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

FORM 10-Q

(Mark One)

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

For the quarterly period ended **June 30, 2017**

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 **001-36569**

LANTHEUS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

35-2318913
(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)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
		Emerging Growth Company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 37,350,751 shares of common stock, \$0.01 par value, outstanding as of July 28, 2017.

LANTHEUS HOLDINGS, INC.

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PART I. FINANCIAL INFORMATION**Item 1. Financial Statements (Unaudited)**

Lantheus Holdings, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except par value)

	<u>June 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 57,154	\$ 51,178
Accounts receivable, net	43,246	36,818
Inventory	21,151	17,640
Other current assets	4,072	5,183
Total current assets	<u>125,623</u>	<u>110,819</u>
Property, plant & equipment, net	91,863	94,187
Intangibles, net	13,456	15,118
Goodwill	15,714	15,714
Other long-term assets	21,222	20,060
Total assets	<u>\$ 267,878</u>	<u>\$ 255,898</u>
Liabilities and Stockholders' Deficit		
Current liabilities		
Current portion of long-term debt	\$ 2,750	\$ 3,650
Revolving line of credit	—	—
Accounts payable	17,674	18,940
Accrued expenses and other liabilities	22,640	21,249
Total current liabilities	<u>43,064</u>	<u>43,839</u>
Asset retirement obligations	9,891	9,370
Long-term debt, net	265,929	274,460
Other long-term liabilities	36,174	34,745
Total liabilities	<u>355,058</u>	<u>362,414</u>
Commitments and contingencies (See Note 12)		
Stockholders' deficit		
Preferred stock (\$0.01 par value, 25,000 shares authorized; no shares issued and outstanding)	—	—
Common stock (\$0.01 par value, 250,000 shares authorized; 37,348 and 36,756 shares issued and outstanding, respectively)	373	367
Additional paid-in capital	228,083	226,462
Accumulated deficit	(314,665)	(332,398)
Accumulated other comprehensive loss	(971)	(947)
Total stockholders' deficit	<u>(87,180)</u>	<u>(106,516)</u>
Total liabilities and stockholders' deficit	<u>\$ 267,878</u>	<u>\$ 255,898</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

Lantheus Holdings, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Revenues	\$88,837	\$77,966	\$170,196	\$154,440
Cost of goods sold	42,890	42,215	84,487	84,988
Gross profit	45,947	35,751	85,709	69,452
Operating expenses				
Sales and marketing	11,603	9,843	21,817	19,150
General and administrative	11,203	9,238	23,473	18,751
Research and development	5,244	2,608	10,595	5,644
Total operating expenses	28,050	21,689	55,885	43,545
Gain on sale of assets	—	(117)	—	(5,945)
Operating income	17,897	14,179	29,824	31,852
Interest expense	4,285	6,983	9,705	14,008
Loss on extinguishment of debt	—	—	2,161	—
Other income	(552)	(401)	(1,129)	(466)
Income before income taxes	14,164	7,597	19,087	18,310
Provision for income taxes	569	247	1,354	637
Net income	\$13,595	\$ 7,350	\$ 17,733	\$ 17,673
Net income per common share outstanding:				
Basic	\$ 0.37	\$ 0.24	\$ 0.48	\$ 0.58
Diluted	\$ 0.35	\$ 0.24	\$ 0.46	\$ 0.58
Weighted-average common shares outstanding:				
Basic	37,235	30,378	37,063	30,373
Diluted	38,900	30,543	38,726	30,454

The accompanying notes are an integral part of these condensed consolidated financial statements.

Lantheus Holdings, Inc.
Condensed Consolidated Statements of Comprehensive Income
(Unaudited)
(in thousands)

	<u>Three Months Ended</u> <u>June 30,</u>		<u>Six Months Ended</u> <u>June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Net income	\$ 13,595	\$ 7,350	\$ 17,733	\$ 17,673
Other comprehensive income (loss):				
Foreign currency translation	(20)	(84)	(24)	256
Total other comprehensive income (loss)	(20)	(84)	(24)	256
Total comprehensive income	<u>\$ 13,575</u>	<u>\$ 7,266</u>	<u>\$ 17,709</u>	<u>\$ 17,929</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

Lantheus Holdings, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Six Months Ended June 30,	
	2017	2016
Operating activities		
Net income	\$ 17,733	\$17,673
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation, amortization and accretion	11,271	8,423
Amortization of debt related costs	696	935
Provision for excess and obsolete inventory	730	818
Stock-based compensation	2,107	992
Gain on sale of assets	—	(5,945)
Loss on extinguishment of debt	2,161	—
Other	781	118
Increases (decreases) in cash from operating assets and liabilities:		
Accounts receivable	(6,368)	(2,009)
Inventory	(4,232)	525
Other current assets	(249)	393
Accounts payable	767	1,474
Accrued expenses and other liabilities	694	(1,982)
Net cash provided by operating activities	<u>26,091</u>	<u>21,415</u>
Investing activities		
Proceeds from sale of assets	1,234	9,000
Capital expenditures	(8,301)	(2,388)
Other	—	74
Net cash (used in) provided by investing activities	<u>(7,067)</u>	<u>6,686</u>
Financing activities		
Payments on long-term debt	(285,265)	(1,861)
Proceeds from issuance of long-term debt	274,313	—
Proceeds from stock option exercises	1,078	—
Payments for minimum statutory tax withholding related to net share settlement of equity awards	(1,557)	—
Deferred financing costs	(1,576)	—
Other	(74)	(11)
Net cash used in financing activities	<u>(13,081)</u>	<u>(1,872)</u>
Effect of foreign exchange rates on cash and cash equivalents	33	26
Net increase in cash and cash equivalents	5,976	26,255
Cash and cash equivalents, beginning of period	51,178	28,596
Cash and cash equivalents, end of period	<u>\$ 57,154</u>	<u>\$54,851</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

Lantheus Holdings, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Note Regarding Company References and Trademarks

Unless the context otherwise requires, references to the “Company” and “Lantheus” refer to Lantheus Holdings, Inc. and its direct and indirect wholly-owned subsidiaries, references to “Holdings” refer to Lantheus Holdings, Inc. and not to any of its subsidiaries, and references to “LMI” refer to Lantheus Medical Imaging, Inc., the direct subsidiary of Holdings. Solely for convenience, the Company refers to trademarks, service marks and trade names without the TM, SM and ® symbols. Those references are not intended to indicate, in any way, that the Company will not assert, to the fullest extent permitted under applicable law, its rights to its trademarks, service marks and trade names.

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of Lantheus Holdings, Inc. and its direct and indirect wholly-owned subsidiaries and have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all of the information and footnotes required by generally accepted accounting principles in the United States of America (“U.S. GAAP”) for complete financial statements. In the opinion of management, all adjustments (consisting of normal and recurring adjustments) considered necessary for a fair statement have been included. The results of operations for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the year ended December 31, 2017 or any future period.

The condensed consolidated balance sheet at December 31, 2016 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These condensed consolidated financial statements and accompanying notes should be read in conjunction with the consolidated financial statements and notes thereto included in Item 8 of the Company’s most recent Annual Report on Form 10-K for the year ended December 31, 2016 filed with the Securities Exchange Commission (“SEC”) on February 23, 2017. Certain immaterial amounts in the prior period have been reclassified to conform to the current period financial statement presentation.

Manufacturing Concentrations

The Company currently relies on Jubilant HollisterStier (“JHS”) as its sole source manufacturer of DEFINITY, Neurolite, Cardiolite and evacuation vials for TechnoLite. The Company currently has on-going development and technology transfer activities for its next generation DEFINITY product with Samsung BioLogics (“SBL”) located in South Korea but can give no assurances as to when those technology transfer activities will be completed and when the Company will begin to receive supply of its next generation DEFINITY product from SBL.

2. Summary of Significant Accounting Policies

Collaboration and License Agreement with GE Healthcare Limited

On April 25, 2017, the Company announced that it entered into a definitive, exclusive Collaboration and License Agreement (the “License Agreement”) with GE Healthcare Limited (“GE Healthcare”) for the continued Phase III development and worldwide commercialization of flurpiridaz F 18, an investigational positron emission tomography myocardial perfusion imaging agent that may improve the diagnosis of coronary artery disease. Under the License Agreement, GE Healthcare will complete the worldwide development of flurpiridaz F 18, pursue worldwide regulatory approvals and, if successful, lead a worldwide launch and commercialization of the agent, with LMI collaborating on both development and commercialization through a joint steering committee. LMI has an option to co-promote the agent in the U.S. GE Healthcare’s development plan will initially focus on obtaining regulatory approval for flurpiridaz F 18 in the U.S., Japan, Europe and Canada.

Under the terms of the License Agreement, the Company received an up-front payment of \$5.0 million. In addition, the Company is eligible to receive, from GE Healthcare, up to \$60.0 million in regulatory and sales-based milestones and tiered double-digit royalties on U.S. sales and mid-single digit royalties on sales outside the U.S. Because the Company concluded there was only one significant deliverable under the License Agreement, consisting of the license of the product which occurred upon the signing of the License Agreement, the Company recognized approximately \$5.0 million associated with entering into the license as revenue in the three and six months ended June 30, 2017. In addition, because the Company concluded that the regulatory and sales-based milestones are solely dependent on GE Healthcare’s performance and there are no continuing performance obligations from the Company, all development and sales milestones under the License Agreement are considered non-substantive. As of June 30, 2017, the Company has not recognized those milestones as revenue under the License Agreement and will recognize such revenue in the

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periods the milestones are achieved. Similarly, the Company will recognize royalty revenues in the periods of the sale of the related products, provided that the reported sales are reliably measurable, collectability is reasonably assured and the Company has no further performance obligations.

Recent Accounting Pronouncements

The following table provides a description of recent accounting pronouncements that may have a material effect on the Company's condensed consolidated financial statements:

Standard	Description	Effective Date for Company	Effect on the Condensed Consolidated Financial Statements
Recently Issued Accounting Standards Not Yet Adopted			
ASU 2017-09, <i>Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting</i>	<p>This ASU clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions.</p> <p>The new guidance will be applied prospectively to awards modified on or after the adoption date. The guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 31, 2017 for all entities. Early adoption is permitted, including adoption in any interim period for which financial statements have not yet been issued or made available for issuance.</p>	January 1, 2018	The Company does not expect that the adoption of this standard will have a material impact on the Company's condensed consolidated financial statements.
ASU 2014-09, <i>Revenue from Contracts with Customers (Topic 606)</i> and related additional amendments ASU 2015-14, ASU 2016-08, ASU 2016-10, ASU 2016-11, ASU 2016-12, ASU 2016-20	<p>This ASU and related amendments affect any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets, unless those contracts are within the scope of other standards. The guidance in this ASU supersedes the revenue recognition requirements in Topic 605, Revenue Recognition and most industry-specific guidance. The core principle of the guidance is that an entity should recognize revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new guidance also includes a set of disclosure requirements that will provide users of financial statements with comprehensive information about the nature, amount, timing, and uncertainty of revenue and cash flows arising from a reporting organization's contracts with customers. In August 2015, the Financial Accounting Standards Board issued ASU No. 2015-14, "Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date," which defers the effective date of ASU 2014-09 by one year.</p> <p>The standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods:</p> <ul style="list-style-type: none"> • A full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or • A modified retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). 	January 1, 2018	The Company has established an implementation team which includes third-party specialists to assist in the evaluation and implementation of the new standard. The Company is currently in the process of performing an assessment of the impact of the standards on its contract portfolio by reviewing the Company's current accounting policies and practices and to identify potential differences that would result from applying the requirements of the new standard to its revenue contracts. The Company has categorized its customers into multiple customer types and assessed significant customer arrangements within those customer types. At this time, the Company does not anticipate a significant impact to its financial statements upon adoption of the new standard. However, the assessment is ongoing and further analysis of contracts may identify a more significant impact. The Company currently expects, in part due to the limited anticipated impact, it will utilize the modified retrospective approach of adopting the ASU. In addition, during 2017 the Company plans to identify and implement, if necessary, appropriate changes to its business processes, systems and controls to support recognition and disclosure under the new standard.
Accounting Standards Adopted During the Six Months Ended June 30, 2017			

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Standard	Description	Effective Date for Company	Effect on the Condensed Consolidated Financial Statements
ASU 2016-09, <i>Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting</i>	<p>ASU 2016-09 simplifies several aspects of the stock compensation guidance in Topic 718 and other related guidance providing the following amendments:</p> <ul style="list-style-type: none"> Accounting for income taxes upon vesting or exercise of share-based payments and related EPS effects Classification of excess tax benefits on the statement of cash flows Accounting for forfeitures Liability classification exception for statutory tax withholding requirements Cash flow presentation of employee taxes paid when an employer withholds shares for tax-withholding purposes Elimination of the indefinite deferral in Topic 718 <p>For public business entities, the amendments are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods.</p>	January 1, 2017	The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

3. Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, financial instruments are categorized based on a hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

- Level 1* — Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- Level 2* — Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).
- Level 3* — Unobservable inputs that reflect a Company's estimates about the assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available, including its own data.

At June 30, 2017 and December 31, 2016, the Company's financial assets measured at fair value on a recurring basis consist of money market funds. The Company invests excess cash from its operating cash accounts in overnight investments and reflects these amounts in cash and cash equivalents in the condensed consolidated balance sheets at fair value using quoted prices in active markets for identical assets.

The table below presents information about the Company's assets and liabilities measured at fair value on a recurring basis:

	Total Fair Value	Level 1	Level 2	Level 3
	(in thousands)			
June 30, 2017				
Money market funds	\$ 5,416	\$5,416	\$ —	\$ —
	<u>\$ 5,416</u>	<u>\$5,416</u>	<u>\$ —</u>	<u>\$ —</u>
December 31, 2016				
Money market funds	\$ 3,565	\$3,565	\$ —	\$ —
	<u>\$ 3,565</u>	<u>\$3,565</u>	<u>\$ —</u>	<u>\$ —</u>

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 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 change in valuation allowance and the rate impact of uncertain tax positions. Cumulative adjustments to the tax provision are recorded in the interim period in which a change in the estimated annual effective tax rate is determined. The Company's tax provision was \$0.6 million and \$0.2 million for the three months ended June 30, 2017 and 2016, respectively, and \$1.4 million and \$0.6 million for the six months ended June 30, 2017 and 2016, respectively.

The Company regularly assesses its ability to realize its deferred tax assets. Assessing the realizability of deferred tax assets requires significant management judgment. In determining whether its deferred tax assets are more-likely-than-not realizable, the Company evaluated all available positive and negative evidence, and weighed the objective evidence and expected impact. Evidence the Company considered included its history of net operating losses, which resulted in the Company recording a full valuation allowance against its domestic net deferred tax assets beginning in 2011, and in each year thereafter. The Company was profitable on a cumulative basis for the three-year period ended June 30, 2017, but substantially all of that profitability was achieved during 2016 and the six months ended June 30, 2017.

The Company continues to evaluate other negative evidence including customer concentration and contractual risk, DEFINITY supplier risk, the risk of Moly supply availability and cost, and certain product development risks, all of which provide for uncertainties around the Company's future level of profitability. Based on its review of all available evidence, the Company determined that it has not yet attained a sustained level of profitability sufficient to outweigh the objectively verifiable negative evidence, and has recorded a full valuation allowance against its domestic net deferred tax assets at June 30, 2017. The Company will continue to assess the level of the valuation allowance required. If a sufficient weight of positive evidence exists in future periods to support a release of some or all of the valuation allowance recorded against domestic deferred tax assets, such a release would likely have a material impact on the Company's results of operations in that future period.

In connection with the Company's acquisition of the medical imaging business from Bristol-Myers Squibb ("BMS") in 2008, the Company entered into 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 in the condensed consolidated statement of operations. In accordance with the Company's accounting policy, the change in the contingent tax liability, and penalties and interest associated with these obligations (net of any offsetting federal or state benefit) is recognized within the tax provision. Accordingly, as these reserves change, adjustments are included in the tax provision while the offsetting adjustment is included in other income. 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

Inventory consisted of the following:

<u>(in thousands)</u>	<u>June 30, 2017</u>	<u>December 31, 2016</u>
Raw materials	\$ 9,261	\$ 9,658
Work in process	5,932	3,965
Finished goods	5,958	4,017
Total inventory	<u>\$21,151</u>	<u>\$ 17,640</u>

As of June 30, 2017 and December 31, 2016, the Company had \$1.2 million of inventory classified within other long-term assets, which represent raw materials not expected to be used by the Company during the next twelve months.

6. Property, Plant & Equipment, Net

Property, plant & equipment, net, consisted of the following:

<u>(in thousands)</u>	<u>June 30, 2017</u>	<u>December 31, 2016</u>
Land	\$ 14,950	\$ 14,950
Buildings	70,934	70,628
Machinery, equipment and fixtures	67,135	65,407
Computer software	18,488	18,482
Construction in progress	11,603	7,224
	<u>183,110</u>	<u>176,691</u>
Less: accumulated depreciation and amortization	<u>(91,247)</u>	<u>(82,504)</u>
Total property, plant & equipment, net	<u>\$ 91,863</u>	<u>\$ 94,187</u>

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Depreciation and amortization expense related to property, plant & equipment, net, was \$4.0 million and \$2.8 million for the three months ended June 30, 2017 and 2016, respectively, and \$9.1 million and \$5.3 million for the six months ended June 30, 2017 and 2016, respectively.

Property, plant & equipment dedicated to research and development (“R&D”) activities had a carrying value of \$2.0 million as of June 30, 2017. The Company believes these assets will be utilized for either internally funded ongoing R&D activities or R&D activities funded by a strategic partner.

7. Asset Retirement Obligations

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

The Company is required to provide the U.S. Nuclear Regulatory Commission and Massachusetts Department of Public Health financial assurance demonstrating the Company’s ability to fund the decommissioning of its North Billerica, Massachusetts production facility upon closure, although the Company does not intend to close the facility. The Company has provided this financial assurance in the form of a \$28.2 million surety bond.

The fair value of a liability for asset retirement obligations is recognized in the period in which the liability is incurred. As of June 30, 2017, the liability is measured at the present value of the obligation expected to be incurred, of approximately \$26.9 million, and is adjusted in subsequent periods as accretion expense is recorded. The corresponding asset retirement costs are capitalized as part of the carrying values of the related long-lived assets and depreciated over the assets’ useful lives.

The following table provides a summary of the changes in the Company’s asset retirement obligations:

<u>(in thousands)</u>	<u>Amount</u>
Balance at January 1, 2017	\$9,370
Accretion expense	521
Balance at June 30, 2017	<u>\$9,891</u>

8. Financing Arrangements

On March 30, 2017, the Company refinanced its previous \$365.0 million seven-year term loan agreement (the facility thereunder, the “2015 Term Facility”) with a new five-year \$275.0 million term loan facility (the “2017 Term Facility” and the loans thereunder, the “Term Loans”). In addition, the Company replaced its previous \$50.0 million five-year asset based loan facility (the “ABL Facility”) with a new \$75.0 million five-year revolving credit facility (the “2017 Revolving Facility” and, together with the 2017 Term Facility, the “2017 Facility”). The terms of the 2017 Facility are set forth in that certain Amended and Restated Credit Agreement, dated as of March 30, 2017 (the “Credit Agreement”), by and among Holdings, the Company, the lenders from time to time party thereto and JPMorgan Chase Bank, N.A., as administrative agent and collateral agent. The 2017 Term Facility was issued net of a \$0.7 million discount. The Company has the right to request an increase to the 2017 Term Facility or request the establishment of one or more new incremental term loan facilities, in an aggregate principal amount of up to \$75.0 million, plus additional amounts, in certain circumstances.

The net proceeds of the 2017 Term Facility, together with approximately \$15.3 million of cash on hand, were used to refinance in full the aggregate remaining principal amount of the loans outstanding under the 2015 Term Facility and pay related interest, transaction fees and expenses. No amounts were outstanding under the ABL Facility at that time. The Company accounted for the refinancing as both a debt extinguishment and debt modification by evaluating the refinancing on a creditor by creditor basis. The Company recorded a loss on extinguishment of debt of \$2.2 million related to the write-off of unamortized debt issuance costs and incurred general and administrative expenses of \$1.7 million related to third-party costs associated with the modified debt. In addition, the Company incurred and capitalized \$1.6 million of new debt issuance costs related to the refinancing.

2017 Term Facility

The Term Loans under the 2017 Term Facility bear interest, with pricing based from time to time at the Company’s election at (i) LIBOR plus a spread of 4.50% or (ii) the Base Rate (as defined in the Credit Agreement) plus a spread of 3.50%. Interest is payable (i) with respect to LIBOR Term Loans, at the end of each Interest Period (as defined in the Credit Agreement) and (ii) with respect to Base Rate Term Loans, at the end of each quarter. At June 30, 2017, the Company’s interest rate under the 2017 Term Facility was 5.5%.

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The Company is permitted to voluntarily prepay the Term Loans, in whole or in part, subject to a 1.00% prepayment premium applicable if, during the first 6 months of the 2017 Term Facility, the Company makes any prepayment of the Term Loans in connection with a repricing transaction (as defined in the Credit Agreement). The 2017 Term Facility requires the Company to make mandatory prepayments of the outstanding Term Loans in certain circumstances. The 2017 Term Facility amortizes at 1.00% per year until its June 30, 2022 maturity date.

The Company's maturities of principal obligations under the 2017 Term Facility are as follows as of June 30, 2017:

<u>(in thousands)</u>	<u>Amount</u>
Remainder of 2017	\$ 1,375
2018	2,750
2019	2,750
2020	2,750
2021	2,750
2022	261,937
Total principal outstanding	274,312
Unamortized debt discount	(2,392)
Unamortized debt issuance costs	(3,241)
Total	268,679
Less: current portion	(2,750)
Total long-term debt	<u>\$265,929</u>

2017 Revolving Facility

Under the terms of the 2017 Revolving Facility, the lenders thereunder agreed to extend credit to the Company from time to time until March 30, 2022 (the "Revolving Termination Date") consisting of revolving loans (the "Revolving Loans" and, together with the Term Loans, the "Loans") in an aggregate principal amount not to exceed \$75.0 million (the "Revolving Commitment") at any time outstanding. The 2017 Revolving Facility includes a \$20.0 million sub-facility for the issuance of letters of credit (the "Letters of Credit"). The Letters of Credit and the borrowings under the 2017 Revolving Facility are expected to be used for working capital and other general corporate purposes.

The Revolving Loans under the 2017 Revolving Facility bear interest, with pricing based from time to time at the Company's election at (i) LIBOR plus a spread of 3.50% or (ii) the Base Rate (as defined in the Credit Agreement) plus a spread of 2.50%. The 2017 Revolving Facility also includes an unused line fee, which is set at 0.375% while the Company's secured leverage ratio (as defined in the Credit Agreement) is greater than 3.00 to 1.00 and 0.25% when the Company's secured leverage ratio is less than or equal to 3.00 to 1.00.

The Company is permitted to voluntarily prepay the Revolving Loans, in whole or in part, or reduce or terminate the Revolving Commitment, in each case, without premium or penalty. On any business day on which the total amount of outstanding Revolving Loans and Letters of Credit exceeds the total Revolving Commitment, the Company must prepay the Revolving Loans in an amount equal to such excess. As of June 30, 2017, there were no outstanding borrowings under the 2017 Revolving Facility.

2017 Facility Covenants

The 2017 Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. The 2017 Facility requires the Company to be in quarterly compliance, measured on a trailing four quarter basis, with a financial covenant. The maximum consolidated leverage ratio permitted by the financial covenant is displayed in the table below:

2017 Facility Financial Covenant

<u>Period</u>	<u>Consolidated Leverage Ratio</u>
Q2 2017 through Q1 2018	5.00 to 1.00
Q2 2018 through Q1 2019	4.75 to 1.00
Thereafter	4.50 to 1.00

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The 2017 Facility contains usual and customary restrictions on the ability of the Company and its subsidiaries to: (i) incur additional indebtedness (ii) create liens; (iii) consolidate, merge, sell or otherwise dispose of all or substantially all of its assets; (iv) sell certain assets; (v) pay dividends on, repurchase or make distributions in respect of capital stock or make other restricted payments; (vi) make certain investments; (vii) repay subordinated indebtedness prior to stated maturity; and (viii) enter into certain transactions with its affiliates.

Upon an event of default, the administrative agent under the Credit Agreement will have the right to declare the Loans and other obligations outstanding immediately due and payable and all commitments immediately terminated or reduced.

The 2017 Facility is guaranteed by Holdings and Lantheus MI Real Estate, LLC (“LMI-RE”), and obligations under the 2017 Facility are generally secured by first priority liens over substantially all of the assets of each of LMI, Holdings and LMI-RE (subject to customary exclusions set forth in the transaction documents) owned as of March 30, 2017 or thereafter acquired.

9. Stock-Based Compensation

The following table presents stock-based compensation expense recognized in the Company’s accompanying condensed consolidated statements of operations:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Cost of goods sold	\$ 177	\$ 73	\$ 316	\$139
Sales and marketing	167	80	291	128
General and administrative	675	345	1,226	578
Research and development	143	87	274	147
Total stock-based compensation expense	<u>\$ 1,162</u>	<u>\$ 585</u>	<u>\$2,107</u>	<u>\$992</u>

Increase in Shares Reserved Under the 2015 Equity Incentive Plan

At the Company’s annual meeting of stockholders, held on April 27, 2017 (the “Annual Meeting”), the Company’s stockholders approved an amendment to the 2015 Equity Incentive Plan to increase the number of shares of common stock reserved for issuance thereunder by 1,200,000 shares, to an aggregate of 5,755,277 shares.

Employee Stock Purchase Plan

At the Annual Meeting, the Company’s stockholders also approved the 2017 Employee Stock Purchase Plan (“2017 ESPP”), which authorized the issuance of up to 250,000 shares of common stock thereunder. Under the terms of the 2017 ESPP, eligible U.S. employees can elect to acquire shares of the Company’s common stock through periodic payroll deductions during a series of six-month offering periods, which will generally begin in March and September of each year. The purchases under the 2017 ESPP will be effected on the last business day of the each offering period at a 15% discount to the closing price on that day. The 2017 ESPP was implemented, subject to stockholder approval, on March 10, 2017, and the first purchases thereunder will be on September 13, 2017. During the three and six months ended June 30, 2017, participant contributions made through payroll deductions toward the future purchase of shares under the plan were not material.

10. Net Income Per Common Share

Basic net income per common share is computed by dividing net income by the weighted-average number of shares of common stock outstanding during the period. Diluted net income per common share is computed by dividing net income by the weighted-average number of shares of common stock outstanding during the period, plus the potential dilutive effect of other securities if those securities were converted or exercised. During periods in which the Company incurs net losses, both basic and diluted loss per share is calculated by dividing the net loss by the weighted-average shares outstanding and potentially dilutive securities are excluded from the calculation because their effect would be antidilutive.

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(in thousands, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net income	\$ 13,595	\$ 7,350	\$ 17,733	\$ 17,673
Basic weighted-average common shares outstanding	37,235	30,378	37,063	30,373
Effect of dilutive stock options	324	165	347	81
Effect of dilutive restricted stock awards	1,341	—	1,316	—
Diluted weighted-average common shares outstanding	38,900	30,543	38,726	30,454
Basic income per common share outstanding	\$ 0.37	\$ 0.24	\$ 0.48	\$ 0.58
Diluted income per common share outstanding	\$ 0.35	\$ 0.24	\$ 0.46	\$ 0.58
Antidilutive securities excluded from diluted income per common share				
Stock options and nonvested restricted stock	339	2,183	379	2,183

11. Other Income

Other income consisted of the following:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Foreign currency gains	\$ 55	\$ 256	\$ 140	\$ 19
Tax indemnification income	490	140	980	436
Other income	7	5	9	11
Total other income	\$ 552	\$ 401	\$ 1,129	\$ 466

12. 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 governmental and 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.

As of June 30, 2017, the Company has no material ongoing litigation in which the Company was a party or any material ongoing regulatory or other proceedings and had no knowledge of any investigations by government or regulatory authorities in which the Company is a target that could have a material adverse effect on its current business.

13. Related Party Transactions

The Company's largest stockholder, Avista Capital Partners, L.P. and its affiliates ("Avista"), has an ownership interest in certain of the Company's vendors. Related party expenses consisted of the following:

(in thousands)	Transaction Type	Three Months Ended June 30,		Six Months Ended June 30,	
		2017	2016	2017	2016
Avista	Offering costs paid on behalf of Avista pursuant to registration rights agreement	\$ 177	\$ —	\$ 326	\$ —
INC Research Holdings, Inc. ("INC")*	Pharmacovigilance services	—	332	—	456
VWR Scientific	Inventory supplies	89	86	297	189
Total related party expenses		\$ 266	\$ 418	\$ 623	\$ 645

* During the year ended December 31, 2016, Avista's relationship with INC changed and Avista was no longer considered a principal owner of that Company. Related party expenses included in this table represent expenses incurred during the period under which the Company and INC were under common ownership by Avista.

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Amounts billed and unbilled for related parties included in accounts payable and accrued expenses are immaterial at both June 30, 2017 and December 31, 2016.

14. Segment Information

The Company reports two operating segments, U.S. and International, based on geographic customer base. The results of these operating segments are regularly reviewed by the Company's chief operating decision maker, the President and Chief Executive Officer. The Company's segments derive revenues through the manufacture, marketing, selling and distribution of medical imaging products, focused primarily on cardiovascular diagnostic imaging. All goodwill has been allocated to the U.S. operating segment. The Company does not identify or allocate assets to its segments.

Selected information for each operating segment is as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues from external customers				
U.S.	\$78,100	\$65,134	\$149,127	\$130,067
International	10,737	12,832	21,069	24,373
Total revenues from external customers	<u>\$88,837</u>	<u>\$77,966</u>	<u>\$170,196</u>	<u>\$154,440</u>
Operating income				
U.S.	\$16,895	\$12,895	\$ 28,063	\$ 24,293
International	1,002	1,284	1,761	7,559
Operating income	17,897	14,179	29,824	31,852
Interest expense	4,285	6,983	9,705	14,008
Loss on extinguishment of debt	—	—	2,161	—
Other income	(552)	(401)	(1,129)	(466)
Income before income taxes	<u>\$14,164</u>	<u>\$ 7,597</u>	<u>\$ 19,087</u>	<u>\$ 18,310</u>

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 on Form 10-Q are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements, including, in particular, statements about our plans, strategies, prospects and industry estimates are subject to risks and uncertainties. These statements identify prospective information and include words such as "anticipates," "intends," "plans," "seeks," "believes," "estimates," "expects," "should," "could," "predicts," "hopes" and similar expressions. Examples of forward-looking statements include, but are not limited to, statements we make regarding: (i) our outlook and expectations including, without limitation, in connection with continued market expansion and penetration for our commercial products, particularly DEFINITY in the face of increased competition and future patent and regulatory exclusivity expirations; (ii) our outlook and expectations in connection with future performance of Xenon in the face of increased competition; (iii) our outlook and expectations related to our ability to maintain and profitably renew our key customer contracts; and (iv) our outlook and expectations related to products manufactured at Jubilant HollisterStier ("JHS") and global isotope supply. 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, such statements 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. Such statements 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 on Form 10-Q 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 ability to continue to increase segment penetration for DEFINITY in suboptimal echocardiograms in the face of increased segment competition from other echocardiography contrast agents, including Optison from GE Healthcare Limited ("GE Healthcare") and Lumason from Bracco Diagnostics Inc. ("Bracco") and future patent and regulatory exclusivity expirations;
- Risks associated with revenues and unit volumes for Xenon in pulmonary studies and the potential competition in this generic segment from Curium (formerly known as Mallinckrodt Nuclear Imaging; purchased by IBA Molecular in January 2017 and renamed Curium in April 2017);
- Our dependence on key customers for our medical imaging products, and our ability to maintain and profitably renew our contracts with those key customers, including Cardinal Health ("Cardinal"), United Pharmacy Partners ("UPPI"), GE Healthcare and Triad Isotopes ("Triad");
- Our dependence upon third parties for the manufacture and supply of a substantial portion of our products, including DEFINITY at JHS;
- Risks associated with the technology transfer programs to secure production of our products at alternate contract manufacturer sites, including our next generation DEFINITY product at Samsung BioLogics ("SBL") located in South Korea;
- Risks associated with the manufacturing and distribution of our products and the regulatory requirements related thereto;
- The instability of the global Molybdenum-99 ("Moly") supply;
- The dependence of certain of our customers upon third party healthcare payors and the uncertainty of third party coverage and reimbursement rates;
- Uncertainties regarding the impact of on-going U.S. healthcare reform proposals on our business, including related reimbursements for our current and potential future products;
- Our being subject to extensive government regulation and our potential inability to comply with those regulations;
- Potential liability associated with our marketing and sales practices;
- The occurrence of any serious or unanticipated side effects with our products;
- Our exposure to potential product liability claims and environmental liability;
- Risks associated with our lead agent in development, flurpiridaz F 18, including:
 - The ability of GE Healthcare to successfully complete the Phase III development program;

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- The ability to obtain Food and Drug Administration (“FDA”) approval; and
- The ability to gain post-approval market acceptance and adequate reimbursement;
- The extensive costs, time and uncertainty associated with new product development, including further product development potentially relying on external development partners;
- Our inability to introduce new products and adapt to an evolving technology and diagnostic landscape;
- Our inability to identify and in-license or acquire additional products to grow our business;
- 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 prevailing economic or political conditions and events and financial, business and other factors beyond our control;
- Risks associated with our international operations;
- Our inability to adequately protect our facilities, equipment and technology infrastructure;
- Our inability to hire or retain skilled employees and key personnel;
- Risks related to our outstanding indebtedness and our ability to satisfy those obligations;
- Costs and other risks associated with the Sarbanes-Oxley Act and the Dodd-Frank Act;
- Our inability to utilize or limitations in our ability to utilize net operating loss carryforwards to reduce our future tax liability;
- Risks related to the ownership of our common stock; and
- Other factors that are described in Part I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016.

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 SEC. Any forward-looking statement made by us in this Quarterly Report on Form 10-Q 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.

Investor Information

We routinely make available important information, including copies of our annual, periodic and current reports filed or furnished with the SEC under the Exchange Act, free of charge on our website at <http://www.investor.lantheus.com>. We recognize our website as a key channel of distribution to reach public investors and as a means of disclosing material non-public information to comply with our disclosure obligations under SEC Regulation FD. Information contained on our website shall not be deemed incorporated into, or to be part of, this Quarterly Report on Form 10-Q, and any website references are not intended to be made through active hyperlinks.

The following discussion and analysis of our financial condition and results of operations should be read together with the condensed 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 Part I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016.

Overview

Our Business

We are a global leader in the development, manufacture and commercialization of innovative diagnostic medical imaging agents and products that assist clinicians in the diagnosis and treatment of cardiovascular and other diseases. Clinicians use our imaging agents and products across a range of imaging modalities, including echocardiography and nuclear imaging. We believe that the resulting improved diagnostic information enables healthcare providers to better detect and characterize, or rule out, disease, potentially achieving improved patient outcomes, reducing patient risk and limiting overall costs for payers and the entire healthcare system.

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Our commercial products are used by cardiologists, nuclear physicians, radiologists, internal medicine physicians, technologists and sonographers working in a variety of clinical settings. We sell our products to radiopharmacies, integrated delivery networks, hospitals, clinics and group practices.

We sell our products globally and have operations in the U.S., Puerto Rico and Canada and third-party distribution relationships in Europe, Canada, Australia, Asia Pacific and Latin America.

Our Product Portfolio

Our product portfolio includes an ultrasound contrast agent and nuclear imaging products. Our principal products include the following:

- DEFINITY is an ultrasound contrast agent used in ultrasound exams of the heart, also known as echocardiography exams. DEFINITY contains perflutren-containing lipid microspheres and is indicated in the U.S. for use in patients with suboptimal echocardiograms to assist in imaging the left ventricular chamber and left endocardial border of the heart in ultrasound procedures. We launched DEFINITY in 2001, and in the U.S., its composition of matter patent will expire in 2019 and its manufacturing patent will expire in 2021. In numerous foreign jurisdictions, patent protection or regulatory exclusivity will expire in 2019. We also have an active next generation development program for this agent including in connection with a new formulation and expanded indication, but we can give no assurance that the program will be successful.
- TechneLite is a technetium generator which provides the essential nuclear material used by radiopharmacies to radiolabel Cardiolite, Neurolite and other technetium-based radiopharmaceuticals used in nuclear medicine procedures. TechneLite uses Moly as its active ingredient.
- Xenon is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also for imaging cerebral blood flow. Xenon is manufactured by a third party and is processed and finished by us.

Sales of our contrast agent, DEFINITY, are made in the U.S. and Canada through our direct sales team of approximately 80 employees. In the U.S., our nuclear imaging products, including TechneLite, Xenon, Neurolite and Cardiolite, are primarily distributed through commercial radiopharmacies, the majority of which are controlled by or associated with Cardinal, UPPI, GE Healthcare and Triad. A small portion of our nuclear imaging product sales in the U.S. are made through our direct sales force to hospitals and clinics that maintain their own in-house radiopharmaceutical capabilities. Outside the U.S., we own one radiopharmacy in Puerto Rico, where we sell our own products as well as products of third parties to end-users.

In January 2016, we sold our Canadian radiopharmacies to Isologic Innovative Radiopharmaceuticals Ltd. (“Isologic”) and entered into a supply agreement under which we supply Isologic with certain of our products on commercial terms, including certain product purchase commitments by Isologic. In August 2016, we sold our Australian radiopharmacy servicing business to Global Medical Solutions (“GMS”), and entered into a supply agreement under which we supply GMS with certain of our products on commercial terms, including certain minimum product purchase commitments by GMS. We also maintain our own direct sales force in Canada so that we can control the importation, marketing, distribution and sale of our imaging agents in Canada. In Europe, Australia, Asia Pacific and Latin America, we rely on third party distributors to market, sell and distribute 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 revenues derived from our principal products:

(in thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2017	% of Revenues	2016	% of Revenues	2017	% of Revenues	2016	% of Revenues
DEFINITY	\$40,128	45.2%	\$33,474	42.9%	\$ 77,840	45.7%	\$ 64,896	42.0%
TechneLite	26,718	30.1%	25,252	32.4%	53,544	31.5%	50,088	32.4%
Xenon	7,927	8.9%	6,774	8.7%	15,987	9.4%	14,948	9.7%
Other	14,064	15.8%	12,466	16.0%	22,825	13.4%	24,508	15.9%
Total revenues	<u>\$88,837</u>	<u>100.0%</u>	<u>\$77,966</u>	<u>100.0%</u>	<u>\$170,196</u>	<u>100.0%</u>	<u>\$154,440</u>	<u>100.0%</u>

Key Factors Affecting Our Results

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

Growth of DEFINITY

We believe the market opportunity for our contrast agent, DEFINITY, remains significant. DEFINITY is currently our fastest growing and highest margin commercial product. We believe that DEFINITY sales will continue to grow and that DEFINITY will constitute a greater share of our overall product mix. 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.

The future growth of our DEFINITY sales will be dependent on our ability to continue to increase segment penetration for DEFINITY in suboptimal echocardiograms and, as discussed below in “—Inventory Supply,” on the ability of JHS to continue to manufacture and release DEFINITY on a timely and consistent basis. See “Part II—Item 1A. Risk Factors—The growth of our business is substantially dependent on increased market penetration for the appropriate use of DEFINITY in suboptimal echocardiograms.”

There are three echocardiography contrast agents approved by the FDA for sale in the U.S.—DEFINITY, which we estimated as having approximately 80% of the U.S. market for contrast agents in echocardiography procedures as of December 31, 2016, Optison from GE Healthcare and Lumason from Bracco.

Competition for Xenon

Xenon gas for lung ventilation diagnosis is our third largest product by revenues. In order to increase the predictability of our Xenon business, we have entered into Xenon supply agreements with customers at committed volumes and reduced prices. These steps have resulted in more predictable Xenon unit volumes. Historically, several companies, including Mallinckrodt Nuclear Imaging (now known as Curium), sold packaged Xenon as a pulmonary imaging agent in the U.S., but from 2010 through the first quarter of 2016, we were the only supplier of this imaging agent in the U.S. In March 2016, Mallinckrodt Nuclear Imaging received regulatory approval from the FDA to again sell packaged Xenon in the U.S. and has begun to do so. Depending upon the pricing, extent of availability and market penetration of such offering, we believe we are at risk for volume loss and price erosion for those customers which are not subject to price or volume commitments with us. See Part I, Item 1A. “Risk Factors —We face potential supply and demand challenges for Xenon” of our Annual Report on Form 10-K for the year ended December 31, 2016.

Inventory Supply

We obtain a substantial portion of our imaging agents from third party suppliers. JHS is currently our sole source manufacturer of DEFINITY, Neurolite, Cardiolite and evacuation vials, the latter being an ancillary component for our TechneLite generators. We are currently seeking approval from certain foreign regulatory authorities for JHS to manufacture certain of our products. Until we receive these approvals, we will face continued limitations on where we can sell those products outside of the U.S.

In addition to JHS, we are also currently working to secure additional alternative suppliers for our key products as part of our ongoing supply chain diversification strategy. We currently have on-going development and technology transfer activities for our next generation DEFINITY product with SBL, which is located in South Korea, but we cannot give any assurances as to if and when those technology transfer activities will be completed and when we will begin to receive supply of our next generation DEFINITY product from SBL. See Part I, Item 1A. “Risk Factors—Our dependence upon third parties for the manufacture and supply of a substantial portion of our products could prevent us from delivering our products to our customers in the required quantities, within the required timeframes, or at all, which could result in order cancellations and decreased revenues” of our Annual Report on Form 10-K for the year ended December 31, 2016.

Radiopharmaceuticals are decaying radioisotopes with half-lives ranging from a few hours to several days. These products cannot be kept in inventory because of their limited shelf lives and are subject to just-in-time manufacturing, processing and distribution, which takes place at our North Billerica, Massachusetts facility.

Global Isotope Supply

We currently have Moly supply agreements with NTP Radioisotopes (“NTP”) of South Africa and ANSTO of Australia, and with Institute for Radioelements (“IRE”) of Belgium, each running through December 31, 2017, and a Xenon supply agreement with IRE which runs through June 30, 2019, subject to extensions.

We believe we are well-positioned with ANSTO, IRE and NTP to have a secure supply of Moly, including low-enriched Moly produced from targets containing less than 20% of Uranium-235 (“LEU Moly”). From November 2016, the NRU reactor transitioned from providing regular supply of medical isotopes to providing only emergency back-up supply of HEU based Moly through March 2018. ANSTO has already significantly increased its Moly production capacity from its existing facility in August 2016 and has under construction, in cooperation with NTP, a new Moly processing facility that ANSTO believes will expand its production capacity, which is expected to be in commercial operation in the first half of 2018. In addition, IRE received approval from its regulator to expand its production capability by up to 50% of its former capacity. The new ANSTO and IRE production capacity is expected to replace and exceed what was the NRU’s most recent routine production.

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We are receiving bulk unprocessed Xenon from IRE, which we are processing and finishing for our customers. We believe we are well-positioned to supply Xenon to our customers. See Part I, Item 1A. “Risk Factors —We face potential supply and demand challenges for Xenon” of our Annual Report on Form 10-K for the year ended December 31, 2016.

Demand for TechneLite

We believe that due to 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, the total MPI market has been essentially flat since 2011. Our 2016 sales of TechneLite generators exceeded our expectations because of opportunistic sales when customers could not obtain sufficient generators from other suppliers. We can give no assurances that such opportunistic sales will be replicated in 2017.

In November 2016, CMS announced the 2017 final Medicare payment rules for hospital outpatient settings. Under the final rules, each technetium dose produced from a generator for a diagnostic procedure in a hospital outpatient setting is reimbursed by Medicare at a higher rate if that technetium dose is produced from a generator containing at least 95% LEU Moly. In January 2013, we began to offer a TechneLite generator which contains at least 95% LEU Moly and which satisfies the requirements for reimbursement under this incentive program. Although demand for LEU generators appears to be growing, we do not know when, or if, this incremental reimbursement for LEU Moly generators will result in a material increase in our generator sales.

Research and Development Expenses

To remain a leader in the marketplace, we have historically made substantial investments in new product development. As a result, the positive contributions of those internally funded R&D programs have been a key factor in our historical results and success. On April 25, 2017, we announced entering into a definitive, exclusive Collaboration and License Agreement with GE Healthcare for the continued Phase III development and worldwide commercialization of flurpiridaz F 18. In the future, we may also seek to engage strategic partners for our 18F LMI 1195 and LMI 1174 programs. See Part I, Item 1. “Business—Research and Development—Proposed GE Healthcare Transaction” and Part I, Item 1A. “Risk Factors—We may not be able to further develop or commercialize our agents in development without successful strategic partners” of our Annual Report on Form 10-K for the year ended December 31, 2016.

Segments

We report our results of operations in two operating segments: U.S. and International. We generate a greater proportion of our revenues and net income in the U.S. segment, which consists of all regions of the U.S. with the exception of Puerto Rico.

Executive Overview

Our results for the three and six months ended June 30, 2017 as compared to the corresponding periods in 2016 reflect the following:

- increased revenues and segment penetration for DEFINITY in the suboptimal echocardiogram segment as a result of our continued focused sales efforts;
- increased revenues for TechneLite, mainly the result of higher contracted volumes from certain customers;
- increased revenues of approximately \$5.0 million from GE Healthcare for the continued Phase III development and worldwide commercialization of flurpiridaz F 18;
- lower international revenues and cost of goods sold as a result of the sales of our Canadian and Australian radiopharmacies in 2016;
- increased depreciation expense as a result of the scheduled decommissioning of certain long-lived assets;
- general and administrative expense of \$1.7 million incurred in connection with the refinancing of our debt as well as a related \$2.2 million loss on the extinguishment of debt; and
- decreased interest expense due to the refinancing of long-term debt and a lower principal balance on our long-term debt.

Results of Operations

The following is a summary of our consolidated results of operations:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues	\$88,837	\$77,966	\$170,196	\$154,440
Cost of goods sold	42,890	42,215	84,487	84,988
Gross profit	45,947	35,751	85,709	69,452
Operating expenses				
Sales and marketing	11,603	9,843	21,817	19,150
General and administrative	11,203	9,238	23,473	18,751
Research and development	5,244	2,608	10,595	5,644
Total operating expenses	28,050	21,689	55,885	43,545
Gain on sale of assets	—	(117)	—	(5,945)
Operating income	17,897	14,179	29,824	31,852
Interest expense	4,285	6,983	9,705	14,008
Loss on extinguishment of debt	—	—	2,161	—
Other income	(552)	(401)	(1,129)	(466)
Income before income taxes	14,164	7,597	19,087	18,310
Provision for income taxes	569	247	1,354	637
Net income	\$13,595	\$ 7,350	\$ 17,733	\$ 17,673

Comparison of the Periods Ended June 30, 2017 and 2016

Revenues

Segment revenues are summarized by product as follows:

(in thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2017	2016	Change \$	Change %	2017	2016	Change \$	Change %
U.S.								
DEFINITY	\$39,211	\$32,698	\$ 6,513	19.9%	\$ 76,134	\$ 63,491	\$12,643	19.9%
TechneLite	23,220	21,643	1,577	7.3%	46,529	43,376	3,153	7.3%
Xenon	7,925	6,773	1,152	17.0%	15,983	14,945	1,038	6.9%
Other	7,744	4,020	3,724	92.6%	10,481	8,255	2,226	27.0%
Total U.S. revenues	78,100	65,134	12,966	19.9%	149,127	130,067	19,060	14.7%
International								
DEFINITY	917	776	141	18.2%	1,706	1,405	301	21.4%
TechneLite	3,498	3,609	(111)	(3.1)%	7,015	6,712	303	4.5%
Xenon	2	1	1	100.0%	4	3	1	33.3%
Other	6,320	8,446	(2,126)	(25.2)%	12,344	16,253	(3,909)	(24.1)%
Total International revenues	10,737	12,832	(2,095)	(16.3)%	21,069	24,373	(3,304)	(13.6)%
Total revenues	\$88,837	\$77,966	\$10,871	13.9%	\$170,196	\$154,440	\$15,756	10.2%

The increase in the U.S. segment revenues for the three months ended June 30, 2017, as compared to the prior year period is primarily due to a \$6.5 million increase in DEFINITY revenues as a result of higher unit volumes, a \$1.6 million increase in TechneLite revenues primarily as a result of a contract with a significant customer that increased unit volumes and a \$1.2 million increase in Xenon as a result of higher unit volumes. In addition, there was an increase of approximately \$5.0 million in other revenue associated with the License Agreement with GE Healthcare for the continued Phase III development and worldwide commercialization of flurpiridaz F 18. Offsetting these increases was a \$0.6 million decrease in Ablavar revenues as the product is no longer sold, as well as a \$0.7 million decrease due to rebate and allowance provisions.

The increase in the U.S. segment revenues for the six months ended June 30, 2017, as compared to the prior year period is primarily due to a \$12.6 million increase in DEFINITY revenues as a result of higher unit volumes, a \$3.2 million increase in TechneLite revenues primarily as a result of a contract with a significant customer that increased unit volumes and a \$1.0 million

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increase in Xenon as a result of higher unit volumes. In addition, there was an increase of approximately \$5.0 million in other revenue associated with the License Agreement with GE Healthcare for the continued Phase III development and worldwide commercialization of flurpiridaz F 18. Offsetting these increases was a \$1.4 million decrease in Ablavar revenues as the product is no longer sold, as well as a \$1.2 million decrease due to rebate and allowance provisions.

The decrease in the International segment revenues for the three and six months ended June 30, 2017, as compared to the prior year periods, is primarily the result of the sale of the Australian radiopharmacy business during 2016.

Rebates and Allowances

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

An analysis of the amount of, and change in, reserves is summarized as follows:

<u>(in thousands)</u>	<u>Rebates and Allowances</u>
Balance, as of January 1, 2017	\$ 2,297
Current provisions relating to revenues in current year	4,515
Adjustments relating to prior years' estimate	(158)
Payments/credits relating to revenues in current year	(2,599)
Payments/credits relating to revenues in prior years	(1,507)
Balance, as of June 30, 2017	<u>\$ 2,548</u>

Costs of Goods Sold

Cost of goods sold consists of manufacturing, distribution, intangible asset amortization, write-offs of excess and obsolete inventory and other costs related to our commercial products.

Cost of goods sold is summarized by segment as follows:

<u>(in thousands)</u>	<u>Three Months Ended June 30,</u>				<u>Six Months Ended June 30,</u>			
	<u>2017</u>	<u>2016</u>	<u>Change \$</u>	<u>Change %</u>	<u>2017</u>	<u>2016</u>	<u>Change \$</u>	<u>Change %</u>
U.S.	\$34,409	\$32,448	\$ 1,961	6.0%	\$67,466	\$65,658	\$ 1,808	2.8%
International	8,481	9,767	(1,286)	(13.2)%	17,021	19,330	(2,309)	(11.9)%
Total cost of goods sold	<u>\$42,890</u>	<u>\$42,215</u>	<u>\$ 675</u>	<u>1.6%</u>	<u>\$84,487</u>	<u>\$84,988</u>	<u>\$ (501)</u>	<u>(0.6)%</u>

The increases in the U.S. segment cost of goods sold for the three and six months ended June 30, 2017 as compared to the prior year periods are primarily due to costs associated with the increase in sales volume as noted above. We also incurred, increases in technology transfer expense, partially offset by lower amortization expense as a result of a fully amortized intangible asset.

The decreases in the International segment cost of goods sold for the three and six months ended June 30, 2017 compared to the prior year periods are primarily due to lower manufacturing costs as a result of the sale of our Australian radiopharmacy business, partially offset by higher manufacturing costs for certain products due to higher sales volume and higher material costs for certain products.

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Gross Profit

Gross profit is summarized by segment as follows:

(in thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2017	2016	Change \$	Change %	2017	2016	Change \$	Change %
U.S.	\$43,691	\$32,686	\$11,005	33.7%	\$81,661	\$64,409	\$17,252	26.8%
International	2,256	3,065	(809)	(26.4)%	4,048	5,043	(995)	(19.7)%
Total gross profit	<u>\$45,947</u>	<u>\$35,751</u>	<u>\$10,196</u>	<u>28.5%</u>	<u>\$85,709</u>	<u>\$69,452</u>	<u>\$16,257</u>	<u>23.4%</u>

The increase in the U.S. segment gross profit for the three and six months ended June 30, 2017 over the prior year periods are primarily due to higher DEFINITY unit volumes, higher Xenon unit volumes and the recognition of approximately \$5.0 million in other revenue associated with the License Agreement with GE Healthcare for the continued Phase III development and worldwide commercialization of flurpiridaz F 18 without any associated cost of goods sold.

The decreases in the International segment gross profit for the three and six months ended June 30, 2017 over the prior year periods are primarily due to higher manufacturing and material costs for certain products.

Sales and Marketing

Sales and marketing expense is summarized by segment as follows:

(in thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2017	2016	Change \$	Change %	2017	2016	Change \$	Change %
U.S.	\$10,809	\$8,576	\$2,233	26.0%	\$20,374	\$16,881	\$3,493	20.7%
International	794	1,267	(473)	(37.3)%	1,443	2,269	(826)	(36.4)%
Total sales and marketing	<u>\$11,603</u>	<u>\$9,843</u>	<u>\$1,760</u>	<u>17.9%</u>	<u>\$21,817</u>	<u>\$19,150</u>	<u>\$2,667</u>	<u>13.9%</u>

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 expenses include the development and printing of advertising and promotional material, professional services, market research and sales meetings.

The increases in the U.S. segment sales and marketing expenses for the three and six months ended June 30, 2017 over the prior year periods are primarily due to employee related expenses, advertising, market research and promotional program expenses.

The decreases in the International segment sales and marketing expenses for the three and six months ended June 30, 2017 over the prior year periods are primarily due to lower headcount.

General and Administrative

General and administrative expense is summarized by segment as follows:

(in thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2017	2016	Change \$	Change %	2017	2016	Change \$	Change %
U.S.	\$11,048	\$8,781	\$2,267	25.8%	\$23,154	\$17,935	\$5,219	29.1%
International	155	457	(302)	(66.1)%	319	816	(497)	(60.9)%
Total general and administrative	<u>\$11,203</u>	<u>\$9,238</u>	<u>\$1,965</u>	<u>21.3%</u>	<u>\$23,473</u>	<u>\$18,751</u>	<u>\$4,722</u>	<u>25.2%</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.

The increase in the U.S. segment general and administrative expenses for the three months ended June 30, 2017 over the prior year period are primarily due to higher employee related expenses and campus consolidation costs.

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The increase in U.S. segment general and administrative expenses for the six months ended June 30, 2017 over the prior year period are primarily due to \$1.7 million of debt refinancing costs, higher employee related expenses, campus consolidation costs and higher legal fees.

The decreases in the International segment general and administrative expenses for the three and six months ended June 30, 2017 over the prior year periods are primarily due to lower employee headcount and related expenses.

Research and Development

Research and development expense is summarized by segment as follows:

(in thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2017	2016	Change \$	Change %	2017	2016	Change \$	Change %
U.S.	\$4,939	\$2,434	\$2,505	102.9%	\$10,069	\$5,300	\$4,769	90.0%
International	305	174	131	75.3%	526	344	182	52.9%
Total research and development	<u>\$5,244</u>	<u>\$2,608</u>	<u>\$2,636</u>	<u>101.1%</u>	<u>\$10,595</u>	<u>\$5,644</u>	<u>\$4,951</u>	<u>87.7%</u>

Research and development expenses relate primarily to the development of new products to add to our portfolio and costs related to its medical affairs, medical information and regulatory functions. We do not allocate research and development expenses incurred in the United States to our International segment.

The increase in the U.S. segment research and development expenses for the three months ended June 30, 2017 over the prior year period is primarily due to an increase in depreciation expense and other charges as a result of the scheduled decommissioning of certain long-lived assets associated with research and development operations as well as higher employee related expenses.

The increase in the U.S. segment research and development expenses for the six months ended June 30, 2017 over the prior year period is primarily due to an increase in depreciation expense and other charges as a result of the scheduled decommissioning of certain long-lived assets associated with research and development operations as well as higher employee related expenses, partially offset by lower pharmacovigilance expenses due to the transition to a new vendor in the prior year.

The increases in International segment research and development expenses for the three and six months ended June 30, 2017 over the prior year periods were driven by a European Phase IV study for one of our products.

Gain on Sale of Assets

Effective January 7, 2016, our Canadian subsidiary entered into an asset purchase agreement, pursuant to which it would sell substantially all of the assets of our Canadian radiopharmacies and Gludef manufacturing and distribution business to one of our existing Canadian radiopharmacy customers. The purchase price for the asset sale was \$9.0 million in cash, resulting in a pre-tax gain of \$5.9 million recorded within operating income during the six months ended June 30, 2016.

Interest Expense

Interest expense decreased by approximately \$2.7 million and \$4.3 million for the three and six months ended June 30, 2017, respectively, as compared to the prior year periods, due to the March 2017 refinancing of our long-term debt and reductions in the principal balance of our long-term debt related to the 2017 refinancing and the voluntary principal prepayments we made during September and November 2016.

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Loss on Extinguishment of Debt

For the six months ended June 30, 2017, we incurred a \$2.2 million loss on extinguishment of debt in connection with the refinancing of our existing indebtedness with the new term loan and revolving credit facilities, see Note 8, "Financing Arrangements" to our condensed consolidated financial statements.

Provision for Income Taxes

Provision for income taxes for the periods presented is as follows:

(in thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2017	2016	Change \$	Change %	2017	2016	Change \$	Change %
	Provision for income taxes	\$569	\$247	\$ 322	130.4%	\$1,354	\$637	\$ 717

Our provision for income taxes results primarily from interest and penalties associated with uncertain tax positions, offset by reversals of those positions as statutes lapse or such positions are settled during the year, as well as taxes due in certain foreign jurisdictions where we generate taxable income. The \$0.3 million and \$0.7 million increases in the tax provision for the three and six months ended June 30, 2017, as compared to the same periods in 2016 primarily reflect a reduced amount of statute lapses and consequent liability releases in the current period, when compared with the prior year period.

We regularly assess our ability to realize our deferred tax assets. Assessing the realizability of deferred tax assets requires significant management judgment. In determining whether our deferred tax assets are more likely than not realizable, we evaluated all available positive and negative evidence, and weighed the objective evidence and expected impact. Evidence considered included our history of net operating losses, which resulted in our recording of a full valuation allowance against our domestic net deferred tax assets beginning in 2011, and in each year thereafter. We were profitable on a cumulative basis for the three-year period ended June 30, 2017, but substantially all of that profitability was achieved during 2016 and the six months ended June 30, 2017.

We continue to evaluate other negative evidence, including customer concentration and contractual risk, the risk of Moly supply availability and cost, DEFINITY supplier risk, and certain product development risks, all of which provide for uncertainties around our future level of profitability. Based on our review of all available evidence, we determined that we have not yet attained a sustained level of profitability sufficient to outweigh the objectively verifiable negative evidence, and have recorded a full valuation allowance against our domestic net deferred tax assets at June 30, 2017. We will continue to assess the level of the valuation allowance required. If a sufficient weight of positive evidence exists in future periods to support a release of some or all of the valuation allowance recorded against domestic deferred tax assets, such a release would likely have a material impact on our results of operations in that future period.

Our effective tax rate for the periods presented are as follows:

	Six Months Ended June 30,	
	2017	2016
Effective tax rate	7.1%	3.5%

Liquidity and Capital Resources

Cash Flows

The following table provides information regarding our cash flows:

(in thousands)	Six Months Ended June 30,	
	2017	2016
Net cash provided by operating activities	\$ 26,091	\$21,415
Net cash (used in) provided by investing activities	\$ (7,067)	\$ 6,686
Net cash used in financing activities	\$(13,081)	\$(1,872)

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Net Cash Provided by Operating Activities

Cash provided by operating activities of \$26.1 million in the six months ended June 30, 2017 was driven primarily by net income of \$17.7 million plus \$11.3 million of depreciation, amortization and accretion expense, \$2.1 million of stock-based compensation expense and a \$2.2 million loss on debt extinguishment. These net sources of cash were offset by a net decrease of \$9.4 million related to movements in our working capital accounts during the period. The overall decreases in cash from our working capital accounts were primarily driven by higher accounts receivable related to increases in revenues to certain major customers and timing of inventory purchases during the period.

Cash provided by operating activities of \$21.4 million in the six months ended June 30, 2016 was driven primarily by net income of \$17.7 million plus \$8.4 million of depreciation, amortization and accretion expense, which was offset by the gain on sale of assets of \$5.9 million. These net sources of cash were further offset by a net decrease of \$1.6 million related to movements in our working capital accounts during the period. The overall decreases in cash from our working capital accounts were driven primarily by higher accounts receivable related to increases in revenues to certain major customers and lower accrued expenses and other liabilities due to the payment of prior year annual bonuses, partially offset by higher accounts payable as a result of the timing of payment runs.

Net Cash Provided by (Used in) Investing Activities

Net cash used in investing activities during the six months ended June 30, 2017 reflected \$8.3 million in capital expenditures offset by the cash proceeds of \$1.2 million received from the sale of assets from our Australian radiopharmacy business during the third quarter of 2016.

Net cash provided by investing activities during the six months ended June 30, 2016 was primarily due to cash proceeds of \$9.0 million received from the sale of assets from our Canadian radiopharmacy business, which was offset by \$2.4 million in capital expenditures.

Net Cash Used in Financing Activities

Net cash used in financing activities during the six months ended June 30, 2017 is primarily related to the net outflow of \$11.9 million in connection with our refinancing of our previous \$365.0 million seven-year term loan agreement with a new five-year \$275.0 million term loan facility.

External Sources of Liquidity

On June 30, 2015, we completed our initial public offering, entered into a \$365.0 million seven-year term facility (the “2015 Term Facility”) and amended and restated our revolving facility (the “2015 Revolving Facility”) that had a borrowing capacity of \$50.0 million. The net proceeds of the 2015 Term Facility and the initial public offering together with available cash were used to repay in full the aggregate principal amount of the \$400.0 million of Senior Notes due in 2017 then outstanding, and pay related premiums, interest and expenses and pay down \$8.0 million of borrowings under the 2015 Revolving Facility.

In September 2016, we completed a follow-on underwritten offering of 5,200,000 shares of common stock and utilized the net proceeds to us from this offering, combined with cash on hand, to prepay \$55.0 million of the principal balance of our 2015 Term Facility. In November 2016, we completed a second follow-on underwritten offering that included 1,000,000 shares of common stock offered by us and utilized the net proceeds to us from this offering, combined with cash on hand, to prepay \$20.0 million of the principal balance of our 2015 Term Facility. As of December 31, 2016, the principal balance outstanding on our 2015 Term Facility was \$284.5 million.

In March 2017, we refinanced the 2015 Term Facility with a new five-year \$275.0 million term loan facility (the “2017 Term Facility”) and the loans thereunder, the “Term Loans”). In addition, we replaced our 2015 Revolving Facility with a new \$75.0 million five-year revolving credit facility (the “2017 Revolving Facility”) and, together with the 2017 Term Facility, the “2017 Facility”, the terms of which are set forth in the Credit Agreement). The 2017 Term Facility was issued net of a \$0.7 million discount. We have the right to request an increase to the 2017 Term Facility or request the establishment of one or more new incremental term loan facilities, in an aggregate principal amount of up to \$75.0 million, plus additional amounts, in certain circumstances.

We used the net proceeds of the 2017 Term Facility, together with approximately \$15.3 million of cash on hand, to refinance in full the aggregate remaining principal amount of the loans outstanding under the 2015 Term Facility and pay related interest, transaction fees and expenses. No amounts were outstanding under the 2015 Revolving Facility at that time.

The Term Loans under the 2017 Term Facility bear interest, with pricing based from time to time at our election at (i) LIBOR plus a spread of 4.50% or (ii) the Base Rate (as defined in the Credit Agreement) plus a spread of 3.50%. Interest is payable (i) with respect to LIBOR Term Loans, at the end of each Interest Period (as defined in the Credit Agreement) and (ii) with respect to Base Rate Term Loans, at the end of each quarter. At June 30, 2017, our interest rate under the 2017 Term Facility was 5.5%.

We are permitted to voluntarily prepay the Term Loans, in whole or in part, subject to a 1.00% prepayment premium applicable if, during the first 6 months of the 2017 Term Facility, we make any prepayment of the Term Loans in connection with a repricing transaction (as defined in the Credit Agreement). The 2017 Term Facility requires us to make mandatory prepayments of the outstanding Term Loans in certain circumstances. The 2017 Term Facility amortizes at 1.00% per year until its June 30, 2022 maturity date.

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Under the terms of the 2017 Revolving Facility, the lenders thereunder agreed to extend credit to us from time to time until March 30, 2022 (the “Revolving Termination Date”) consisting of revolving loans (the “Revolving Loans” and, together with the Term Loans, the “Loans”) in an aggregate principal amount not to exceed \$75.0 million (the “Revolving Commitment”) at any time outstanding. The 2017 Revolving Facility includes a \$20.0 million sub-facility for the issuance of letters of credit (the “Letters of Credit”). The Letters of Credit and the borrowings under the 2017 Revolving Facility are expected to be used for working capital and other general corporate purposes.

The Revolving Loans under the 2017 Revolving Facility bear interest, with pricing based from time to time at our election at (i) LIBOR plus a spread of 3.50% or (ii) the Base Rate (as defined in the Credit Agreement) plus a spread of 2.50%. The 2017 Revolving Facility also includes an unused line fee, which is set at 0.375% while our secured leverage ratio (as defined in the Credit Agreement) is greater than 3.00 to 1.00 and 0.25% when our secured leverage ratio is less than or equal to 3.00 to 1.00.

We are permitted to voluntarily prepay the Revolving Loans, in whole or in part, or reduce or terminate the Revolving Commitment, in each case, without premium or penalty. On any business day on which the total amount of outstanding Revolving Loans and Letters of Credit exceeds the total Revolving Commitment, we must prepay the Revolving Loans in an amount equal to such excess. The 2017 Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. The 2017 Facility requires us to be in quarterly compliance, measured on a trailing four quarter basis, with a financial covenant. The maximum consolidated leverage ratio permitted by the financial covenant is displayed in the table below:

2017 Facility Financial Covenant

<u>Period</u>	<u>Consolidated Leverage Ratio</u>
Q2 2017 through Q1 2018	5.00 to 1.00
Q2 2018 through Q1 2019	4.75 to 1.00
Thereafter	4.50 to 1.00

The 2017 Facility contains usual and customary restrictions on our ability and that of our subsidiaries to: (i) incur additional indebtedness (ii) create liens; (iii) consolidate, merge, sell or otherwise dispose of all or substantially all of its assets; (iv) sell certain assets; (v) pay dividends on, repurchase or make distributions in respect of capital stock or make other restricted payments; (vi) make certain investments; (vii) repay subordinated indebtedness prior to stated maturity; and (viii) enter into certain transactions with its affiliates.

Upon an event of default, the administrative agent under the Credit Agreement will have the right to declare the Loans and other obligations outstanding immediately due and payable and all commitments immediately terminated or reduced.

The 2017 Facility is guaranteed by Holdings and Lantheus MI Real Estate, LLC (“LMI-RE”), and obligations under the 2017 Facility are generally secured by first priority liens over substantially all of the assets of each of LMI, Holdings and LMI-RE (subject to customary exclusions set forth in the transaction documents) owned as of March 30, 2017 or thereafter acquired.

Our ability to fund our future capital needs will be affected by our ability to continue to generate cash from operations and may be affected by our ability to access the capital markets, money markets, or other sources of funding, as well as the capacity and terms of our financing arrangements.

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 prepayments of our term loans or other retirements or refinancing of outstanding debt, privately negotiated transactions or otherwise. The amount of debt that may be retired, if any, would be decided at the sole discretion of our Board of Directors and will depend on market conditions, our cash position and other considerations.

Funding Requirements

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

- Our ability to have product manufactured and released from JHS and other manufacturing sites in a timely manner in the future;

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- The pricing environment and the level of product sales of our currently marketed products, particularly DEFINITY and any additional products that we may market in the future;
- Revenue mix shifts and associated volume and selling price changes that could result from contractual status changes with key customers and additional competition;
- The costs of further commercialization of our existing products, particularly in international markets, including product marketing, sales and distribution and whether we obtain local partners to help share such commercialization costs;
- The costs of investing in our facilities, equipment and technology infrastructure;
- The costs and timing of establishing manufacturing and supply arrangements for commercial supplies of our 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;
- The legal costs relating to maintaining, expanding and enforcing our intellectual property portfolio, pursuing insurance or other claims and defending against product liability, regulatory compliance or other claims; and
- The cost of interest on any additional borrowings which we may incur under our financing arrangements.

Until we successfully become dual sourced for our principal products, we are vulnerable to future supply shortages. Disruption in the financial performance could also occur if we experience significant adverse changes in customer mix, broad economic downturns, adverse industry or company conditions or catastrophic external events. If we experience one or more of these events in the future, we may be required to implement additional expense reductions, such as a delay or elimination of discretionary spending in all functional areas, as well as scaling back select operating and strategic initiatives.

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, assets securitizations, debt financings, sale-leasebacks or other financing or strategic alternatives, to the extent such transactions are permissible under the covenants of the agreements governing our senior secured credit facilities. 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 agreements governing our senior secured credit facilities, 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 those covenants. 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.

At June 30, 2017, our only current committed external source of funds is our borrowing availability under our 2017 Revolving Facility. We had \$57.2 million of cash and cash equivalents at June 30, 2017. Our 2017 Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. Incremental borrowings under the 2017 Revolving Facility may affect our ability to comply with the covenants in the 2017 Facility, including the financial covenant restricting total net leverage. Accordingly, we may be limited in utilizing the full amount of our 2017 Revolving Facility as a source of liquidity.

Based on our current operating plans, we believe that our existing cash and cash equivalents, results of operations and availability under our 2017 Revolving Facility will be sufficient to continue to fund our liquidity requirements for the foreseeable future.

Critical Accounting Policies and 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. Actual results may differ materially from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

There have been no material changes to our critical accounting policies or in the underlying accounting assumptions and estimates used in such policies in the six months ended June 30, 2017. For further information, refer to our summary of significant accounting policies and estimates in our Annual Report on Form 10-K filed for the year ended December 31, 2016.

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Off-Balance Sheet Arrangements

We are required to provide the U.S. Nuclear Regulatory Commission and Massachusetts Department of Public Health financial assurance demonstrating our ability to fund the decommissioning of our North Billerica, Massachusetts production facility upon closure, though we do not intend to close the facility. We have provided this financial assurance in the form of a \$28.2 million surety bond.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

For quantitative and qualitative disclosures about market risk, see Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk,” of our Annual Report on Form 10-K for the year ended December 31, 2016. Our exposures to market risk have not changed materially since December 31, 2016.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

The Company’s management, with the participation of the Company’s Chief Executive Officer and Chief Financial Officer (its principal executive officer and principal financial officer, respectively), has evaluated the effectiveness of the Company’s disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act as of June 30, 2017. Based on that evaluation, the Company’s Chief Executive Officer and Chief Financial Officer concluded that the Company’s disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) were effective as of June 30, 2017.

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2017, 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, 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 governmental and 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.

As of June 30, 2017, the Company has no material ongoing litigation in which the Company was a party or any material ongoing regulatory or other proceedings and had no knowledge of any investigations by government or regulatory authorities in which the Company is a target that could have a material adverse effect on its current business.

Item 1A. Risk Factors

There have been no material changes to the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2016, except as set forth below. For further information, refer to Part I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016.

The growth of our business is substantially dependent on increased market penetration for the appropriate use of DEFINITY in suboptimal echocardiograms.

The growth of our business is substantially dependent on increased market penetration for the appropriate use of DEFINITY in suboptimal echocardiograms. Of the total number of echocardiograms performed each year in the U.S., over 31.8 million in 2016, based on medical literature, a third party source estimates that 20%, or approximately 6.4 million echocardiograms in 2016, produced suboptimal images. We estimate that DEFINITY had an approximately 80% share of the U.S. market for contrast agents in echocardiography procedures as of December 2016. We launched DEFINITY in 2001, and in the U.S., its composition of matter patent will expire in 2019 and its manufacturing patent will expire in 2021. In numerous foreign jurisdictions, patent protection or regulatory exclusivity will expire in 2019. We have an active next generation development program for this agent, including in

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connection with a new formulation and expanded indication, but we can give no assurance that this program will be successful. If we are not able to continue to grow DEFINITY sales through increased market penetration, we will not be able to grow our revenue and cash flow from our DEFINITY business or provide support from our DEFINITY business for the substantial overhead of our business, which could have a negative effect on our business, results of operations and prospects.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Repurchases

The following table presents information with respect to purchases of common stock we made during the quarter ending June 30, 2017. The Company does not have a share repurchase program in effect. The 2015 Equity Incentive Plan, adopted by the Company on June 24, 2015, and amended April 26, 2016 and as further amended on April 27, 2017, provides for the withholding of shares held by employees to satisfy tax obligations. It does not specify a maximum number of shares that can be withheld for this purpose. The shares of common stock withheld to satisfy minimum tax withholding obligations may be deemed to be “issuer purchases” of shares that are required to be disclosed pursuant to this Item.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program
April 2017**	97,212	\$ 12.05	*	*
May 2017**	2,403	\$ 12.90	*	*
June 2017	—	\$ —	*	*
Total	99,615		*	

* These amounts are not applicable as the Company does not have a share repurchase program in effect.

** Reflects shares withheld to satisfy minimum statutory tax withholding amounts due from employees related to the receipt of stock which resulted from the exercise of vesting of equity awards.

Dividend Policy

We did not declare or pay any dividends and we do not currently intend to pay dividends in the foreseeable future. We currently expect to retain future earnings, if any, for the foreseeable future, to repay indebtedness and to finance the growth and development of our business. Our ability to pay dividends are restricted by our financing arrangements. See Part I, Item 2. “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Liquidity and Capital Resources-External Sources of Liquidity” for further information.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The list of exhibits called for by this item is incorporated by reference to the Exhibit Index of this Quarterly Report on Form 10-Q included herewith.

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 HOLDINGS, INC.

By: /s/ MARY ANNE HEINO

Name: Mary Anne Heino

Title: *President and Chief Executive Officer
(Principal Executive Officer)*

Date: August 1, 2017

LANTHEUS HOLDINGS, INC.

By: /s/ JOHN W. CROWLEY

Name: John W. Crowley

Title: *Chief Financial Officer and Treasurer (Principal
Financial Officer and Principal Accounting Officer)*

Date: August 1, 2017

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION OF EXHIBITS	INCORPORATED BY REFERENCE			
		FORM	FILE NUMBER	EXHIBIT	FILING DATE
10.1*†	Collaboration and License Agreement by and between Lantheus Medical Imaging, Inc. and GE Healthcare Limited dated April 25, 2017.				
10.2*†	Amended and Restated Supply Agreement, dated as of April 25, 2017, by and between Lantheus Medical Imaging, Inc. and Medi-Physics Inc., doing business as GE Healthcare.				
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification Pursuant to 18 U.S.C. Section 1350 as adopted pursuant to 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 Extension Calculation Linkbase Document				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed 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.**

COLLABORATION AND LICENSE AGREEMENT

BY AND BETWEEN

LANTHEUS MEDICAL IMAGING, INC.

AND

GE HEALTHCARE LIMITED

DATED

APRIL 25, 2017

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COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (the “**Agreement**”) is entered into as of April 25, 2017 (the “**Effective Date**”) by and between **GE HEALTHCARE LIMITED**, a company organized and existing under the laws of England and Wales, registered under Company No: 01002610, having its principal place of business at Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, United Kingdom (“**GEHC**”) and **LANTHEUS MEDICAL IMAGING, INC.**, a Delaware corporation having its principal place of business at 331 Treble Cove Road, North Billerica, MA 01862 (“**LMI**”). GEHC and LMI are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

BACKGROUND

WHEREAS, LMI owns or controls the LMI Patent Rights, the LMI Know-How, and other assets related to the Precursor, Licensed Compound, and Licensed Product.

WHEREAS, GEHC desires to obtain and LMI desires to grant to GEHC licenses under the LMI Patent Rights and LMI Know-How to exploit the Precursor, Licensed Compound, and Licensed Product.

WHEREAS, GEHC desires to receive and LMI desires to transfer and assign to GEHC certain assets relating to the Precursor, Licensed Compound, and Licensed Product.

WHEREAS, the Parties wish to collaborate with respect to the further Development and Commercialization of the Precursor, Licensed Compound and the Licensed Product.

NOW THEREFORE, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, will have the meanings set forth in this ARTICLE 1 (Definitions).

- 1.1 “**AAA Rules**” has the meaning set forth in Section 13.3 (Arbitration).
- 1.2 “**Abandonment**” has the meaning set forth in Section 12.4 (Termination for Cessation of Activities).
- 1.3 “**Acquiring Party**” has the meaning set forth in Section 3.12.1 (Options).
- 1.4 “**Affiliate**” means, with respect to a particular Person, any other Person that controls, is controlled by, or is under common control with such Person. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Person, whether by the ownership of more than 50% of the voting stock or economic interest of such Person, or by contract, ownership of securities, or otherwise. Neither Avista Capital Partners, nor its affiliated funds or other portfolio companies will be considered to be Affiliates of LMI.
- 1.5 “**Agreement**” has the meaning set forth in Recitals.

- 1.6 “**Alliance Manager**” has the meaning set forth in Section 2.1 (Alliance Managers).
- 1.7 “**Analog**” means any contrast imaging agent having the structure set forth on Schedule 1.7, other than flurpiridaz, known as [18F]flurpiridaz, the structure of which is set forth on Schedule 1.84.
- 1.8 “**Applicable Law**” means the applicable laws, rules, and regulations, including any rules, regulations, guidelines, court orders, legislation, principles of common law, codes, treaties, ordinances, or other requirements of Governmental Authorities (*e.g.*, Regulatory Authorities), including applicable regulations and guidance of the FDA and European Medicines Agency (and national implementations thereof) that constitute good laboratory practices, good manufacturing practices, and good clinical practices (and, if and as appropriate and applicable under the circumstances, ICH guidance or other comparable regulations and guidance of any applicable Governmental Authority), in each case as may be in effect from time-to-time and that have the binding effect of law under the laws and regulations of the country and state and local government and Governmental Authority wherein the relevant activities are or were conducted or which have jurisdiction thereover, or in the case of guidelines or guidances of any applicable Governmental Authority, insofar as such guidelines and guidance documents contain or may reasonably be interpreted to contain provisions that represent or mandate specific standard, routine or accepted practice in the industry.
- 1.9 “**Application**” has the meaning set forth in Section 3.10.4(a) (Grant of Option).
- 1.10 “**Arbitration Draft**” has the meaning set forth in Section 13.4.1 (Arbitration Draft).
- 1.11 “**Bankruptcy Code**” has the meaning set forth in Section 12.6 (Termination for Insolvency).
- 1.12 “**Business Day**” means a day other than (a) a Saturday or a Sunday, or (b) a bank or other public holiday in New York, New York.
- 1.13 “**Challenge**” means, with respect to any LMI Patent Right, to contest the validity or enforceability of any such LMI Patent Right, in whole or in part, in any court, arbitration proceeding or other tribunal, including the United States Patent and Trademark Office and the United States International Trade Commission. As used in this definition the term “contest” includes (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such LMI Patent Right; (b) filing, or joining in, a petition under 35 U.S.C. § 311 to institute *inter partes* review of any such LMI Patent Right or any portion thereof; (c) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of any such LMI Patent Right or any portion thereof; (d) filing or commencing any opposition, nullity, or similar proceedings challenging the validity of any such LMI Patent Right in any country, or (e) any foreign equivalent of clauses (a), (b), (c), or (d).
- 1.14 “**Change of Control**” means any of the following: (a) a merger or consolidation of LMI into or with any Person that is not an Affiliate of LMI (an “**Unaffiliated Acquirer**”), or a transfer of the outstanding voting equity securities of LMI to one or more Unaffiliated Acquirers, in each case, in a single transaction or series of transactions, in which any Third Party operating entity becomes the beneficial owner of 50% or more of the combined voting power of the outstanding securities of LMI; or (b) the sale or other disposition to a Third Party of all or substantially all of LMI’s assets or business, *provided, however*, that a “Change of Control” will not include (i) any public offering of securities or any transaction or series of transactions in which a financial investor becomes the beneficial owner of 50% or more of the combined voting power, and (ii) ***.

- 1.15 “**Claim**” has the meaning set forth in Section 10.1 (Indemnification by LMI).
- 1.16 “**Clinical Trial**” means any human clinical trial of the Licensed Product.
- 1.17 “**Commercialization Diligence Obligations**” has the meaning set forth in Section 5.4 (Commercialization Diligence).
- 1.18 “**Commercialization Plan**” has the meaning set forth in Section 5.2.1 (Plan).
- 1.19 “**Commercialize**” means to market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize the Precursor, Licensed Compound or Licensed Product. For clarity, Commercialization does not include Manufacturing. When used as a noun, “**Commercialization**” means any and all activities involved in Commercializing.
- 1.20 “**Commercially Reasonable Efforts**” means, with respect to GEHC’s obligations under this Agreement to Exploit the Licensed Product, development, manufacturing, and commercialization efforts (a) *** and (b) consistent with the commercially reasonable practices of companies in the radiopharmaceutical industry that are similarly situated to GEHC with respect to the development, manufacture, and commercialization of a similarly situated radiopharmaceutical product with similar market or profit potential that is at a similar stage of development or commercialization based on ***.
- 1.21 “**Committee**” means, individually or collectively, the Joint Steering Committee, and any other joint committees and subcommittees established under ARTICLE 2 (Governance), as applicable.
- 1.22 “**Competing Product**” means ***.
- 1.23 “**Confidential Information**” means, with respect to a Party or any of its Affiliates, and subject to Section 11.1 (Confidential Information), all Know-How of or in the possession of such Party or such Affiliate that it treats as confidential or proprietary that is disclosed to or observed by the other Party or any of its Affiliates under this Agreement that is marked as “Confidential,” “proprietary” or the like or that should be reasonably understood to be confidential or proprietary, which may include specifications, know-how, trade secrets, technical information, models, business information, inventions, discoveries, methods, procedures, formulae, protocols, techniques, data, and unpublished patent applications, whether disclosed or observed in oral, written, graphic, or electronic form.
- 1.24 “**Control**” means, with respect to any material or Intellectual Property Right and a Person, that such Person (or an Affiliate of such Person): (a) owns such material or Intellectual Property Right; or (b) has a license or right to use such material or Intellectual Property Right, in each case ((a) and (b)) with the legal right to grant to the applicable Person access, a right to use, or a license, or a sublicense (as applicable) to such material or Intellectual Property Right without violating the terms of any agreement or other arrangement with any Third Party or creating a payment obligation upon such Party, or misappropriating the proprietary or trade secret information of a Third Party. Notwithstanding the foregoing, no Patent Rights or Know-How will be “Controlled” by a Party hereunder if such Patent Rights or Know-How are owned or in-licensed by a Third Party that becomes an Affiliate of such Party after the Effective Date as a result of either Party (i) acquiring such Third Party or a portion of the business of such Third Party or (ii) being acquired by such Third Party (in each case ((i) and (ii)), whether by merger, stock purchase, or purchase of assets); *provided that* prior to the date of such transaction, neither Party nor any of its Affiliates had any rights to any such Patent Rights or Know-How.

- 1.25 “**Co-Promotion Agreement**” has the meaning set forth in Section 5.5.2 (Co-Promotion Principles).
- 1.26 “**Co-Promotion Territory**” means the U.S.
- 1.27 “**Core Market**” means each of the U.S. Territory, Japan, Canada, the United Kingdom, and each of the European G4 Markets.
- 1.28 “**Cover**” or “**Covered**” or “**Covering**” means, with respect to a particular subject matter at issue and a relevant Patent Right, that the Manufacture or Commercialization of the subject matter would fall within the scope of a claim in the Patent Right.
- 1.29 “**Data Package**” has the meaning set forth in Section 3.10.4(c) (Delivery of Data Package).
- 1.30 “**Defense Action**” has the meaning set forth in Section 8.4.1 (Notification).
- 1.31 “**Deliverable**” means any equipment, software, or other item designated in a statement of work to be delivered by LMI or its Affiliates to GEHC as part of the LMI Development Services.
- 1.32 “**Development**” means to discover, research, or otherwise develop the Precursor, Licensed Compound, or Licensed Product, including conducting non-clinical research or Clinical Trials prior to or after receiving Regulatory Approval and any formulation or process development with respect to the Precursor, Licensed Compound, or Licensed Product. When used as a noun, “**Development**” means any and all activities involved in Developing.
- 1.33 “**Development Diligence Obligations**” has the meaning set forth in Section 4.4 (Development Diligence).
- 1.34 “**Development Milestone Achievement Dates**” has the meaning set forth in Section 4.2.1 (Plan).
- 1.35 “**Development Plan**” has the meaning set forth in Section 4.2.1 (Plan).
- 1.36 “**Development Plan Milestones**” has the meaning set forth in Section 4.2.1 (Plan).
- 1.37 “**Effective Date**” has the meaning set forth in Recitals.
- 1.38 “**Effective Transfer Date**” means the date that the FDA cites as the receipt date for the transfer request for the Licensed Product IND.
- 1.39 “**End User**” means any physician practice, clinic, hospital, or other healthcare provider.
- 1.40 “**Enforcing Party**” has the meaning set forth in Section 8.4.3(b) (Enforcement Process).
- 1.41 “**Estimated *** Royalties**” has the meaning set forth in Section 7.4.10(a) (Estimated *** Royalty Payments).
- 1.42 “**European G4 Markets**” means France, Germany, Spain, and Italy.
- 1.43 “**Event of Force Majeure**” has the meaning set forth in Section 14.7 (Force Majeure).

- 1.44 “**Ex-Field License Agreement**” has the meaning set forth in Section 3.10.4(a) (Grant of Option).
- 1.45 “**Ex-Field License Agreement Negotiation Period**” has the meaning set forth in Section 3.10.4(d) (Exercise of Option).
- 1.46 ***
- 1.47 “**Executive Officer**” means, in the case of LMI, any individual who is a senior vice president or above, or in the case of GEHC, any individual who is a senior executive band, or the equivalent (*e.g.*, GM Core Imaging, or above).
- 1.48 “**Exploit**” means, with respect to the Precursor, Licensed Compound, or Licensed Product (as applicable), to use, have used, manufacture, have manufactured, sell, have sold, offer for sale, have offered for sale, import, and have imported, including to Develop, Commercialize, Manufacture, have Manufactured, or otherwise exploit such Precursor, Licensed Compound, or Licensed Product (as applicable). “**Exploitation**” has a correlative meaning.
- 1.49 “**FCPA**” has the meaning set forth in Section 9.5.1 (Compliance with FCPA).
- 1.50 “**FD&C Act**” means the United States Federal Food, Drug and Cosmetic Act, as amended from time to time.
- 1.51 “**FDA**” means the United States Food and Drug Administration or its successor.
- 1.52 “**Field**” means ***.
- 1.53 “**First Commercial Sale**” means, with respect to the Licensed Product, the first sale to an End User of such Licensed Product by or on behalf of GEHC or its Affiliates or Sublicensees after receipt of Regulatory Approval, and where applicable, Pricing Approval, for such Licensed Product.
- 1.54 “**FTE**” means the equivalent of a full-time employee’s or consultant’s work for a *** period (consisting of a total of *** hours per *** of dedicated effort performed by a fully qualified employee or consultant). Any person who devotes more or less than *** hours per *** on the applicable activities will be treated as an FTE on a *pro-rata* basis, based upon the actual number of hours worked by such person on such activities, divided by ***.
- 1.55 “**FTE Rate**” means, (a) for employees at a seniority level of vice president or above, an initial hourly rate of \$*** per hour of time spent by such FTE, and (b) for employees at a seniority level below vice president, an initial hourly rate of \$*** per hour of time spent by such FTE. Commencing ***, each FTE rate will be changed *** by the percentage increase in the U.S. City Average Consumer Price Index, All Items, All Urban Consumers (CPI-U) as reported by the Bureau of Labor Statistics of the United States Department of Labor during the Term.
- 1.56 “**GEHC**” has the meaning set forth in Recitals.
- 1.57 “**GEHC Improvement Invention**” means an invention conceived by or on behalf of GEHC (or its Affiliates, Subcontractors, or Sublicensees or its or their respective directors, officers, employees, or agents) alone or together with Third Parties the practice of which is Covered by an LMI Patent Right at the time the invention is made.

- 1.58 “**GEHC Improvement Patent Right**” means a Patent Right Controlled by GEHC that Covers a GEHC Improvement Invention.
- 1.59 “**GEHC Indemnitees**” has the meaning set forth in Section 10.1 (Indemnification by LMI).
- 1.60 “**GEHC Invention**” has the meaning set forth in 8.1.3 (Sole Inventions).
- 1.61 “**GEHC Net Sales**” means, over the applicable period, (a) if LMI has not exercised the option set forth in Section 5.5.1 (Co-Promotion Option), *** (b) if LMI has exercised the option set forth in Section 5.5.1 (Co-Promotion Option), ***.
- 1.62 “**GEHC Patent Rights**” has the meaning set forth in Section 8.1.3 (Sole Inventions).
- 1.63 “**GEHC Sales Royalties**” has the meaning set forth in Section 7.4.1 (GEHC Sales Royalties).
- 1.64 “**GEHC Target Accounts**” has the meaning set forth in Section 5.5.2(e) (Co-Promotion Principles).
- 1.65 ***
- 1.66 “**Generic Product**” means, on a country-by-country, product-by-product basis, any pharmaceutical product sold by a Third Party in such country, other than as a Sublicensee under this Agreement, that: (a) contains the same active ingredient or active ingredients as the Precursor or Licensed Product, and (b) is categorized by the applicable Regulatory Authority in such country to be equivalent to, or interchangeable with, such Precursor or Licensed Product, such that the pharmaceutical product may be substituted for the Precursor or Licensed Product.
- 1.67 “**Generic Toggle *****” means ***.
- 1.68 “**Governmental Authority**” means any multi-national, federal, state, local, municipal, or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, arbitrator, court, or other tribunal).
- 1.69 “**Handover Period**” has the meaning set forth in Section 3.7.4 (Costs and Cooperation).
- 1.70 “**IND**” means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA in the U.S.; (b) a Clinical Trial Authorization filed with the European Union member states; or (c) the equivalent application to the equivalent Regulatory Authority in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of an investigational new drug in humans in such jurisdiction.
- 1.71 “**Indemnified Party**” has the meaning set forth in Section 10.3 (Indemnification Procedures).
- 1.72 “**Indemnifying Party**” has the meaning set forth in Section 10.3 (Indemnification Procedures).
- 1.73 “**Institutional Customer**” has the meaning set forth in Section 5.5.2(e)(ii) (Co-Promotion Principles).
- 1.74 “**Intellectual Property Rights**” means all rights in inventions, Patent Rights, copyrights, design rights, trade names, trademarks, service marks, Know-How, database rights, domain names, and all other intellectual property (whether registered or unregistered) and all applications and rights to apply for any of them, anywhere in the world.

- 1.75 “**Japan Sales Royalties**” has the meaning set forth in Section 7.4.3 (Japan Sales Royalties).
- 1.76 “**Japan Territory**” means Japan and its territories and possessions.
- 1.77 “**Joint Inventions**” has the meaning set forth in Section 8.1.4 (Joint Inventions).
- 1.78 “**Joint Patent Right**” has the meaning set forth in Section 8.1.4 (Joint Inventions).
- 1.79 “**JSC**” has the meaning set forth in Section 2.2.1 (Purpose; Formation).
- 1.80 “**Know-How**” means any data, results, and information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, clinical and non-clinical study reports, regulatory submission documents and summaries, expertise, stability, technology, test data including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data, analytical and quality control data, stability data, studies, and procedures.
- 1.81 “**Knowledge**” means, with respect to LMI, the actual knowledge of the *** taking into account the patent searches described in Section 9.2.5 and any information or materials disclosed by or on behalf of LMI to GEHC relating to LMI’s Intellectual Property Rights.
- 1.82 “**Liabilities**” means liabilities, obligations or commitments of any nature whatsoever, asserted or unasserted, known or unknown, absolute or contingent, accrued or unaccrued, matured or unmatured, or otherwise.
- 1.83 “**License**” has the meaning set forth in Section 3.1.1 (License to GEHC).
- 1.84 “**Licensed Compound**” means (a) flurpiridaz, known as [¹⁸F]flurpiridaz, the structure of which is set forth on Schedule 1.84 or (b) any Analog.
- 1.85 “**Licensed Product**” means a pharmaceutical product that contains the Licensed Compound, whether alone or in combination with one or more other active pharmaceutical ingredients, in any and all current and future forms, formulations, dosages, and delivery modes.
- 1.86 “**Licensed Product IND**” means the IND filed related to the Licensed Product in existence as of the Effective Date.
- 1.87 “**Licensed Technology**” means the LMI Patent Rights and LMI Know-How.
- 1.88 “**LMI**” has the meaning set forth in Recitals.
- 1.89 “**LMI Development Services**” has the meaning set forth in Section 4.3.1 (Engagement of LMI).
- 1.90 “**LMI Improvement Invention**” means an invention conceived by or on behalf of LMI (or its Affiliates, Subcontractors, or Sublicensees or its or their respective directors, officers, employees, or agents) alone or together with Third Parties the practice of which is Covered by an LMI Patent Right at the time the invention is made.

- 1.91 “**LMI Improvement Patent Right**” means a Patent Right Controlled by LMI that Covers an LMI Improvement Invention.
- 1.92 “**LMI Indemnitees**” has the meaning set forth in Section 10.2 (Indemnification by GEHC).
- 1.93 “**LMI Joint Inventions**” has the meaning set forth in Section 8.1.4 (Joint Inventions).
- 1.94 “**LMI Joint Patent Right**” has the meaning set forth in Section 8.1.4 (Joint Inventions).
- 1.95 “**LMI Know-How**” means all Know-How Controlled as of the Effective Date or thereafter during the Term by LMI that (a) is reasonably necessary or useful for the Exploitation of the Precursor, Licensed Compound, or Licensed Product in the Field, including all LMI Improvement Inventions, or (b) is disclosed to or observed by GEHC or any of its Affiliates under this Agreement, including all Know-How that is disclosed to or observed by GEHC or any of its Affiliates during the Handover Period.
- 1.96 “**LMI Manufacturing Know-How**” has the meaning set forth in Section 3.7.2 (Manufacturing Know-How Transfer).
- 1.97 “**LMI Net Sales**” means, over the applicable period, Net Sales to LMI Target Accounts in the Co-Promotion Territory.
- 1.98 “**LMI Patent Rights**” means (a) those Patent Rights set forth on Schedule 1.98, and (b) all Patent Rights Controlled by LMI as of the Effective Date or thereafter during the Term that Cover or are otherwise necessary or useful for the Exploitation of the Precursor, Licensed Compound, or Licensed Product in the Field, including all LMI Improvement Patent Rights.
- 1.99 “**LMI Sales Royalties**” has the meaning set forth in Section 7.4.2 (LMI Sales Royalties).
- 1.100 “**LMI Services Assigned Patent Rights**” has the meaning set forth in Section 8.1.2 (LMI Services Know-How).
- 1.101 “**LMI Services Know-How**” has the meaning set forth in Section 8.1.2 (LMI Services Know-How).
- 1.102 “**LMI Target Accounts**” has the meaning set forth in Section 5.5.2(d) (Co-Promotion Principles).
- 1.103 “**LMI Trademark**” means “***”, including all word forms thereof, and all registrations thereof in any countries, including all registrations set forth on Schedule 1.103.
- 1.104 “**LMI Trademark Option**” has the meaning set forth in Section 3.9 (Option to Purchase the LMI Trademark).
- 1.105 “**Major Competitors**” means, at any given time, ***.
- 1.106 “**Manufacture**” means all activities by or on behalf of a Party related to the manufacturing of the Precursor, Licensed Compound, Licensed Product, or any ingredient thereof, including test method development and stability testing, formulation, manufacturing scale-up, manufacturing for Development or Commercialization, labeling, filling, processing, packaging, in-process and finished Licensed Product testing, dispensing, shipping, storing, or release of the Precursor,

Licensed Compound, or Licensed Product or any ingredient thereof, quality assurance and quality control activities related to manufacturing and release of the Precursor, Licensed Compound, or Licensed Product, ongoing stability tests, and regulatory activities related to any of the foregoing. When used as a noun, “**Manufacture**” or “**Manufacturing**” means any and all activities involved in Manufacturing.

- 1.107** “**Marketing Authorization Application**” or “**MAA**” means an application for Regulatory Approval to market the Licensed Product in a country, territory, or possession, including a New Drug Application as defined in the FD&C Act and applicable rules and regulations promulgated thereunder by the FDA in the U.S.
- 1.108** “**Marks**” has the meaning set forth in Section 8.5 (Trademarks).
- 1.109** “**Material Breach**” means either (a) with respect to a breach by GEHC, *** or (b) with respect to a breach by LMI, ***.
- 1.110** “**Milestone Event**” has the meaning set forth in Section 7.2 (Development Milestones).
- 1.111** “**Net Sales**” means, over the applicable period, the *** for sales of the Licensed Product by GEHC or its Affiliates or its Sublicensees or their Affiliates (the “**Selling Party**”) to Third Parties, less the following to the extent allocated to such sales of such Licensed Product to Third Parties and actually taken, paid, accrued, allowed, included or allocated (where applicable) in accordance with the allocation procedures, allowance methodologies and accounting methods, in accordance with U.S. GAAP, where applicable, or other applicable generally accepted accounting principles, in each case, consistently applied:

- 1.111.1** ***;
- 1.111.2** ***;
- 1.111.3** ***;
- 1.111.4** ***;
- 1.111.5** ***;
- 1.111.6** ***;
- 1.111.7** ***; and
- 1.111.8** ***.

For the avoidance of doubt, if a single item falls into more than one of the categories set forth in Section 1.111.1 through Section 1.111.8, then such item may not be deducted more than once. In addition, except as otherwise provided above, to the extent that any deductions set forth above are not solely attributable to the Licensed Product, then such deductions will be allocated ***.

Sales of the Licensed Product between or among GEHC and its Affiliates or Sublicensees will be excluded from the computation of Net Sales and no payments will be payable on such sales except where such Affiliates or Sublicensees are End Users. Subject to the exceptions set forth in the next paragraph, with respect to the sale or other disposition of any Licensed Product (a) to a Third Party for any reason other than for resale or distribution to an End User, (b) for any consideration other than an exclusively monetary consideration, or (c) on terms other than *bona fide* arm’s length terms, Net Sales will equal ***.

Where the Licensed Product is sold to a Third Party reseller or distributor for resale to End Users, Net Sales will be *** for such sales to such reseller or distributor; *provided, however*, that ***. For the avoidance of doubt, sales of the Licensed Product *** will be excluded from Net Sales calculations for all purposes. Subject to the exceptions and deductions above, if a Selling Party sells the Precursor (and not a Licensed Product) to a Third Party (other than a Sublicensee or its Affiliates), and there is no subsequent sale of a Licensed Product by such Selling Party to such Third Party, then Net Sales with respect to sales of such Precursor will be calculated based on the sale of the Precursor by the Selling Party to such Third Party, and each reference to Licensed Product in this Net Sales definition will be deemed to refer to the Precursor (rather than a Licensed Product) for the purposes of calculating Net Sales for such Precursor.

- 1.112 “**New Drug Application**” or “**NDA**” has the meaning therefor as defined in the FD&C Act and applicable rules and regulations promulgated thereunder by the FDA in the U.S.
- 1.113 “**Nihon Medi-Physics**” or “**NMP**” means the joint venture among GEHC, GEHC Healthcare IVD (Netherlands) BV, and Sumitomo Chemical Company Ltd.
- 1.114 “**Non-Acquiring Party**” has the meaning set forth in Section 3.12.1 (Options).
- 1.115 “**Non-Enforcing Party**” has the meaning set forth in Section 8.4.3(b)(Enforcement Process).
- 1.116 “**Option**” has the meaning set forth in Section 3.10.4(a) (Grant of Option).
- 1.117 “**Option Exercise Notice**” has the meaning set forth in Section 3.10.4(d) (Exercise of Option).
- 1.118 “**Option Term**” has the meaning set forth in Section 3.10.4(b) (Option Term).
- 1.119 “**Party**” and “**Parties**” has the meaning set forth in Recitals.
- 1.120 “**Patent Right**” means: (a) any national, regional or international patent or patent application, including any provisional patent application; (b) any patent application filed either from such a patent, patent application or provisional application or from an application claiming priority from any of these, including any divisional, continuation, continuation-in-part, provisional, converted provisional, and continued prosecution application; (c) any patent that has issued or in the future issues from any of the foregoing patent applications ((a) and (b)), including any utility model, petty patent, design patent, and certificate of invention; (d) any extension or restoration by existing or future extension or restoration mechanisms, including any revalidation, reissue, re-examination, and extension (including any supplementary protection certificate and the like) of any of the foregoing patents or patent applications ((a), (b), and (c)); and (e) any similar rights, including any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent application or patent.
- 1.121 “**Person**” means an individual, entity, or organization, including a government or political subdivision, department, or agency of a government.
- 1.122 “**PET**” means positron emission tomography.
- 1.123 “**PET Service Area**” has the meaning set forth in Section 5.5.2(e)(i) (Co-Promotion Principles).

- 1.124** “**Phase III Clinical Trial**” means a pivotal human clinical trial of a Licensed Product that would satisfy the requirements of 21 C.F.R. Part 312.21(c) (as amended from time to time), for the principal purpose of achieving a determination of safety and efficacy that is prospectively designed, statistically powered, and conducted to provide an adequate basis for submission of an application for Regulatory Approval in the U.S. for patients with the disease or condition under study.
- 1.125** “**PMF**” has the meaning set forth in Section 5.5.2(e)(i) (Co-Promotion Principles).
- 1.126** “**Precursor**” means that certain precursor to the Licensed Compound, the structure of which is set forth on Schedule 1.126.
- 1.127** “***** Agreement**” means an agreement with respect to the Licensed Product with the territorial scope of *** that is entered into by ***.
- 1.128** “***** Agreement Payments**” means any (a) cash, other than royalty payments, or (b) cash equivalent amount, in each case ((a) and (b)), paid pursuant to any *** Agreement in consideration for ***.
- 1.129** “********” means ***.
- 1.130** “**Pricing Approval**” means, in any country or regulatory jurisdiction where a Governmental Authority has the authority to determine reimbursement, or approve or determine pricing, for any imaging agent prior to the commercial sale of such imaging agent in such country or regulatory jurisdiction, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination with respect to a Licensed Product.
- 1.131** “**Product Infringement**” has the meaning set forth in Section 8.4.1 (Notification).
- 1.132** “**Regulatory Approval**” means all approvals necessary for the manufacture, marketing, importation, and sale of the Licensed Product for one or more indications in the Field and in a country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements, but which will exclude any pricing and reimbursement approvals. Regulatory Approvals include approvals by Regulatory Authorities of MAAs.
- 1.133** “**Regulatory Authority**” means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval or Pricing Approvals or, to the extent required in such country or regulatory jurisdiction, pricing or reimbursement approval of the Licensed Product in such country or regulatory jurisdiction.
- 1.134** “**Regulatory Materials**” means regulatory applications, submissions, notifications, registrations, or other filings or submissions made to or with a Regulatory Authority that are necessary or reasonably desirable in order to Develop, Manufacture, market, sell, or otherwise Commercialize the Precursor, Licensed Compound, or Licensed Product in a particular country or regulatory jurisdiction. Regulatory Materials include INDs and MAAs (as applications, but not the approvals with respect thereto).
- 1.135** “**ROW Sales Royalties**” has the meaning set forth in Section 7.4.4 (ROW Sales Royalties).

- 1.136 “**ROW Territory**” means all countries and territories of the world other than the U.S. Territory and the Japan Territory.
- 1.137 “**Royalties**” means the GEHC Sales Royalties, LMI Sales Royalties, Japan Sales Royalties, and ROW Sales Royalties.
- 1.138 “**Royalty Report**” has the meaning set forth in Section 7.4.9 (Royalty Reports).
- 1.139 “**Royalty Term**” means, on a country-by country, product-by-product basis, the period commencing on the First Commercial Sale of the Precursor or Licensed Product in such country and expiring upon the latest of: (a) expiration of the last Valid Claim of any (i) LMI Patent Right, (ii) *** Patent Right that Covers the Exploitation of the Precursor, Licensed Compound, or Licensed Product, as applicable, in such country ***, or (iii) ***that Covers the Exploitation of the Precursor, Licensed Compound, or Licensed Product, as applicable, in such country *** (b) the date of expiration of the data, regulatory, or marketing exclusivity period conferred by the applicable Regulatory Authority or Applicable Law in such country with respect to the Precursor or Licensed Product, as applicable; or (c) ***, or such shorter term as may be required by Applicable Law.
- 1.140 “**Royalty True-Up Amount**” has the meaning set forth in Section 7.4.10(b) (Royalty True-Up).
- 1.141 “**SEC**” means the U.S. Securities and Exchange Commission.
- 1.142 “**Selected Agreements**” means, with respect to the Terminated Product, any agreement entered into by and between GEHC or any of its Affiliates or its Sublicensees, on the one hand and one or more Third Parties, on the other hand, that is reasonably necessary for LMI to continue Exploiting such Terminated Product (or the Licensed Compound contained therein) in the Field in the Territory, including, to the extent relevant and reasonably necessary, (a) agreements pursuant to which GEHC, its Affiliates, or its Sublicensees receives a license or other rights to Exploit such Terminated Product, (b) supply agreements pursuant to which GEHC, its Affiliates, or its Sublicensees obtain or may obtain quantities of such Terminated Product or materials used in their manufacture, (c) clinical trial agreements, (d) contract research organization agreements, and (e) other service agreements.
- 1.143 “**Selling Party**” has the meaning set forth in Section 1.111 (Net Sales).
- 1.144 “**Sole Inventions**” has the meaning set forth in Section 8.1.3 (Sole Inventions).
- 1.145 “**Subcontractor**” has the meaning set forth in Section 3.3 (Subcontractors).
- 1.146 “**Sublicense Agreement**” has the meaning set forth in Section 3.2.3 (Sublicense Agreements).
- 1.147 “**Sublicensee**” has the meaning set forth in Section 3.2.2 (Sublicensees).
- 1.148 “**Sublicensor**” has the meaning set forth in Section 3.2.1 (Sublicensing).
- 1.149 “**Term**” has the meaning set forth in Section 12.1 (Term).
- 1.150 “**Terminated Country**” has the meaning set forth in Section 12.7.1 (All Termination Events).
- 1.151 “**Terminated Product**” has the meaning set forth in Section 12.7.2 (Effects of Termination).

- 1.152 “**Territory**” means worldwide.
- 1.153 “**Third Party**” means any Person other than LMI or GEHC or an Affiliate of either of them.
- 1.154 “**Third Party Stacking Payments**” mean any and all royalties or other amounts with respect to the sales of the Licensed Product (but not any milestone or upfront payments) paid or payable to a Third Party pursuant to a license agreement entered into after the Effective Date to license, sublicense, acquire, or otherwise access Patent Rights or Know-How if, in the absence of such license, sublicense, acquisition or access, the Licensed Product would infringe or misappropriate, in the reasonable judgment of GEHC, such Patent Rights or Know-How.
- 1.155 “**Transition Plan**” has the meaning set forth in Section 3.7.1 (Transition Services).
- 1.156 “**Transition Services**” means all activities set forth under the Transition Plan.
- 1.157 “**Triggering Event**” means the occurrence of any of the following: (a) LMI admits in writing its inability to pay its debts when due or a public announcement is made that LMI has or intends to file bankruptcy, dissolve, wind-down its business or liquidate, sell or otherwise dispose of all or substantially all of its assets; and (b) LMI has ceased paying its debts as they come due in the ordinary course of business or has ceased conducting all or substantially all of its business, as measured from the date of such cessation.
- 1.158 “**Unaffiliated Acquirer**” has the meaning set forth in Section 1.14 (Change of Control).
- 1.159 “**U.S.**” means the United States of America (including all possessions and territories thereof).
- 1.160 “**U.S. GAAP**” means (a) United States generally accepted accounting principles, or (b) the applicable national accounting standards to which the entity making the Net Sales is subject, in each case ((a) and (b)), consistently applied.
- 1.161 “**U.S. Territory**” means the U.S., including Puerto Rico.
- 1.162 “**Valid Claim**” means either: (a) a claim of an issued and unexpired patent included within the LMI Patent Rights, Joint Patent Rights, or GEHC Improvement Patent Rights that has not been permanently revoked or declared unenforceable or invalid by an unreversed and unappealable or unreversed and unappealed decision of a court or other appropriate body of competent jurisdiction and which has not been abandoned, disclaimed, denied, or admitted to be invalid or unenforceable or surrendered through reissue, re-examination, disclaimer, or otherwise; or (b) a claim of a pending patent application included within the LMI Patent Rights, Joint Patent Rights, or GEHC Improvement Patent Rights that was filed in good faith and has not been cancelled, withdrawn, abandoned, or finally disallowed without the possibility of appeal or refiling of such application and has not been pending for more than *** years.
- 1.163 “**VAT**” has the meaning set forth in Section 7.9.2 (Value Added Tax).

ARTICLE 2

GOVERNANCE

- 2.1. Alliance Managers.** Each Party will appoint an appropriately qualified individual to serve as an alliance manager under this Agreement (the “**Alliance Manager**”). Such persons will endeavor to assure clear and responsive communication between the Parties and the effective exchange of information, and may serve as the primary point of contact for any matters arising under this Agreement. The Alliance Managers will ensure each Party’s awareness and compliance of the governance procedures and rules under this Agreement. The Alliance Managers may attend meetings of all Committees under this Agreement and may raise issues for the applicable Committee for discussion. The Alliance Managers will not have any decision-making authority under this Agreement.
- 2.2. Joint Steering Committee.**
- 2.2.1 Purpose; Formation.** The Parties hereby establish a joint steering committee that will serve as an advisory committee and will monitor and provide strategic oversight of the activities under this Agreement and facilitate communications between the Parties with respect to the Development, Manufacture, and Commercialization of the Precursor, Licensed Compound, and Licensed Product, all in accordance with this Section 2.2 (Joint Steering Committee) (the “**JSC**”).
- 2.2.2 Composition.** Each Party will appoint *** representatives (or their designees) to the JSC, which members will include a member of each of such Party’s senior financial, commercial, or scientific leadership with respect to the Licensed Product, but neither Party will appoint its chief executive officer as a representative to the JSC. The Parties’ initial representatives to the JSC will be provided to each other Party within *** after the Effective Date. The JSC may change its size from time-to-time by mutual consent of its members. Each Party may replace its JSC representatives at any time upon written notice to the other Party. Each Party may invite up to *** of its own employees or consultants and the JSC may invite other non-members to participate in the discussions and meetings of the JSC; *provided that* such participants will have no voting authority at the JSC. GEHC will designate a single JSC chairperson who will be in or above GEHC’s executive band, or the equivalent. The role of the chairperson will be to convene and preside at meetings of the JSC. The Alliance Managers will work with the chairperson to prepare and circulate agendas and to ensure the preparation of minutes. The chairperson will have the final say on any issue or decision that will not significantly or substantially affect the Development or Commercialization of the Licensed Product.
- 2.2.3 Specific Responsibilities.** In addition to its overall responsibility for monitoring and providing strategic oversight with respect to the Parties’ activities under this Agreement, the JSC will in particular:
- (a) review, discuss, and determine whether to approve the updated Transition Plan;
 - (b) review, discuss, and determine whether to approve the Development Plan, the planned PMF network, and the Commercialization Plan, and all amendments thereto (but, for clarity, not including the terms of the Co-promotion Agreement);
 - (c) review and discuss any material revisions to the Development Milestone Achievement Dates proposed by GEHC in accordance with Section 4.2.2 (Amendments to the Development Plan), and measure performance against the then-current Development Milestone Achievement Dates;

- (d) discuss and provide input regarding when to initiate or discontinue any Clinical Trial under each Development Plan; *provided that* nothing is intended to limit a Party's ability to comply with Applicable Law or manage subject safety;
- (e) discuss the requirements for Regulatory Approval and, where applicable, Pricing Approval, in the Core Markets and review and determine overall regulatory strategy with respect to the Licensed Product in the Field;
- (f) review and discuss the Development, Manufacture, and Commercialization of the Licensed Product in the Field, including measuring performance against, and compliance with, the then-current Development Plan and Commercialization Plan;
- (g) facilitate the flow of information between the Parties with respect to the Development and Commercialization of the Licensed Product in the Field;
- (h) discuss, on *** basis, any *** (as applicable) during the previous ***;
- (i) attempt to resolve issues presented to it by either Party relating to this Agreement, and disputes within any other subcommittee;
- (j) establish additional Committees and restructure existing Committees as it deems necessary to achieve the objectives and intent of this Agreement; and
- (k) perform such other functions as appropriate, and direct each other Committee to perform such other functions as appropriate, to further the purposes of this Agreement, in each case, as agreed in writing by the Parties.

2.3. JSC Meetings. The JSC will meet at least one time per calendar quarter during the Term unless the Parties agree in writing to a different frequency for such meetings. No later than five Business Days prior to any meeting of the JSC, the chairperson or the Alliance Managers will prepare and circulate an agenda for such meeting; provided, however, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. Either Party may also call a special meeting of the JSC (by videoconference, teleconference, or in person) by providing at least five Business Days prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, in which event such Party will work with the chairperson of the JSC and the Alliance Managers of both Parties to provide the members of the JSC no later than two Business Days prior to the special meeting with an agenda for the meeting and materials reasonably adequate to enable an informed decision on the matters to be considered. The JSC may meet in person, by videoconference or by teleconference. Notwithstanding the foregoing, at least one meeting per calendar year will be in person in the U.S. unless the Parties agree in writing to waive such requirement. In-person JSC meetings will be held at locations alternately selected by LMI and by GEHC. Each Party will bear the expense of its respective members' participation in JSC meetings. Meetings of the JSC will be effective only if at least one representative of each Party is present or participating in such meeting. The chair, or their designee, will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect, without limitation, material decisions made and action items identified at such meetings. The chair, or their designee, will send draft meeting minutes to each member of the JSC for review and approval within a reasonable time period after each JSC meeting. Such minutes will be deemed approved unless one or more members of the JSC object to the accuracy of such minutes prior to the next meeting. Minutes will be officially approved by each Committee at the next meeting of such Committee.

2.4. Decision Making and Resolution of Disputes.

- 2.4.1 Committee Decision-Making.** Each Committee will attempt in good faith to act by consensus, and the representatives from each Party on such Committee will have, collectively, one vote on behalf of that Party. If a Committee other than the JSC cannot reach consensus on an issue that comes before such Committee (as applicable) and over which such Committee has oversight, then the representatives of either Party may refer such matter to the JSC for resolution. The JSC will have the authority to resolve disputes within the jurisdiction of the any other Committees, but otherwise will have no authority except where expressly specified in this Agreement or agreed by the Parties in writing. If the JSC is unable to reach consensus on any issue or decision that at least one Party reasonably considers will significantly or substantially affect the Development or Commercialization of the Licensed Product, then within 10 Business Days after a Party provides written notice that affirmatively states that a decision needs to be made, either Party may elect to submit such material issue to the Parties' Executive Officers in accordance with Section 2.4.2 (Referral to Executive Officers). ***.
- 2.4.2 Referral to Executive Officers.** If a Party makes an election under Section 2.4.1 (Committee Decision Making) to refer a matter to the Executive Officers, then the Executive Officers will use good faith efforts to resolve promptly such matter, which good faith efforts will include at least one meeting by phone or other means between such Executive Officers within 20 Business Days after the JSC's submission of such matter to them. ***.
- 2.4.3** ***. If the JSC or any other Committee (as applicable) fails to reach consensus on any Development Plan or Commercialization Plan or any amendment thereto, and the Executive Officers are unable to reach consensus in good faith on such matter within the 20 Business Day period set forth under Section 2.4.2 (Referral to Executive Officers), ***.
- 2.4.4 General Committee Authority.** Each Committee will have solely the powers expressly assigned to it in this ARTICLE 2 (Governance) and elsewhere in this Agreement. No Committee will have any power to amend, modify, or waive compliance with this Agreement. It is expressly understood and agreed that the control of decision-making authority by GEHC, as applicable, pursuant to Section 2.4.2 (Referral to Executive Officers), so as to resolve a disagreement or deadlock on a Committee for any matter will not authorize either Party to perform any function or exercise any decision-making right not delegated to a Committee or such Party, and that neither LMI nor GEHC will have any right to unilaterally modify or amend, or waive its own compliance with, the terms of this Agreement.
- 2.4.5 General Decision Making Authority.** Except as otherwise provided in this Agreement, GEHC will be solely responsible for conducting Development, Commercialization, and Manufacturing activities related to the Licensed Product in the Field and will have decision making authority with respect thereto.

ARTICLE 3

LICENSES AND EXCLUSIVITY

3.1. License Grants.

- 3.1.1 License to GEHC.** Subject to the terms and conditions of this Agreement, LMI hereby grants to GEHC a royalty-bearing, worldwide license, with the right to grant sublicenses as provided in Section 3.2 (Sublicensing Rights), under the Licensed Technology to Exploit the Precursor (subject to Section 5.6 (Precursors)), Licensed Compound, and Licensed Product in the Field in the Territory (the “**License**”). The License will be exclusive (even as to LMI) throughout Territory. LMI’s exercise of its rights or performance of its obligations under Section 5.5 (Co-Promotion Right) will not constitute a conflict with the license granted to GEHC under this Section 3.1.1 (License to GEHC).
- 3.1.2 License to LMI.** Subject to the terms and conditions of this Agreement, GEHC hereby grants to LMI (a) a non-exclusive, royalty-free, worldwide license, with the right to grant sublicenses as provided in Section 3.2 (Sublicensing Rights), under all Joint Inventions, Joint Patent Rights, GEHC Improvement Inventions, GEHC Improvement Patent Rights, LMI Services Know-How, LMI Services Assigned Patent Rights, GEHC Inventions, and GEHC Patent Rights to perform the LMI Development Services, and any activities allocated to it under this Agreement with respect to the Development of the Precursor, Licensed Compound, and the Licensed Product in the Field, including responsibilities under any Development Plan, and (b) a non-exclusive, royalty-free, worldwide license, with the right to grant sublicenses as provided in Section 3.2 (Sublicensing Rights), under all Joint Inventions, Joint Patent Rights, ***, to Exploit the Precursor, Licensed Compound, and the Licensed Product outside of the Field in the Territory.
- 3.1.3 LMI’s Right of Reference.** Subject to the terms and conditions of this Agreement, GEHC hereby grants to LMI (or its Affiliates or its Sublicensees) access to, and a right of reference with respect to, GEHC Regulatory Materials and corresponding documentation to the extent Controlled by GEHC at any time during the Term (including the Licensed Product IND and all other Regulatory Materials assigned to GEHC pursuant to Section 3.6 (Transfer of Regulatory Materials)), as reasonably necessary for LMI to reasonably Exploit the Precursor, Licensed Compound, and Licensed Product outside of the Field. GEHC will execute, acknowledge, and deliver any further documents or instruments and to perform all such other acts as may be necessary or appropriate in order to effect such right of reference.

3.2. Sublicensing Rights.

- 3.2.1 Sublicensing.** GEHC will have the right to grant sublicenses (through multiple tiers) under the Licensed Technology to Exploit the Precursor, Licensed Compound, or Licensed Product in the Field in each case without any requirement of consent ***. Subject to Section 3.10.4 (GEHC Options for Ex-Field Licenses) and Section 3.10.5 (GEHC Right of First Offer), LMI will have the right to grant sublicenses of the license granted to it in Section 3.1.2 (License to LMI) and the right of reference granted to it in Section 3.1.3 (LMI’s Right of Reference) outside the Field and to its Subcontractors in accordance with Section 3.2.2 (Sublicensees). The Party granting the sublicense will be referred to herein as the “**Sublicensor**.”

- 3.2.2 Sublicensees.** Each sublicensee granted rights under Section 3.2.1 (Sublicensing) will be a “**Sublicensee**” and such sublicense will be granted under a Sublicense Agreement as set forth in Section 3.2.3 (Sublicense Agreement). The Sublicensor will remain responsible and liable for the performance of its Sublicensees to the same extent as if such activities were conducted by such Sublicensor, and will cause its Sublicensees to comply with the relevant terms and conditions of this Agreement. In addition, the Sublicensor will remain responsible for any payments due hereunder with respect to activities conducted by its Sublicensees. Any sublicense granted hereunder that is inconsistent with this Section 3.2.2 (Sublicensees) will be null and void.
- 3.2.3 Sublicense Agreement.** The Sublicensor will cause each agreement with a Sublicensee granting a sublicense pursuant to Section 3.2.1 (Sublicensing) (each, a “**Sublicense Agreement**”) to be consistent with the terms and conditions of this Agreement and to: (a) require each Sublicensee and Affiliate to comply with the applicable terms and conditions of this Agreement (including, as applicable, the reporting obligations set forth under Section 7.4.9 (Royalty Reports), the record keeping and audit requirements set forth under Section 7.12 (Financial Records; Audits), the provisions regarding Intellectual Property Rights set forth under ARTICLE 8 (Intellectual Property), and the confidentiality requirements set forth under ARTICLE 11 (Confidentiality)), (b) preclude the granting of further sublicenses in contravention of the terms and conditions of this Agreement; *provided, however*, no such provision limits the Sublicensor’s rights to grant sublicenses through multiple tiers, and (c) unless otherwise agreed or provided in Section 3.2.4 (Continuation of Sublicenses upon Termination of this Agreement) or Section 12.7.2(e) (License Grant to LMI), provide, where GEHC is the Sublicensor, that it will automatically terminate with respect to Licensed Technology upon termination of this Agreement.
- 3.2.4 Continuation of Sublicenses upon Termination of this Agreement.** If the License granted to GEHC under Section 3.1.1 (License to GEHC) and the sublicenses granted to Sublicensees terminate pursuant to Section 12.3 (Termination by Either Party for Breach) or Section 12.6 (Termination for Insolvency), then, at the request of any Sublicensee who is not then in breach of its Sublicense Agreement and is otherwise in good standing, LMI will enter into, without any assistance by GEHC, a direct license agreement with such Sublicensee under the Licensed Technology that is sublicensed to such Sublicensee on substantially the same terms, *i.e.*, provides Sublicensee and LMI (as a substitute thereunder for GEHC) the same rights and obligations, as set forth in such Sublicense Agreement between GEHC and such Sublicensee effective as of the date of termination of the Sublicense Agreement granted to Sublicensee by GEHC; *provided, however*, that (a) such direct license agreement would not impose on LMI any obligations over and above its obligations under this Agreement and would not impose on any such Sublicensee any obligations over and above its obligations under the applicable Sublicense Agreement, and (b) as consideration for such direct license, the direct license agreement would require Sublicensee to pay LMI the same amount as LMI would have received from GEHC (had this Agreement survived) as a result of the Sublicensee’s performance under such Sublicense Agreement. During the pendency of any negotiation of a direct license agreement between LMI and the applicable Sublicensee in accordance with this Section 3.2.4 (Continuation of Sublicenses Upon Termination of this Agreement), so as to ensure no disruption in the rights granted to such Sublicensee, such Sublicensee is hereby licensed to continue to exercise its rights and will continue to perform its obligations, in each case, as set forth under such Sublicense Agreement and the applicable terms under such Sublicense Agreement will apply *mutatis mutandis* to

LMI rather than GEHC, except that LMI will not have any obligations over and above its obligations under this Agreement. As provided in this Section 3.2.4 (Continuation of Sublicenses Upon Termination of this Agreement), in the event of any termination of this Agreement, LMI will not have the right to terminate or otherwise restrict any rights granted to a Sublicensee that is not also in breach of this Agreement or the applicable Sublicense Agreement.

- 3.3. Subcontractors.** Each Party may perform any of its obligations under the Development Plan, the Commercialization Plan, or otherwise under this Agreement through one or more subcontractors, consultants, distributors, co-promotion partners, or other vendors (each, a “**Subcontractor**”) *provided that:* (a) any Party that engages a Subcontractor will remain responsible for (i) the work allocated to, and payment to, such Subcontractors to the same extent it would if it had done such work itself, (ii) the management of any such Subcontractor, and (iii) any breach of this Agreement by a Subcontractor; (b) any Subcontractor must undertake in writing commercially reasonable obligations of confidentiality and non-use regarding Confidential Information that are at least as restrictive as those set forth in ARTICLE 11 (Confidentiality); and, (c) the Subcontractor agrees in writing to (i) presently assign all of its rights, title, and interests in, or, (ii) if such Subcontractor cannot so assign, provide a perpetual, fully-paid, worldwide, fully sublicenseable (through multiple tiers) exclusive license under and to, any Intellectual Property Rights with respect to the Precursor, Licensed Compound, or Licensed Product developed in the course of performing any such work under any Development Plan, Commercialization Plan, or this Agreement to LMI or GEHC in order to give full effect to the rights granted to each Party under this Agreement. Any contract with a Subcontractor pertaining to the Precursor, Licensed Compound, or Licensed Product will be consistent with the provisions of this Agreement. Furthermore, if the Subcontractor (such as a distributor) is purchasing Licensed Product for resale, then the agreement between GEHC and such Subcontractor must require such Subcontractor (and the agreement between such Subcontractor and any subsequent distributor or reseller in the chain of distribution must require such subsequent distributor or reseller) to comply with the reporting obligations set forth under Section 7.4.9 (Royalty Reports), and the record keeping and audit requirements set forth under Section 7.13 (Financial Records; Audits). The engagement of any Subcontractor will not relieve a Party of its obligations under this Agreement.
- 3.4. Retained Rights.** Subject to, and without limiting any of LMI’s obligations under this Agreement, including the obligations under Section 3.10 (Activity Outside The Field), Section 3.11 (Exclusivity) and ARTICLE 11 (Confidentiality), any rights of LMI not expressly granted to GEHC under the provisions of this Agreement will be retained by LMI (and may be exercised by LMI itself or through its Affiliates or Third Parties in its sole discretion). GEHC will not exploit or sublicense the Licensed Technology except as expressly licensed in this Agreement. In addition, LMI expressly retains the right to perform or exercise, or have performed or exercised by an Affiliate, LMI’s obligations and rights under this Agreement, subject to the terms of Section 3.2 (Sublicensing Rights) and Section 3.3 (Subcontractors).
- 3.5. No Implied Licenses.** Except as explicitly set forth in this Agreement, neither Party grants to the other Party any license, express or implied, under its Intellectual Property Rights. Except for the limited licenses set forth in Section 3.1.2 (License to LMI), Section 12.7.2(b) (License Grant to LMI), and Section 12.7.2(c) (License Grant to LMI), GEHC is not granting LMI any license, express or implied, under any Intellectual Property Rights Controlled by GEHC.
- 3.6. Transfer of Regulatory Materials.** Promptly after the Effective Date, LMI will transfer to GEHC, all of the rights and obligations of LMI as owner/sponsor of the Licensed Product IND and all other Regulatory Materials for the Precursor, Licensed Compound, or Licensed Product

that are necessary to transfer such Licensed Product IND to GEHC in the Territory (such transfer, the “Transfer”). Until the Effective Transfer Date, LMI will be the owner/sponsor of the Licensed Product IND and all other Regulatory Materials for the Licensed Product in the Territory and will have all rights and obligations relating thereto, including pharmacovigilance responsibilities; provided that GEHC will reimburse LMI for any approved costs or expenses incurred by LMI after the Effective Date in connection with exercising such rights or fulfilling such obligations. LMI will take all steps reasonably necessary to effect the Transfer, including submitting to each applicable Regulatory Authority within *** after the Effective Date a letter or other necessary documentation (with a copy to GEHC) notifying such Regulatory Authority of the transfer of such ownership of the Licensed Product IND. During the period commencing on the Effective Date and ending on Effective Transfer Date, LMI will not take any action related to the Licensed Product IND or any other Regulatory Materials without the prior written approval of GEHC. Within *** after the Effective Transfer Date, LMI will provide GEHC with complete copies of the Regulatory Materials for the Precursor, Licensed Compound, Licensed Product in the Territory, including all correspondence and regulatory files relating thereto. Until the end of the Handover Period, at GEHC’s reasonable request and at no cost to GEHC, LMI will make its employees and representatives reasonably available to GEHC in accordance with the Transition Plan to supply background on the Licensed Product IND and other Regulatory Materials for the Precursor, Licensed Compound, and Licensed Product in the Territory. As the result of and effective as of such Transfer, GEHC will act as the sponsor of the Licensed Product IND for the Licensed Product in the Territory, and will take over from LMI all responsibilities of sponsors as defined under the FD&C Act, other FDA regulations, and all other Applicable Laws, including pharmacovigilance responsibilities. Commencing on the Effective Date, and thereafter during the Term, GEHC will bear all approved Third Party expenses incurred in connection with the transfer and assignment of the Licensed Product IND, and any other copies of Regulatory Materials provided to GEHC pursuant to this Section 3.6 (Transfer of Regulatory Materials). Subject to the terms and conditions of this Agreement (including Section 3.1.3 (Right of Reference)), upon GEHC’s written request, LMI will execute and deliver, or will cause to be executed and delivered, to GEHC such endorsements, assignments, and other documents as may be reasonably necessary to assign, convey, transfer, and deliver to GEHC all of LMI’s rights, title, and interests in and to the Licensed Product IND and any other copies of Regulatory Materials provided to GEHC pursuant to this Section 3.6 (Transfer of Regulatory Materials), including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with copy to GEHC) notifying such Regulatory Authority of the transfer of ownership of the Licensed Product IND assigned to GEHC pursuant to this Section 3.6 (Transfer of Regulatory Materials).

3.7. Technology Transfer.

3.7.1 Transition Services. LMI will cooperate with GEHC to facilitate the transition of the Licensed Product and the LMI Know-How in accordance with the transition plan to be agreed to by the Parties on or prior to the Effective Date (as such Transition Plan may be further revised by the Parties, the “**Transition Plan**”). In support of such transition, each Party will perform all Transition Services in accordance with the timelines and standards for performance set forth in the Transition Plan.

3.7.2 Manufacturing Know-How Transfer. In addition, LMI will use reasonable efforts to make available to GEHC all Know-How Controlled by LMI that is reasonably necessary or useful to enable the Manufacture of the Precursor, Licensed Compound, and Licensed Product by or on behalf of GEHC (the “**LMI Manufacturing Know-How**”), by providing copies or samples of relevant documentation, materials, and other embodiments of such Know-How, all in accordance with the Transition Plan. LMI may make such LMI Manufacturing Know-How available in such form as LMI reasonably determines, *provided that* such form reasonably enables GEHC to Manufacture the Precursor, Licensed Compound, and Licensed Product.

- 3.7.3 Other LMI Know-How Transfer.** In addition, LMI will use reasonable efforts to make available to GEHC all relevant LMI Know-How (other than LMI Manufacturing Know-How or Regulatory Materials) by providing copies or samples of relevant documentation, materials, and other embodiments of such LMI Know-How, all in accordance with the Transition Plan. LMI may make such LMI Know-How available in such form as LMI reasonably determines; *provided that* such form reasonably enables GEHC to Develop or Commercialize the Precursor, Licensed Compound, and Licensed Product (as applicable).
- 3.7.4 Costs and Cooperation.** During the first *** after the Effective Date (the “**Handover Period**”), each Party will bear all of its own costs and all Third Party expenses, in each case, incurred by such Party in connection with performance of all Transition Services and any other Know-How transfer activities allocated to such Party in the Transition Plan. Such Transition Services and Know-How transfer activities will be performed in a reasonable manner by knowledgeable personnel with responses that are comprehensive and timely. *** submitted by LMI within *** of the date of receipt of the invoice. It is the expectation of the Parties that during the Handover Period LMI will provide approximately *** FTEs (on *** basis) to perform the Transition Services and any other Know-How transfer activities allocated to LMI in the Transition Plan; *provided that* no LMI employee will be required to dedicate more than ***% of their time to providing such Transition Services.
- 3.7.5 Existing Contracts.** No later than *** after the Effective Date, LMI will make available to GEHC copies of all agreements entered into by LMI prior to the Effective Date relating (solely or in part) to the Exploitation of the Precursor, Licensed Compound, or Licensed Product in the Field. During the Handover Period, at GEHC’s request, LMI will assign and transfer to GEHC those agreements (or part thereof) that relate solely to the Exploitation of the Precursor, Licensed Compound, or Licensed Product to the extent that such agreements are assignable without consent. To the extent that consent is required for such an assignment, at GEHC’s request, LMI will use reasonable efforts to obtain such consent. LMI will be solely responsible and liable for fulfillment of any commitments, and will pay any amounts due, pursuant to all agreements entered into by LMI prior to or after the Effective Date, unless and except to the extent assigned to GEHC pursuant to this Section 3.7.5 (Existing Contracts). To the extent that there is an agreement between LMI and a Third Party relating to the Exploitation of the Precursor, Licensed Compound, or Licensed Product in the Field that is not assigned, at GEHC’s request, LMI will use reasonable efforts to assist GEHC to enter into an agreement with the applicable counterparty relating to the Exploitation of such Precursor, Licensed Compound, or Licensed Product in the Field.
- 3.8. Material Transfer.** If LMI transfers to GEHC any biological or chemical materials under this Agreement (including any materials provided by LMI in connection with the transfer of the LMI Manufacturing Know-How), then GEHC will: (a) use such materials and any portions or derivatives thereof solely for the purpose of exercising its rights or fulfilling its obligations under this Agreement and for no other purpose; and (b) not transfer such materials to any Third Party except NMP without LMI’s prior written consent; *provided that* GEHC will have the right to transfer such materials to its Sublicensees or Subcontractors solely to the extent necessary for such Third Party to conduct the activities on behalf of GEHC in furtherance of this Agreement. If

the Parties anticipate the transfer from LMI to GEHC of any patient samples or patient information, then the Parties will negotiate in good faith and enter into an agreement governing such transfer and subsequent use, in compliance with all Applicable Laws. GEHC will use commercially reasonable efforts to prevent deleterious exposure and to ensure that all materials transferred pursuant to this Section 3.8 (Material Transfer) are handled only by trained personnel.

3.9. Option to Purchase the LMI Trademark. LMI has provided GEHC with an accurate list identifying the countries in which the LMI Trademark is registered, the associated registration numbers and expiration dates (if applicable). Upon the payment of the upfront payment by GEHC as set forth in Section 7.1 (Upfront Payment), LMI will and hereby does grant to GEHC an exclusive option to purchase the LMI Trademark (the “**LMI Trademark Option**”), subject to the terms and conditions of this Agreement. GEHC may exercise the LMI Trademark Option at any time during the period commencing on the Effective Date and ending on the date that is *** prior to the anticipated First Commercial Sale of the Licensed Product by giving written notice to LMI. If GEHC exercises the LMI Trademark Option during the time period set forth in the preceding sentence, then the Parties will exclusively negotiate in good faith and enter into a separate agreement pursuant to which LMI would assign to GEHC all rights, title, and interests in and to the LMI Trademark and GEHC would pay to LMI an amount to reasonably compensate LMI for the value of such trademark, and that otherwise would contain reasonable and customary terms and conditions within ***. If, either (a) GEHC fails to provide notice to LMI of its exercise of the LMI Trademark Option before the date that is *** prior to the anticipated First Commercial Sale of the Licensed Product, or (b) prior to the date that is *** prior to the anticipated First Commercial Sale of the Licensed Product, GEHC provides notice to LMI that it does not intend to exercise the LMI Trademark Option, then LMI will have no further obligations to offer to GEHC the LMI Trademark for purchase.

3.10. Activity Outside the Field.

3.10.1 Separate Fields. If LMI or one or more LMI licensees Commercializes a Precursor, Licensed Compound, or Licensed Product outside of the Field, then (a) LMI will not and will cause any such licensee not to use any of the Marks or any confusingly similar trademarks; (b) LMI and GEHC will work cooperatively to each adopt measures designed to allow each Party to *** and to ***; and (c) LMI will, and will cause all of its licensees that are Commercializing the Precursor, Licensed Compound, or Licensed Product outside of the Field to, use reasonable efforts to *** and GEHC will, and will cause all of its Sublicensees that are Commercializing the Precursor, Licensed Compound, or Licensed Product in the Field to, use reasonable efforts to ***, unless otherwise agreed in an Ex-Field License Agreement.

3.10.2 ***. If following LMI’s launch of a Licensed Product outside of the Field, ***, then either Party may call a meeting of the JSC to discuss ***. If the JSC determines that ***, then the JSC will determine ***. Likewise, if the JSC determines that ***, then the JSC will determine ***. If the JSC is unable to unanimously determine whether or not ***, or if the JSC unanimously determines that ***, but cannot unanimously determine ***, then either Party may refer the dispute to the Parties’ Executive Officers for resolution as provided in Section 2.4.2 (Referral to Executive Officers), and if the Parties’ Executive Officers are unable to resolve the dispute within the timeframe set forth in Section 2.4.2 (Referral to Executive Officers), then either Party may refer the dispute to arbitration in accordance with Section 13.3 (Arbitration for Certain Matters). Notwithstanding Section 3.2 (Sublicensing Rights) or other provisions of this Agreement, and without limiting a Party’s right to seek injunctive relief, compensation paid pursuant to this Section 3.10.2 (***) will be ***.

3.10.3 Ex-Field Supply of Licensed Product. At LMI's written request, GEHC will use commercially reasonable efforts, taking into account factors such as ***, to supply to LMI the Licensed Compound or Licensed Product "as is" (*i.e.*, without any modifications for LMI) for Development purposes outside of the Field at ***.

3.10.4 GEHC Options for Ex-Field Licenses.

- (a) Grant of Option. LMI hereby grants to GEHC options, during the Option Term, to enter into license and collaboration agreements with LMI (each an "**Ex-Field License Agreement**") under which LMI would grant GEHC exclusive licenses under all reasonably necessary or useful Patent Rights and Know-How Controlled by LMI to Exploit the Precursor, the Licensed Compound, and Licensed Product for use in connection with *** (as applicable) (each, an "**Application**") outside of the Field on an Application-by-Application basis (each an "**Option**"), in accordance with the following provisions of this Section 3.10.4 (GEHC Option for Ex-Field License).
- (b) Option Term. GEHC may exercise an Option at any time during the period commencing on the Effective Date and ending *** (each an "**Option Term**"). Until expiration of an Option Term with respect to a particular Application without GEHC's exercise of an Option, LMI will not grant any Third Party any right to Develop (except as a subcontractor on LMI's behalf) or Commercialize, the Precursor, the Licensed Compound, or Licensed Products outside of the Field in any indications with respect to the Application that is the subject of such Option.
- (c) Delivery of Data Package. No later than ***, LMI will provide GEHC a data package containing the following information: (i) all summaries, analyses, and raw scientific data generated or compiled by or on behalf LMI with respect to such Licensed Product outside of the Field, including clinical data; (ii) a schedule identifying all Patent Rights owned or otherwise Controlled by LMI or its Affiliates that claim such Licensed Product outside of the Field, including Patent Rights that claim the composition of matter of or any method of using such Licensed Product outside of the Field; (iii) copies of any agreement pursuant to which LMI or its Affiliates Control any Patent Rights or Know-How reasonably necessary or useful to Exploit such Licensed Product outside of the Field; and (iv) any other information in LMI's possession that would be reasonably necessary or useful for GEHC to make an informed decision regarding whether to exercise the Option (the "**Data Package**").
- (d) Exercise of Option. GEHC may exercise each Option at any time during the applicable Option Term by sending written notice of such exercise (each, an "**Option Exercise Notice**") to LMI. If GEHC exercises an Option during the applicable Option Term, then the Parties will negotiate in good faith and, at GEHC's election, enter into an Ex-Field License Agreement on reasonable and customary terms. If the Parties have not reached agreement on the financial and non-financial terms of such Ex-Field License Agreement within *** after the effective date of the Option Exercise Notice (as may be extended or shortened by written agreement of the Parties, the "**Ex-Field License Agreement Negotiation Period**"), then:

- (i) If the Parties have not agreed upon the financial terms of the Ex-Field License Agreement during the Ex-Field License Agreement Negotiation Period, then GEHC or LMI may submit to an independent valuation firm agreed by the Parties a request for such firm to determine the financial terms of the Ex-Field License Agreement as set forth in Section 13.4.2 (Determination of Financial Terms).
- (ii) Within *** after each Party has received such valuation firm's determination of the financial terms of the Ex-Field License Agreement, if GEHC seeks to enter into the Ex-Field License Agreement on such financial terms, then GEHC will have the right, by providing written notice to LMI within such period, to initiate the "baseball" arbitration process set forth in Section 13.4 (Baseball Arbitration) to determine those non-financial terms and conditions on which the Parties failed to agree during the Ex-Field License Agreement Negotiation Period.
- (iii) If the Parties agreed upon the financial terms of the Ex-Field License Agreement during the Ex-Field License Agreement Negotiation Period, but failed to agree upon the non-financial terms and conditions of the Ex-Field License Agreement during the Ex-Field License Agreement Negotiation Period, then either Party may, by providing written notice to the other Party, initiate the "baseball" arbitration process set forth in Section 13.4 (Baseball Arbitration) within *** after the conclusion of the Ex-Field License Agreement Negotiation Period to determine those non-financial terms and conditions on which the Parties failed to agree during the Ex-Field License Agreement Negotiation Period.
- (iv) Within *** after each Party has received the arbitration determination for the non-financial terms and conditions pursuant to Section 13.4 (Baseball Arbitration), GEHC will have the right to elect by written notice to enter into such Ex-Field License Agreement on such non-financial terms and conditions that were determined by arbitration and on those financial terms that were either agreed by the Parties during the Ex-Field License Agreement Negotiation Period or determined by the independent valuation firm. In the event GEHC elects to enter into such Ex-Field License Agreement, then the Parties will enter into and promptly execute such Ex-Field License Agreement on such terms.
- (e) Effect of Expiration or Termination of the Option. If GEHC does not (i) exercise the Option during the Option Term by providing the Option Exercise Notice to LMI; (ii) initiate the "baseball" arbitration process set forth in Section 13.4 (Baseball Arbitration) to determine those non-financial terms and conditions on which the Parties have failed to agree within *** after receipt of the valuation firm's determination of, or the Parties' agreement with respect to, the financial terms; or (iii) require LMI to enter into an Ex-Field License on the terms determined by baseball arbitration within *** of receipt of the arbitration determination, then, in each case ((i) – (iii)), LMI will be free to grant rights to the Licensed Product to one or more Third Parties in a manner consistent with Section 3.10.5 (GEHC Right of First Offer) and Applicable Law.

3.10.5 GEHC Right of First Offer.

- (a) Right. During the Term, after the expiration of each applicable Option Term, if LMI intends to license, grant, or otherwise transfer, including by option or sale, to any Third Party any rights to Exploit, in whole or in part, the Precursor, Licensed Compound, or Licensed Product outside of the Field in the applicable Application, then, in each case, LMI will first notify GEHC in writing prior to providing such notice to or engaging in discussions with any Third Party. GEHC will have *** to inform LMI whether or not it wishes to engage in negotiations with LMI with respect to such license or other transfer. If GEHC so notifies LMI in writing within such *** period with respect to the applicable Application, then for a period of *** commencing as of the date of such notice, or as of such other date upon which the Parties agree, the Parties will negotiate in good faith the terms and conditions of an agreement pursuant to which GEHC would obtain rights to Exploit the Precursor, Licensed Compound, or Licensed Product outside of the Field to such Application. If (i) GEHC does not provide written notice to LMI indicating its desire to enter into negotiations with LMI within *** of receiving LMI's offer notice, or (ii) GEHC and LMI cannot agree on the terms of a definitive agreement within ***, then, in either case ((i) or (ii)), LMI will be free to license, grant, or otherwise transfer to a Third Party the rights to Exploit, in whole or in part, the Precursor, Licensed Compound, or Licensed Product solely with respect to the applicable Application; *provided that*, in the case of (ii) above, during the *** period following the conclusion of the negotiations between the Parties, LMI will not grant to a Third Party rights to Exploit, in whole or in part, the Precursor, Licensed Compound, or Licensed Product on terms and conditions that are more favorable in the aggregate to the applicable Third Party than the terms and conditions last proposed by LMI to GEHC in writing during the *** negotiation period or prior thereto pursuant to Section 3.10.4 (GEHC Options for Ex-Field Licenses).
- (b) Exceptions Resulting from Option Exercise. Notwithstanding the right of first option in Section 3.10.5(a) (Right), if GEHC exercises an Option with respect to an Application during the applicable Option Term in accordance with Section 3.10.4(d) (Exercise of Option) and the Parties submit to an independent valuation firm a request for such firm to determine the financial terms of the Ex-Field License Agreement as set forth in Section 13.4.2 (Determination of Financial Terms), but after receiving such financial terms GEHC does not initiate the "baseball" arbitration process set forth in Section 13.4 (Baseball Arbitration) to determine those non-financial terms and conditions on which the Parties have failed to agree within *** of receipt thereof, then the right of first offer granted to GEHC pursuant to this Section 3.10.5 (GEHC Right of First Offer) will not be available to GEHC for the applicable Application for a period of *** thereafter, but during such *** period LMI will not grant to a Third Party rights to Exploit, in whole or in part, the Precursor, Licensed Compound, or Licensed Product with respect to such Application on financial terms that are more favorable in the aggregate to the applicable Third Party than the lower of (i) the financial terms last proposed by LMI to GEHC during the Ex-Field License Agreement Negotiation Period or (ii) the financial terms determined by the independent

valuation firm. In addition, if GEHC exercises an Option with respect to an Application during the applicable Option Term in accordance with Section 3.10.4(d) (Exercise of Option), but does not require LMI to enter into an Ex-Field License on the terms determined by baseball arbitration and the independent valuation firm pursuant to Section 3.10.4(d) (Exercise of Option) within *** of receipt of such arbitration determination, then the right of first offer granted to GEHC pursuant to this Section 3.10.5 (GEHC Right of First Offer) will not be available to GEHC for the applicable Application for a period of *** thereafter; *provided that*, during such *** period LMI will not grant to a Third Party rights to Exploit, in whole or in part, the Precursor, Licensed Compound, or Licensed Product with respect to such Application on terms and conditions that are more favorable in the aggregate to the applicable Third Party than the terms determined by baseball arbitration and the independent valuation firm pursuant to Section 3.10.4(d) (Exercise of Option).

3.11. Exclusivity. ***.

3.12. Competing Product Acquisitions.

3.12.1 Options. If, during the term of the exclusivity covenant in Section 3.11 (Exclusivity), either Party or any of its Affiliates acquires or is acquired by a Third Party (whether such acquisition occurs by way of a purchase of assets, merger, consolidation, or similar transaction), and where such Third Party is, at such time, actively commercializing a Competing Product or is otherwise, at such time actively engaged in activities that would constitute a breach of Section 3.11 (Exclusivity), unless the Parties agree otherwise in writing, then such Party, or its applicable Affiliate (the “**Acquiring Party**”) will (with respect to the applicable Competing Product), at its option and no later than *** following the date of consummation of the relevant merger, consolidation, or acquisition, notify the other Party (the “**Non-Acquiring Party**”) in writing of its intent to either:

- (a) divest, or cause the relevant Affiliate to divest, whether by license or otherwise, its interest in the Competing Product, to the extent necessary to be in compliance with Section 3.11 (Exclusivity);
- (b) terminate the commercialization of the Competing Product; or
- (c) if GEHC is the Acquiring Party, terminate this Agreement pursuant to Section 12.2 (Termination by GEHC for Convenience).

3.12.2 Divestiture or Termination. If the Acquiring Party notifies the Non-Acquiring Party in writing that it or its relevant Affiliate intends to divest such Competing Product or terminate either this Agreement or the commercialization of the Competing Product as provided in Section 3.12.1 (Options), then the Acquiring Party or its relevant Affiliate will effect the consummation of such divestiture within *** or effect such termination within ***, subject to compliance with Applicable Law (as applicable), after the consummation of the relevant merger, consolidation, or acquisition contemplated in Section 3.12.1 (Options), and will confirm to the Non-Acquiring Party in writing when such divestiture or termination has been completed. The Acquiring Party will keep the Non-Acquiring Party reasonably informed of its efforts and progress in effecting such divestiture or termination until it is completed. Prior to such divestiture or termination, the Acquiring Party or its relevant Affiliate will take reasonable steps to limit data access

and sharing between its personnel working on the Precursor, Licensed Compound, or Licensed Product or having access to data from activities performed under this Agreement and Confidential Information of the Non-Acquiring Party and personnel working on such Competing Product.

ARTICLE 4

DEVELOPMENT

- 4.1. **Development Activities.** Other than the LMI Development Services, or other activities agreed to in writing by the Parties and set forth in this Agreement or the Development Plan and designated as being performed specifically by or on behalf of LMI, GEHC will be solely responsible for managing and conducting all Development activities with respect to the Precursor, Licensed Compound, and Licensed Product (including all regulatory matters). GEHC will be responsible for all costs and expenses related to the Development of the Precursor, Licensed Compound, and Licensed Product after the Effective Date, including any post-approval Development related to the Licensed Product.
- 4.2. **Development Plan.**
- 4.2.1 **Plan.** During the Term, the Parties will conduct Development activities in connection with the Precursor, Licensed Compound, or Licensed Product in accordance with the terms and conditions set forth in this ARTICLE 4 (Development) and the Licensed Compound development plan (as such plan may be amended from time-to-time pursuant to Section 4.2.2 (Amendments to the Development Plan), the “**Development Plan**”). The Development Plan will include in reasonable detail the anticipated (a) overall program of Development for the Licensed Product *** within the Field in the Territory, including Clinical Trials; (b) (i) start dates and data availability dates of all such Clinical Trials, (ii) dates for first and last patient visits in such Clinical Trials, (iii) date for filing of applications for Regulatory Approvals in at least each Core Market; *provided that* GEHC will submit the NDA in the U.S. within a reasonable timeframe following the conclusion of the applicable pivotal trial, based on Regulatory Authority feedback and the size of such Clinical Trial, and (iv) date for achievement of all Milestone Events (such events in this clause (b), the “**Development Plan Milestones**” and the dates for achievement thereof, the “**Development Milestone Achievement Dates**”); (c) respective roles and responsibilities of each Party in connection with such activities; *provided that* subject to Section 3.7.4 (Costs and Cooperation), LMI will not be required to expend any resources, whether internal or external, under the Development Plan unless LMI provides its written consent, or its approval of the Development Plan through its representatives on the JSC, and (d) high-level summary of material anticipated costs associated with those Development activities set forth in clauses (a) through (c). The initial Development Plan has been agreed and approved by the Parties as of the Effective Date. In the event of any inconsistency between the Development Plan and this Agreement, the terms of this Agreement will prevail.
- 4.2.2 **Amendments to the Development Plan.** The Parties understand that the Development Plan is intended to be a working document and may be modified by GEHC from time to time during the Term, subject to this Section 4.2.2 (Amendments to the Development Plan). GEHC will prepare an update to the Development Plan at least *** and GEHC may prepare amendments to the then-current Development Plan at any time during the Term. Each material amended Development Plan will meet the requirements set forth in

Section 4.2.1 (Plan) and will be subject to review and approval by the JSC as set forth in Section 2.2.3(b); *provided that* GEHC will not be in breach of its Development Diligence Obligations as a result of its failure to carry out the tasks assigned to it under any Development Plan during the pendency of the approval by the JSC of any updates or amendments to such Development Plan relating to such tasks. Following such review and approval by the JSC, the amended Development Plan will become effective and will supersede the previous Development Plan. *** GEHC will apprise LMI of material developments by proposing an appropriate update to the Development Plan in accordance with the update process set forth above.

4.3. LMI Development Services.

- 4.3.1 Engagement of LMI.** If after the conclusion of the Handover Period GEHC requests further Development services, then, unless otherwise agreed by the Parties, LMI will provide such services subject to the following: (a) during the first *** after the Handover Period, LMI will provide up to *** (on *** basis), (b) for the remainder of the period during which GEHC is performing activities under the Development Plan, LMI will provide up to *** (on *** basis), and (c) no LMI employee will be required to dedicate more than ***% of their time to providing such Development services (such Development services, the “**LMI Development Services**”). GEHC will compensate LMI for such services as set forth under Section 4.3.5 (Compensation for LMI Development Services); except to the extent otherwise provided in Section 3.7.4 (Costs and Cooperation).
- 4.3.2 Terms of LMI Development Services.** The LMI Development Services will be performed in connection with the activities set forth in the Development Plan and described in detail in one or more statements of work approved by each Party’s representatives on the JSC. Each applicable statement of work, including each amendment thereto, will be presented to LMI and will include at a minimum: (a) a description of the services and all Deliverables to be provided by LMI, (b) the planned FTE usage in connection with such services, (c) the schedule for performing such services, (d) the fees payable and approved budgets for such services, (e) the location where such services will be provided, and (f) such other commercially reasonable terms and conditions as the Parties may agree. LMI will not be obligated to perform, and GEHC will not be obligated to pay for, any LMI Development Services if the Parties do not agree in writing in advance on a statement of work. LMI will accrue its actual costs incurred in connection with the LMI Development Services ***, and, unless otherwise agreed by the Parties in writing, GEHC will pay for the LMI Development Services in accordance with the provisions of Section 4.3.5 (Compensation for LMI Development Services). Notwithstanding any terms set forth in a statement of work, LMI will have no obligation to perform LMI Development Services beyond the *** anniversary of the Effective Date unless otherwise agreed by LMI in a writing signed by both Parties.
- 4.3.3 Amendments of LMI Development Services.** Any change in the scope, duration, timing, budget, or other terms regarding any LMI Development Service or Deliverable described in a statement of work must be agreed to by the Parties in writing.

4.3.4 Responsibilities of the Parties.

- (a) Responsibilities of LMI. LMI will use commercially reasonable efforts to maintain sufficient resources to perform the LMI Development Services and will perform all LMI Development Services in a good and workman/workwoman like manner and in accordance with the applicable statement of work and all Applicable Laws. Any specific performance criteria for any LMI Development Service will be set forth in the applicable statement of work.
- (b) Responsibilities of GEHC. GEHC will use commercially reasonable efforts to provide (i) LMI with access to its facilities as is reasonably necessary for LMI to perform the LMI Development Services it is obligated to provide hereunder; (ii) LMI with information and documentation within GEHC's control and reasonably necessary for LMI to perform the LMI Development Services it is obligated to provide hereunder; and (iii) timely decisions to the extent necessary for LMI to perform LMI Development Services it is obligated to provide hereunder.
- (c) Mutual Responsibilities. The Parties will use commercially reasonable efforts to cooperate with each other in all matters relating to the provision and receipt of LMI Development Services. Each Party will require its personnel to comply with any security regulations and other published policies of the other Party, which will be provided or made otherwise available to such Party, while on the other Party's premises.

4.3.5 Compensation for LMI Development Services. For the performance of the LMI Development Services, GEHC will pay the amounts set forth in the applicable statement of work and will reimburse LMI for any reasonable approved out of pocket costs incurred by LMI in connection with providing such services (including the reasonable cost of materials); *provided, however*, that all LMI FTE costs will be charged at the applicable FTE Rate. LMI will invoice GEHC for the LMI Development Services and any out of pocket costs *** in arrears. GEHC will pay all undisputed amounts set forth in invoices submitted by LMI pursuant to this Section 4.3.5 (Compensation for LMI Development Services) within *** of the date of receipt of the invoice.

4.4. Development Diligence. GEHC will use Commercially Reasonable Efforts to (a) Develop the Licensed Product in at least one indication within the Field; (b) obtain Regulatory Approval, and, where applicable, Pricing Approval, for the Licensed Product in at least one indication within the Field in each of the Core Markets in accordance with the Development Plan ***, and recognizing that such efforts may occur sequentially with respect to each of the different territories ***; and (c) carry out the tasks assigned to it under the Development Plan in a timely and effective manner and in compliance with Applicable Law (clauses (a) and (b), collectively, the “**Development Diligence Obligations**”). To the extent that LMI's failure to perform the LMI Development Services in accordance with this Agreement adversely affects GEHC's ability to perform its Development Diligence Obligations set forth in this Section 4.4 (Development Diligence), then GEHC will be excused from any resulting delay or failure to perform its Development Diligence Obligations (i.e., it will not constitute a breach of this Agreement).

4.5. Development Reports. Reasonably prior to each JSC meeting, GEHC will provide the JSC with a written report outlining by *** GEHC's or its applicable Affiliate's or Sublicensee's activities under the Development Plan in the Core Markets and performance since the previous report, progress with respect to achieving Milestone Events and Regulatory Approvals and, where applicable, Pricing Approvals and the future activities under the Development Plan that it expects to initiate in the Core Markets in the next ***. In addition, such report will contain a summary of GEHC's material Development and regulatory activities in countries outside of the Core Markets.

- 4.6. Clinical Trial Data.** Within a reasonably practicable time period after release of top line Phase III Clinical Trial data for the Licensed Product from any Phase III Clinical Trial conducted by or on behalf of GEHC, GEHC will provide to LMI the clinical data from such Clinical Trial for the Licensed Product and, when it becomes available, the draft clinical study report for such Clinical Trial. In addition, if requested by LMI, within a reasonably practicable time period after it becomes available, GEHC will provide to LMI the draft clinical study report for any other Clinical Trial conducted by or on behalf of GEHC for the Licensed Product. All such information will constitute Confidential Information of GEHC hereunder. Following GEHC's provision of such summary information to LMI, LMI's clinical team and GEHC's clinical team will meet to review and discuss relevant data and results from such Clinical Trial(s) for the Licensed Products, and the LMI clinical team will provide the GEHC clinical team with the benefit of their experience and discuss such data with GEHC clinical team. The final conclusions drawn from any clinical data and results from Clinical Trial(s) for the Licensed Products and any decisions or actions reliant upon such data or results that affect the Licensed Product will be made solely by GEHC. LMI will be responsible for all costs and expenses incurred in connection with the LMI clinical team's activities under this Section 4.6 (Clinical Trial Data).
- 4.7. Regulatory Matters.** Subject to the terms and conditions of this Agreement, GEHC will have sole control and discretion with respect to (a) (i) proposing and planning the appropriate regulatory strategy for the Licensed Product, (ii) preparing and submitting all Regulatory Materials for the Licensed Product, and (iii) obtaining and maintaining all Regulatory Approvals, and, where applicable, Pricing Approvals, for the Licensed Product in each country in the Territory; and (b) communications with Regulatory Authorities with respect to any of the foregoing, or otherwise with respect to the Licensed Product; provided that, upon LMI's reasonable request, as permitted by Applicable Law and the Regulatory Authority and at LMI's expense, LMI may attend as an observer any substantive face-to-face or telephonic meetings with the FDA or any other Regulatory Authority related to the Licensed Product (or, if applicable, the relevant portions thereof); provided, further, that if GEHC invites LMI with reasonable notice to any such preparatory meetings and LMI does not attend such meetings, then LMI will not have the right to attend the applicable meetings with the FDA or any other Regulatory Authority. All Regulatory Materials, Regulatory Approvals, and, where applicable, Pricing Approvals, relating to the Licensed Product will be held in the name of GEHC or its designated Affiliate, Sublicensee, or GEHC's designee. Other than as required in connection with LMI's right to attend meetings with the FDA or any other Regulatory Authority as set forth in this Section 4.7 (Regulatory Matters), LMI will not contact any Regulatory Authorities with respect to any matters relating to the Licensed Product or Licensed Compound that could reasonably affect the Field without the prior written approval of GEHC. If LMI is contacted by a Regulatory Authority with respect to any matters relating to the Licensed Compound or Licensed Product that could reasonably affect the Field, then LMI will notify GEHC within *** of such contact and provide GEHC with any official correspondence received from any Regulatory Authority regarding the Licensed Product or the Licensed Compound within *** of receipt. To the extent that any correspondence, meetings, or other communications with the FDA or any other Regulatory Authority is reasonably likely to be material to the Licensed Compound or Licensed Product both within and outside of the Field, the Parties will, and will cause their respective Sublicensees (with respect to GEHC) and licensees (with respect to LMI) to notify each other thereof promptly and, if permitted by Applicable Law, and subject to the obligations of confidentiality hereunder, provide each other with copies of relevant correspondence or communications.
- 4.8. Cooperation.** Throughout the Term, each Party will reasonably cooperate with the other Party to facilitate the Development of the Licensed Product in accordance with the Development Plan, and will diligently respond with knowledgeable personnel to any reasonable requests by the other

Party for information or materials relating to the Licensed Compound, the Licensed Product, or LMI's Development activities related to the Licensed Compound or the Licensed Product prior to the Effective Date; *provided that* if any GEHC request for such cooperation is reasonably likely to result in the expenditure by LMI personnel of a significant amount of time, and such services are not Transition Services designated in the Transition Plan to be completed during the Handover Period, then LMI may require that such assistance be provided at GEHC's reasonable expense as LMI Development Services, and the Parties will enter into a statement of work in accordance with Section 4.3.2 (Terms of LMI Development Services) with respect to the performance by LMI of such requested services.

ARTICLE 5

COMMERCIALIZATION

- 5.1. Commercialization Activities.** Subject to the terms and conditions of this Agreement, including Section 5.5 (Co-Promotion Right), GEHC will be solely responsible for (a) managing and conducting all Commercialization activities with respect to the Precursor, Licensed Compound, and Licensed Product in the Field, and (b) all costs and expenses related to the Commercialization of the Precursor, Licensed Compound, and Licensed Product in the Field after the Effective Date.
- 5.2. Commercialization Plan.**
- 5.2.1 Plan.** During the Term, GEHC will use Commercially Reasonable Efforts to perform all Commercialization activities in connection with the Licensed Compound or Licensed Product in accordance with the terms and conditions set forth in this ARTICLE 5 (Commercialization) and the Licensed Product commercialization plan (as such plan may be amended from time-to-time pursuant to Section 5.2.2 (Amendments to the Commercialization Plan) the "**Commercialization Plan**"). The Commercialization Plan will include reasonable detail regarding the pre-launch, launch, and subsequent Commercialization of the Licensed Product in the Core Markets, for example, an estimate of the planned costs associated with such Commercialization activities and a preliminary, nonbinding forecast prepared in good faith reflecting (i) estimated GEHC Net Sales for the upcoming *** and (ii) Net Sales for the Licensed Product in each country in the Core Markets for the upcoming ***; *provided, however*, that under no circumstances will GEHC be held liable for any errors or omissions in any such preliminary forecast. At least *** prior to the anticipated First Commercial Sale of the Licensed Product in a Core Market, GEHC will prepare its planned PMF network and submit such planned network to the JSC for review and approval as set forth in Section 2.2.3(b). Simultaneously with the submission to the JSC of GEHC's planned PMF network, GEHC will also submit a preliminary draft of the Commercialization Plan for the Licensed Product in such Core Markets for JSC review. At least *** prior to such anticipated First Commercial Sale, GEHC will prepare the initial Commercialization Plan for the Licensed Product in such Core Markets and submit such initial Commercialization Plan to the JSC for review and approval as set forth in Section 2.2.3(b). Following such review and approval by the JSC, the initial Commercialization Plan will become effective. In the event of any inconsistency between the Commercialization Plan and this Agreement, the terms of this Agreement will prevail.
- 5.2.2 Amendments to the Commercialization Plan.** After GEHC prepares the initial Commercialization Plan for the Licensed Product in a Core Market, GEHC will prepare the Commercialization Plan for the following *** and provide such plan to the JSC no

later than *** after receipt of Regulatory Approval in such Core Market. In *** after receipt of Regulatory Approval in such Core Market, the Parties will review the progress of the execution of the Commercialization Plan. GEHC may prepare amendments to the then-current Commercialization Plan as reasonable or necessary at any time during the Term. Each amended Commercialization Plan will meet the requirements set forth in Section 5.2.1 (Plan), and will be subject to the review and approval of the JSC as set forth in Section 2.2.3(b); *provided that* GEHC will not be in breach of its Commercialization Diligence Obligations solely as a result of its failure to carry out the tasks assigned to it under any Commercialization Plan during the pendency of the JSC's approval of any updates or amendments to such Commercialization Plan involving such tasks. Following such review and approval by the JSC, the Commercialization Plan will become effective and will supersede the previous Commercialization Plan. ***. GEHC will apprise LMI of material developments by proposing an appropriate update to the Commercialization Plan in accordance with the update process set forth above.

5.3. Commercialization Reports. To the extent not required to be provided to LMI pursuant to the Co-Promotion Agreement, at least *** in advance of each JSC meeting, GEHC will provide the JSC with a reasonably detailed written report outlining by *** GEHC's Commercialization activities and performance since the previous report, including GEHC's progress under the Commercialization Plan, GEHC's Commercialization activities in progress, and the future Commercialization activities it expects to initiate.

5.4. Commercialization Diligence. During the Term, GEHC will use Commercially Reasonable Efforts to (a) achieve First Commercial Sale of the Licensed Product in each country in the Territory in which Regulatory Approval is obtained within *** of first achieving Regulatory Approval for a Licensed Product if no Pricing Approvals apply in such jurisdiction with respect to the initial indication for which such Regulatory Approval is obtained in such country or, if Pricing Approvals apply in such jurisdiction, then within *** of the receipt of approval with respect to pricing and reimbursement, (b) Commercialize the Licensed Product in each country in the Territory for which GEHC or its Affiliate has obtained Regulatory Approval, and, where applicable, Pricing Approval, for such Licensed Product, and (c) carry out the tasks assigned to it under the Commercialization Plan, including maintenance of Regulatory Approval, in a timely and effective manner and in compliance with Applicable Law (clauses (a) through (b), collectively, the "**Commercialization Diligence Obligations**").

5.5. Co-Promotion Right.

5.5.1 Co-Promotion Option. LMI will have the option to elect to co-promote the Licensed Product in the Co-Promotion Territory on the terms and subject to the conditions set forth herein. LMI may exercise such option by providing written notice to GEHC within the *** period following the JSC's receipt of GEHC's *** and preliminary draft of the Commercialization Plan for the Licensed Product in accordance with Section 5.2.1 (Plan). In the event LMI fails to exercise such option during such *** period, LMI will have no further rights to co-promote the Licensed Product in the Field.

5.5.2 Co-Promotion Principles. If LMI exercises the option set forth in Section 5.5.1 (Co-Promotion Option), then the Parties will negotiate in good faith and enter into a definitive written co-promotion agreement on customary terms and consistent with the following principles and the terms set forth in this Section 5.5 (Co-Promotion Right), as such principles and terms may be revised by agreement of the Parties (the "**Co-Promotion Agreement**"):

- (a) Whereas, the potential market for the Licensed Product in the Co-Promotion Territory is ***, and this provides an opportunity for LMI, through supplemental promotional activities, to generate incremental sales by working collaboratively with GEHC;
- (b) The Co-Promotion Agreement and LMI's activities thereunder will not ***;
- (c) Subject to LMI's co-promotion rights in this Section 5.5 (Co-Promotion Right), as between LMI and GEHC, ***;
- (d) To avoid redundancy of promotional efforts, LMI will only co-promote to targets as agreed to by the Parties in accordance with the criteria set forth in Section 5.5.2(e) ("**LMI Target Accounts**");
- (e) The targets to which GEHC will promote ("**GEHC Target Accounts**") and the LMI Target Accounts to which LMI will co-promote will be selected in a manner consistent with the following general approach, as such approach may be modified by the Parties:
 - (i) GEHC Target Accounts and LMI Target Accounts will be ***;
 - (ii) ***;
 - (iii) ***;
 - (iv) Unless LMI otherwise consents, the LMI Target Accounts *** will represent no fewer than ***% of ***;
 - (v) After the Effective Date, new Institutional Customers will be allocated between the Parties from time to time in a manner consistent with these same general principles and respective percentages of the total installed base; and
 - (vi) The Parties will reasonably adjust the LMI Target Accounts and the GEHC Target Accounts in particular *** as reasonably required to ***, while maintaining the principles set forth in Section 5.5.2(e)(iii) and in Section 5.5.2(e)(iv) on a nationwide basis.
- (f) LMI's co-promotion right will apply in the Co-Promotion Territory only;
- (g) GEHC will be solely responsible for setting up the ***;
- (h) Any compensation to LMI will be based solely on LMI Net Sales generated and determined as set forth in Section 7.4.2 (LMI Sales Royalties);
- (i) The Co-Promotion Agreement will contain a mutual non-solicit provision consistent with Section 14.6 (Non-Solicitation by GEHC) prohibiting each Party from soliciting members of the other Party's sales force, except if a Major Competitor acquires control of LMI through a Change of Control of LMI; and
- (j) Each Party will bear all costs associated with its respective sales force.

- 5.5.3 LMI Co-Promotion.** If LMI exercises the option set forth in Section 5.5.1 (Co-Promotion Option), then LMI will co-promote the Licensed Product to such LMI Target Accounts in good faith and in accordance with: (a) the co-promotion agreement; (b) GEHC's directions, messaging, and compliance guidelines, and (c) utilizing materials provided or approved by GEHC.
- 5.5.4 Complete Compensation.** The compensation set forth in Section 7.4.2 (LMI Sales Royalties) will be the sole compensation paid by GEHC to LMI pursuant to this Agreement with respect to LMI's co-promotion of the Licensed Product in the Co-Promotion Territory or sales of the Licensed Product to the LMI Target Accounts.
- 5.6. Precursors.** GEHC will, and will cause its Affiliates and Sublicensees to, use Commercially Reasonable Efforts to sell the Licensed Product (and not any precursors to the Licensed Compound), provided, however, that LMI recognizes that in certain circumstances and geographies it may be preferable and consistent with the use of such Commercially Reasonable Efforts to sell the Precursor for combination by radiopharmacies.

ARTICLE 6

MANUFACTURE AND SUPPLY

- 6.1. Manufacturing Responsibilities.**
- 6.1.1 Research, Development, and Commercial Supply.** GEHC will be solely responsible for the Manufacture and supply of the Licensed Product for Development and Commercialization (either by itself or through its contract manufacturer) pursuant to Section 6.1.2 (Manufacturing Through Third Party or Affiliates). GEHC will conduct all Manufacturing activities in compliance with all Applicable Laws.
- 6.1.2 Manufacturing Through Third Party or Affiliates.** GEHC will have the right to exercise its rights with respect to Manufacturing through one or more Third Parties or directly, using its or its Affiliates' internal Manufacturing capabilities.
- 6.2. Manufacturing Reports.** GEHC will provide the JSC with written summary reports of its Manufacturing activities at each regularly scheduled JSC meeting. The Parties will discuss the status, progress, and results of GEHC's Manufacturing activities at JSC meetings. In addition, GEHC will also inform LMI of any incident related to the commercial Manufacture of the Licensed Product that triggers a recall or field alert.

ARTICLE 7

FINANCIALS

- 7.1. Upfront Payment.** In partial consideration of the licenses and rights granted to GEHC hereunder, GEHC will pay to LMI \$5,000,000 on April 25, 2017 in immediately available funds by wire transfer, in accordance with wire instructions to be given by LMI to GEHC prior to the Effective Date.
- 7.2. Development Milestones.** GEHC will notify LMI as soon as practicable, and in any event within ***, upon achievement of each Milestone Event for the Licensed Product. In further consideration of the licenses and rights granted to GEHC, within *** after the end of the relevant

*** in which the first occurrence of each milestone event for the Licensed Product set forth in TABLE 7.2 below is achieved (each, a “**Milestone Event**”), whether such event is achieved by GEHC or its Affiliate or Sublicensee, GEHC will pay to LMI the corresponding non-creditable and non-refundable one-time milestone payment set forth in TABLE 7.2 below.

TABLE 7.2 – DEVELOPMENT MILESTONES

<u>Milestone Event</u>	<u>Milestone Payment</u>
1. First Regulatory Approval in Japan	\$ ***
2. First Commercial Sale	\$ ***

7.3. Sales Milestones.

7.3.1 Events and Payments. GEHC will notify LMI as soon as practicable, and in any event within ***, upon the first achievement of each sales milestone event set forth in TABLE 7.3.1 below for the Licensed Product. In further consideration of the licenses and rights granted to GEHC, within *** after the end of the relevant *** in which GEHC’s, its Affiliates’, and its Sublicensees’ cumulative Net Sales in the Territory first reach the respective thresholds set forth in TABLE 7.3.1, GEHC will pay to LMI the corresponding non-creditable and non-refundable milestone payment set forth in TABLE 7.3.1. For clarity, no sales milestone payments will be due until the first *** in which aggregate *** Net Sales in the Territory exceed \$***.

TABLE 7.3.1 – SALES MILESTONES

<u>Sales Milestone Event</u>	<u>Sales Milestone Payment</u>
1. First *** in which aggregate *** Net Sales in the Territory exceed \$***	\$ ***
2. First *** in which aggregate *** Net Sales in the Territory exceed \$***	\$ ***
3. First *** in which aggregate *** Net Sales in the Territory exceed \$***	\$ ***
4. First *** in which aggregate *** Net Sales in the Territory exceed \$***	\$ ***
5. First *** in which aggregate *** Net Sales in the Territory exceed \$***	\$ ***
6. First *** in which aggregate *** Sales in the Territory exceed \$***	\$ ***
7. First *** in which aggregate *** Net Sales in the Territory exceed \$***	\$ ***
8. First *** in which aggregate *** Net Sales in the Territory exceed \$***	\$ ***
9. First *** in which aggregate *** Net Sales in the Territory exceed \$***	\$ ***
10. First *** in which aggregate *** Net Sales in the Territory exceed \$***	\$ ***

7.3.2 Achievement of Multiple Sales Milestones. If *** aggregate Net Sales reach any of the Net Sales thresholds specified in TABLE 7.3.1 above for the first time at any time when any sales milestone payment corresponding to any lower amount of *** aggregate Net Sales has not yet been paid, then all such unpaid sales milestone payments will be paid at the same time. For example, if *** aggregate Net Sales equal \$*** in ***, and GEHC has not yet paid the sales milestone payment for the achievement of \$*** of *** aggregate Net Sales, then GEHC will pay to LMI a total of \$***. The sales milestone payments provided for in this Section 7.3.2 (Achievement of Multiple Sales Milestones) will be due and payable within *** after the end of the relevant *** in which the relevant sales milestone event is achieved, even if such event is achieved prior to the end of the relevant ***.

7.4. Royalties.

7.4.1 GEHC Sales Royalties. In further consideration of the licenses and rights granted to GEHC, during the applicable Royalty Term LMI will earn royalties during each *** in an amount equal to (a) the applicable royalty rate percentage set forth in TABLE 7.4.1 below, multiplied by (b) the GEHC Net Sales in such *** in the U.S. Territory (the “**GEHC Sales Royalties**”). ***. The GEHC Sales Royalties will be paid on *** basis and subject to true-up on *** basis, all pursuant to and in accordance with Section 7.4.10 (U.S. Royalty Payments and *** True-Up).

TABLE 7.4.1 – GEHC SALES ROYALTIES

<u>Aggregate GEHC Net Sales in the U.S. Territory in a ***</u>	<u>Royalty Rate</u>
Aggregate GEHC Net Sales in a *** less than or equal to \$***	***%
Aggregate GEHC Net Sales in a *** above \$*** and less than or equal to \$***	***%
Aggregate GEHC Net Sales in a *** above \$*** and less than or equal to \$***	***%
Aggregate GEHC Net Sales in a *** above \$***	***%

7.4.2 LMI Sales Royalties. In further consideration of the licenses and rights granted to GEHC, upon LMI’s exercise of the co-promotion option set forth in Section 5.5.1 (Co-Promotion Option), in consideration for LMI’s co-promotion activities, with respect to any *** in which LMI co-promotes the Licensed Product to LMI Target Accounts, during the applicable Royalty Term LMI will earn royalties during each *** in an amount equal to (a) the applicable royalty rate percentage set forth in TABLE 7.4.2 below, *multiplied by* (b) the LMI Net Sales in such *** (the “**LMI Sales Royalties**”). The royalty rate percentage set forth in TABLE 7.4.2 below applicable at any given time will be determined in reference to the same *** GEHC Net Sales level utilized in Section 7.4.1 (GEHC Sales Royalties) at such time. ***. The LMI Sales Royalties will be paid on *** basis and subject to true-up on *** basis, all pursuant to and in accordance with Section 7.4.10 (U.S. Royalty Payments and *** True-Up).

TABLE 7.4.2 – LMI SALES ROYALTIES

*** GEHC Net Sales	Royalty Rate
*** GEHC Net Sales less than or equal to \$****	***%
*** GEHC Net Sales above \$*** and less than or equal to \$***	***%
*** GEHC Net Sales above \$*** and less than or equal to \$***	***%
*** GEHC Net Sales above \$***	***%

* Notwithstanding the foregoing, if LMI Net Sales are equal to or greater than \$*** in a *** in which GEHC Net Sales are less than \$***, then the applicable royalty rate percentage for LMI Net Sales for such *** will be **%, instead of ***%.

- 7.4.3 Japan Sales Royalties.** In further consideration of the licenses and rights granted to GEHC, during the applicable Royalty Term in the Japan Territory, LMI will earn royalties during each *** in an amount equal to (a) ***% of Net Sales for the portion of aggregate Net Sales in the Japan Territory in such *** less than or equal to ¥***, *plus* (b) ***% of Net Sales for the portion of aggregate Net Sales in the Japan Territory in such *** greater than ¥*** (such payments collectively, the “**Japan Sales Royalties**”). GEHC will pay LMI the Japan Sales Royalties on *** basis, based on Net Sales in the Japan Territory for such ***.
- 7.4.4 ROW Sales Royalties.** In further consideration of the licenses and rights granted to GEHC, during the applicable Royalty Term in each country in the ROW Territory, LMI will earn running royalties during each *** in an amount equal to ***% of the aggregate Net Sales in such country in such *** (such payments with respect to all such countries in the ROW Territory, collectively, the “**ROW Sales Royalties**”). GEHC will pay LMI the ROW Sales Royalties on *** basis, based on Net Sales in the ROW Territory for such ***.
- 7.4.5 Expiration of Valid Claims.** Subject to Section 7.4.8 (Cumulative Reductions Floor), if during the Royalty Term for the Licensed Product on a country-by-country, product-by-product, basis there is no longer a Valid Claim of any (a) LMI Patent Right that Covers on-going Exploitation of the Precursor, Licensed Compound, or Licensed Product by GEHC or LMI in the Field in such country and provides exclusivity for the Precursor, or Licensed Product in such country, (b) GEHC Improvement Patent Right that Covers on-going Exploitation of the Precursor, Licensed Compound, or Licensed Product by GEHC or LMI in the Field in such country ***, or (c) Joint Patent Right that Covers on-going Exploitation of the Precursor, Licensed Compound, or Licensed Product by GEHC or LMI in the Field in such country *** from the first *** this Section 7.4.5 (Expiration of Valid Claims) applies, all Royalties payable to LMI with respect to Net Sales of such Precursor or Licensed Product, as applicable, in such country will automatically be reduced by ***%.
- 7.4.6 Generic Toggle ***.** Subject to Section 7.4.8 (Cumulative Reductions Floor), during and after the Generic Toggle ***, the royalty rates set forth in TABLE 7.4.1 (GEHC Sales Royalties) and TABLE 7.4.2 (LMI Sales Royalties) above will automatically be reduced by ***%.

- 7.4.7 Third Party Stacking Payments.** Subject to Section 7.4.8 (Cumulative Reductions Floor), GEHC will be entitled to deduct ***% of all Third Party Stacking Payments paid or payable by GEHC or any of its Affiliates or Sublicensees with respect to any country in the Territory for a given *** from Royalties paid or payable on the Net Sales in such country for such ***; *provided, however*, that if such Third Party Stacking Payments are paid with respect to a license to Patent Rights or Know-How relating to the manufacturing process of the Precursor, Licensed Compound, or Licensed Product, then GEHC will be entitled to deduct only ***% of such Third Party Stacking Payments instead of ***%. Any such deduction that cannot be used in such *** due to the application of Section 7.4.8 (Cumulative Reductions Floor) may not be carried forward for deduction from future Royalties owed by GEHC to LMI.
- 7.4.8 Cumulative Reductions Floor.** In no event will the Royalty amount due to LMI in any country in the Territory in a given *** during the Royalty Term be reduced by more than ***% of the amount that otherwise would have been due and payable to LMI in such country in such *** but for the reductions set forth in Section 7.4.5 (Expiration of Valid Claims), Section 7.4.6 (Generic Toggle ***) and Section 7.4.7 (Third Party Stacking Payments).
- 7.4.9 Royalty Reports.** Commencing with the First Commercial Sale of the Licensed Product, within *** after the end of each *** GEHC will provide to LMI a detailed, itemized report, in such form as the Parties may agree from time-to-time, of (a) total *** sales volumes and Net Sales in the Territory on a country-by-country basis for such ***, (b) during each *** in which LMI co-promotes the Licensed Product, total *** sales volumes and LMI Net Sales to each LMI Target Account for such ***, (c) all Royalties payable to LMI for such *** (including any foreign exchange rates used and any adjustments made pursuant to Section 7.4.6 (Generic Toggle ***), Section 7.4.7 (Third Party Stacking Payments), or Section 7.4.8 (Cumulative Reductions Floor)) on a country-by-country basis (including a breakdown between GEHC Sales Royalties and LMI Sales Royalties), (d) any Royalty True-Up Amount calculated pursuant to Section 7.4.10 (U.S. Royalty True-Up and *** True-Up) for the *** in which such *** occurs and (e) any *** Agreement Payments received by GEHC for such *** and information supporting the calculation of such payments (the “**Royalty Report**”). Without limiting the generality of the foregoing, GEHC will require its Affiliates and Sublicensees to account for *** volumes, Net Sales, and Third Party Stacking Payments and to provide such reports with respect thereto as if such volumes, Net Sales, and Third Party Stacking Payments were made by GEHC. If no Royalties are due to LMI for a given ***, then the applicable Royalty Report will so state. All Royalty Reports will be subject to audit rights as set forth in Section 7.12 (Financial Records; Audit Rights). In addition, in order to enable LMI to prepare its quarterly and annual public disclosures regarding LMI’s results of operations, within *** after the end of each ***, GEHC will deliver to LMI a good faith, preliminary estimate of the Royalties payable to LMI and any Royalty True-Up Amount for such *** with respect to each of the Core Markets. Under no circumstances will GEHC be held liable for any errors or omissions in any such preliminary estimate.
- 7.4.10 U.S. Royalty Payments and *** True-Up.**
- (a) Estimated *** Royalty Payments. For ***, GEHC will pay LMI the GEHC Sales Royalties and the LMI Sales Royalties earned in any such *** based on (i) the estimated, applicable royalty rate determined in reference to the estimated GEHC Net Sales for the *** in which such *** occurs (as reflected in GEHC’s

preliminary forecast set forth in the most recently approved Commercialization Plan, as described in Section 5.2.1 (Commercialization Plan)), multiplied by (ii) the actual GEHC Net Sales or LMI Net Sales, respectively, for such *** (the estimated Royalties for such *** calculated pursuant to this Section 7.4.10(Royalty Payments and *** True-Up) referred to as the “**Estimated *** Royalties**”).

- (b) Final *** Payment and *** Royalty True-Up. For ****, GEHC will also pay LMI the remaining GEHC Sales Royalties and LMI Sales Royalties earned in such *** based on (i) the difference (if any) between (A) the actual Royalties due and payable to LMI for the *** in an aggregate amount equal to (1) the actual, applicable royalty rate determined in reference to the actual GEHC Net Sales for such ***, multiplied by (2) the actual GEHC Net Sales or LMI Net Sales, respectively, for such ***, minus (B) the aggregate amount of Estimated *** Royalties actually paid for such *** (such aggregate difference, which may be a positive or negative number, the “**Royalty True-Up Amount**”), and (ii) the actual Royalties payable for the *** based on (A) the actual, applicable royalty rate determined in reference to the actual GEHC Net Sales for such ***, multiplied by (B) the actual GEHC Net Sales or LMI Net Sales, respectively, for such ***.

7.4.11 Royalty Payments. Concurrently with the Royalty Report (and not the preliminary estimate) for a ***, GEHC will make a payment to LMI of all applicable Royalties due pursuant to Section 7.4 (Royalties) for such *** as follows:

- (a) for the ***, the Estimated *** Royalties; and
(b) for the ***, the Royalty True-Up Amount, plus the actual Royalties earned for such ***.

7.5. ***

7.6. ***

7.7. **Other Amounts Payable.** Except as otherwise provided herein or in an applicable statement of work, GEHC will pay to LMI any other undisputed amounts due under this Agreement and set forth in an invoice within *** following receipt of such invoice.

7.8. **No Refunds; Offsets.** Except as otherwise provided under this Agreement, all payments under this Agreement will be irrevocable, non-refundable, and non-creditable. Except as otherwise provided herein, GEHC will have no right to offset, set off, or deduct any amounts from or against the amounts due to LMI under this Agreement or pursuant to any other commercial arrangement between the Parties.

7.9. **Taxes.**

7.9.1 Taxes on Income. Each Party will be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

- 7.9.2 Value Added Tax.** All payments due and payable by GEHC to LMI under this Agreement are exclusive of any Value Added Tax (“VAT”), sales and use tax, goods, and services tax and similar indirect taxes. In the event that any VAT, sales and use tax, goods and services tax and similar indirect taxes are properly due under any Applicable Law, such amounts will be charged by LMI in addition to any other payments due hereunder and will be payable by GEHC on receipt of a valid invoice issued by LMI, unless GEHC provides LMI with valid exemption documentation allowing LMI not to charge the relevant indirect taxes.
- 7.9.3 Tax Cooperation.** To the extent GEHC is required to deduct and withhold taxes on any payments to LMI, GEHC will pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to LMI an official tax certificate or other evidence of such withholding sufficient to enable LMI to claim such payments of taxes. LMI will provide to GEHC any tax forms that may be reasonably necessary in order for GEHC not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax.
- 7.9.4 Treatment of Certain Withholding Taxes.** GEHC will exercise reasonable efforts to ensure that any withholding taxes that are imposed are reduced as far as possible under the provisions of any relevant tax treaty by providing such support to LMI as LMI may reasonably request in applying for tax reductions or exemptions from appropriate taxing authorities. If GEHC is required to make a payment to LMI subject to a deduction of tax or withholding tax, then (a) if such withholding or deduction obligation arises as a result of any action by GEHC, including any assignment or sublicense, or any failure on the part of GEHC to comply with applicable tax laws or filing or record retention requirements, that has the effect of modifying the tax treatment of the Parties, then the sum payable by GEHC (in respect of which such deduction or withholding is required to be made) will be increased to the extent necessary to ensure that LMI receives a sum equal to the sum which it would have received had no such action occurred, and (b) otherwise, the sum payable by GEHC (in respect of which such deduction or withholding is required to be made) will be made to LMI after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount will be remitted in accordance with Applicable Law.

7.10. Payment Method; Invoicing.

- 7.10.1 Invoicing.** All invoices hereunder will include such detail and supporting documentation as reasonably required by GEHC and requested by GEHC in writing in advance, and will be submitted in such manner as required by GEHC, consistent with its customary invoicing practices.
- 7.10.2 Currency.** With respect to Net Sales invoiced in U.S. dollars, the Net Sales and Royalties under Section 7.4 (Royalties) will each be expressed in U.S. dollars. With respect to Net Sales invoiced in a currency other than U.S. dollars, payments will be calculated based on amounts converted to U.S. dollars using currency exchange rates for the *** for which remittance is made for such Royalties. The rate of exchange to be used in computing the amount of currency equivalent in U.S. dollars of Net Sales invoiced in other currencies will be made using the average rate of exchange over the applicable *** as reported in *The Wall Street Journal*, Internet U.S. Edition at www.wsj.com, as of *** (or, if unavailable on such date, the first date thereafter on which such rate is available).

- 7.10.3 Method of Payment.** All payments from GEHC to LMI will be made by wire transfer in U.S. Dollars to the credit of such bank account as may be designated by LMI in writing to GEHC from time-to-time. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.
- 7.11. Late Payments.** Any late payments will bear interest at ****% above the Prime Rate of interest as reported in the The Wall Street Journal, Internet U.S. Edition at www.wsj.com on the date payment is due (but in no event in excess of the maximum rate permissible under Applicable Law), such interest compounded *** from the date on which payment of such sum became due until payment thereof in full together with such interest, provided, however, that no such interest will accrue with respect to any sums disputed in good faith.
- 7.12. Financial Records; Audits.** GEHC will maintain complete and accurate records in sufficient detail to permit LMI to confirm the accuracy of the Royalty payments and other compensation or reimbursement payable under this Agreement. Upon reasonable prior notice, such records will be open during regular business hours for a period of *** from the creation of individual records, for examination at LMI's expense, and not more often than *** every ***, by an independent certified public accountant selected by LMI and reasonably acceptable to GEHC for the sole purpose of verifying for LMI the accuracy of the financial reports furnished by GEHC pursuant to this Agreement or of any payments made, or required to be made, by GEHC to LMI pursuant to this Agreement. LMI will have the right to receive the report of any such audit; provided that such report will not disclose GEHC's Confidential Information to LMI. Any amounts shown to be owed but unpaid, or overpaid and in need of reimbursement, will be paid or refunded (as the case may be) within *** after the accountant's report, plus interest (as set forth in Section 7.11 (Late Payments)) from the original due date. LMI will bear the full cost of such audit unless such audit reveals an underpayment by GEHC of more than ****% of the amount set forth in such report, in which case GEHC will pay the expenses of the third party auditor.
- 7.13. Pre-Effective Date Costs and Liabilities.** LMI will be solely responsible for all costs and other Liabilities relating to any actions or omissions occurring prior to the Effective Date relating to the Exploitation of the Precursor, Licensed Compound, Licensed Product, or otherwise resulting from or arising out of the business, operations, properties, assets, or obligations of LMI or any of its Affiliates conducted, existing, or arising on or prior to the Effective Date.

ARTICLE 8

INTELLECTUAL PROPERTY

- 8.1. Ownership of Inventions.**
- 8.1.1 Pre-existing Intellectual Property.** Subject only to the rights expressly granted to the other Party under this Agreement, each Party will retain all rights, title, and interests in and to any Intellectual Property Rights that are owned, licensed, or sublicensed by such Party prior to or independent of this Agreement.
- 8.1.2 LMI Services Know-How.** All Know-How developed by or on behalf of LMI in the course of its performance of any LMI Development Service that is related solely to the Precursor, Licensed Compound, or Licensed Product or is reasonably necessary or useful

for GEHC to Exploit the Precursor, Licensed Compound, or Licensed Product in the Field in the Territory, other than LMI Improvement Inventions, (“**LMI Services Know-How**”), and all Patent Rights that Cover LMI Services Know-How and no other Know-How created or invented by or on behalf of LMI (“**LMI Services Assigned Patent Rights**”), in each case, will be owned by GEHC. Upon LMI’s request, the Parties will negotiate in good faith the terms and conditions of a worldwide, royalty-bearing license to LMI under the LMI Services Assigned Patent Rights and LMI Services Know-How solely to Exploit the Precursor, Licensed Compound, and Licensed Product outside of the Field, in consideration for which LMI would pay to GEHC reasonable royalties based on ***.

- 8.1.3 Sole Inventions.** Except as provided in Section 8.1.2 (LMI Services Know-How), as between the Parties, each Party will own any and all inventions, improvements, works, and Know-How conceived, discovered, developed, or otherwise made, (including as necessary to establish authorship (in case of publication and other copyrightable work), inventorship (in case of inventions, whether patentable or not) or ownership under Applicable Law), solely by or on behalf of such Party (or its Affiliates, Subcontractors, or Sublicensees or its or their respective directors, officers, employees, or agents), and reasonably necessary or useful for the Exploitation of the Precursor, Licensed Compound, or Licensed Product whether or not patentable (collectively, “**Sole Inventions**”), and any and all Patent Rights and other Intellectual Property Rights thereto. If a Sole Invention is either a GEHC Improvement Invention or an LMI Improvement Invention, then the terms and conditions set forth in this Agreement applicable to GEHC Improvement Inventions and GEHC Improvement Patent Rights or LMI Improvement Inventions and LMI Improvement Patent Rights (as applicable) will apply. If a Sole Invention is neither a GEHC Improvement Invention nor a LMI Improvement Invention, then such Sole Invention will constitute Licensed Technology if owned by LMI and will constitute a “**GEHC Invention**” if owned by GEHC, and GEHC will own all Patent Rights Covering any GEHC Invention (“**GEHC Patent Rights**”) and any other Intellectual Property Rights thereto.
- 8.1.4 Joint Inventions.** As between the Parties, (a) GEHC will own all inventions, improvements, works, and Know-How that are conceived, discovered, developed, or otherwise made, as necessary to establish authorship (in case of publication and other copyrightable work), inventorship (in case of inventions, whether patentable or not) or ownership under Applicable Law, jointly by or on behalf of each Party (or their respective Affiliates, Subcontractors, or Sublicensees or its or their respective directors, officers, employees, or agents) in the course of performing activities under this Agreement that are reasonably necessary or useful for the Exploitation of the Precursor, Licensed Compound, or Licensed Product in the Field (regardless of whether useful outside of the Field as well), and whether or not patentable (collectively, “**Joint Inventions**”), and any and all Patent Rights that Cover Joint Inventions (“**Joint Patent Rights**”) and other Intellectual Property Rights thereto, and (b) LMI will own any other inventions, improvements, works, and Know-How that are conceived, discovered, developed, or otherwise made, as necessary to establish authorship (in case of publication and other copyrightable work), inventorship (in case of inventions, whether patentable or not) or ownership under Applicable Law, jointly by or on behalf of each Party (or their respective Affiliates, Subcontractors, or Sublicensees or its or their respective directors, officers, employees, or agents) in the course of performing activities under this Agreement that are reasonably necessary or useful for the Exploitation of the Precursor, Licensed Compound, or Licensed Product solely outside of the Field, and whether or not

patentable (collectively, “**LMI Joint Inventions**”), and any and all Patent Rights that Cover LMI Joint Inventions (“**LMI Joint Patent Rights**”) and other Intellectual Property Rights thereto. For clarity, LMI Services Know-How and LMI Services Assigned Patent Rights will not be considered Joint Inventions or Joint Patent Rights.

8.1.5 Assignment. LMI will and hereby does assign to GEHC all rights, title, and interests in and to the LMI Services Know-How, LMI Services Assigned Patent Rights, Joint Inventions, and Joint Patent Rights, together with the right to pursue and own any Patent Rights or other Intellectual Property Rights thereon. GEHC will and hereby does assign to LMI all rights, title, and interests in and to the LMI Joint Inventions and LMI Joint Patent Rights, together with the right to pursue and own any Patent Rights or other Intellectual Property Rights thereon.

8.2. Disclosure of Inventions. LMI will promptly disclose to GEHC all inventions and Know-How including all Sole Inventions, Joint Inventions, and LMI Joint Inventions, LMI Improvement Inventions, LMI Services Know-How, LMI Services Assigned Patent Rights, and Licensed Technology, in each case, including all invention disclosures or other similar documents submitted to LMI by its, or its Affiliates’, independent contractors’ or sublicensees’ (including Sublicensees’) directors, officers, employees, or agents describing such Sole Inventions, Joint Inventions, LMI Joint Inventions, LMI Improvement Inventions, LMI Services Know-How, LMI Services Assigned Patent Rights, or Licensed Technology such as is reasonably necessary or useful for the Exploitation of the Precursor, Licensed Compound, or Licensed Product in the Field, as applicable. GEHC will promptly disclose to LMI all GEHC Improvement Inventions, GEHC Improvement Patent Rights, Joint Inventions, Joint Patent Rights, LMI Joint Inventions and LMI Joint Patent Rights in each case, including all invention disclosures or other similar documents submitted to GEHC by its, or its Affiliates’, independent contractors’ or sublicensees’ (including Sublicensees’) directors, officers, employees, or agents describing such GEHC Improvement Invention, GEHC Improvement Patent Right, Joint Invention, Joint Patent Right, LMI Joint Inventions or LMI Joint Patent Rights, such as is reasonably necessary for the Exploitation of the Precursor, or the Licensed Compound or Licensed Product outside of the Field, as applicable.

8.3. Prosecution of Patent Rights.

8.3.1 LMI Patent Rights. LMI will be responsible for filing, prosecuting (including in connection with any reexaminations, oppositions, and the like), and maintaining the LMI Patent Rights and the LMI Joint Patent Rights in the Territory. LMI will diligently file, prosecute, and maintain the LMI Patent Rights using qualified outside patent counsel and foreign patent associates selected by LMI; *provided that* LMI identifies such counsel for GEHC in advance and GEHC consents to such counsel (such consent not to be unreasonably withheld, conditioned, or delayed). Without limiting Section 8.3.3 (Cooperation in Prosecution), LMI will (a) furnish GEHC with copies of all correspondence relating to the LMI Patent Rights from any patent office, (b) where reasonably practicable, give GEHC at least *** to review and comment on the text of all proposed responses to such correspondence, (c) where reasonably practicable, consult with GEHC with respect to all such proposed responses, (d) where reasonably practicable, supply GEHC with a copy of any draft patent application within the LMI Patent Rights at least *** before filing so as to give GEHC an opportunity to review, (e) supply GEHC with a copy of any patent application within the LMI Patent Rights at the time of filing, together with notice of its filing date and serial number, (f) use reasonable efforts to keep GEHC advised of the status of actual and prospective filings within the

LMI Patent Rights, and (g) give GEHC a reasonable opportunity to provide comments on and make requests of LMI concerning the preparation, filing, prosecution, and maintenance of the LMI Patent Rights and consider such comments and requests in good faith. LMI will be responsible for all costs and expenses in connection with such filing, prosecution, and maintenance. If LMI determines to abandon a patent or patent application, or not file a patent application included in LMI Patent Rights, or otherwise take any action in any country prior to any applicable filing deadline or other date by which LMI must act to avoid losing any of the LMI Patent Rights in the Field, in any country, promptly and, in any event reasonably prior to, and, to the extent reasonably practicable, at least *** in advance of any relevant deadline: (i) LMI will notify GEHC of its determination in writing; (ii) upon receipt of such notice, GEHC may, or may allow a Third Party to, file, prosecute, and maintain (in its sole discretion) such LMI Patent Right in the Field; (iii) upon GEHC's request, LMI will promptly provide all files related to filing, prosecuting, and maintaining such LMI Patent Right in the Field to counsel selected by GEHC; and (iv) LMI will no longer be responsible for such costs and expenses relating to filing, prosecuting, and maintaining (as applicable) such LMI Patent Right. GEHC will become responsible for such costs and expenses to the extent that GEHC elects, in its sole discretion, to continue the filing, prosecution, or maintenance of such LMI Patent Right and such LMI Patent Right will cease to be royalty bearing in such country or be deemed to have any remaining Valid Claims for purposes of Section 7.4.5 (Expiration of Valid Claims).

8.3.2 LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, GEHC Patent Rights, and Joint Patent Rights. GEHC will be responsible for filing, prosecuting (including in connection with any reexaminations, oppositions, and the like), and maintaining the LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, GEHC Patent Rights, and Joint Patent Rights in the Territory. GEHC will be responsible for all costs and expenses incurred in connection with such filing, prosecution, and maintenance. If GEHC determines to abandon a patent or patent application, or not file a patent application included in, any of the GEHC Improvement Patent Rights, LMI Services Assigned Patent Rights, or the Joint Patent Rights in the Field, then at least *** in advance of the relevant deadline to the extent reasonably practicable: (a) GEHC will notify LMI of its determination in writing; (b) upon receipt of such notice, LMI may, or may allow a Third Party to, file, prosecute, and maintain (in its sole discretion) such LMI Services Assigned Patent Right, GEHC Improvement Patent Right or Joint Patent Right in the Field; (c) GEHC will promptly provide all files related to filing, prosecuting, and maintaining such LMI Services Assigned Patent Right, GEHC Improvement Patent Right, or Joint Patent Right in the Field to LMI or counsel selected by LMI; and (d) GEHC will no longer be responsible for such costs and expenses relating to filing, prosecuting, and maintaining (as applicable) such LMI Services Assigned Patent Right, GEHC Improvement Patent Right, or Joint Patent Right. LMI will become responsible for such costs and expenses to the extent that LMI elects, in its sole discretion, to continue the filing, prosecution, or maintenance of such LMI Services Assigned Patent Right, GEHC Improvement Patent Right, or Joint Patent Right.

8.3.3 Cooperation in Prosecution. Each Party will provide the other Party all reasonable notice, assistance, and cooperation in the Patent Right prosecution efforts provided above in this Section 8.3 (Prosecution of Patent Rights), including providing any necessary powers of attorney and executing any other reasonably required documents or instruments for such prosecution. In addition, to the extent contemplated above, the prosecuting Party will provide the other Party with complete prosecution history

including correspondence with the relevant patent offices pertaining to such prosecuting Party's prosecution and maintenance of the LMI Patent Rights, LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, or Joint Patent Rights in the Field (as applicable). On *** basis, the prosecuting Party will provide to the other Party a report detailing the status of all LMI Patent Rights, LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, or Joint Patent Rights in the Field, including any patent term extensions, and the anticipated expiration dates of any issued patents. The prosecuting Party will keep the non-prosecuting Party informed as to material developments with respect to the filing, prosecution, and maintenance of the LMI Patent Rights, LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, or Joint Patent Rights in the Field, including by providing copies of all material communications (including office actions and notices of interferences, reissues, re-examinations or oppositions) from any patent office regarding such LMI Patent Rights, LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, or Joint Patent Rights in the Field and will provide the non-prosecuting Party drafts of submissions relating thereto, including drafts of any material filings or responses to be made to such patent offices, within a reasonable amount of time in advance of submitting such filings or responses to permit the non-prosecuting Party an opportunity to review and comment thereon. The prosecuting Party will consider in good faith, take into account, and implement where possible the reasonable comments made by the non-prosecuting Party.

8.3.4 Patent Term Extensions. The Parties will reasonably negotiate and attempt to agree for which, if any, of the LMI Patent Rights, LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, and Joint Patent Rights the Parties should seek patent term extensions or supplemental protection certificates or their equivalents in any country in the Territory. GEHC will have the sole right and responsibility for applying for all extensions, supplemental protection certificates or their equivalents with respect to the LMI Patent Rights, LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, and Joint Patent Rights, and LMI will provide any and all assistance needed to perfect the timely filing for such extensions, and GEHC will be responsible for all expenses associated with such extensions, including any Third Party expenses incurred by such Party in furtherance of such filing. In the event of any deadlock between the Parties with respect to any decision under this Section 8.3.4 (Patent Term Extension), GEHC may make a final determination based on its assessment of the best interest of the Licensed Product.

8.4. Infringement of Collaboration Patent Rights by Third Parties.

8.4.1 Notification. Each Party will promptly notify the other Party in writing of its becoming aware of (a) any actual or threatened infringement, misappropriation, or other violation by a Third Party of any Licensed Technology, LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, or Joint Patent Rights, including as a result of the manufacture, use, sale, or importation of any compound or product that is the same as or competitive with the Precursor, Licensed Compound, or Licensed Product, including any action, suit, or proceeding under 21 U.S.C. §355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV), or other similar law (each "**Product Infringement**"); or (b) initiation by a Third Party of a challenge to the validity, scope, or enforceability of any LMI Patent Right, LMI Services Assigned Patent Right, GEHC Improvement Patent Right, or Joint Patent Right or of an opposition proceeding against any LMI Patent Right, LMI Services Assigned Patent Right, GEHC Improvement Patent Right, or Joint Patent Right, or any allegation by a Third Party that any Intellectual Property Right owned by it is infringed, misappropriated,

or violated by the Exploitation of any Precursor, Licensed Compound, or Licensed Product or initiation by GEHC of an opposition or *inter partes* review against any such Third Party Intellectual Property Right (each, a “**Defense Action**”).

8.4.2 Common Interest. GEHC and LMI have a common legal interest in the preparation, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of the LMI Patent Rights, LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, and Joint Patent Rights. The Parties hereby stipulate and agree that the provision to, receipt by, retention of, permitted use, or sharing between the Parties of information relating to the LMI Patent Rights, LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, and Joint Patent Rights will be subject to all privileges under Applicable Law, and litigation privilege or any other applicable privilege and will not be deemed a waiver of any such privileges, Applicable Laws, or doctrines. Each Party will remain entitled to such protection under the common interest doctrine.

8.4.3 Enforcement Rights.

- (a) Right to Enforce the Licensed Technology.
- (i) GEHC Rights. GEHC will have the first right (but not the obligation), at its own expense, and in its sole discretion, to control enforcement of the Licensed Technology against any Product Infringement (A) in the Field or (B) ***.
- (ii) LMI Second Right. In the event that GEHC elects not to pursue enforcement of a particular alleged infringement of the Licensed Technology as set forth in Section 8.4.3(a)(i) (GEHC Rights) GEHC will notify LMI of such decision and LMI will have the right (but not the obligation), at its own expense, to control enforcement of the Licensed Technology against any such Product Infringement ***.
- (iii) Other LMI Rights. For any Product Infringement of the Licensed Technology with respect to which GEHC does not have the first right to enforce pursuant to Section 8.4.3(a)(i) (GEHC Rights), LMI shall have the sole right (but not the obligation), at its own expense, to control enforcement of the Licensed Technology.
- (b) Enforcement Process. Prior to commencing involvement in any such suit, action, or proceeding, the Party controlling the suit, action, or proceeding pertaining to enforcement of the Licensed Technology against a Product Infringement (the “**Enforcing Party**”) will notify the other party (the “**Non-Enforcing Party**”) and will consider the Non-Enforcing Party’s recommendations made within *** after such notice regarding the proposed suit, action, or proceeding, except to the extent imminent action is determined by Enforcing Party to be required or the delay could reasonably be expected to result in the loss of rights by the Non-Enforcing Party or the Enforcing Party or otherwise adversely affect or prejudice the Enforcing Party. The Enforcing Party will give the Non-Enforcing Party timely notice of any proposed settlement of any such suit, action, or proceeding that the Enforcing Party controls and the Enforcing Party will not settle, stipulate to any facts, or make any admission with respect to any Product Infringement

without the Non-Enforcing Party's prior written consent (not to be unreasonably withheld, conditioned, or delayed) if such settlement, stipulation, or admission would: (i) adversely affect the validity, enforceability, or scope, or admit non-infringement, of any of the Licensed Technology; (ii) give rise to liability of the Non-Enforcing Party or its Affiliates; or (iii) impair the Non-Enforcing Party's or any of its Affiliates' rights in any Licensed Technology or the Non-Enforcing Party's or any of its Affiliates' rights under this Agreement.

- (c) Cooperation. Notwithstanding anything to the contrary herein, the Non-Enforcing Party may, at the sole discretion of the Enforcing Party and at the Non-Enforcing Party's expense join as a party to such suit, action, or proceeding in accordance with this Section 8.4.3 (Enforcement Rights); *provided that* such Party will join as a party to such suit, action, or proceeding upon the reasonable request and expense of the Enforcing Party if necessary for standing purposes. With respect to a Product Infringement, the Non-Enforcing Party will have the right to be represented by counsel (which will act in an advisory capacity only, except for matters solely directed to such Party) of its own choice and at its own expense (subject to Section 8.4.3(d) (Recoveries)) in any such suit, action, or proceeding.
- (d) Recoveries. Any and all recoveries resulting from a suit, action, or proceeding relating to a claim of Product Infringement will first be applied to reimburse the Enforcing Party's costs and expenses in connection with such suit, action, or proceeding (and if the other Party is obligated to join for standing purposes, the costs of the joining party shall also be reimbursed, with such recoveries to be applied *pro rata* in accordance with the costs and expenses incurred by such Party if the amount of such recoveries is less than the total amount of all such costs and expenses). Any remaining recoveries will be allocated between the Parties ***.
- (e) Rights with Respect to GEHC Owned Intellectual Property and Patent Rights. For clarity, GEHC will have the sole right (but not the obligation), at its own expense, and in its sole discretion, to control enforcement of the GEHC Inventions, GEHC Patent Rights, Joint Inventions, Joint Patent Rights, GEHC Improvement Inventions, GEHC Improvement Patent Rights, LMI Services Know-How, and LMI Services Assigned Patent Rights against any Product Infringement and ***.

8.4.4 Defense Actions. Upon GEHC's request, LMI will reasonably cooperate with GEHC to the extent necessary to defend GEHC or any Affiliate or Sublicensee of GEHC in a Defense Action related to GEHC's or its Affiliate's or Sublicensee's Exploitation of the Precursor, Licensed Compound, or Licensed Product (in accordance with ARTICLE 3 (Licenses and Exclusivity)). GEHC will reimburse LMI for its reasonable costs incurred in providing such cooperation for a Defense Action that is not a challenge to the validity, scope, or enforceability of any LMI Patent Right, LMI Services Assigned Patent Right, or of an opposition proceeding against any LMI Patent Right, LMI Services Assigned Patent Right. GEHC will have the first right, in GEHC's sole discretion, to control the defense of any Defense Action related to GEHC's or its Affiliate's or Sublicensee's Exploitation of the Precursor, Licensed Compound, or Licensed Product (in accordance with ARTICLE 3 (Licenses and Exclusivity)) and the exclusive right to compromise, litigate, settle, or otherwise dispose of any such Defense Action; *provided that* GEHC will keep LMI timely informed of the proceedings and filings, and will provide LMI with copies of

all material communications pertaining to each such Defense Action. GEHC will not settle, stipulate to any facts, or make any admission with respect to any such Defense Action without LMI's prior written consent (not to be unreasonably withheld, conditioned, or delayed) if such settlement, stipulation, or admission would (a) adversely affect the validity, enforceability, or scope, or admit infringement, of any of the Licensed Technology; (b) give rise to liability of LMI or its Affiliates for which it is not indemnified; or (c) grant to a Major Competitor a license or covenant not to sue under, or with respect to, any Intellectual Property Rights Controlled by LMI (including the Licensed Technology). In the event that GEHC elects not to control the defense of any Defense Action that is a challenge to the validity, scope, or enforceability of any LMI Patent Right, LMI Services Assigned Patent Right, GEHC Improvement Patent Right, or Joint Patent Right or an opposition proceeding against any LMI Patent Right, LMI Services Assigned Patent Right, GEHC Improvement Patent Right, or Joint Patent Right, then GEHC will notify LMI of such decision and LMI will have the right (but not the obligation) to do so at its own expense, and to compromise, litigate, settle, or otherwise dispose of any such Defense Action; *provided that* LMI will keep GEHC timely informed of the proceedings and filings, and will provide GEHC with copies of all material communications pertaining to each such Defense Action. LMI will not settle, stipulate to any facts, or make any admission with respect to any Defense Action without GEHC's prior written consent (not to be unreasonably withheld, conditioned, or delayed) if such settlement, stipulation, or admission would (i) adversely affect the validity, enforceability, or scope, or admit infringement, of any of the Licensed Technology, or (ii) give rise to liability of GEHC or its Affiliates for which it is not indemnified.

- 8.5. Trademarks.** GEHC will have the sole right to determine the images, symbols, and trademarks to be used throughout the Territory in connection with the Commercialization of the Licensed Product in the Field. Subject to the foregoing, GEHC will be responsible for the selection, registration, maintenance, and defense of all trademarks for use in connection with the sale or marketing of the Licensed Product in the Field in the Territory (the "**Marks**"); *provided that* GEHC may not use the LMI Trademark for any purpose unless and until GEHC exercises the LMI Trademark Option in accordance with Section 3.9 (Option to Purchase the LMI Trademark Option). GEHC will be responsible for all fees and expenses incurred in connection therewith for the Marks. GEHC will ensure that all uses of the Marks comply with Applicable Law (including those laws and regulations particularly applying to the proper use and designation of trademarks in the applicable countries). Neither Party will, without the other Party's prior written consent, use any trademarks or house marks of the other Party (including the other Party's corporate name), or marks confusingly similar thereto, in connection with such Party's marketing or promotion of the Licensed Product under this Agreement, except to the extent required to comply with Applicable Law. GEHC will own all Marks with respect to the Licensed Product in the Field.

ARTICLE 9

REPRESENTATIONS, WARRANTIES, AND COVENANTS

- 9.1. Mutual Representations and Warranties.** Each Party hereby represents and warrants (as applicable) to the other Party as of the Effective Date as follows:

- 9.1.1 Corporate Existence and Power.** It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

- 9.1.2 Authority and Binding Agreement.** (a) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.
- 9.1.3 No Conflict.** It is not a party to any agreement that would prevent it from granting the rights or exclusivity granted or intended to be granted to the other Party under this Agreement or performing its obligations under this Agreement.
- 9.1.4 No Debarment.** Such Party is not debarred, has not been convicted, and is not subject to debarment or conviction pursuant to Section 306 of the FD&C Act. In the course of the Development of Licensed Product, such Party has not used prior to the Effective Date and will not use, during the Term, any employee, agent, or independent contractor who has been debarred by any Regulatory Authority, or, to the best of such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority or has been convicted pursuant to Section 306 of the FD&C Act.
- 9.2. Additional Representations and Warranties by LMI.** Except as disclosed in writing by LMI to GEHC in that certain letter to GEHC from LMI dated as of the Effective Date and countersigned by GEHC LMI represents and warrants to GEHC as of the Effective Date that:
- 9.2.1** LMI solely owns the LMI Patent Rights and the LMI Know-How. LMI is entitled to grant the License granted in Section 3.1.1 (License to GEHC) and other rights herein granted. LMI has obtained from its employees and all Third Parties involved in the development of the LMI Patent Rights and LMI Know-How all rights necessary to permit LMI to grant GEHC the licenses and other rights herein granted.
- 9.2.2** LMI has not granted to any Third Party any rights or licenses relating to any of the LMI Patent Rights or LMI Know-How that is in conflict with or would conflict with the License granted to GEHC in Section 3.1.1 (License to GEHC) or any of the other rights or licensed herein granted to GEHC.
- 9.2.3** Schedule 1.98 (LMI Patent Rights) includes all Patent Rights that are or have been Controlled by LMI that are necessary or useful to Exploit the Deliverables, Precursor, Licensed Compound, and Licensed Product.
- 9.2.4** No Intellectual Property Rights of Third Parties are necessary for or have been used by LMI in connection with set-up of the Manufacturing site, contract Manufacturing, or any other Manufacturing activities involving the Precursor, Licensed Compound, Licensed Product.
- 9.2.5** In the course of prosecuting the LMI Patent Rights, LMI has conducted, or had conducted on its behalf by suitably qualified patent counsel, prior art searches, and immediately prior to the Effective Date, LMI has had conducted on its behalf by suitably qualified patent counsel, a freedom to operate search with respect to Exploitation of the Precursor, Licensed Compound, and Licensed Product, and the results of such prior art searches and freedom to operate search have been disclosed to GEHC.

- 9.2.6** There have been and are no actual, pending, alleged (or to its Knowledge threatened) actions, suits, claims, interferences, oppositions, or governmental investigations involving the Precursor, Licensed Compound, Licensed Product, or any component thereof, the Licensed Technology, or alleging that the Exploitation of the Precursor, Licensed Compound, or Licensed Product by or on behalf of LMI within the Territory has infringed, misappropriated, or otherwise violated the Intellectual Property Rights of a Third Party, and to the Knowledge of LMI, such Exploitation has not infringed, misappropriated, or otherwise violated the Intellectual Property Rights of a Third Party. Neither LMI nor any of its Affiliates has received any written notice from a Third Party regarding any of the foregoing.
- 9.2.7** LMI has brought no enforcement action alleging that a Third Party is or was infringing, misappropriating, or otherwise violating the Licensed Technology in the Field within the Territory or otherwise sought to enforce any of the Licensed Technology against any Third Party, and ***.
- 9.2.8** LMI has not shared any non-public, pre-clinical, or clinical data relating to the Licensed Product or any component thereof with any Third Parties other than Regulatory Authorities or pursuant to written agreements containing confidentiality provisions that restrict the disclosure and use thereof.
- 9.2.9** LMI has disclosed to GEHC all material data and information and all correspondence to or from any Regulatory Authority relating to the Precursor, Licensed Compound, or Licensed Product, or any component thereof, regardless of whether such data and information would have a positive, neutral, or negative impact on the potential commercial, scientific, or strategic value or attractiveness of flurpiridaz or the Precursor, Licensed Compound, or Licensed Product.
- 9.2.10** LMI owns or Controls all rights to use any Intellectual Property Rights generated pursuant to any agreement entered into by LMI with a Third Party relating to the Precursor, Licensed Compound, or Licensed Product that are necessary or useful for GEHC to Exploit the Precursor, Licensed Compound, or Licensed Product in the Field.
- 9.2.11** To the Knowledge of LMI, none of the issued LMI Patent Rights is invalid or unenforceable, and, to the Knowledge of LMI, there is no actual, pending, alleged, or threatened infringement by a Third Party of any of the Licensed Technology. Additionally, LMI has no Knowledge that any claims of any LMI Patent Rights or any claims directed to the Precursor, Licensed Compound, or Licensed Product are unpatentable, invalid or unenforceable. The LMI Patent Rights have been diligently prosecuted in accordance with all Applicable Law, and have been filed and maintained properly and correctly, and all applicable fees have been paid to file and maintain such LMI Patent Rights. All documents affecting chain of title from the inventors of each LMI Patent Right to the ultimate assignee, LMI, have been properly recorded with any applicable Governmental Authority and have been made available to GEHC. True, complete and correct copies of all material documents and other materials that relate to the prosecution, defense, maintenance, validity and enforceability of the LMI Patent Rights, and all licenses and other agreements regarding the Licensed Technology have been made available to GEHC. LMI has taken reasonable measures to protect the confidentiality of all LMI Know-How that constitutes LMI Confidential Information.

- 9.2.12** All research, development, testing, manufacturing and other work performed by or on behalf of LMI or any of its Affiliates with respect to the Precursor, Licensed Compound and Licensed Product has been and will be conducted in good scientific manner, and in compliance with all requirements of Applicable Law. Neither LMI nor any of its Affiliates is or has been in violation of any Applicable Law that adversely affects the Precursor, Licensed Compound, or Licensed Product or any component thereof, the exercise of any of the rights granted to GEHC hereunder, or the performance by LMI of any of its obligations hereunder.
- 9.2.13** LMI's research and development activities with respect to the Precursor, Licensed Compound, Licensed Product, LMI Patent Rights, and the LMI Know-How were undertaken in accordance with the following good data management practices: (a) data was generated using sound scientific techniques and processes; (b) data was accurately and reasonably contemporaneously recorded in accordance with good scientific practices by Persons conducting research hereunder; and (c) data and results were stored securely and can be easily retrieved.
- 9.2.14** No Regulatory Authority or other Governmental Authority or other Person has commenced, or to the Knowledge of LMI, threatened to initiate, any action relating to the Precursor, Licensed Compound, or Licensed Product.
- 9.2.15** Neither LMI nor any of its Affiliates, nor any of its or their respective officers, employees, or agents, has made an untrue statement of a material fact or fraudulent statement, to FDA or any other Regulatory Authority or other Governmental Authority, failed to disclose a material fact required to be disclosed to the Regulatory Authority or other Governmental Authority, or committed an act, made a statement, or failed to make a statement that could reasonably be expected to provide a basis for FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto, and the accuracy of LMI's and its Affiliates' Regulatory Materials has not been contested by any Regulatory Authority or other Governmental Authority.
- 9.2.16** The Licensed Technology and any Deliverables are free of liens, mortgages, security interests and similar encumbrances; and the Licensed Technology and Deliverables are not subject to any license, covenant not to sue or other right that would allow a Third Party to exercise any of the rights exclusively granted to GEHC hereunder.
- 9.2.17** Except as required by Applicable Law (including filings with the SEC, Government Authority, or any patent office), LMI is under no obligation to disclose, license or otherwise make available to any Third Party any information, Licensed Technology or Intellectual Property Rights generated by GEHC or LMI in connection with this Agreement.
- 9.2.18** There are no pending or threatened actions relating to actions or omissions occurring prior to the Effective Date relating to the Precursor, Licensed Compound, or Licensed Product, or the Exploitation thereof, or resulting from or arising out of the business, operations, properties, assets or obligations of LMI or any of its Affiliates conducted, existing or arising on or prior to the Effective Date.

9.3. Additional Covenants of LMI. LMI covenants to GEHC that it will not grant to any Third Party any rights, licenses, covenants not to use or other rights relating to any of the LMI Patent Rights, LMI Know-How, LMI Services Know-How, LMI Services Assigned Patent Rights, Sole Inventions, Joint Inventions, or Joint Patent Rights that is in conflict with or would conflict with the License granted to GEHC in Section 3.1.1 (License to GEHC) or any of the other rights or licensed herein granted to GEHC. LMI has obtained or will obtain from its employees and Third Parties who are involved in the development of the LMI Patent Rights, LMI Know-How, LMI Services Know-How, LMI Services Assigned Patent Rights, Joint Inventions, and Joint Patent Rights all rights necessary to permit LMI to grant GEHC the licenses and other rights herein granted with respect thereto. If, after the Effective Date, LMI grants any Third Party any liens, mortgages, security interests, or similar encumbrances with respect to any Licensed Technology or any Deliverables, then (a) LMI will promptly notify GEHC of such encumbrance, (b) LMI will notify such Third Party of this Agreement and GEHC's rights hereunder prior to granting such encumbrance, and (c) any such encumbrance will be expressly subject to the rights granted to GEHC herein. Within *** after the Effective Date, LMI will cause to be released all liens, mortgages, security interests, and similar encumbrances listed on that certain letter to GEHC from LMI dated as of the Effective Date and countersigned by GEHC and provide to GEHC evidence of filing of lien releases for all such liens, mortgages, security interests and similar encumbrances with respect to the Licensed Technology with the U.S. Patent and Trademark Office no later than *** after the Effective Date and will provide GEHC with written evidence of such satisfaction and release promptly upon, but in no event later than *** after, receipt thereof.

9.4. Additional Covenants. Each Party covenants to the other that:

- 9.4.1** it will, and will ensure all Third Parties that it engages, comply with all Applicable Laws with respect to the performance of its obligations under this Agreement, including, as applicable, all materials declaration requirements and conflict minerals laws and regulations;
- 9.4.2** it has not and will not directly or indirectly offer or pay, or authorize such offer or payment of, any money, or transfer anything of value, to improperly seek to influence: (a) any elected or appointed government official (*e.g.*, a member of a ministry of health); (b) any employee or person acting for or on behalf of a Governmental Authority; (c) any political party officer, employee, or person acting for or on behalf of a political party or candidate for public office; (d) an employee or person acting for or on behalf of a public international organization; or (e) any person otherwise categorized as a government official under local law; and
- 9.4.3** neither such Party nor any of its Affiliates will use in any capacity, in the course of the Development of Licensed Product, any employee, agent, or independent contractor who has been debarred by any Regulatory Authority, or, to the best of such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority or has been convicted pursuant to Section 306 of the FD&C Act. Such Party will inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in such Section 306 or if any action, suit, claim, investigation, or legal or administrative proceeding is pending, or is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder.

9.5. Foreign Corrupt Practices Act Compliance.

9.5.1 Compliance with FCPA. The U.S. government imposes and enforces prohibitions on the payment or transfer of anything of value to foreign governments, government officials, political parties, political party officials (or relatives or associates of such officials), whether directly or indirectly, to obtain or retain business. This U.S. law is referred to as the Foreign Corrupt Practices Act (“**FCPA**”), and it can have application to conduct of a U.S. corporation’s foreign subsidiaries, employees, agents and distributors. Each Party stipulates and agrees that it will comply with the FCPA in marketing, selling, or servicing the Licensed Product under this Agreement and will not, in the course of its responsibilities under the Agreement, offer, promise, give, demand, seek, or accept, directly or indirectly, any gift or payment, consideration or benefit in kind that would or could be construed as an illegal or corrupt practice.

9.5.2 No Action. In no event will either Party be obligated under the Agreement to take any action or omit to take any action that such Party believes, in good faith, would cause it to be in violation of any Applicable Laws, including the anti-bribery laws referenced in this Section 9.5 (Foreign Corrupt Practices Act Compliance).

9.6. Limitations on Claims for Certain Representations and Warranties. Any claim or cause of action for breach by either Party of any of the representations and warranties set forth in Section 9.1 (Mutual Representations and Warranties) or Section 9.2 (Additional Representations and Warranties by LMI) (whether based on the indemnification set forth herein, breach of contract, or otherwise) must be made, if at all, by delivery by the non-breaching Party of written notice to the breaching Party or through the commencement by the non-breaching Party of a legal proceeding against the breaching Party in a court of competent jurisdiction on or prior to ***.

9.7. No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES, NOR RELIES ON, ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WARRANTIES OF TITLE, NON-INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRECURSOR, LICENSED COMPOUND, LICENSED PRODUCT, OR THE SUBJECT MATTER OF THIS AGREEMENT.

ARTICLE 10

INDEMNIFICATION; INSURANCE; LIMITATION ON LIABILITY

10.1. Indemnification by LMI. LMI will defend, indemnify, and hold GEHC, its Affiliates, Subcontractors, Sublicensees, and distributors, and its and their respective officers, directors, employees, and agents (the “**GEHC Indemnitees**”) harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys’ fees and costs of litigation or other legal actions incurred by such GEHC Indemnitees, all to the extent resulting from claims, suits, proceedings or causes of action brought by or on behalf of such Third Party (“**Claims**”) against such GEHC Indemnitee arising or resulting from: ***, and (g) any actions or omissions occurring prior to the Effective Date relating to the Exploitation of the Precursor, Licensed Compound, or Licensed Product, or resulting from or arising out of the business, operations, properties, assets, or obligations of LMI or any of its Affiliates conducted, existing, or arising prior to the Effective Date except, in each case ((a) – (f)), to the extent such Claims arise from or occur as a result of the breach by GEHC of this Agreement or the fraud, negligence, or willful misconduct on the part of GEHC or its Affiliates or its or their respective directors, officers, employees, or agents.

- 10.2. Indemnification by GEHC.** GEHC will defend, indemnify, and hold LMI, its Affiliates, Subcontractors, Sublicensees, and distributors, and each of their respective officers, directors, employees, and agents, (the “**LMI Indemnitees**”) harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys’ fees and costs of litigation or other legal actions incurred by such LMI Indemnitees, all to the extent resulting from any Claims against such LMI Indemnitee arising or resulting from: ***, to the extent such Claims arise from or occur as a result of the breach by LMI of this Agreement or the fraud, negligence, or willful misconduct on the part of LMI or its directors, officers, employees, or agents.
- 10.3. Indemnification Procedures.** In connection with any Claim for which a Party (the “**Indemnified Party**”) seeks indemnification from the other Party (the “**Indemnifying Party**”) pursuant to this Agreement, the Indemnified Party will: (a) give the Indemnifying Party prompt written notice of the Claim; provided, however, that failure to provide such notice will not relieve the Indemnifying Party from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with the Indemnifying Party, at the Indemnifying Party’s expense, in connection with the defense and settlement of the Claim; and (c) permit the Indemnifying Party to control the defense and settlement of the Claim; provided, however, that the Indemnifying Party may not settle the Claim without the Indemnified Party’s prior written consent (not to be unreasonably withheld, conditioned, or delayed), if such settlement materially adversely impacts the Indemnified Party’s rights or obligations. Further, the Indemnified Party will have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and at its own expense.
- 10.4. Insurance.** Each Party will, at its own expense, procure and maintain during the Term, insurance policies (or a program of self-insurance) adequate to cover its responsibilities hereunder and consistent with the normal business practices of prudent pharmaceutical and medical device companies of similar size and scope. Such insurance will not create a limit to such Party’s liability under this Agreement.
- 10.5. LIMITATION OF LIABILITY.** EXCEPT WITH RESPECT TO (A) ARTICLE 11 (CONFIDENTIALITY) OR (B) A CLAIM FOR FRAUD, GROSS NEGLIGENCE, OR WILLFUL MISCONDUCT, NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, INCIDENTAL, LOST PROFITS, OR PUNITIVE DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES, AND REGARDLESS OF THE LEGAL THEORY ASSERTED INCLUDING CONTRACT, FAULT, NEGLIGENCE, STRICT LIABILITY, OR ANY OTHER LEGAL THEORY. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.5 (LIMITATION OF LIABILITY) IS INTENDED TO LIMIT OR RESTRICT (I) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTIONS 10.1 AND 10.2 (INDEMNIFICATION) OR (II) THE DAMAGES TO WHICH A PARTY MAY BE ENTITLED PURSUANT TO A CLAIM OF INTELLECTUAL PROPERTY INFRINGEMENT OR MISAPPROPRIATION.

ARTICLE 11

CONFIDENTIALITY

- 11.1. Confidential Information.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, during the Term and for *** years thereafter or for such longer period as such Confidential Information remains a trade secret, it will, and will cause its Affiliates, to keep confidential and not publish or otherwise disclose to any Third Party, and not use for any purpose other than to exercise its rights or obligations hereunder or as otherwise provided for in this Agreement, any Confidential Information of the other Party or any of its Affiliates; *provided that* each Party and its Affiliates may disclose the Confidential Information of the other Party or its Affiliates to the receiving Party's and its Affiliates' officers, directors, employees, and agents who need to know such information, in each case, are bound by obligations of confidentiality with respect to the use and disclosure of such Confidential Information no less restrictive than those set forth in this Section 11.1 (Confidential Information). LMI will use at least the same degree of care which it uses to prevent the disclosure of its own other confidential information of like importance, and in any event, no less than reasonable care, to prevent the disclosure of the Licensed Technology, except to the extent (a) the Licensed Technology is in the public domain through no fault of LMI, its Affiliates or any of its or their respective officers, directors, employees, or agents, (b) such disclosure or use is expressly permitted under Section 11.2 (Authorized Disclosure of Confidential Information), or (c) such disclosure or use is otherwise expressly permitted by the terms of this Agreement. Notwithstanding the foregoing, Confidential Information of a Party or its Affiliate will exclude that portion of such information or materials that the receiving Party (or the receiving Party's Affiliate) can demonstrate by competent written proof:
- 11.1.1** was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party; *provided, however,* that the foregoing will not relieve LMI from its obligations pursuant to Section **Error! Reference source not found.** (***);
 - 11.1.2** was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
 - 11.1.3** became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act, omission, fault, negligence, or breach of this Agreement of the receiving Party;
 - 11.1.4** is subsequently lawfully disclosed to the receiving Party or its Affiliate by a Third Party without breaching any obligations of confidentiality with respect thereto; or
 - 11.1.5** is independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of Confidential Information.
- 11.2. Authorized Disclosure of Confidential Information.** Notwithstanding Section 11.1 (Confidential Information), each Party may disclose Confidential Information of the other Party to the extent such disclosure is reasonably necessary in the following situations, subject to the requirements set forth in this Section 11.2 (Authorized Disclosure of Confidential Information) and Section 11.3 (Terms of Agreement):

- 11.2.1 filing or prosecuting LMI Patent Rights, LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, or Joint Patent Rights in accordance with ARTICLE 8 (Intellectual Property);
- 11.2.2 regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), including filings with the SEC or FDA, with respect to the Precursor, Licensed Compound, or Licensed Product as permitted hereunder;
- 11.2.3 responding to a valid order of a court of competent jurisdiction or other competent authority; *provided that* the receiving Party will first have given to the disclosing Party advance notice of such disclosure requirement and, if allowable, a reasonable opportunity to quash the order or obtain a protective order requiring that the Confidential Information be held in confidence or used only for the purpose for which the order was issued; and *provided, further*, that if such order is not quashed or a protective order is not obtained, the Confidential Information disclosed will be limited to the information that is legally required to be disclosed;
- 11.2.4 complying with Applicable Law, including regulations promulgated by securities exchanges;
- 11.2.5 disclosure to its Affiliates and Third Parties only on a need-to-know basis and solely in order for its Affiliate and Third Parties to assist with the performance by the disclosing Party of its obligations or the exercise of its rights under this Agreement (including with respect to Development and Commercialization of the Licensed Product); *provided that* each disclosee, prior to any such disclosure, must be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in Section 11.1 (Confidential Information); and
- 11.2.6 disclosure of the material terms of this Agreement to any *bona fide* potential or actual investor, lender, financing source (including in connection with any royalty factoring transaction), investment banker, acquirer, or merger partner, each in connection with a material transaction affecting substantially all of the business or business unit to which this Agreement relates, whether in a merger, sale of stock, sale of assets, investment, license, collaboration, or other transaction; *provided that* each disclosee must be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in Section 11.1 (Confidential Information) prior to any such disclosure.

Notwithstanding the foregoing, in the event that a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 11.2.1, Section 11.2.2, or Section 11.2.4 (Authorized Disclosure of Confidential Information), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use reasonable efforts to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

11.3. Terms of Agreement.

- 11.3.1 **Disclosure of Terms of Agreement.** The Parties agree that the terms of this Agreement are the Confidential Information of both Parties and will be treated by each Party as the Confidential Information of the other Party, subject to the special authorized disclosure provisions set forth in Section 11.2 (Authorized Disclosure of Confidential Information) and this Section 11.3 (Terms of Agreement). On or within *** after the Effective Date the Parties will make a joint public announcement of the execution of this Agreement, to be agreed to in advance by the Executive Officers of each Party.

- 11.3.2 Public Announcements.** After issuance of such press release, if either Party or any of its Affiliates desires to make a press release or other public announcement concerning the terms of this Agreement or any activities under this Agreement, such press release or other public announcement must be approved in advance by the other Party. The Party desiring to make such disclosure will give reasonable prior advance notice of the proposed text of such press release or announcement to the other Party for its prior review and approval, such approval not to be unreasonably withheld, except that, subject to Section 11.3.3 (Disclosure Required by Law), in the case of a press release or governmental filing required by law, the disclosing Party will provide the other Party with such advance notice as it reasonably can and will not be required to obtain approval therefor. A Party commenting on such a proposed press release or announcement will provide its comments, if any, within *** after receiving the press release for review. In relation to a Party's review of such a proposed press release or announcement, the Party may make reasonable comments on such proposed press release or announcement within the prescribed time for commentary, and may refuse to permit disclosure of any information not previously agreed to be disclosed, but will not withhold its approval to disclosure of any information that is required by Applicable Law to be disclosed. Neither Party will be required to notify or seek the permission of the other Party to repeat any information regarding the terms of this Agreement that have already been publicly disclosed by such Party or such Party's Affiliate, by the other Party or any of its Affiliates, or that the Parties have previously agreed upon, in each case, in accordance with this Section 11.3 (Terms of Agreement).
- 11.3.3 Disclosure Required by Law.** The Parties acknowledge that either or both Parties may be obligated to make a filing (including filing a copy of this Agreement) with the SEC or other Governmental Authorities. Each Party will be entitled to make such a required filing; *provided that* it requests confidential treatment of at least the commercial terms and sensitive technical terms hereof and thereof and any other terms requested by the other Party, all to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party will provide the other Party with a copy of the Agreement marked to show provisions for which such Party intends to seek confidential treatment and will reasonably consider and incorporate the other Party's comments thereon to the greatest extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed.
- 11.3.4 Publications.** Subject to GEHC's prior written approval, not to be unreasonably withheld, conditioned, or delayed, LMI personnel may publish in scientific journals or present at scientific conferences scientific, pre-clinical, or clinical data derived from Development related to the Precursor, Licensed Compound, and Licensed Product in the Field that was conducted by LMI or its Affiliates prior to the Effective Date. LMI stipulates that GEHC may require LMI to delay publication where it reasonably believes doing so is in the best interest of the Licensed Product. GEHC personnel may publish in scientific journals or present at scientific conferences scientific, pre-clinical, or clinical data derived from Development related to the Precursor, Licensed Compound, and Licensed Product in the Field after the Effective Date. Any such publications by LMI or GEHC will be submitted, and no such presentation will be made unless a written copy of such proposed publication or presentation is submitted, to the non-publishing Party no later than *** before submission for publication or presentation for informational

purposes only. Thereafter, nothing herein will limit GEHC's ability to disclose any study results or other information developed by or on behalf of GEHC. The non-publishing Party and the publishing Party will each comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication. The publishing Party will not be required to seek the permission of the non-publishing Party to republish any information or data that has already been publicly disclosed by the publishing Party in accordance with this Section 11.3.4 (Publications), so long as such information or data remains accurate. The provisions of this Section 11.3.4 (Publications) will not relieve a Party of its obligations of confidentiality including LMI's obligations pursuant to Section 11.4 (***)

11.4. ***.

ARTICLE 12

TERM AND TERMINATION

- 12.1. Term.** This Agreement will become effective on the Effective Date and, unless earlier terminated pursuant to this ARTICLE 12 (Termination), will expire when no further payments are due pursuant to Section 7.4 (Royalties) (the "**Term**"). Upon expiration of the Royalty Term in a country within the Territory, the License granted to GEHC in Section 3.1.1 (License to GEHC) under the LMI Know-How will become fully-paid, royalty-free, non-exclusive, perpetual, and irrevocable in such country.
- 12.2. Termination by GEHC for Convenience.** GEHC may terminate this Agreement at will in its entirety or on a country-by-country basis, in its sole discretion, on not less than *** prior written notice to LMI.
- 12.3. Termination by Either Party for Breach.** Each Party will have the right to terminate this Agreement in the event the other Party commits a Material Breach hereunder and fails to cure such breach within *** of receiving written notice thereof; provided, however, that if either Party initiates a dispute resolution procedure under Section 13.1 (Disputes) to resolve a dispute regarding the Material Breach for which termination is being sought and is diligently pursuing such procedure, then the cure period set forth in this Section 12.3 (Termination by Either Party for Breach) will be tolled during the pendency of such dispute resolution procedures. Notwithstanding the foregoing cure period, with respect to any Material Breach by GEHC that is a breach of the Development Diligence Obligations or the Commercialization Diligence Obligations, LMI will have the right to terminate in accordance with this Section 12.3 (Termination by Either Party for Breach) if GEHC fails to cure such breach within (a) *** of receiving written notice thereof if such breach relates to the U.S., (b) *** of receiving written notice thereof if such breach relates to a Core Market other than the U.S., or (c) *** of receiving written notice thereof if such breach relates to a country other than the Core Markets. Any termination by a Party under this Section 12.3 (Termination by Either Party for Breach) will be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party and will be subject to Section 3.2.4 (Continuation of Sublicenses Upon Termination of this Agreement). ***.
- 12.4. Termination for Cessation of Activities.** Without prejudice to any other remedies available to it at law or in equity (including for any breach of the terms hereof), if ***, LMI may terminate this Agreement with respect to such country with *** written notice to GEHC, unless within such *** period GEHC provides to LMI evidence of GEHC's conduct of any such material Development or Commercialization activities during the applicable time period. ***.

- 12.5. Termination by LMI for Patent Challenges.** If GEHC or any of its Affiliates Challenges an LMI Patent Right in any country in the Territory, then LMI may, in its sole discretion either (a) terminate this Agreement on a country-by-country basis, or (b) leave the Agreement in effect, ***% and, in any case, if LMI so chooses, sue GEHC for infringement in any forum of competent jurisdiction of LMI's choosing.
- 12.6. Termination for Insolvency.** If, at any time during the Term any of the following occur (each an "**Insolvency Event**"): (a) a case is commenced by or against LMI under Title 11, United States Code, as amended, or analogous provisions of Applicable Law outside the U.S. (the "**Bankruptcy Code**") and, in the event of an involuntary case under the Bankruptcy Code, such case is not dismissed within *** after the commencement thereof, (b) LMI files for or is subject to the institution of bankruptcy, liquidation, or receivership proceedings (other than a case under the Bankruptcy Code), (c) LMI assigns all or a substantial portion of its assets for the benefit of creditors, or (d) a receiver or custodian is appointed for LMI's business, or (e) substantially all of either LMI's business is subject to attachment or similar process; then, in any such case ((a), (b), (c), or (d)), GEHC may terminate this Agreement upon written notice to the extent permitted under Applicable Law.
- 12.7. Effects of Termination or Expiration and Certain Events.**
- 12.7.1 All Termination Events.** In the event of any termination (but not expiration) of this Agreement after the Effective Date, (a) except as otherwise provided in this Section 12.7 (Effects of Termination or Expiration) all rights and licenses granted by LMI hereunder will immediately terminate and revert to LMI, (or, where such termination relates to a specific country, each a "**Terminated Country**," solely to the extent relating to such Terminated Country), and (b) except as otherwise provided in this Section 12.7 (Effects of Termination or Expiration and Certain Events) all other rights and obligations of the Parties under this Agreement with respect to the Licensed Compound and Licensed Product will terminate (or, where such termination relates to a Terminated Country, solely to the extent relating to such Terminated Country).
- 12.7.2 Effects of Certain Terminations.** In the event of termination of this Agreement in its entirety or on a country-by-country basis (as set forth in this Section 12.7.2 (Effects of Certain Terminations)) for any reason other than termination by GEHC pursuant to Section 12.3 (Termination by Either Party for Breach) or Section 12.6 (Termination for Insolvency):
- (a) ***
- (b) License Grant to LMI in the Event of Termination in Entirety. In the case of a termination of this Agreement in its entirety, GEHC will and hereby does, and will cause its Affiliates to, effective as of the effective date of termination, grant to LMI an exclusive (subject to any pre-existing agreements), fully paid-up, royalty-free, transferable, perpetual, and irrevocable license and right of reference, with the right to sublicense, solely to Exploit the Terminated Product in the Territory, in and to the following that are related, but not solely related, to the Terminated Product thereof: (i) *** and (ii) ***.

- (c) License Grant to LMI in the Event of Partial Termination. In the case of a termination of this Agreement on a country-by-country basis, GEHC will and hereby does, and will cause its Affiliates to, effective as of the effective date of termination, grant to LMI an exclusive (subject to any pre-existing agreements), fully paid-up, royalty-free, transferable, perpetual, and irrevocable license and right of reference, with the right to sublicense, solely to Exploit the Terminated Product solely in the Terminated Country, in and to (i) ***, and (ii) ***.
- (i) Prosecution and Enforcement of Patent Rights Subject to Exclusive License to LMI. ***.
- (ii) Abandonment. If LMI has commenced Development or Commercialization of a Terminated Product in a Core Market and provided written notice to GEHC of the same, then if GEHC determines to abandon such a Patent Right regarding the Terminated Product in the Territory (in the event of termination in the entirety) or the Terminated Countries (in the event of a partial termination), , or otherwise take any action in any country in the Territory (in the event of termination in the entirety) or the Terminated Countries (in the event of a partial termination) prior to any applicable filing deadline or other date by which GEHC must act to avoid losing any of such Patent Rights with claims Covering the Terminated Product in such country, promptly and, in any event reasonably prior to, and, to the extent reasonably practicable, at least *** in advance of any relevant deadline: (i) GEHC will notify LMI of its determination in writing; (ii) upon receipt of such notice, LMI may, or may allow a Third Party to, file, prosecute, and maintain (in its sole discretion) such Patent Right; (iii) upon LMI's request, GEHC will promptly provide all files related to filing, prosecuting, and maintaining such Patent Right to counsel selected by LMI; and (iv) GEHC will no longer be responsible for such costs and expenses relating to filing, prosecuting, and maintaining (as applicable) such Patent Right. LMI will become responsible for such costs and expenses to the extent that LMI elects, in its sole discretion, to file or continue the prosecution, or maintenance of such Patent Right.
- (iii) Enforcement. If the Agreement has been terminated in its entirety, then the following will apply:
- (1) ***.
- (2) ***.
- (3) ***.
- (4) ***.
- (5) ***.
- (6) ***.
- (d) Further Assurances. ***.

- (e) Sublicense Agreements. If the License granted to GEHC under Section 3.1.1 (License to GEHC) and the sublicenses granted to a Sublicensee terminates, then LMI will enter into a direct license agreement with such Sublicensee in accordance with Section 3.2.4 (Continuation of Sublicenses Upon Termination of this Agreement).
- (f) Patent Information. In the event of termination of this Agreement in its entirety, GEHC, if requested in writing by LMI, will, at LMI's cost and expense, provide (i) material correspondence, as determined in GEHC's sole discretion, with the relevant patent offices pertaining to GEHC's prosecution of the LMI Patent Rights, LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, and Joint Patent Rights in the Territory (or, where such termination relates to a Terminated Country, solely in such Terminated Country), to the extent not previously provided to LMI during the course of the Agreement, and (ii) a report reasonably detailing the status of all LMI Patent Rights, LMI Services Assigned Patent Rights, GEHC Improvement Patent Rights, and Joint Patent Rights at the time of termination or expiration in the Territory (or, where such termination relates to a Terminated Country, solely in such Terminated Country), to the extent not previously provided to LMI or known to LMI.
- (g) Transitional Trademark License. If the effective date of termination in a Terminated Country occurs after the First Commercial Sale in such country, then effective as of the date of termination, GEHC agrees to grant LMI a royalty-free license on GEHC's standard terms and conditions (which terms and conditions will be provided to LMI in writing) to use the Marks Controlled by GEHC solely identifying the Terminated Product for use in connection with the Terminated Product in the Territory (or, where such termination relates to a Terminated Country, solely in such Terminated Country) for a *** period following the effective date of such termination.
- (h) Ongoing Clinical Trials.
 - (i) ***.
 - (II) ***.
 - (III) ***.
 - (IV) ***.
 - (V) ***.
 - (VI) ***.
- (i) Selected Agreements. At LMI's reasonable written request, GEHC will use reasonable efforts where legally able to, and will request its Affiliates and its Sublicensees to, use reasonable efforts to facilitate the transfer to LMI of any Selected Agreement requested by LMI that relates solely to the Terminated Product and to the Terminated Country. If any Selected Agreement relates to another product in addition to the Terminated Product or to another country in addition to the Terminated Country, then at LMI's request, GEHC will use reasonable efforts where legally able, and will request its Affiliates and its Sublicensees to use reasonable efforts where legally able, to facilitate LMI entering into an alternative arrangements to such Selected Agreement.

(j) Supply of Licensed Product. ***.

(k) Further Assistance. GEHC will cooperate as reasonably necessary to facilitate the transfer to LMI of certain rights as set forth in this Section 12.7.2 (Effects of Certain Terminations) and will execute such documents as may be reasonably requested by LMI as reasonably necessary in order to give effect to this Section 12.7.2 (Effects of Certain Terminations).

12.7.3 Survival. Notwithstanding anything to the contrary set forth herein, the following provisions will survive and apply after expiration or termination of this Agreement in its entirety: Sections 3.1.2(b) (License to LMI) (subject to the limitation set forth in this Section 12.7.3), 3.2.4 (Continuation of Sublicenses Upon Termination of this Agreement), 3.4 (Retained Rights), 3.5 (No Implied Licenses), 3.11 (Exclusivity) (to the extent provided therein), Section 7.12 (Financial Records; Audits), Section 7.13 (Pre-Effective Date Costs and Liabilities), 8.1 (Ownership of Inventions), 9.6 (Limitation on Claims for Certain Representations and Warranties), ARTICLE 10 (Indemnification; Insurance; Limitation on Liability), ARTICLE 11 (Confidentiality), 12.7 (Effects of Termination), Section 12.8 (Accrued Rights), Section 12.9 (Rights in Bankruptcy), Section 12.10 (Antitrust), ARTICLE 13 (Dispute Resolution), ARTICLE 14 (Miscellaneous) (other than Section 14.4 (Sale of LMI Patent Rights)). In addition, the other applicable provisions of ARTICLE 7 (Financials) will survive such expiration or termination of this Agreement in its entirety to the extent required to make final reimbursements, reconciliations, or other payments incurred or accrued prior to the date of termination or expiration. For any surviving provisions requiring action or decision by a Committee or an Executive Officer, each Party will appoint representatives to act as its Committee members or Executive Officer, as applicable. All provisions not surviving in accordance with the foregoing will terminate upon expiration or termination of this Agreement and be of no further force and effect. Notwithstanding the foregoing, upon expiration or termination, the license rights granted to LMI pursuant to Section 3.1.2(a) (License to LMI) will terminate and the license granted to LMI pursuant to Section 3.1.2(b) (License to LMI) will not apply to any Patent Rights or Know-How that comes into the Control of GEHC after expiration or termination. In addition, upon expiration, but not termination, the license granted to GEHC pursuant to Section 3.1.1 (License to GEHC) will survive as provided in Section 12.1 (Term).

12.8. Accrued Rights. Expiration or termination of this Agreement will not relieve the Parties of any liability that accrued hereunder prior to the effective date of such expiration or termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, and any such termination will be without prejudice to the rights of either Party against the other. The remedies provided in this ARTICLE 12 (Term and Termination) are not exclusive of any other remedies a Party may have in law or equity, and will not limit a Party from seeking damages, injunctive relief, or other remedies. Without limiting the generality of the foregoing, upon expiration or termination of this Agreement, GEHC will pay to LMI all undisputed amounts due under this Agreement to LMI as of the effective date of termination or expiration and set forth in an invoice within *** following the later of such effective date of termination or expiration and the receipt of such invoice. All payments made pursuant to this Section 12.8 (Accrued Rights) will be non-creditable and non-refundable.

- 12.9. Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by LMI and GEHC are, and will otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of right to “intellectual property” as defined under Section 101 of the Bankruptcy Code. The Parties agree that each Party, as licensee of certain rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties agree that payments by GEHC to LMI owed pursuant to Section 7.3 (Sales Milestones), and Section 7.4 (Royalties) will constitute “royalties” within the meaning of the Bankruptcy Code.
- 12.10. Antitrust.** Notwithstanding anything to the contrary contained in this Agreement, in connection with any investigation by a Government Authority charged with enforcing the antitrust or competition laws of any jurisdiction, (a) GEHC will not be required to terminate this Agreement, and (b) neither GEHC nor any of its Affiliates will be required to (i) license, divest, sell, hold separate, or otherwise take or commit to take any action that limits its freedom of action with respect to, or its ability to retain, the rights, assets or patents licensed under this Agreement (or any of the businesses, product lines, licenses, patents or assets of any of its Affiliates), (ii) alter or restrict in any way the business or commercial practices of GEHC or any of its Affiliates, or (iii) defend through litigation any proceeding commenced by any Governmental Authority in connection with the foregoing matters.

ARTICLE 13

DISPUTE RESOLUTION

- 13.1. Disputes.** In the event of any disputes, controversies, differences, or claims which may arise between the Parties out of or in relation to or in connection with this Agreement (other than disputes arising from a Committee), including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement (“**Disputes**”), other than any Dispute between the Parties arising from or related to Section 3.10.2 (***) , Section 3.10.4 (GEHC Option for Ex-Field License), or Section **Error! Reference source not found.**, upon the request of either Party by written notice, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts will include at least one in-person meeting between the Executive Officers of each Party. If the matter is not resolved within *** following the written request for discussions, then either Party may then invoke the provisions of Section 13.2 (Jurisdiction and Venue). For the avoidance of doubt, other than any Dispute between the Parties arising from or related to Section 3.10.2 (***) , or Section 7.6 (***) , which will be resolved solely in accordance with Section 13.3 (Arbitration for Certain Matters), or any Dispute between the Parties arising from or related to Section 3.10.4 (GEHC Option for Ex-Field License), which will be resolved solely in accordance with Section 13.4 (Baseball Arbitration), any Disputes arising from a Committee pursuant to ARTICLE 2 (Governance) will be resolved solely in accordance with Section 2.4 (Decision Making and Resolution of Disputes).
- 13.2. Jurisdiction and Venue.** Except for any Dispute between the Parties arising from or related to Section 3.10.2 (***) , Section 3.10.4 (GEHC Option for Ex-Field License), or Section **Error! Reference source not found.** (***) , the exclusive jurisdiction and venue for any action arising out of or related to this Agreement will be the state or federal courts in New York, New York and the Parties hereby agree and submit to the personal and exclusive jurisdiction and venue of these courts and agree not to commence any action, suit, or proceeding related to this Agreement except in such courts. THE PARTIES HEREBY EXPRESSLY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL.

- 13.3. Arbitration for Certain Matters.** Any Dispute between the Parties arising from or related to Section 3.10.2 (***) or Section **Error! Reference source not found.** (***) will be settled by binding arbitration administered by the American Arbitration Association in accordance with the then-current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection) (“**AAA Rules**”), or such other rules as the Parties may agree (which will be deemed “AAA Rules” for purposes of this Agreement) as follows. Either Party, following the end of the *** period referenced in Section 2.4.2 (Referral to Executive Officers), may refer such issue to arbitration by submitting a written notice of such request to the other Party. Promptly following receipt of such notice, the Parties will meet and discuss in good faith and agree on an arbitrator to resolve the issue, which arbitrator will be neutral and independent of both Parties and all of their respective Affiliates, will have significant experience and expertise in licensing and partnering agreements in the pharmaceutical and biotechnology industries. If the Parties cannot agree on such arbitrator within *** of request by a Party for arbitration, then such arbitrator will be appointed in accordance with the AAA Rules, which arbitrator must meet the foregoing criteria. The place of arbitration will be New York, New York. All proceedings and communications will be in English. The arbitration will be governed by the procedural and substantive law set forth in Section 14.9 (Governing Law) and the United States Arbitration Act, 9 U.S.C. §§1-16 to the exclusion of any inconsistent state laws. The Parties will have the right to be represented by counsel. Any judgment or award rendered by the arbitrator is subject to Section 10.5 (Limitation of Liability) and will be final and binding on the Parties, and will be governed by the terms and conditions of this Agreement. The Parties agree that such a judgment or award may be enforced in any court of competent jurisdiction. Each Party will bear its own costs and expenses and attorneys’ fees in the arbitration, except that the arbitrator may order the non-prevailing Party to bear all or an appropriate part (reflective of the relative success on the issues) of the costs and expenses and reasonable attorneys’ fees incurred by the prevailing Party based on the relative merits of each Party’s positions on the issues in the dispute.
- 13.4. Baseball Arbitration.** Following GEHC’s exercise of the Option, if the Parties cannot reach agreement and enter into the Ex-Field License Agreement within the Ex-Field License Agreement Negotiation Period, then, subject to Section 3.10.4(d) (Exercise of the Option), the final terms and conditions of such agreement will be determined through binding arbitration as follows:
- 13.4.1 Arbitration Drafts.** Each Party will (a) prepare a draft of the Ex-Field License Agreement to be used in such arbitration proceeding (each, an “**Arbitration Draft**”) and (b) submit its Arbitration Draft to the other Party. Within *** of such submissions, the Parties will meet to determine whether they agree to enter into either Party’s Arbitration Draft or a modified version thereof as the Ex-Field License Agreement.
- 13.4.2 Determination of Financial Terms.** If the Parties are unable to agree within the *** period set forth in Section 13.4.1 (Arbitration Drafts) on the financial terms of the Ex-Field License Agreement, then such financial terms to be included in the Ex-Field License Agreement will be determined by an independent Third Party valuation firm to be agreed by the Parties.
- 13.4.3 Arbitration for Non-Financial Terms.** If the Parties are unable to agree within the *** period set forth in Section 13.4.1 (Arbitration Drafts), following the determination of the valuation firm of the applicable financial terms pursuant to Section 13.4.2 (Determination

of Financial Terms), either Party may require an arbitral tribunal to be appointed in accordance with the provisions of Section 13.3 (Arbitration for Certain Matters) and, within *** after the appointment of such an arbitral tribunal, each Party will submit its Arbitration Draft to the arbitral tribunal for determination of the non-financial terms. The arbitral tribunal will be instructed to select one of the Parties' Arbitration Drafts within *** following the receipt of the latter of such Arbitration Drafts and to select the draft that it determines to contain the most fair, balanced, and customary terms consistent with the intent of this Agreement. Such decision will be made in accordance with the provisions of Section 13.3 (Arbitration for Certain Matters); *provided that* the arbitral tribunal will be limited to selecting only one or the other of the Arbitration Drafts submitted by the Parties. The selection by the arbitral tribunal of one Party's Arbitration Draft will be binding and conclusive upon both Parties and their Affiliates.

13.4.4 Arbitration Fee and Costs. The (a) fees of the arbitrators, and (b) costs and expenses of the arbitration will be borne by the Party whose Arbitration Draft is not selected by the arbitral tribunal.

13.5. Confidentiality. Any arbitration proceeding will be confidential and the arbitrator will issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by law, no Party will make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the arbitrator without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, will be kept in confidence by the Parties and the arbitrator, except as required in connection with the enforcement of such award or as otherwise required by Applicable Law. All proceedings and decisions of the arbitrator will be Confidential Information of each of the Parties and will be subject to ARTICLE 11 (Confidentiality).

13.6. Injunctive Relief. Nothing in this ARTICLE 13 (Dispute Resolution) will preclude either Party from seeking equitable relief or interim or provisional relief from any court of competent jurisdiction, including a temporary restraining order, preliminary injunction, or other interim equitable relief.

ARTICLE 14

MISCELLANEOUS

14.1. Notices. Any notice required or permitted to be given under this Agreement will be in writing, will specifically refer to this Agreement, and will be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 14.1 (Notices), and will be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by a reputable international expedited delivery service, or (b) after actual receipt or refusal, if mailed by first class certified or registered mail, postage prepaid, return receipt requested. This Section 14.1 (Notices) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

If to GEHC: GE Healthcare Limited
The Grove Center
White Lion Road
Amersham, England
HP7 9LL
Attention: PET Global Product Leader

With a copies to: GE Healthcare
100 Results Way
Marlborough, MA 01752
Attention: General Counsel

GE Healthcare
100 Results Way
Marlborough, MA 01752
Attention: Head of Licensing

If to LMI: Lantheus Medical Imaging
331 Treble Cove Road
North Billerica, MA 01862
Attention: General Counsel

With a copy to: Ropes & Gray LLP
800 Boylston Street
Boston, MA 02199-3600
Attention: David M. McIntosh

14.2. Assignment. Except as permitted under Section 3.2 (Sublicensing Rights) and Section 3.3 (Subcontractors), neither Party may assign or otherwise transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, which consent will not be unreasonably withheld, conditioned, or delayed. Notwithstanding the foregoing, (a) either Party may assign its rights under this Agreement to an Affiliate or to a Third Party successor, by way of sale, acquisition, or transfer of itself or the sale, acquisition or transfer of the portion of its business or assets to which this Agreement relates, whether through merger, acquisition, consolidation, transfer or sale of assets, or sale of stock or ownership interest, without the other Party's prior written consent; provided that (i) written notice of such assignment is promptly given to the other Party and (ii) with respect to LMI, such assignment will be subject to the provisions of Section 14.3(b) (Change of Control); and (b) a Party may assign its right to receive payments under this Agreement as part of a royalty factoring transaction undertaken for bona fide financing purposes; provided that prior written notice of such assignment is given to the other Party. Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 14.2 (Assignment) will be null, void, and of no legal effect.

- 14.3. Change of Control.** ***.
- 14.4. Sale of the LMI Patent Rights.** During the Term, if LMI intends to sell, to any Third Party the LMI Patent Rights, other than in connection with a sale of LMI's radiopharmaceutical business, a Change of Control, or a royalty factoring transaction undertaken for bona fide financing purposes, then, in each case, LMI will first notify GEHC in writing prior to providing such notice to or engaging in discussions with any Third Party. GEHC will have *** to inform LMI whether or not it wishes to engage in negotiations with LMI with respect to such sale. If GEHC so notifies LMI in writing within such *** period, then for a period of *** the Parties will negotiate in good faith the terms and conditions of purchase and sale agreement for the LMI Patent Rights. If (a) GEHC does not provide written notice to LMI indicating its desire to enter into negotiations with LMI within *** of receiving LMI's offer notice, or (b) GEHC and LMI cannot agree on the terms of a definitive agreement within ***, then, in either case ((a) or (b)), LMI will be free to sell to a Third Party the LMI Patent Rights; *provided that*, in the case of (b) above, during the *** period following the conclusion of the negotiations between the Parties, LMI will not sell to any Third Party the LMI Patent Rights on terms and conditions that are more favorable in the aggregate to the applicable Third Party than the terms and conditions last proposed by LMI to GEHC during the *** negotiation period.
- 14.5. Entire Agreement; Amendment.** This Agreement, including the Schedules and Exhibits hereto, sets forth the complete, final, and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions, and understandings between the Parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings between the Parties existing as of the Effective Date with respect to the subject matter hereof. In the event of any inconsistency between any plan hereunder (including the Development Plan, or Commercialization Plan) and this Agreement, the terms of this Agreement will prevail. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change, or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.
- 14.6. Non-Solicitation by GEHC.** GEHC agrees that, during the Term prior to the First Commercial Sale of a Licensed Product, it will not, directly or indirectly, solicit to employ or engage as an independent contractor any ***. Notwithstanding the above, the following solicitations will not be prohibited: (a) solicitations by independent contractors of GEHC or its Affiliates, so long as they are not specifically directed by GEHC to solicit such individuals; (b) solicitations initiated through general advertisements and general circulation materials not directly targeted at such individuals; and (c) solicitations of such individuals who have first contacted GEHC on their own initiative, directly or through Third Party recruiters, regarding employment or engagement as an independent contractor. If a Major Competitor acquires control of LMI in a Change of Control transaction this Section 14.6 (Non-Solicitation by GEHC) and Section 5.5.2(i) (the non-solicitation subsection in Co-Promotion Principles) will be automatically terminated, and upon the occurrence of a Triggering Event, the restrictions on solicitation set forth in this Section 14.6 (Non-Solicitation by GEHC) and in Section 5.5.2(i) (the non-solicitation subsection in Co-Promotion Principles) will be suspended during the pendency of such Triggering Event.
- 14.7. Force Majeure.** Neither Party will be liable to the other for damage, or have any right to terminate this Agreement during an Event of Force Majeure. An "Event of Force Majeure" means a cause beyond the reasonable control of the affected Party, including fire, floods, embargoes, terrorism, war, acts of war (whether war is declared or not), insurrections, riots, civil

commotions, strikes, lockouts, or other labor disturbances, acts of God or acts, omissions or delays in acting by any Governmental Authority, Third Party, or the other Party. Upon the occurrence of an Event of Force Majeure, the affected Party will provide prompt written notice to the other Party of the occurrence of such Event of Force Majeure, and to the extent so affected, such Party's obligations will be suspended during the period of such disability. The Party prevented from performing by an Event of Force Majeure will use reasonable efforts to continue performance as soon as reasonably practicable after such causes are removed. The Party so affected will provide the other Party a good faith estimate of the continuing effect of the Event of Force Majeure and the duration of the affected Party's nonperformance and the Parties will discuss such matter in the JSC; *provided, however*, that if the Event of Force Majeure continues for *** or longer, then the Party not affected by the Event of Force Majeure may terminate this Agreement effective immediately upon written notice to the affected Party and the effects of Section 12.7 (Effects of Termination or Expiration and Certain Events) will apply, to the extent feasible.

- 14.8. No Strict Construction; Headings.** This Agreement has been prepared jointly and will not be strictly construed against either Party. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.
- 14.9. Governing Law.** This Agreement will be governed by and construed under the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the law of another jurisdiction.
- 14.10. Further Actions.** Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 14.11. Compliance with Applicable Law.** Each Party will comply with Applicable Law in the course of performing its obligations or exercising its rights pursuant to this Agreement.
- 14.12. Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by an arbitrator or by any court of competent jurisdiction from which no appeal can be or is taken, the provision will be considered severed from this Agreement and will not serve to invalidate any remaining provisions hereof. The Parties will make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.
- 14.13. No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.
- 14.14. Rules of Construction.** Interpretation of this Agreement will be governed by the following rules of construction: (a) words in the singular will be held to include the plural and vice versa, and words of one gender will be held to include the other gender as the context requires; (b) references to the terms "Section," or "Schedule" are to a Section or Schedule of this Agreement unless otherwise specified; (c) the terms "hereof," "hereby," "hereto," and derivative or similar words refer to this entire Agreement; (d) references to "\$" or "Dollars" will mean the currency of the U.S. and all references to "€" or "Euros" will mean the currency of the European Union; (e) the word "including" and words of similar import when used in this Agreement will mean

“including without limitation,” unless otherwise specified; (f) the word “or” will not be exclusive; (g) references to “written” or “in writing” include in electronic form; (h) the titles and headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement; (i) each of the Parties has participated in the negotiation and drafting of this Agreement and if an ambiguity or question of interpretation should arise, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or burdening either Party by virtue of the authorship of any of the provisions in this Agreement or any interim drafts of this Agreement; (j) the word “will” will be construed to have the same meaning and effect as the word “shall”; (k) references to “days” will mean calendar days, unless otherwise specified; and (l) a reference to any Person includes such Person’s successors and permitted assigns.

14.15. Independent Contractors. Each Party will act solely as an independent contractor, and nothing in this Agreement will be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein will be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

14.16. Counterparts. This Agreement may be executed in any number of counterparts and by facsimile signature or other electronic transmission, each of which will be enforceable against the Party actually executing the counterpart, and all of which together will constitute one instrument.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have cause their duly authorized representatives to execute this Collaboration and License Agreement in duplicate originals as of the Effective Date.

GE HEALTHCARE LIMITED

By: /s/ Emmanuel Ligner
Name: Emmanuel Ligner
Title: General Manager, GE Healthcare

LANTHEUS MEDICAL IMAGING, INC.

By: /s/ Mary Anne Heino
Name: Mary Anne Heino
Title: President and Chief Executive Officer

Schedule 1.7

Analog Structure

Schedule 1.84

Licensed Compound

Schedule 1.126

Precursor

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.**

**AMENDED AND RESTATED
SUPPLY AGREEMENT**

THIS AMENDED AND RESTATED SUPPLY AGREEMENT (this "**Agreement**") is entered into as of April 25, 2017 (the "**Effective Date**") by and between MEDI-PHYSICS INC., a Delaware corporation doing business as "GE Healthcare," having a place of business at 100 Results Way, Marlborough, MA 01752, United States of America ("**GE Healthcare**") and LANTHEUS MEDICAL IMAGING, INC., a Delaware corporation having its principal place of business at 331 Treble Cove Road, North Billerica, MA 01862, United States of America ("**LMI**"). GE Healthcare and LMI are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS:

WHEREAS, the Parties entered into a Distribution Agreement, dated as of October 31, 2001, as amended by the First Amendment to Distribution Agreement, dated as of January 1, 2005, as further amended by the Second Amendment to Distribution Agreement, dated as of January 1, 2012 and as further amended by the Third Amendment to Distribution Agreement, dated as of December 1, 2014 (such agreement, as amended, the "**Original Agreement**"), pursuant to which LMI manufactured and supplied to GE Healthcare TechnoLite® generators and other products.

WHEREAS, the Parties now desire to amend and restate the Original Agreement in its entirety such that this Agreement is in effect from and after the Effective Date.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE 1. Definitions

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, will have the meanings set forth in this ARTICLE 1.

1.1 “**Adverse Drug Experience**” shall mean any unfavorable and/or unintended change in the structure (signs), function (symptoms), or chemistry (laboratory data) of the body temporally associated with the use of a Product (as defined in ARTICLE 2) or of a derivative thereof in humans, whether or not considered drug related, including the following: an adverse experience occurring in the course of the use of a drug in professional practice, an adverse experience occurring from drug overdose, whether accidental or intentional, an adverse experience occurring from drug withdrawal, and any significant failure of expected pharmacological action.

1.2 “**Agreement**” has the meaning set forth in the Preamble.

1.3 “***** Forecast**” has the meaning set forth in Section 3.3 (*** Forecasting).

1.4 “**Disclosing Party**” has the meaning set forth in ARTICLE 9 (Confidentiality).

1.5 “**Effective Date**” has the meaning set forth in the Preamble.

1.6 “**FDA**” means the United States Food and Drug Administration.

1.7 “**Firm Order**” has the meaning set forth in Section 3.4 (Firm Orders).

1.8 “**GEH Mo-99**” means GE Healthcare’s supply of Mo-99.

1.9 “**GE Healthcare**” has the meaning set forth in the Preamble. For the avoidance of doubt, GE Healthcare shall also mean GE Healthcare Radiopharmacies unless specifically stated otherwise in the terms of this Agreement.

1.10 “**GE Healthcare Radiopharmacies**” means, at any given time, those free-standing radiopharmacies in the Territory in which GE Healthcare or any of its affiliates has at least *** percent (***) direct or indirect (through their respective affiliates) ownership interest at such time unless otherwise agreed to by the Parties. In addition, in the future to the extent ***, the Parties agree to negotiate reasonably and in good faith ***, with the intent of most closely aligning with the economics reflected in this Agreement as of the Effective Date.

1.11 “**Integrity Guide**” has the meaning set forth in Section 7.1(g) (LMI Warranties).

1.12 “**LMI**” has the meaning set forth in the Preamble.

1.13 “**Minimum Purchase Requirements**” has the meaning set forth in Section 3.1(a) (Minimum Purchase Requirements).

1.14 “**NDA**” has the meaning set forth in Section 6.2 (Replacement Products).

- 1.15 “**Negotiation Period**” has the meaning set forth in Section 10.3 (Termination for Economic Reasons).
- 1.16 “**New GE Healthcare Radiopharmacy**” has the meaning set forth in Section 3.1(a) (Minimum Purchase Requirements).
- 1.17 “**Original Agreement**” has the meaning set forth in the Recitals.
- 1.18 “**Party**” or “**Parties**” has the meaning set forth in the Preamble.
- 1.19 “**Products**” has the meaning set forth in ARTICLE 2 (Supply Relationship).
- 1.20 “**Product Information**” has the meaning set forth in Section 4.5 (Product Information).
- 1.21 “**Proprietary Information**” has the meaning set forth in ARTICLE 9 (Confidentiality).
- 1.22 “**Purchase Order**” has the meaning set forth in Section 3.2 (Purchase Orders).
- 1.23 “**Quarter**” means each of the three (3) month periods ending on March 31, June 30, September 30 and December 31 of any year; provided that the last quarter shall end on the date of termination of this Agreement.
- 1.24 “**Receiving Party**” has the meaning set forth in ARTICLE 9 (Confidentiality).
- 1.25 “**Shortfall Payment for Gallium and Xe-133**” has the meaning set forth in Section 3.1(b) (Minimum Purchase Requirements).
- 1.26 “**Shortfall Payment for TechneLite®**” has the meaning set forth in Section 3.1(c) (Minimum Purchase Requirements).
- 1.27 “**TechneLite®**” means terminally sterilized Technetium (Tc-99m) generators branded as TechneLite®.
- 1.28 “**Term**” has the meaning set forth in Section 10.1.
- 1.29 “**Territory**” means ***, including ***.
- 1.30 “**Trademarks**” means the trademarks listed in Exhibit B.

ARTICLE 2. Supply Relationship

All purchases by GE Healthcare from LMI of the TechneLite[®], Gallium Citrate Ga-67 Injection and Xe-133 gas products listed on Exhibit A (the “**Products**”) during the Term will be governed by this Agreement. Subject to the terms and conditions of this Agreement, LMI hereby grants to GE Healthcare the non-exclusive right to market, distribute and sell TechneLite[®] Products in *** solely by way of ***. In addition, subject to the terms and conditions of this Agreement, LMI agrees to supply Products to GE Healthcare Radiopharmacies in the Territory solely for their unit dose preparation in the Territory.

ARTICLE 3. Supply of Products

3.1 Minimum Purchase Requirements.

(a) GE Healthcare guarantees, subject to LMI’s ability to supply, a minimum purchase requirement of Products as set forth in this Section 3.1. From and after the Effective Date, LMI agrees to use commercially reasonable best efforts to manufacture and sell to GE Healthcare, and GE Healthcare agrees to purchase from LMI, the following requirements (collectively, the “**Minimum Purchase Requirements**”):

- (i) *** percent (***) of GE Healthcare’s and its affiliates’ requirements for Xe-133 gas Product from the Effective Date through the end of the Term; and
- (ii) *** percent (***) of GE Healthcare’s and its affiliates’ requirements for Gallium Citrate Ga 67 Product from the Effective Date through the end of the Term; and
- (iii) such percentages of GE Healthcare’s and its affiliates’ requirements for Technetium-99m products as set forth on Exhibit A hereto;

provided that (A) the Minimum Purchase Obligations described in clause (iii) above apply only to locations that are GE Healthcare Radiopharmacies as of the Effective Date, and only the purchases of TechneLite[®] Products by such GE Healthcare Radiopharmacies will apply towards meeting GE Healthcare’s overall requirements set forth on Exhibit A hereto; (B) the Minimum Purchase Obligations for any location that first becomes a GE Healthcare Radiopharmacy (however such a transaction is structured) after the Effective Date (each, a “**New GE Healthcare Radiopharmacy**”) will equal ***; and (C) GE Healthcare agrees to negotiate reasonably and in good faith a further commitment for each existing GE Healthcare Radiopharmacy and New GE Healthcare Radiopharmacy to ***.

(b) Compliance with the Minimum Purchase Requirements for Gallium Citrate Ga-67 Injection and Xe-133 gas Products set forth in Sections 3.1(a)(i) and (ii) will be determined as of *** and as of the end of each *** thereafter (as evidenced by reasonable documentation made available to LMI or its representatives upon the request of LMI or its representatives). Not later than *** (***) days after the end of each ***, GE Healthcare shall provide to LMI, upon the request of LMI or its representatives, a timely, complete and accurate report that sets forth GE Healthcare's total requirements for each Gallium Citrate Ga-67 Injection and Xe-133 gas Product and certifies that GE Healthcare has complied or failed to comply with its obligation to purchase the Minimum Purchase Requirements for such Products for such ***. In any *** in which GE Healthcare does not purchase at least the applicable Minimum Purchase Requirements for such Products from LMI, GE Healthcare shall promptly pay to LMI the Shortfall Payment for Gallium and Xe-133 (as hereinafter defined). For purposes of minimizing such payments, GE Healthcare will make a good faith estimate of the Product orders for each *** in the then-current *** and will use commercially reasonable best efforts to (i) place purchase orders in the last *** of such *** for such additional amounts of such Product(s) as may be necessary to avoid (or at least minimize) such payments (subject to LMI's ability and mutual agreement to fill such excess orders, which LMI will use its commercially reasonable best efforts to do) or (ii) make any necessary payments prior to the end of such ***; provided that, notwithstanding the foregoing obligations, (x) in order to assist LMI with optimizing its manufacturing schedule for Gallium Citrate Ga-67 Injection and Xe-133 gas Product, GE Healthcare will use commercially reasonable best efforts to place purchase orders for Gallium Citrate Ga-67 Injection and Xe-133 gas Products in a manner that results in a consistent *** average of *** for each such Product (measured on a **** basis) and (y) by the *** of the *** immediately succeeding such ***, GE Healthcare shall make any necessary true-up payments to comply with the requirements of this Section 3.1(b).

“**Shortfall Payment for Gallium and Xe-133**” shall mean the *** payment for any portion of the Minimum Purchase Requirements for Gallium Citrate Ga-67 Injection and Xe-133 gas Products not purchased by GE Healthcare from LMI during such *** (subject to LMI's ability to supply). Such payments will be calculated using the shortfall in the Minimum Purchase Requirements for such Products for such *** (i.e., the remaining portion of the applicable Minimum Purchase Requirements for such Products for which purchase orders were not received) multiplied by the price of the applicable Product(s) hereunder (based on ***).

(c) Compliance with the Minimum Purchase Requirements for TechnoLite® Products set forth in Section 3.1(a)(iii) and Exhibit A hereto will be determined as of *** (which, for the avoidance of doubt, will be measured in reference to the purchase commitments in effect under the Original Agreement prior to this amendment and restatement) and as of the end of each *** or portion thereof following the Effective Date thereafter (as evidenced by reasonable documentation made available to LMI or its representatives upon the request of LMI or its

representatives). Not later than *** (*** days after the end of each ***, GE Healthcare shall provide to LMI, upon the request of LMI or its representatives, a timely and accurate report that sets forth GE Healthcare's total requirements for Technetium-99m products and, for the report as of the end of the ***, certifies that GE Healthcare has complied or failed to comply with its obligation to purchase the Minimum Purchase Requirements for TechneLite® Products for such period. In any *** in which GE Healthcare does not purchase at least the applicable Minimum Purchase Requirements for TechneLite® Products from LMI, GE Healthcare shall promptly pay to LMI the Shortfall Payment for TechneLite® (as hereinafter defined). By the end of the *** of the *** immediately succeeding such ***, GE Healthcare shall make any necessary true-up payments to comply with the requirements of this Section 3.1(c). Notwithstanding the foregoing obligations, in order to assist LMI with optimizing its manufacturing schedule for TechneLite® Products, GE Healthcare will use commercially reasonable best efforts to place purchase orders for TechneLite® Products in a manner that results in a consistent *** average of curies of molybdenum of TechneLite® Products (measured on a *** basis).

“**Shortfall Payments for TechneLite®**” will be calculated using the shortfall in the Minimum Purchase Requirements for TechneLite® Product for such *** (i.e., the remaining portion of the applicable Minimum Purchase Requirements for which purchase orders were not received) multiplied by the price of the applicable TechneLite® Products hereunder (based on ***), and such Shortfall Payments shall not result in a deemed increase in curie volume which could otherwise lead to a potentially higher rebate amount payable by LMI to GE Healthcare as specified in Exhibit A hereto.

(d) For purposes of clarity, the Parties acknowledge and agree that (i) the Minimum Purchase Requirements set forth herein shall include all of GE Healthcare's and its affiliates' requirements (including any requirements to ***) for similar products (for example, the Minimum Purchase Requirements for TechneLite® Products shall include all of GE Healthcare's and its affiliates' requirements for Technetium-99m products) and (ii) the requirements of GE Healthcare and its affiliates at any given time will include the requirements of all GE Healthcare Radiopharmacies existing at that time.

3.2 **Purchase Orders.** All orders for purchases of Products by GE Healthcare shall be submitted on GE Healthcare's standard purchase order form as from time to time in use by GE Healthcare (“**Purchase Order**”). The terms of this Agreement shall take precedence over any standard terms of any Purchase Order where in conflict or impose additional terms or conditions.

3.3 ***** Forecasting.** Upon the Effective Date and no later than *** of any *** during the Term of this Agreement, GE Healthcare shall provide LMI with a written forecast of the numbers and type of Products which GE Healthcare expects to purchase from LMI during the forthcoming ***, as the case may be (the “*** Forecast”).

3.4 **Firm Orders.** GE Healthcare shall place *** standing orders setting forth the quantities, delivery schedules and dates, and its shipping instructions *** (**) weeks prior to the *** through *** cycle (each, a “**Firm Order**”). Once placed by GE Healthcare, such Firm Orders may be cancelled, increased or decreased only in accordance with LMI’s order cancellation and modification as in effect from time to time (which LMI can change upon written notice to GE Healthcare) or otherwise with prior LMI approval. Subject to GE Healthcare’s limited right to adjust Firm Orders set forth in the previous sentence, such Firm Orders shall constitute binding contractual obligations of GE Healthcare.

3.5 **Number and Mix of Products.** Although an *** Forecast shall not constitute a binding obligation upon GE Healthcare to order the quantities specified therein, GE Healthcare agrees to use all commercially reasonable best efforts to make each *** Forecast a reasonably accurate prediction of the number and mix of Products GE Healthcare will actually order for delivery in the relevant period pursuant to its Firm Orders.

3.6 **Shipment; Manufacturing.** LMI shall use commercially reasonable best efforts to ship Products pursuant to GE Healthcare’s Firm Orders. All Products shall be shipped *** place designated by GE Healthcare in its Purchase Order. Days of manufacture of (i) TechneLite® Products are currently ***, ***, ***, and ***, (ii) Xe-133 gas Products are currently ***, calibrated for the following ***, and (iii) Gallium Citrate Ga-67 Injection Products are currently ***, calibrated for the following ***. LMI will provide GE Healthcare with *** (**) days’ prior written notice of any LMI initiated, permanent changes in the manufacturing schedule for the Products or fundamental change to the chemical composition or functionality of one or more of the Products, provided, however, that LMI will make a *** that, based on GE Healthcare’s Standing Orders at the time of any such change, are adversely affected by the new manufacturing schedule. Any *** to GE Healthcare that can reasonably be linked to the LMI manufacturing schedule change will be reimbursed by LMI to GE Healthcare via a corresponding ***. For purposes of the foregoing, GE Healthcare’s *** will be measured by the *** that LMI is required to provide GE Healthcare on *** as a direct result of the change to the manufacturing schedule (e.g., ***). In the event LMI is unable to deliver all Product requirements on a given day, LMI will make *** of the available Product to GE Healthcare, such *** to be determined by LMI in its reasonable discretion acting reasonably after due consideration of ***, other percentage supply requirements and the available amount of Product for LMI’s customers, including GE Healthcare, affected by such supply disruption***. In the event that delivery of a TechneLite® Product is delayed more than *** (**) hours past the agreed upon local delivery time, LMI will reduce the price GE Healthcare pays for such Product up to *** percent (***)%. However, after *** (**) hours’ delay, GE Healthcare shall not be required to accept such Product and may make arrangements with LMI to return unopened TechneLite® Product for full credit. Following the *** hour period outlined above, in the event that GE Healthcare is required to find an alternate source of technetium generator product, LMI shall pay the difference between LMI’s price under this Agreement and the price GE Healthcare is required to pay to

obtain such technetium generator product, up to a limit of *** percent (***) of LMI's then current price, provided that such obligation shall only apply if GE Healthcare has purchased all of its Minimum Purchase Requirements hereunder and GE Healthcare has used its commercially reasonable best efforts to avoid or mitigate any such payments. The foregoing shall not apply to delays caused by force majeure events such as weather conditions, effecting transportation of components or Products, for which there will be no ***.

3.7 Purchase Prices and Handling Fees. The purchase prices and handling fees to be charged to GE Healthcare for the *** are shown in Exhibit A and the mechanism to calculate future pricing and handling fees for each Product is set forth in Exhibit A. Included in the prices of the TechneLite® Products are:

- (i) *** (***) external generator shields per initial TechneLite® Standing Order (***);
- (ii) *** (***) elution shields per initial TechneLite® Standing Order (***) and
- (iii) *** vials of any combination of saline and evacuation vials (***) or (***) per each TechneLite® Standing Order.

In the event that GE Healthcare can secure *** for all of the handling services that LMI performs in connection with shipping Product under this Agreement (e.g., coordinating and securing pickup and shipping, preparation of shipping documentation, tracking of shipments and handling any delivery issues) and such third party is qualified and complies with applicable laws and regulations, then LMI shall allow GE Healthcare to take on, and GE Healthcare shall take on, the sole responsibility, at GE Healthcare's sole cost and expense, for all such handling activities (and, to the extent that GE Healthcare performs (or has performed) all handling activities, LMI will not be entitled to charge GE Healthcare handling fees). In such an event, notwithstanding Section 3.8, delivery shall be *** (LMI's loading dock in North Billerica, MA), and title and all risk of loss to Product will transfer to GE Healthcare at LMI's loading dock. Timelines for (i) transfer of responsibility for the handling activities and (ii) an appropriate price adjustment as a result of such transfer of responsibility shall each be agreed by the Parties acting reasonably and in good faith before starting.

3.8 Delivery Terms. Subject to the last paragraph of Section 3.7, delivery of Products to GE Healthcare hereunder shall be made by the carriers and methods selected by LMI, and LMI will charge GE Healthcare for delivery of Products the handling fees set forth on Exhibit A. If so requested by GE Healthcare, LMI will arrange for alternative shipment of Products in accordance with GE Healthcare's shipping instructions contained in a Firm Order. This includes shipment of *** calibrated TechneLite® for delivery "prior to first run ***." Notwithstanding any other provision in this Agreement, LMI shall incur no liability of any nature whatsoever to GE Healthcare or its affiliates, with respect to LMI's performance of shipping duties on GE Healthcare's behalf other than because of LMI's gross negligence.

3.9 Payment Terms. All payment for Products ordered by GE Healthcare from and after the Effective Date during the term of this Agreement shall be made within *** (***) days after receipt of invoice. Interest will be payable on all amounts not paid on the due date at a rate of ***% per month (or, if lower, the maximum interest rate permitted by applicable law) and will accrue from the due date until such sum is paid.

3.10 Access to Low Enriched Uranium (LEU) molybdenum. From the Effective Date until such time as LMI sources all of its requirements for molybdenum from LEU targets, in the event that LMI sources LEU molybdenum on a consistent and reliable basis for any of its designated LEU TechneLite® Generator production days, then LMI shall provide to GE Healthcare an option to purchase up to *** (measured based on GE Healthcare's actual purchases of LEU TechneLite® Ci's over the previous *** (***) months, relative to the purchases of all of LMI's other customers over such time) of Ci's of LEU TechneLite® Generators available for purchase on such production day.

ARTICLE 4. Distribution and Sale of Products

4.1 Compliance with Law. GE Healthcare shall be responsible for compliance with all federal and state rules and regulations which relate to the sale, promotion, distribution, use and final disposition of Products in the Territory. All communications that GE Healthcare or its affiliates make about the Products in promotional materials or otherwise shall be consistent with the New Drug Applications or other governmental registrations for the Product, fully truthful, based on documented facts, and fairly balanced. GE Healthcare and its affiliates shall not under any circumstances state or imply in promotional materials or otherwise that the Xenon gas vials purchased by GE Healthcare hereunder can be used with Xenon gas delivery systems other than the Xenon-133 Calidose™ Dispenser System. LMI agrees to supply free of charge *** (***) Xenon-133 Calidose™ Dispenser System per ***.

4.2 Required Licenses. GE Healthcare shall ensure that LMI receives a copy of the license renewals or amendments of each GE Healthcare customer to which TechneLite® Products are to be drop shipped directly by LMI, authorizing such customer's receipt and use of the Products in order to keep current LMI's present file of such licenses (other than in cases where the relevant regulatory authorities permit shipment notwithstanding the failure to supply or provide such copies). LMI shall not be obligated to ship to any such GE Healthcare drop ship customers which fails to provide such license, and LMI shall, immediately upon receiving the order from GE Healthcare, verify the GE Healthcare drop ship customer's licensed status and notify GE Healthcare immediately if such inability to ship exists so GE Healthcare may take such steps as are available to it to remedy the situation. Such refusal to ship to a drop ship customer, whose license file in LMI's custody is not current and which defect is not remedied by GE Healthcare, shall not be deemed an inability or failure on LMI's part to deliver Product in a timely fashion in order to meet GE Healthcare's required deadlines.

4.3 Promotional Literature. GE Healthcare agrees to provide to LMI copies of GE Healthcare's promotional literature related to Products for LMI to transmit to FDA. LMI will play no role in obtaining approval of that material other than taking any administrative action necessary because of LMI's ownership of the registration.

4.4 Pricing Decisions. GE Healthcare shall have the sole right to determine the resale price, discount and any other terms and conditions for GE Healthcare's drop shipment sales of TechneLite® Products or its sales of unit doses prepared using the Products. GE Healthcare shall have complete control over the manner and methods of the marketing, distribution *** and sale of Products, and GE Healthcare may distribute *** and sell Products directly or through affiliates and may hire or retain marketing or other experts to advise and assist GE Healthcare in the distribution and sale of Products. Except as specifically stated herein, LMI shall play no role in GE Healthcare's marketing, distribution and sale of Products.

4.5 Product Information. Prior to use of any label, labeling, advertising or promotional item related to the Products (hereinafter referred to collectively as "**Product Information**") by GE Healthcare or its affiliates, including but not limited to any package insert, product label, detail aid, direct mail piece, file card, journal article, or reminder advertisement, GE Healthcare shall submit a sample of the Product Information to LMI for review. Provided, however that:

(a) GE Healthcare shall not submit any information about pricing of Products to LMI. If a sample of Product Information contains pricing information, GE Healthcare shall redact that information from the sample prior to providing it to LMI; and

(b) LMI shall review the Product Information solely for the following purposes: (1) to ensure compliance with the terms of LMI's New Drug Applications or other governmental registrations for the Products; (2) to ensure that the Product Information is within the terms of the labeled indications for the Products and is otherwise consistent with the approved package inserts for the Products; and (3) to ensure that the Product Information is not likely to give rise to any formal or informal action, complaint or comment by or from the United States FDA regarding the Product Information or the Products; and

(c) Review by LMI of a sample of Product Information shall not serve as admission, a representation or evidence thereof, by LMI, that the Product Information: (1) is correct, accurate, or complete; or (2) is within the scope of or consistent with the Product claims made by LMI; or (3) is in compliance with the terms of this Agreement. Review of Product Information by LMI shall not in any way alter or affect the indemnity given by GE Healthcare pursuant to Section 7.5.

(d) GE Healthcare shall provide LMI a sample of all Product Information and LMI shall have *** (***) working days after receiving the sample within which to review and comment on the Product Information. All comments made by LMI shall be binding on GE Healthcare or its affiliates, which shall implement and incorporate into the Product Information all comments made by LMI. If LMI does not respond within *** (***) working days, GE Healthcare or its affiliates may use the Product Information unchanged.

ARTICLE 5. Trademarks

5.1 Use of Trademarks. LMI hereby grants to GE Healthcare and GE Healthcare hereby accepts the right to resell the Products supplied by LMI to GE Healthcare in packages bearing the Trademarks and in promotional materials related to such Products. The rights granted GE Healthcare hereunder to use the Trademarks shall in no way affect LMI's ownership of such Trademarks. No other right, title or interest in the Trademarks is established hereby, and nothing herein shall be construed to grant any right or license to GE Healthcare to use the LMI logo or the LMI trade name, other than as specifically set forth herein. The Parties agree and understand that this Section 5.1 does not expand the rights granted to GE Healthcare under ARTICLE 2.

5.2 Rights of LMI in Trademarks. GE Healthcare shall not make any use or take any action with respect to the Trademarks to prejudice or infringe LMI's rights thereto including the use of any confusingly similar trademark and shall forthwith, upon objection by LMI, desist from any use thereof or action therewith which is in violation of this Agreement.

5.3 Use During the Term. GE Healthcare will only market the Products using the relevant Trademarks during the Term of this Agreement. Upon termination or expiration of this Agreement, GE Healthcare will cease all use of the Trademarks and the license to use any such Trademarks granted hereunder shall immediately cease and be deemed canceled.

5.4 Trademark Protection. GE Healthcare will use the Trademarks in strict accordance with the instructions given by LMI, and shall not make any changes in connection therewith without first obtaining LMI's written consent. GE Healthcare further agrees that at all times the Trademarks shall be used in accordance with good trademark practice, including notation of the fact that they are trademarks belonging to LMI and use of the appropriate notice of registration. LMI reserves the right to unilaterally determine the adequacy of the use and protection given the Trademarks by GE Healthcare as set forth herein.

5.5 Assistance to LMI. GE Healthcare shall promptly notify LMI, in writing, of any conflicting use of, and applications or registrations for, any of the Trademarks, or any acts of infringement, or acts of unfair competition involving the Trademark, after such matters are brought to its attention or it has knowledge thereof. GE Healthcare further agrees to assist LMI, at LMI's expense, in registering or perfecting LMI's rights to the Trademarks in the Territory.

5.6 Enforcement and Defense Actions. In the event of any claim or litigation by a third party against GE Healthcare alleging that any of the Trademarks imitates or infringes a trademark of such third party or is invalid, GE Healthcare shall promptly give notice of such claims or litigation to LMI and LMI shall assume responsibility for and control of the handling, defense, or settlement thereof. GE Healthcare shall cooperate fully with LMI during the pendency of any such claim or litigation, LMI shall keep GE Healthcare notified of the current status of any trademark claim, litigation or infringement of any of the Trademarks and shall permit GE Healthcare to assume the handling, defense or settlement thereof if LMI declines to do so.

ARTICLE 6. Quality Control and Governmental Approvals

6.1 Manufacture and Testing. All Products delivered to GE Healthcare hereunder shall be manufactured in accordance with Current Good Manufacturing Practices as required by the United States Federal Food, Drug and Cosmetic Act and pursuant to applicable rules and regulations of the FDA when applicable. LMI shall manufacture and supply the Products in accordance with the Quality Document attached here as Exhibit C. Each product lot of Products shall be inspected and tested by LMI prior to shipment to GE Healthcare or its customers. A certificate of compliance will be forwarded to GE Healthcare after each manufactured lot is completed.

6.2 Replacement Products. As further set forth herein, GE Healthcare shall have the right to replacement of or refund for Products, up to the expiration date of such Products, if such Products fail to meet LMI's specifications as set forth in LMI's FDA-approved new drug application ("NDA") for such Products or are not of merchantable quality. GE Healthcare will promptly notify LMI by telephone and telecopy of GE Healthcare's request for replacement or refund. Such notice shall specify with particularity the nature of the nonconformance and GE Healthcare will have the Product returned promptly to LMI for examination at LMI's expense. Provided that GE Healthcare promptly returns the Products to LMI, LMI will promptly replace the Products in question if requested by GE Healthcare, determine any nonconformance of the returned Products and report back to GE Healthcare.

In the event that LMI disagrees with GE Healthcare regarding whether the Products are nonconforming and the Parties are unable to resolve the dispute, the Products or samples thereof will be submitted to a qualified independent laboratory agreed upon by the Parties. The laboratory will analyze the Products or samples in a manner agreed upon by the Parties and the results of that analysis will be a binding determination of whether the Products were or were not nonconforming. If it is determined that the Products were nonconforming, LMI shall bear the

cost of the analysis, as well as either providing a refund or replacement Products to GE Healthcare. If it is determined that the Products were not nonconforming GE Healthcare shall bear the cost of the analysis, shall not be entitled to any refund on the Products and shall pay LMI for any replacement Products provided by LMI.

6.3 Tracking. All materials and components used in the fabrication of Products shall be traceable by lot number and purchase order invoice number.

ARTICLE 7. Warranties, Indemnities and Insurance

7.1 LMI Warranties. LMI warrants to GE Healthcare that all Products purchased by GE Healthcare under this Agreement:

(a) shall be free and clear of all liens, claims, encumbrances, pledges, security interests or other adverse interests of third parties;

(b) shall be manufactured, supplied and delivered by LMI with all necessary skill and expertise using qualified personnel so as to comply with all applicable regulatory requirements;

(c) shall be of good and merchantable quality, and free from defects in material and workmanship;

(d) shall be manufactured in accordance with the specifications set forth in LMI's respective and applicable NDA; and

(e) shall be manufactured in accordance with the Current Good Manufacturing Practices and other applicable FDA rules and regulations.

(f) shall obtain and maintain U.S. state licenses required for the supply of Products purchased by GE Healthcare under the Agreement (notwithstanding the foregoing, LMI and GE Healthcare agree that LMI will only arrange shipment or deliver Products to GE Healthcare for use in the states where LMI holds a valid state license, if applicable, or where such license is not required).

(g) shall comply with all of GE Healthcare's policies generally applicable to all of GE Healthcare's similarly situated suppliers, in each case, to the extent applicable to LMI's provision of Products under this Agreement. Without limitation, LMI acknowledges that it has read "GE's Integrity Guide for Suppliers, Contractors and Consultants" (the "Integrity Guide"), which is located at <http://www.gesupplier.com/html/SuppliersIntegrityGuide.htm>, and agrees that LMI, including all of its employees and subcontractors, will fully comply in all material respects with the applicable portions of the Integrity Guide in providing all Products under this Agreement. GE Healthcare may update its policies that are generally applicable to all of GE Healthcare's similarly situated suppliers, including, without limitation, the Integrity Guide, the Global Packaging Guidelines and the GEHC Americas Transportation Routing Guidelines, from time-to-time.

7.2 Indemnification by LMI.

(a) LMI shall defend, indemnify and hold GE Healthcare, its directors, officers, agents, affiliates, and employees harmless from any and all demands, claims, actions, suits, judgments, decrees, proceedings, liabilities, costs, losses, damages and expenses, including, without limitation, court costs and reasonable attorneys' fees and disbursements, at any time from third party claims or suits resulting to any of them, as a result of or in connection with (i) any Products which were nonconforming, damaged, or defective at time of delivery to GE Healthcare whether claimed by or established in favor of any third parties, including purchasers, and (ii) any breach by LMI of the warranties provided for herein. This obligation of LMI to indemnify and defend shall not apply to the extent that claims are attributable to the independent negligence or intentional malfeasance of GE Healthcare.

(b) GE Healthcare shall promptly notify LMI upon receipt by GE Healthcare of any claim or demand which GE Healthcare has determined has given or could give rise to a right of indemnification under this Agreement. If such claim or demand relates to a claim or demand asserted by a third party against GE Healthcare, LMI shall have the right to employ such counsel as is reasonably acceptable to GE Healthcare to defend any such claim or demand asserted against GE Healthcare, and LMI shall have control over the conduct of the defense of the claim or demand, provided, however, that LMI shall not settle such claim or demand without the consent of GE Healthcare unless such settlement requires no more than a monetary payment for which GE Healthcare is fully indemnified under this Agreement or involves other matters not binding upon GE Healthcare. GE Healthcare shall have the right to participate at its cost in the defense of any said claim or demand. So long as LMI is defending in good faith any such claim or demand, GE Healthcare shall not settle such claim or demand. GE Healthcare shall fully cooperate with LMI during the pendency of the claim or demand and shall make available to LMI and its representatives all records and other materials reasonably required by them for their use in contesting any claim or demand asserted by third party against GE Healthcare. Whether or not LMI so elects to defend any such claim or demand, GE Healthcare shall not have any obligation to do so and GE Healthcare shall not waive any rights it may have against LMI hereunder with respect to any such claim or demand by electing or failing to elect to defend any such claim or demand. GE Healthcare's affiliates shall also be bound by this Section 7.2(b).

7.3 Limitations on Indemnification Obligations. The obligation of LMI to indemnify and defend shall not extend to claims or demands to the extent such claims or demands are attributable to the independent negligence or intentional malfeasance of GE Healthcare or its affiliates, nor to any claims or demands to the extent that such claims or demands are attributable

to or arising out of statements or actions made by GE Healthcare or its affiliates with respect to the Products. The obligation of LMI to indemnify and defend shall also not apply to any claims or demands to the extent that such claims or demands are attributable to any breach by GE Healthcare of the terms of this Agreement.

7.4 LMI Insurance. LMI represents that it is insured for the activities to be carried out under this Agreement and that it maintains sufficient reserves covering these activities.

7.5 Indemnification by GE Healthcare.

(a) GE Healthcare shall defend, indemnify and hold LMI, its directors, officers, agents, affiliates, and employees, harmless from any and all demands, claims, actions, suits, judgments, decrees, proceedings, liabilities, costs, losses, damages and expenses, including, without limitation, court costs and reasonable attorneys' fees and disbursements, at any time from third party claims or suits resulting to any of them, as a result of or in connection with (i) any negligence or intentional malfeasance by GE Healthcare or its affiliates, and (ii) any representation made or other action taken by GE Healthcare or its affiliates related to marketing, selling, or distributing the Products, which are outside the scope of or inconsistent with any Product claims made by LMI, and (iii) any breach by GE Healthcare of the terms of this Agreement. This obligation of GE Healthcare to indemnify and defend shall not apply to the extent that claims are attributable to the independent negligence or intentional malfeasance of LMI.

(b) LMI shall promptly notify GE Healthcare upon receipt by LMI of any claim or demand which LMI has determined has given or could give rise to a right of indemnification under this Agreement. If such claim or demand relates to a claim or demand asserted by a third party against LMI, GE Healthcare shall have the right to employ such counsel as is reasonably acceptable to LMI to defend any such claim or demand asserted against LMI and GE Healthcare shall have control over the conduct of the defense of the claim or demand; provided, however, that GE Healthcare shall not settle such claim or demand without the consent of LMI unless such settlement required no more than a monetary payment for which LMI is fully indemnified under this Agreement or involves other matters not binding upon LMI. LMI shall have the right to participate at its costs in the defense of any such claim or demand. So long as GE Healthcare is defending in good faith any such claim or demand, LMI shall not settle such claim or demand. LMI shall fully cooperate with GE Healthcare during the pendency of the claim or demand and shall make available to GE Healthcare and its representatives all records and other materials reasonably required by them for their use in contesting any claim or demand asserted by third party against LMI. Whether or not GE Healthcare so elects to defend any such claim or demand, LMI shall not have any obligation to do so and LMI shall not waive any rights it may have against GE Healthcare hereunder with respect to any such claim or demand by electing or failing to elect to defend any such claim or demand. LMI's subdistributors, dealers, agents, or affiliates shall also be bound by this Section 7.5(b).

(c) The obligation of GE Healthcare to indemnify and defend shall not extend to claims or demands to the extent such claims or demands are attributable to the independent negligence or intentional malfeasance of LMI or its affiliates, nor to any claims or demands to the extent that such claims or demands are attributable to or arising out of statements or actions made by LMI or its affiliates with respect to the Products. The obligation of GE Healthcare to indemnify and defend shall also not apply to any claims or demands to the extent that such claims or demands are attributable to any breach by LMI of the terms of this Agreement.

7.6 GE Healthcare Insurance. GE Healthcare represents that it is self-insured for the activities to be carried out under this Agreement and that it maintains sufficient reserves covering these activities.

7.7 Adverse Event Reporting. GE Healthcare will notify LMI of any adverse drug experience associated with the Products of which GE Healthcare or its affiliates become aware. Such notifications will be made in writing, in a manner reasonably agreed by the Parties, by means which afford the sender evidence of receipt by LMI within *** (***) working days of initial receipt of the report by GE Healthcare or its agent or employee. Such means of notification may include Express Mail, Electronic Mail, courier, or facsimile, but are not so-limited. Advance notification of any fatal or immediately life-threatening experience will be given by telephone. GE Healthcare is responsible for insuring prompt follow-up, as necessary to provide LMI with reasonably complete information on each such adverse drug experience, by the same means and within the same time frame of receipt. Failure of a radiopharmaceutical product to localize as expected is not regarded by LMI as an Adverse Drug Experience, but rather as a complaint, which will be referred to LMI's Marketing and Technical Services personnel for further investigation. Any communications to LMI under the terms of this Section 7.7 shall be directed to the telephone number, facsimile number and/or email address set forth on LMI's website for such purposes from time to time.

ARTICLE 8. Representation and Warranties

8.1 LMI Representations and Warranties. LMI hereby represents and warrants to GE Healthcare as follows:

(a) LMI has the full power, authority and legal right to enter into this Agreement; this Agreement has been duly authorized, executed and delivered by LMI; and this Agreement constitutes a legal, valid and binding obligation of LMI, enforceable against LMI in accordance with its terms.

(b) LMI has executed no agreement in conflict herewith.

(c) The distribution and sale of the Products by GE Healthcare will not infringe the patents or intellectual property rights of any third party.

8.2 GE Healthcare Representations and Warranties. GE Healthcare hereby represents and warrants to LMI that GE Healthcare has the full power, authority and legal right to enter into this Agreement; this Agreement has been duly authorized, executed and delivered by GE Healthcare; this Agreement constitutes a legal, valid and binding obligation on GE Healthcare enforceable against GE Healthcare in accordance with its terms; and GE Healthcare has executed no agreement in conflict with the terms of this Agreement.

ARTICLE 9. Confidentiality

Any and all proprietary information with respect to the Products or the business affairs and activities of either Party (“**Proprietary Information**”) which is furnished or disclosed in connection with the Agreement by such Party (“**Disclosing Party**”) to the other Party (“**Receiving Party**”), including, without limitation, the specifications for the Products, shall remain the property of the Disclosing Party and shall be treated as confidential. The Receiving Party shall not use such Proprietary Information for its own benefit except as specified in this Agreement and shall not disclose such Proprietary Information to others, except to those of its employees whose duties so require, in such event taking all precautions which are reasonably necessary to prevent the unauthorized disclosure of such Proprietary Information by such persons. Information shall not be deemed to be Proprietary Information and such restrictions shall not apply to any such information (i) which is, or subsequently may become, within the knowledge of the general public, without the fault of the Receiving Party; (ii) which may be known to the Receiving Party at the time of receipt thereof from the Disclosing Party as shown by competent written records; (iii) which may be proved to have been developed by the Receiving Party, independently and wholly without resort to the Proprietary Information of the Disclosing Party, as shown by competent written records or (iv) which may subsequently be rightfully obtained from sources other than the Disclosing Party and without confidential restriction in favor of such transmitting Party. The Parties’ respective obligations under this ARTICLE 9 shall continue after the expiration or termination of this Agreement for any reason.

ARTICLE 10. Term and Termination

10.1 Term. Unless earlier terminated as provided in this Agreement, the term of this Agreement shall commence as the Effective Date and conclude December 31, 2020 (the “**Term**”).

10.2 Termination Rights. Upon the happening of any of the following events, either Party shall have the right to terminate this Agreement upon written notice of such termination to the other Party:

(a) Any material breach by the other Party of this Agreement, which material breach continues for a period of *** (***) days after the non-defaulting Party shall have given notice thereof to the defaulting Party, or

(b) The other Party becomes insolvent, is adjudicated as bankrupt or otherwise seeks or receives protection under the bankruptcy laws of the United States, has a receiver or trustee appointed for all or part of its assets and business, executes and delivers an assignment for the benefit of its creditors or is liquidated, dissolved or wound-up; or

(c) The continuance of an event of force majeure for a period of more than *** (***) days.

10.3 Termination for Economic Reasons. The objective of this Agreement is to realize in an economical and reasonable way the interests and requirements of both Parties. If at any time during the Term of this Agreement, this objective is no longer met due to:

(a) regulatory changes(s), or economic circumstances, which could not have been foreseen at the time of execution of this Agreement causing undue and prolonged hardship; or

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

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

In the event the Parties are unable to agree upon a satisfactory modification of this Agreement within *** (***) days of commencement of negotiations ("Negotiation Period"), the Party requesting the modification may terminate this Agreement within *** (***) days following expiry of the negotiation period by providing *** (***) days written notice to the other Party.

10.4 Survival of Representations and Warranties. The terms of the Agreement that by their nature are intended to survive its expiration will continue in full force and effect after its expiration including but not limited to the warranties and indemnities contained in this Agreement, as shall the shortfall payment provisions pursuant to ARTICLE 3, the confidentiality obligations of the Parties pursuant to ARTICLE 9, and the rebate payment provisions pursuant to Exhibit A hereto. Otherwise, upon expiration or termination of this Agreement as provided in this ARTICLE 10, except as expressly provided herein, the Parties shall have no further liabilities, duties or obligations under this Agreement, except for any liabilities, duties or obligations which may have arisen prior to such expiration or termination.

ARTICLE 11. Force Majeure

11.1 Effect on Performance. Neither Party will be liable for any failure to fulfill any term or condition of this Agreement, nor will such failure constitute a breach of or default under this Agreement, if fulfillment has been delayed, hindered or prevented by an event of force majeure, including, without limitation, any war, riot, strike, lock-out or other industrial dispute, acts of the elements, acts of any government or agency hereof (including the enactment of any new laws, rules or regulations), sabotage or industrial accident, plant breakdown or failure of equipment, inability to obtain equipment, fuel, power, materials or transportation, or by any similar circumstances beyond its reasonable control.

11.2 Notice of Force Majeure. Promptly following the date that any event of force majeure commences, the Party concerned will advise the other Party in writing of the date and nature of the event and the period of time such event is expected to continue. During the existence of such event, the duties and obligations of the Parties under this Agreement shall be suspended and the Parties will take all reasonable action to assure resumption of normal performance under this Agreement as soon as possible.

11.3 Supply of Mo-99. Notwithstanding the foregoing provisions, in the event there is a ***, GE Healthcare may, at its reasonable discretion, divert some or all of GEH Mo-99 to LMI for the manufacture of Product by LMI (pursuant to the terms of this Agreement, without the option of toll manufacturing). LMI will use commercially reasonable best efforts to accept such GEH Mo-99, provided that the acceptance of GEH Mo-99 will be subject to LMI's then current manufacturing schedule and LMI's other policies and procedures applicable to such volume, including, but not limited to, LMI's purchasing specifications for Mo-99. LMI will make a good faith effort to optimize the manufacturing schedule related to the GEH Mo-99, provided, however, that LMI will not be required to schedule a manufacturing run for batches of TechneLite® generators that would result in the sale by LMI of less than *** total curies of activity per manufacturing run (as measured in curies of TechneLite® generators purchased by GE Healthcare and other customers from the day of manufacture of such Product at LMI's facility). Notwithstanding anything herein to the contrary, LMI SHALL NOT BE LIABLE TO GE HEALTHCARE FOR, AND GE HEALTHCARE WAIVES ANY AND ALL CLAIMS AGAINST LMI FOR, DAMAGES RELATING TO THE DECAY OR LOSS OF GEH MO-99. GEH Mo-99 will be used exclusively for the manufacture of Product for GE Healthcare, except that LMI shall have the right to use any GEH Mo-99 not used in the manufacture of TechneLite® generators for GE Healthcare in connection with the manufacture and sale of TechneLite® generators for LMI's other customers. During the period of disruption, LMI will continue to provide GE Healthcare with a fair allocation of available Product, such fair allocation

to be determined by LMI in its sole discretion acting reasonably after due consideration of ***, other percentage supply requirements, and the available amount of Product for LMI's customers, including GE Healthcare, affected by such supply disruption, until previous production levels and LMI's supply of Mo-99 have been restored. The Parties hereby agree that, notwithstanding anything herein to the contrary, the foregoing provisions represent GE Healthcare's sole and exclusive remedies with respect to such events.

ARTICLE 12. Assignment

Neither this Agreement, nor any right, interest or obligation hereunder, may be assigned, or otherwise transferred by either Party, whether by operation of law or otherwise, without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed; provided, however that (a) either Party may assign or otherwise transfer any or all of its rights, or delegate any or all of its respective duties or obligations, under this Agreement without the prior written consent of the other Party to (i) an acquirer of, or successor to, all or substantially all of the assets of such Party, or (ii) the surviving entity in any merger, consolidation, equity exchange or reorganization to which such Party is a party, provided that, in each case contemplated by this clause (a), such acquirer, successor or surviving entity, as the case may be, agrees to be bound by all of the obligations of such Party under this Agreement; and (b) LMI may assign or otherwise transfer any or all of its rights, or delegate any or all of its duties or obligations, under this Agreement to an acquirer of, successor to, or other transferee with respect to all or substantially all of the assets used in or related to the manufacture, sale and distribution of the Products or otherwise to the business of LMI to which this Agreement relates, provided that, in each case contemplated by this clause (b), such acquirer, successor or transferee, as the case may be, agrees to be bound by all of the obligations of LMI under this Agreement. In the event of any such assignment or transfer in violation hereof such assignment or transfer shall be null and void and have no force or effect. This Agreement shall be binding upon and inure to the benefit of the Parties, and their respective successors and assigns as permitted hereunder.

In addition, GE Healthcare shall be required to provide LMI with written notice as soon as reasonably practicable after the signing of any definitive agreement relating to any transaction or series of related transactions, whether or not GE Healthcare is a party thereto, which, after giving effect to such transaction or transactions, would result in the sale, lease, transfer or other disposition of some or all of the assets or business of GE Healthcare to which this Agreement relates (including, without limitation, the radiopharmacies owned or controlled by GE Healthcare). Unless otherwise requested by LMI in writing prior to the effective date of such transaction, GE Healthcare shall assign and ensure that, as a condition of such transaction or transactions, such acquirer, successor or transferee, as the case may be, agrees to be bound by all of the obligations of GE Healthcare (or the applicable pro rata portion thereof) under this Agreement.

ARTICLE 13. General Provisions

13.1 The relationship of LMI and GE Healthcare under this Agreement shall be that of independent seller and purchaser, and nothing contained in this Agreement and no action taken by either Party shall be deemed to constitute either Party or any of such Party's employees, agents or representatives to be an employee, agent or representative of the other Party or shall be deemed to create any partnership, joint venture, association or syndicate between the Parties, or shall be deemed to confer on either Party any express or implied right, power or authority to enter into any agreement of commitment, express or implied, or to incur any obligation or liability on behalf of the other Party.

13.2 Notices. Except as specified in Section 7.7, any notice, claim, demand, request or other communication required or permitted under this Agreement shall be valid and effective only if given by written instrument which is personally delivered, sent by facsimile, courier or registered or certified mail, postage prepaid to the addressee as follows:

If to LMI, to:

Lantheus Medical Imaging, Inc.
Attn: Senior Vice President, Commercial
331 Treble Cove Road
North Billerica, Massachusetts 01862

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

If to GE Healthcare, to:

MEDI-PHYSICS INC., DBA GE HEALTHCARE
Attn: GE Healthcare Life Sciences Legal Dept
100 Results Way
Marlborough, MA 01752

Copy to:
Sourcing Department
3350 N Ridge Avenue
Arlington Heights, IL 60004

Except as specified in Section 7.7 above, any notice, claim, demand, request or other communication given as provided in this Section 13.2, if given personally, shall be effective upon delivery; if given by facsimile, shall be effective one (1) day after transmission; and if given by courier, shall be effective two (2) days after deposit with the courier; and if given by mail, shall be effective five (5) days after deposit in the mail. Either Party may change the address at which it is to be given notice by giving written notice to the other Party as provided in this Section 13.2.

13.3 Entire Agreement. This Agreement, together with the Exhibits attached hereto, constitutes the entire agreement, and supersedes all prior agreements and understanding, both written and oral, between the Parties with respect to the subject matter of this Agreement; and this Agreement may not be modified or amended except by an instrument in writing executed by the Parties.

13.4 No Waiver. No waiver, forbearance or failure by either Party of its right to enforce any provision of this Agreement shall constitute a waiver or estoppel of such Party's right to enforce such provision in the future.

13.5 Cumulative Remedies. Unless expressly provided otherwise herein, the remedies set forth in this Agreement shall not be exclusive but shall be cumulative, and in addition to all other rights and remedies provided by law.

13.6 Governing Law. This Agreement (and all claims, controversies and causes of action arising hereunder or relating hereto) shall be governed by and construed in accordance with the internal laws of the State of Delaware, excluding the conflict of law provisions thereof.

13.7 Severability. If any provision of this Agreement shall be found invalid or unenforceable, in whole or in part, by a court of competent jurisdiction, then such provision shall be deemed to be modified or restricted to the extent and in the manner necessary to render the same valid and enforceable, or shall be deemed excised from this Agreement, as the case may require, and this Agreement shall be construed and enforced to the maximum extent permitted by law, as if such provision had been originally incorporated herein as so modified or restricted, or as if such provision had not been originally incorporated herein, as the case may be, provided that the basic intent of the Parties has not thus been rendered incapable of achievement.

13.8 Bar Codes. The Parties agree to exchange inventory bar code specifications, formatting and encryption information related to such inventory bar code specifications. Each Party will be responsible for implementing this information in its own software systems and will use commercially reasonable best efforts to inform the other promptly when changes and/or additions are expected or problems are discovered with the bar codes. In addition, each Party will be responsible for having a manual alternative in their systems for use if the bar codes fail for any reason. Notwithstanding any provision to the contrary, neither Party shall be liable to the other as a result of or in connection with any non-working bar codes.

The agreement to exchange inventory bar code specifications, formatting and encryption information related to such inventory bar code specifications is limited to bar code format information and does not include any source code for either Party's software. Neither Party may distribute the bar code format information to another Party without written permission from the owner. Ownership for the bar code format remains with the originating company.

13.9 Compliance with Law. Each Party represents and warrants that throughout the term of this Agreement said Party shall be and shall remain in compliance with all applicable federal, state and local laws, including, but not limited to, if applicable, the Federal Anti-kickback Statute's discount safe harbor provisions at 42 U.S.C. § 1320a-7b(b) and 42 C.F.R. § 1001.952(h).

[The remainder of this page is left blank intentionally.]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

MEDI-PHYSICS INC.

By: /s/ Megha Shah

Name: Megha Shah

Title: Sourcing Leader

LANTHEUS MEDICAL IMAGING, INC.

By: /s/ Mary Anne Heino

Name: Mary Anne Heino

Title: President and CEO

EXHIBIT A
Products and Pricing

Pricing and Handling for ***

TechneLite®

Generator	Price Effective as of Effective Date	
Size	Weekday	Weekend
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***

Xenon Gas

Xenon	Price Effective as of Effective Date
***	***
***	***
***	***
***	***

Gallium

Gallium	Activity on ****	Activity on ****	Price Effective as of Effective Date
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***

** Manufactured on ***, shipped for delivery on **** and calibrated for the following ****

Handling Charges

Handling	New Price Effective as of Effective Date
Federal Express Door to Door	***
Ground Carrier Door to Door	***
Dual Leg (Air and Ground)	***

TechneLite® Products Volumes for ***

From the Effective Date through ***, GE Healthcare and its affiliates will purchase from LMI *** percent (***) of their aggregate requirements for Technetium-99m products in the Territory for such time period. Subject to LMI's ability and agreement to fill such orders, LMI will work in good faith to accept and fulfill any purchase orders that GE Healthcare submits to make up, before ***, any nominal ordering shortfalls (i.e., from its *** purchase commitment) that occur before the ***.

Pricing, Volumes and Handling for * through the end of the Term and Other Terms**

- If LMI is unable, for any reason, to fill any size of a Product specified in a purchase order on any given day during the Term, then LMI will be entitled to make reasonable size substitutions (e.g., by providing *** (***) *** curie TechneLite® generators or *** (***) *** TechneLite® generator in fulfillment of a purchase order for *** (***) *** curie TechneLite® generator), and LMI will *** for substituted items to reflect requested items *** (e.g., with respect to the example above, by invoicing GE Healthcare for only the price of *** (***) *** curie TechneLite® generator for such order).
- Annual Volumes and Price Adjustments will be calculated as follows:
 - For TechneLite® Products,
In ***
 - Minimum Purchase Requirements will be *** percent (***) of GE Healthcare's and its affiliates' annual requirements for Technetium-99m products in the Territory. Subject to LMI's ability and agreement to fill such orders, LMI will work in good faith to accept and fulfill any purchase orders that GE Healthcare submits to make up, before ***, any nominal ordering shortfalls (i.e., from its *** purchase commitment) that occur before the ***.
 - Pricing for the *** will be *** on *** pricing and adjusted as follows:
 - if the aggregate number of molybdenum curies for TechneLite® Products GE Healthcare purchases in *** is greater than or equal to *** (***) but less than *** (***), then LMI shall pay GE Healthcare a rebate equal to (X) ***% of GE Healthcare's *** curie pricing times (Y) the aggregate number of molybdenum curies purchased by GE Healthcare in ***;

For purposes of illustration:

if:

***/curie is ***

***% of *** = ***/curie

Purchased curies in *** are ***

then:

the rebate amount for *** is: *** x *** = ***

- if the aggregate number of molybdenum curies for TechneLite® Products GE Healthcare purchases in *** is greater than or equal to *** (***), then LMI shall pay GE Healthcare a rebate equal to (X) ***% of GE Healthcare's * times (Y) the aggregate number of molybdenum curies purchased by GE Healthcare in ***;

For purposes of illustration:

if:

***/curie is ***

***% of *** = ***/curie

Purchased curies in *** are ***

then:

the rebate amount for *** is: *** x *** = ***

- pricing for *** will be adjusted by an amount equal to (i) the actual change in costs of molybdenum, plus (ii) the actual change in costs of TechneLite® Product components (other than molybdenum), plus (iii) an amount equal to (A) ***% of the Annual *** to *** change in the Department of Labor, Producer Price Index (PPI), sub category 063 "Drugs and Pharmaceuticals (expressed as a decimal), multiplied by (B) the prior *** cost of TechneLite® Product components (other than molybdenum).

For purposes of illustration:

In * and *****

- Minimum Purchase Requirements will be *** percent (***) of GE Healthcare's and its affiliates' annual requirements for Technetium-99m products in the Territory. Subject to LMI's ability and agreement to fill such orders, LMI will work in good faith to accept and fulfill any purchase orders that GE Healthcare submits to make up, before ***, any nominal ordering shortfalls (i.e., from its *** purchase commitment) that occur before the ***.
- Pricing for *** and *** will be based on *** pricing and adjusted as follows:

- if the aggregate number of molybdenum curies for TechnLite® Products GE Healthcare purchases in *** or *** is greater than or equal to *** (***) but less than *** (***), then LMI shall pay GE Healthcare a rebate equal to ***% of GE Healthcare's *** times the aggregate number of molybdenum curies purchased by GE Healthcare for *** or ***, as applicable;

For purposes of illustration:

if:

***/curie is ***

***% of *** = ***/curie

Purchased curies in *** are ***

then:

the rebate amount for *** is: *** x *** = ***

- if the aggregate number of molybdenum curies for TechnLite® Products GE Healthcare purchases in *** or *** is greater than or equal to *** (***) but less than *** (***), then LMI shall pay GE Healthcare a rebate equal to ***% of GE Healthcare's *** times the aggregate number of molybdenum curies purchased by GE Healthcare for *** or ***, as applicable;

For purposes of illustration:

if:

***/curie is ***

***% of *** = ***/curie

Purchased curies in *** are ***

then:

the rebate amount for *** is: *** x *** = ***

- if the aggregate number of molybdenum curies for TechneLite® Products GE Healthcare purchases in *** or *** is greater than or equal to *** (***), then LMI shall pay GE Healthcare a rebate equal to ***% of GE Healthcare's *** times the aggregate number of molybdenum curies purchased by GE Healthcare for *** or ***, as applicable;

For purposes of illustration:

if:

***/curie is ***

***% of *** = ***/curie

Purchased curies in *** are ***

then:

the rebate amount for *** is: *** x *** = ***

- in addition to any previous molybdenum and component cost and producer price increases, pricing for *** and *** will be adjusted by an amount equal to (i) the actual change in costs of molybdenum, plus (ii) the actual change in costs of TechneLite® Product components (other than molybdenum), plus (iii) an amount equal to (A) ***% of the Annual *** to June *** in the Department of Labor, Producer Price Index (PPI), sub category 063 "Drugs and Pharmaceuticals (expressed as a decimal), multiplied by (B) the prior *** cost of TechneLite® Product components (other than molybdenum).

For purposes of illustration:

In order to enable GE Healthcare to prepare its annual financial statements, at least *** (***) business days before each *** during the Term, LMI will deliver to GE Healthcare a good faith, preliminary estimate of the rebate payable to GE Healthcare hereunder for the then-applicable ***. Under no circumstances will LMI be held liable for any errors or omissions in any such preliminary estimate. Payments by LMI of any rebates earned by GE Healthcare for ***, *** or *** will be made within *** (***) days of the end of the then-applicable ***.

Pricing for each *** will be communicated by LMI to GE Healthcare on a provisional, non-binding basis by *** of the previous *** and on a binding basis by *** of the previous ***.

- Notwithstanding the foregoing, at any time during the term of this Agreement, LMI may adjust the TechneLite® Product pricing to reflect any material change in costs of molybdenum, accounting for increases or decreases. A change in such costs is considered material if the adjustment in the cost of molybdenum over any *** (***) day period is more than *** percent (***)%. In the event of such a material adjustment, LMI shall adjust the TechneLite® Product pricing to reflect the incremental change in such costs effective as of when such costs are actually incurred by LMI, provided that LMI provides GE Healthcare at least *** (***) days written notice and reasonable documentation supporting such change in costs prior to implementing such effective cost adjustments.
- GE Healthcare and LMI will use commercially reasonable best efforts to work together on ***. The Parties will work in good faith to amend the Agreement to adjust *** for the applicable Product(s) in a mutually agreeable amount to reflect any *** actually resulting from the joint efforts described in the previous sentence.
- GE Healthcare is investigating ***. At GE Healthcare's request, the Parties will discuss in good faith whether such an arrangement is mutually beneficial and negotiate in good faith possible amendments to this Agreement to reflect such a mutually beneficial arrangement, provided neither Party will be obligated to enter into such an amendment.
- For Gallium and Xenon Products, pricing each *** after *** will be adjusted by an amount equal to the *** of (i) *** percent (***)% and (ii) ***% of the Annual *** to *** change in the Department of Labor, Producer Price Index (PPI), sub category 063 "Drugs and Pharmaceuticals.

Pricing for each *** will be communicated to GE Healthcare by *** of the previous ***.

- Handling fees for each *** after *** will be adjusted by an amount equal to the *** of (i) *** percent (***)% and (ii) ***% of the Annual *** to *** change in the Department of Labor, Producer Price Index (PPI), sub category 063 "Drugs and Pharmaceuticals. Handling fees for each *** will be communicated to GE Healthcare by *** of the previous ***.

- All *** pricing and handling fees set forth in this Agreement will be in effect from *** through *** of the relevant ***.
- Upon at least *** (***) days' prior written request, GE Healthcare shall, no more than *** per *** during the term of this Agreement, be entitled to retain an independent third party organization (with which neither it nor any of its affiliates has a relationship and which will enter into a confidentiality agreement in favor of LMI that (i) permits the independent organization to disclose only whether LMI's calculations are correct (or the aggregate amount of any discrepancies) and (ii) prohibits disclosure of any of LMI's Proprietary Information to GE Healthcare) to audit the actual costs of molybdenum used to produce TechneLite® Products. LMI shall at its own expense make reasonably related supporting information reasonably available for inspection and audit. G.E Healthcare will pay for the cost of the third party audit process.

EXHIBIT B

Trademarks

Trademark	Country	Registration Number
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EXHIBIT C

Quality Document

1. GUIDING PRINCIPLES

Regarding the working relationship between the Quality Departments of GE Healthcare and LMI Pharmaceuticals (Medical Imaging) for the Product(s) (refer to the Appendix):

- 1.1 Unless otherwise specified, GE Healthcare refers to GE Healthcare Quality and the Contractor refers to LMI Pharmaceuticals (Medical Imaging) Quality.
- 1.2 The Contractor has the responsibility to evaluate/monitor any new U.S. NDA requirements and notify GE Healthcare of any changes in requirements in a timely manner.
- 1.3 The Contractor has responsibility to operate within the Product registration documentation and shall provide Product that meets all criteria throughout its shelf life.
- 1.4 The Appendix of this document specifies the Product(s) currently covered by this Agreement. This Agreement may be amended as new products are added or deleted.

2. MAINTENANCE OF COMPLIANCE BETWEEN THE PRODUCT REGISTRATION AND THE PROCESS

2.1 Technical Changes

- 2.1.1 The Contractor is responsible for maintaining a change control system that will:
 - 2.1.1.1 review and approve all changes;
 - 2.1.1.2 evaluate the impact of changes on validation status;
 - 2.1.1.3 evaluate the impact of changes on product registration, and
 - 2.1.1.4 evaluate the impact of changes on product safety and efficacy.
- 2.1.2 The Contractor is responsible for maintaining a system to implement compendial changes.

2.2 Other Changes

2.2.1 All Parties, prior to implementation, must approve proposed changes in the storage and/or shipping of the Product.

3. BATCH RELEASE

- 3.1 The Contractor will manufacture and test the Product according to established, approved procedures and current Good Manufacturing Practices.
- 3.2 Batch review and release of the Product and all of its components will be the sole responsibility of the Contractor.
- 3.3 The Contractor will have a formal retest policy and procedure in place that is in accordance with applicable regulations.
- 3.4 The Contractor will notify GE Healthcare, within *** hours, in the event that any test reveals contamination, lack of sterility, or degradation beyond specifications in any batch of Product. The Contractor will file any reports required by the applicable regulations.

4. BATCH DOCUMENTATION

- 4.1 Originals of all batch documents will be retained by the Contractor according to regulatory and Contractor requirements; these records will be maintained for a period of *** (***) *** following the Product lot's expiration date.

5. RETAIN SAMPLES

- 5.1 The Contractor shall retain, under proper storage conditions, samples of the Product as required by the regulations for a period of:
 - 5.1.1 At least *** (***) *** following the Product lot's expiration date for radioactive products,
 - 5.1.2 At least *** (***) *** following the Product lot's expiration date for non-radioactive products.

6. STABILITY

- 6.1 The Contractor will ensure that a product monitoring (stability testing) program is in place for the Product.
 - 6.1.1 The Contractor is responsible for performing stability testing in accordance with the filed stability schedule. Samples shall be stored and tested at appropriate intervals, as described in the approved stability protocol.

- 6.1.2 If a confirmed result indicates the Product has failed to remain within specifications, the Contractor is required to notify GE Healthcare within *** business days. Notification will include a discussion of the issues, available data, and a path forward.
- 6.1.3 In all cases, the Contractor must investigate any confirmed out of specification (OOS) result. A copy of the completed investigation report shall be sent to GE Healthcare within *** business days of the initial confirmation of the OOS.

7. COMPLAINTS

- 7.1 GE Healthcare will receive and summarize all customer complaints in accordance with the regulations. Product complaints will be forwarded to the Contractor for evaluation and investigation. The Contractor will provide GE Healthcare all appropriate and reasonable technical assistance necessary to respond to a complaint. Following investigation, the Contractor will summarize the investigation and provide within *** days a report to GE Healthcare. GE Healthcare will provide a response to the complainant and provide a summary back to the Contractor. Within *** working days of receipt, GE Healthcare will promptly communicate to the Contractor, product complaint reports that may require reporting to the regulatory authorities. The Contractor has sole responsibility for determining when a regulatory authority must be notified of the results of a Product complaint.

8. RECALL

- 8.1 The Contractor will maintain a procedure for handling product recalls.
- 8.2 GE Healthcare has the responsibility to provide any data or information that could result in Product recall within an appropriate time frame. The Contractor will evaluate all information and has sole responsibility for the decision to recall any Product lot.
- 8.3 GE Healthcare will provide to the Contractor any information required to perform a Product recall.

9. * PRODUCT REVIEW**

- 9.1 Each *** the Contractor will conduct an *** Product Review, which will minimally contain for each Product manufactured:
 - 9.1.1 Total number of batches made, number of batches released, number of batches rejected, and number of batches recalled.
 - 9.1.2 A review and summary of customer complaints

- 9.1.3 A listing and discussion of any recalls.
- 9.1.4 A listing and discussion of any changes.
- 9.1.5 A listing and discussion of stability data.
- 9.1.6 Overall discussion, evaluation and conclusions.

10. AUDITS

- 10.1 GE Healthcare may schedule periodic audits of the Contractor's facilities. If requested, access for additional Product specific audits will be granted.
- 10.2 GE Healthcare shall have the right to visit the Contractor's plant where the Product is manufactured on any business day upon reasonable prior notice to Contractor. During any such visit, GE Healthcare shall have the right to audit the Contractor's manufacturing and quality control procedures, records, reports, and facilities as well as any regulatory correspondence applicable to the Product to ensure that the Contractor complies with the Product registration and with Good Manufacturing Practices.

11. INSPECTIONS/LEGAL ACTIONS

- 11.1 The Contractor shall notify GE Healthcare of regulatory agency inspection results and/or legal actions that impact the Product.

12. SUPPLIER QUALIFICATION

- 12.1 The Contractor will maintain a formal supplier qualification and management program.

13. TRAINING

- 13.1 Each person engaged in the manufacturing, processing, packing, or holding of the drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular, operations that the employee performs and in current applicable manufacturing regulations as they relate to the employee's functions. Training in applicable manufacturing regulations shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with requirements applicable to them.

14. VALIDATIONS

14.1 The Contractor must maintain a formal validation program for:

14.1.1 Facilities

14.1.2 Equipment

14.1.3 Methods

14.1.4 Cleaning

14.1.5 Process

14.2 Validations may be prospective, concurrent or retrospective but in all cases, critical parameters and acceptance criteria will be documented.

The following is a listing, of LMI Pharmaceuticals, Medical Imaging, Quality Department contacts.

- Carol Walker, Vice President, Quality, ***

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mary Anne Heino, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lantheus Holdings, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. 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
 - d. 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 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.

Date: August 1, 2017

/s/ MARY ANNE HEINO

Name: Mary Anne Heino

Title: *President and Chief Executive Officer
(Principal Executive Officer)*

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John W. Crowley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lantheus Holdings, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. 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
 - d. 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 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.

Date: August 1, 2017

/s/ JOHN W. CROWLEY

Name: John W. Crowley

Title: *Chief Financial Officer and Treasurer*

(Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Mary Anne Heino, the Chief Executive Officer, and John W. Crowley, the Chief Financial Officer, of Lantheus Holdings, Inc. (the "Company"), hereby certify, that, to their knowledge:

1. The Quarterly Report on Form 10-Q for the period ended June 30, 2017 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 1, 2017

/s/ MARY ANNE HEINO

Name: Mary Anne Heino

Title: *President and Chief Executive Officer
(Principal Executive Officer)*

Date: August 1, 2017

/s/ JOHN W. CROWLEY

Name: John W. Crowley

Title: *Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting 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.