reasonable documentation made available to Medical Imaging or its representatives). Rebates for the initial Radiopharmaceutical Reference Quarter will be calculated for each Member based on such Member's or Member Radiopharmacy Family's \*\*\*\* purchases of TechneLite® Generators commencing after the start date of the rebate program for such Member or Member Radiopharmacy Family. All rebates earned shall be issued to such Member by Medical Imaging as a credit against future purchases of TechneLite® Generators by such Member within \*\*\*\* (\*\*\*\*) days of the end of each Quarter. Medical Imaging will not settle any such rebate in cash, except if a Member ceases to be a Member in Good Standing or is otherwise acquired and the successor ceases to be a Member and there are no outstanding invoices payable by such Member to Medical Imaging.

## VI Other Terms

- A. The terms of the existing Exhibit I of the Standard Cardiolite® Terms are being modified as set forth herein. All references to Exhibit I to the Standard Cardiolite® Terms will be understood to reference and incorporate the terms contained herein. For purposes of clarity, the Parties acknowledge and agree that all related rebate or incentive programs offered by Medical Imaging to Members or between Medical Imaging and individual Members or Member Radiopharmacy Families the Amendment Effective Date are no longer applicable and have no further force and effect.
- B. All standing orders will be subject to a \*\*\*\* cancellation policy. Members will no longer be required to provide Medical Imaging with the Required Monthly Vial and Unit Dose Report for purchases of Cardiolite® from and after \*\*\*\* (as described in Section 2.07(b)(i) of the Standard Cardiolite® Terms and Conditions).
- C. Any and all terms and conditions, if any, contained within the Standard Cardiolite® Terms that are inconsistent with this notice are hereby deemed to be amended and modified to be consistent with and governed by the provisions hereof.
- D. Notwithstanding any other provision herein to the contrary, Medical Imaging may increase the TechneLite® Generator purchase prices to reflect any material change in costs of molybdenum. A change in such costs is considered material if the increase in the cost of molybdenum over any \*\*\*\* (\*\*\*\*) day period (a "Moly Cost Increase Period") is more than \*\*\*\* percent (\*\*\*\*%). In the event of such a material increase, Medical Imaging shall be entitled to increase the TechneLite® Generator purchase prices to reflect the incremental increase in such costs over \*\*\*\* percent (\*\*\*\*%) starting as of when such costs are actually incurred by Medical Imaging, provided that Medical Imaging provides UPPI \*\*\*\* (\*\*\*\*) days written notice and reasonable documentation supporting such change in costs. Medical Imaging shall not implement the type of price increase detailed in this paragraph more than \*\*\*\* per calendar year.

- E. Each Member hereby represents and warrants that it will properly store, use and dispose of all materials provided by Medical Imaging in accordance with any instructions set forth on the applicable product labels, the rules and regulations promulgated by the U.S. Nuclear Regulatory Commission and all other applicable local, state and federal government regulations.
- F. Notwithstanding anything in Agreements to the contrary, the Agreement may be freely assigned by Medical Imaging.
- G. In accordance with Section 5.04 of the Standard Cardiolite® Terms, each Member shall report all AEs, Product Quality Complaints and Special Situations to Medical Imaging within 24 hours of the date that Member first becomes aware of an AE, Product Quality Complaint or Special Situation associated with a Sestamibi Product, TechnoLite® Generator or any other product of Medical Imaging that is reported to Member or of which Member or any of its agents, including local radiopharmacists, are otherwise made aware. In addition, Member shall provide Medical Imaging with immediate (or as soon as practicable) notification of any fatal or life-threatening Serious AE.

The report for AEs and Special Situations should contain as much information as is available concerning such event to permit Medical Imaging to file a MedWatch Form 3500A report that satisfies regulatory guidelines for content and timeliness. The reports for Product Quality Complaints shall include the following information: name and contact information of reporter; product/material name or description; lot number; number of defective units; number of complaint samples available for return; indication of whether a patient was dosed; and description of the complaint condition.

Member shall insure prompt follow-up as necessary to provide Medical Imaging with reasonably complete information known or otherwise available to Member with respect to any Serious AE, AEs, Product Quality Complaints or Special Situations. If follow-up information is received after reporting a Serious AE, AE, Product Quality Complaint or Special Situation, Member also must report such information.

All reports and any related communications made hereunder shall be made as follows (or to such other address, contact person, telephone number, facsimile number or e mail address as may be specified by Medical Imaging):

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

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

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

**E-Mail:** [lantheussafety@i3global.com](mailto:lantheussafety@i3global.com)

*i3 Drug Safety is the pharmacovigilance partner of  
 Lantheus Medical Imaging.*

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

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

**Fax:** 734-929-6688

“**AE**” means any untoward medical occurrence in a patient or clinical investigation subject, which results in any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not considered, related to the medicinal product. All noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. Responses to a medicinal product means that a causal relationship between the product and AE is at least a reasonable possibility (i.e., the relationship cannot be ruled out or cannot be determined). The failure of a Sestamibi Product to localize as expected shall not be deemed an adverse experience, whereas a significant failure of expected pharmacologic action would be considered an adverse event.

“**Product Quality Complaint**” means an oral or written report, originating from an external or internal source, stating that a product marketed by Medical Imaging is not meeting the customer’s expectations in relation to identity, quality, effectiveness or performance of the product.

“**Serious AE**” means any untoward medical occurrence that at any dose: results in death; is life-threatening (defined as an event in which the subject or patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe); requires inpatient hospitalization or causes prolongation of existing hospitalizations; results in persistent or significant disability/incapacity; results in a congenital anomaly/birth defect; is an important medical event (defined as a medical event(s) that may not be immediately life-threatening or result in death or hospitalization, but based upon appropriate medical and scientific judgment, may jeopardize the patient/subject or may require intervention, e.g., medical surgical, to prevent one of the other serious outcomes listed in the definition above). Examples of such events include, but are not limited to, intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalization. For reporting purposes, Medical Imaging also considers the occurrences of cancer, pregnancy, or overdose (accidental or intentional and regardless of adverse outcome) as events that must be expeditiously reported as important medical events.

“Special Situation” means any outcomes of pregnancies of patients exposed to product, AE during breastfeeding, data on use of product in children, lack of efficacy (effect), transmission of an infectious disease with product, overdose, misuse, or abuse, medication errors or AE in compassionate use/named patient use. For reporting purposes, Medical Imaging considers Special Situations to be AEs that must be reported within 24 hours.

- H. Except as set forth above, notwithstanding anything in the Individual Pharmacy Agreements to the contrary, upon any amendment, modification or supplement to the Standard Cardiolite® Terms, Medical Imaging shall be required at any time to provide written notice thereof solely to UPPI at the following address:

United Pharmacy Partners, Inc.  
5400 Laurel Springs Parkway, Suite 405  
Suwanee, GA 30024  
Attn: Perry Polsinelli, President & CEO

All notices to be provided to Medical Imaging hereunder shall be delivered to:

Lantheus Medical Imaging, Inc.  
331 Treble Cove Road,  
North Billerica, Massachusetts  
Attn: Cyrille Villeneuve, Vice President, Chief Commercial Officer



Schedule A

Defined Terms

- A. Capitalized terms not otherwise defined herein shall have the meanings specified in the Standard Cardiolite® Terms.
- B. “Agreements” means collectively the Agreement, the Individual Pharmacy Agreements, and the Standard Cardiolite® Terms, each as in effect from time to time.
- C. “Good Standing” means the status of having obtained and retained all federal, state and local licenses and other requirements necessary for the lawful conduct of business as a commercial radiopharmacy.
- D. “Individual Pharmacy Agreements” means the Cardiolite® License and Supply Agreements between Medical Imaging and a Member or Member Radiopharmacy Family, each as in effect from time to time.
- E. “Member” means a Member of UPPI in Good Standing.
- F. “Member Radiopharmacy Family” means \*\*\*\* (\*\*\*\*) or more commercially established radiopharmacies in Good Standing and which are directly or indirectly Controlled by or under common Control with the same Member.
- G. “Month” means a calendar month.
- H. “Radiopharmaceutical Reference Month” means for pricing and rebates, in any then-current Month, the immediately preceding Month.
- I. “Radiopharmaceutical Reference Quarter” means for pricing and rebates, in any then-current calendar Quarter, the immediately preceding Quarter.
- J. “Quarter” means a calendar quarter.
- K. “TechneLite® Generators” means technetium Tc99m generators sold under the trademark TechneLite®.
- L. “TechneLite® Generator Unshipped Curies” means the number of curies that are not shipped if a TechneLite® Generator order, accepted by Medical Imaging, is not filled as ordered resulting in no shipment or a shipment of fewer curies than originally specified on the order.
- M. “\*\*\*\* Sestamibi Product” means \*\*\*\*.

Schedule B

TechneLite® Pricing Grid

\*\*\*\*

*TechneLite® Generators manufactured on Sunday are denoted with a "-U" above.*

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\* Pricing currently available for certain standing orders on \*\*\*\*.

Schedule C

\*\*\*

*TechneLite® Generators manufactured on Sunday are denoted with a “-U” above.*

Medical Imaging reserves the right to change such pricing upon \*\*\* (\*\*\*) days prior written notice.

**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: August 14, 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: August 14, 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](#)

**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 June 30, 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: August 14, 2012

/s/ DONALD R. KIEPERT

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

Dated: August 14, 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](#)

