Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

☐ **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	**35-2318913**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
331 Treble Cove Road North Billerica, MA	**01862**
(Address of principal executive offices)	**(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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.01 per share	LNTH	The Nasdaq Global Market

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 every Interactive Data File required to be submitted 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 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	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging Growth Company	☐

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 68,832,088 shares of common stock, $0.01 par value, outstanding as of October 28, 2022.

LANTHEUS HOLDINGS, INC.
TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

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

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 257,259	$ 98,508
Accounts receivable, net	197,276	89,336
Inventory	34,793	35,129
Other current assets	12,570	12,818
Total current assets	501,898	235,791
Property, plant and equipment, net	120,826	116,772
Intangibles, net	323,591	348,510
Goodwill	61,189	61,189
Deferred tax assets, net	46,806	62,764
Other long-term assets	41,628	38,758
Total assets	$ 1,095,938	$ 863,784
Liabilities and stockholders' equity		
Current liabilities		
Current portion of long-term debt and other borrowings	$ 15,372	$ 11,642
Accounts payable	30,135	20,787
Accrued expenses and other liabilities	190,477	58,068
Total current liabilities	235,984	90,497
Asset retirement obligations	23,358	20,833
Long-term debt, net and other borrowings	152,057	163,121
Other long-term liabilities	46,489	124,894
Total liabilities	457,888	399,345
Commitments and contingencies (See Note 19)		
Stockholders' equity		
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; 68,809 and 67,739 shares issued and outstanding, respectively)	688	677
Additional paid-in capital	708,341	685,472
Accumulated deficit	(73,973)	(221,225)
Accumulated other comprehensive income (loss)	2,994	(485)
Total stockholders' equity	638,050	464,439
Total liabilities and stockholders' equity	$ 1,095,938	$ 863,784

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues	$ 239,292	$ 102,073	$ 671,895	$ 295,646
Cost of goods sold	91,859	59,404	257,363	165,859
Gross profit	147,433	42,669	414,532	129,787
Operating expenses				
Sales and marketing	25,414	17,195	73,260	48,999
General and administrative	23,759	28,550	93,945	87,865
Research and development	12,517	11,252	39,455	33,673
Total operating expenses	61,690	56,997	206,660	170,537
Gain on sale of assets	—	—	—	15,263
Operating income (loss)	85,743	(14,328)	207,872	(25,487)
Interest expense	1,626	1,569	4,604	6,224
Gain on extinguishment of debt	—	—	—	(889)
Other income	1,101	3,940	306	3,209
Income (loss) before income taxes	83,016	(19,837)	202,962	(34,031)
Income tax expense (benefit)	21,784	(6,422)	55,710	(2,967)
Net income (loss)	$ 61,232	$ (13,415)	$ 147,252	$ (31,064)
Net income (loss) per common share:				
Basic	$ 0.89	$ (0.20)	$ 2.15	$ (0.46)
Diluted	$ 0.86	$ (0.20)	$ 2.08	$ (0.46)
Weighted-average common shares outstanding:				
Basic	68,756	67,623	68,482	67,409
Diluted	71,075	67,623	70,669	67,409

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net income (loss)	$ 61,232	$ (13,415)	$ 147,252	$ (31,064)
Other comprehensive income:				
Foreign currency translation	(379)	(240)	(463)	55
Unrealized gain on cash flow hedges, net of tax	1,049	98	3,942	851
Total other comprehensive income (loss)	670	(142)	3,479	906
Comprehensive income (loss)	$ 61,902	$ (13,557)	$ 150,731	$ (30,158)

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

Lantheus Holdings, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)
(in thousands)

	Nine Months Ended September 30, 2022					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2022	67,739	$ 677	$ 685,472	$ (221,225)	$ (485)	$ 464,439
Net income	—	—	—	42,962	—	42,962
Other comprehensive income	—	—	—	—	2,396	2,396
Stock option exercises and employee stock plan purchases	296	3	5,931	—	—	5,934
Vesting of restricted stock awards and units	645	7	(7)	—	—	—
Shares withheld to cover taxes	(110)	(1)	(5,503)	—	—	(5,504)
Stock-based compensation	—	—	5,623	—	—	5,623
Balance, March 31, 2022	68,570	$ 686	$ 691,516	$ (178,263)	$ 1,911	$ 515,850
Net income	—	—	—	43,058	—	43,058
Other comprehensive income	—	—	—	—	413	413
Stock option exercises and employee stock plan purchases	61	1	1,422	—	—	1,423
Vesting of restricted stock awards and units	108	1	(1)	—	—	—
Shares withheld to cover taxes	(13)	(1)	(823)	—	—	(824)
Stock-based compensation	—	—	7,412	—	—	7,412
Balance, June 30, 2022	68,726	$ 687	$ 699,526	$ (135,205)	$ 2,324	$ 567,332
Net income	—	—	—	61,232	—	61,232
Other comprehensive income	—	—	—	—	670	670
Stock option exercises and employee stock plan purchases	53	1	1,555	—	—	1,556
Vesting of restricted stock awards and units	41	1	(1)	—	—	—
Shares withheld to cover taxes	(11)	(1)	(842)	—	—	(843)
Stock-based compensation	—	—	8,103	—	—	8,103
Balance, September 30, 2022	68,809	$ 688	$ 708,341	$ (73,973)	$ 2,994	$ 638,050

	Nine Months Ended September 30, 2021					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2021	66,875	$ 669	$ 665,530	$ (149,946)	$ (2,048)	$ 514,205
Net income	—	—	—	9,008	—	9,008
Other comprehensive income	—	—	—	—	808	808
Stock option exercises and employee stock plan purchases	155	1	2,379	—	—	2,380
Vesting of restricted stock awards and units	489	5	(5)	—	—	—
Shares withheld to cover taxes	(85)	(1)	(1,598)	—	—	(1,599)
Stock-based compensation	—	—	3,317	—	—	3,317
Balance, March 31, 2021	67,434	$ 674	$ 669,623	$ (140,938)	$ (1,240)	$ 528,119
Net loss	—	—	—	(26,657)	—	(26,657)
Other comprehensive income	—	—	—	—	240	240
Stock option exercises and employee stock plan purchases	116	1	2,042	—	—	2,043
Vesting of restricted stock awards and units	51	1	(1)	—	—	—
Shares withheld to cover taxes	(9)	—	(193)	—	—	(193)
Stock-based compensation	—	—	4,588	—	—	4,588
Balance, June 30, 2021	67,592	$ 676	$ 676,059	$ (167,595)	$ (1,000)	$ 508,140
Net loss	—	—	—	(13,415)	—	(13,415)
Other comprehensive loss	—	—	—	—	(142)	(142)
Stock option exercises and employee stock plan purchases	48	1	960	—	—	961
Vesting of restricted stock awards and units	23	—	—	—	—	—
Shares withheld to cover taxes	(4)	—	(67)	—	—	(67)
Stock-based compensation	—	—	3,867	—	—	3,867
Balance, September 30, 2021	67,659	$ 677	$ 680,819	$ (181,010)	$ (1,142)	$ 499,344

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)

	Nine Months Ended September 30,	
	2022	**2021**
Operating activities		
Net income (loss)	$ 147,252	$ (31,064)
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation, amortization and accretion	36,048	30,088
Impairment of long-lived assets	—	9,540
Asset retirement obligation acceleration	1,229	—
Amortization of debt related costs	737	430
Changes in fair value of contingent assets and liabilities	25,400	28,500
Gain on extinguishment of debt	—	(889)
Provision for excess and obsolete inventory	4,980	2,317
Stock-based compensation	21,138	11,772
Gain on sale of assets	—	(15,263)
Deferred taxes	14,461	1,028
Long-term income tax receivable	668	3,092
Long-term income tax payable and other long-term liabilities	(538)	(3,617)
Other	3,188	1,724
(Decreases) increases in cash from operating assets and liabilities:		
Accounts receivable	(112,031)	(7,721)
Inventory	(4,666)	(625)
Other current assets	314	1,998
Other long-term assets	(533)	—
Accounts payable	8,409	4,776
Accrued expenses and other liabilities	30,374	3,941
Net cash provided by operating activities	176,429	40,027
Investing activities		
Capital expenditures	(13,623)	(7,596)
Proceeds from sale of assets, net	1,800	15,823
Net cash (used in) provided by investing activities	(11,823)	8,227
Financing activities		
Payments on long-term debt and other borrowings	(7,891)	(40,757)
Proceeds from stock option exercises	7,538	4,616
Proceeds from issuance of common stock	1,375	768
Payments for minimum statutory tax withholding related to net share settlement of equity awards	(7,171)	(1,859)
Net cash used in financing activities	(6,149)	(37,232)
Effect of foreign exchange rates on cash, cash equivalents and restricted cash	(266)	(99)
Net increase in cash, cash equivalents and restricted cash	158,191	10,923
Cash, cash equivalents and restricted cash, beginning of period	100,651	82,694
Cash, cash equivalents and restricted cash, end of period	$ 258,842	$ 93,617

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

	Nine Months Ended September 30,	
	2022	**2021**
Reconciliation to amounts within the condensed consolidated balance sheets		
Cash and cash equivalents	$ 257,259	$ 91,475
Restricted cash included in other long-term assets	1,583	2,142
Cash, cash equivalents and restricted cash at end of period	$ 258,842	$ 93,617

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, references to "LMI" refer to Lantheus Medical Imaging, Inc., the direct subsidiary of Holdings, references to "Progenics" refer to Progenics Pharmaceuticals, Inc., a wholly-owned subsidiary of LMI, and references to "EXINI" refer to EXINI Diagnostics AB, a wholly-owned subsidiary of Progenics. 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 Holdings and its direct and indirect wholly-owned subsidiaries, including Progenics, 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 notes 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 nine months ended September 30, 2022 are not necessarily indicative of the results that may be expected for the year ended December 31, 2022 or any future period.

The condensed consolidated balance sheet at December 31, 2021 has been derived from the audited consolidated financial statements at that date but does not include all the information and notes 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, 2021 filed with the Securities Exchange Commission ("SEC") on February 24, 2022.

Progenics Acquisition

On June 19, 2020 (the "Closing Date"), pursuant to the Amended and Restated Agreement and Plan of Merger, dated as of February 20, 2020 (the "Merger Agreement"), by and among Holdings, Plato Merger Sub, Inc., a wholly-owned subsidiary of Holdings ("Merger Sub"), and Progenics, Holdings completed the acquisition of Progenics by means of a merger of Merger Sub with and into Progenics, with Progenics surviving such merger as a wholly-owned subsidiary of Holdings (the "Progenics Acquisition"). Subsequently, on June 22, 2020, Holdings contributed all of the capital stock of Progenics to LMI, thereby making Progenics an indirect subsidiary of Holdings.

In accordance with the Merger Agreement, at the effective time of the Progenics Acquisition (the "Effective Time"), each share of Progenics common stock, par value $0.0013 per share, issued and outstanding immediately prior to the Effective Time (other than shares of Progenics common stock owned by Holdings, Progenics or any of their wholly-owned subsidiaries) was automatically cancelled and converted into the right to receive (i) 0.31 (the "Exchange Ratio") of a share of Holdings common stock, par value $0.01 per share, and (ii) one contingent value right (a "CVR") tied to the financial performance of PyL (18F-DCFPyL), Progenics' prostate-specific membrane antigen ("PSMA") targeted imaging agent designed to visualize prostate cancer. This agent was approved by the U.S. Food and Drug Administration ("FDA") on May 26, 2021 under the name PYLARIFY (piflufolastat F 18), and the commercial launch of this agent began in June 2021. Each CVR entitles its holder to receive a pro rata share of aggregate cash payments equal to 40% of U.S. net sales generated by PYLARIFY in 2022 and 2023 in excess of $100.0 million and $150.0 million, respectively. In no event will the Company's aggregate payments in respect of the CVRs, together with any other non-stock consideration treated as paid in connection with the Progenics Acquisition, exceed 19.9% of the total consideration the Company pays in the Progenics Acquisition. Based on the Company's 2022 PYLARIFY net sales, the Company believes that all of its aggregate payment obligations under the CVRs (which the Company currently estimates to be approximately $99.7 million) will become payable in the first half of 2023. As a result of the acquisition, Holdings issued 26,844,877 shares of Holdings common stock and 86,630,633 CVRs to former Progenics stockholders and option holders.

2. Summary of Significant Accounting Policies

Recent Accounting Pronouncements

The Company has not adopted any new accounting standards during the nine months ended September 30, 2022.

3. Revenue from Contracts with Customers

The following table summarizes revenue by revenue source as follows:

Major Products/Service Lines (in thousands)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Product revenue, net[1]	$ 233,366	$ 96,678	$ 631,157	$ 277,559
License and royalty revenues[2]	5,926	5,395	40,738	18,087
Total revenues	$ 239,292	$ 102,073	$ 671,895	$ 295,646

(1) The Company's principal products include PYLARIFY, DEFINITY and TechneLite and are primarily categorized within product revenue, net. This category represents the delivery of physical goods. The Company applies the same revenue recognition policies and judgments for all its principal products.

(2) The Company recognized $24.0 million license revenue in the first quarter of 2022 related to an agreement with Novartis Pharma AG.

The Company classifies its revenues into three product categories: precision diagnostics, radiopharmaceutical oncology, and strategic partnerships and other revenue. Precision diagnostics includes DEFINITY, TechneLite and other diagnostic imaging products. Radiopharmaceutical oncology consists primarily of PYLARIFY and AZEDRA. Strategic partnerships and other revenue includes strategic partnerships and other arrangements related to other products of the Company, such as royalty revenue from our license of RELISTOR.

On January 31, 2022, the Company entered into a global settlement agreement with Novartis Pharma AG ("Novartis"), Advanced Accelerator Applications USA, Inc. ("AAA"), Endocyte, Inc. ("Endocyte") and their affiliates (the "Novartis Agreement") to settle certain disputes between the parties. Under the Novartis Agreement, Novartis agreed to make a lump sum payment to the Company, as well as to reimburse the Company for certain fees and expenses in connection with certain German litigation, and the Company agreed to license certain intellectual property to Novartis. In addition, the Company agreed to supply PYLARIFY for clinical purposes at an arms-length value which will be recorded revenue in the future as product is provided. In accordance with the Company's ASC 606, *Revenue from Contracts with Customers*, assessment, Novartis is considered to be a customer. The Company determined that the $24.0 million constituted a single element which was satisfied on the date of the execution of the Novartis Agreement. The Company determined that the license of intellectual property carried a fair value of $24.0 million. As such, the Company assigned the value to the fair value of the license, which constitutes the entire transaction price and does not require further allocation. The Company determined that the $24.0 million represented the point at which the licensee was able to use and benefit from the license and recognized revenue when the license was granted to Novartis upon execution of the Novartis Agreement. The Company recognized the $24.0 million fee as revenue on its consolidated statement of operations for the quarter ended March 31, 2022. The Company received the $24.0 million payment in April 2022.

Revenue by product category on a net basis is as follows:

(in thousands)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
DEFINITY	$ 60,740	$ 57,636	$ 181,374	$ 173,448
TechneLite	22,094	22,680	64,139	69,252
Other precision diagnostics	6,175	7,563	16,803	21,289
Total precision diagnostics	89,009	87,879	262,316	263,989
PYLARIFY	143,754	7,724	366,763	7,997
Other radiopharmaceutical oncology	928	1,166	3,183	5,206
Total radiopharmaceutical oncology	144,682	8,890	369,946	13,203
Strategic partnerships and other revenue	5,601	5,304	39,633	18,454
Total revenues	$ 239,292	$ 102,073	$ 671,895	$ 295,646

The Company's performance obligations are typically part of contracts that have an original expected duration of one year or less. As such, the Company is not disclosing the aggregate amount of the transaction price allocated to performance obligations that are unsatisfied (or partially satisfied) as of the end of the reporting period.

4. 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 of 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.

The Company's financial assets and liabilities measured at fair value on a recurring basis consist of money market funds, interest rate swaps, a contingent receivable and contingent consideration liabilities. 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 fair value of the interest rate swaps is determined based on observable market-based inputs, including interest rate curves and reflects the contractual terms of these instruments, including the period to maturity. Please refer to Note 13, "Derivative Instruments", for further details on the interest rate swaps. The Company recorded a contingent receivable and the contingent consideration liabilities resulting from the Progenics Acquisition at fair value based on inputs that are not observable in the market.

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

	September 30, 2022			
(in thousands)	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market	$ 176,909	$ 176,909	$ —	$ —
Interest rate swaps	5,660	—	5,660	—
Contingent receivable	8,200	—	—	8,200
Total assets	$ 190,769	$ 176,909	$ 5,660	$ 8,200
Liabilities:				
Contingent consideration liabilities	$ 110,500	$ —	$ —	$ 110,500
Total liabilities	$ 110,500	$ —	$ —	$ 110,500

	December 31, 2021			
(in thousands)	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market	$ 40,140	$ 40,140	$ —	$ —
Interest rate swaps	357	—	357	—
Contingent receivable	9,300	—	—	9,300
Total assets	$ 49,797	$ 40,140	$ 357	$ 9,300
Liabilities:				
Contingent consideration liabilities	$ 86,200	$ —	$ —	$ 86,200
Total liabilities	$ 86,200	$ —	$ —	$ 86,200

During the three and nine months ended September 30, 2022, there were no transfers into or out of Level 3.

As part of the Progenics Acquisition, the Company acquired the right to receive certain future milestone and royalty payments due to Progenics from CytoDyn Inc. related to a prior sale of certain intellectual property. The Company has the right to receive $5.0 million upon regulatory approval and a 5% royalty on net sales of approved products. The Company considers the contingent receivable a Level 3 instrument (one with significant unobservable inputs) in the fair value hierarchy. The estimated fair value was determined based on probability adjusted discounted cash flows that included significant estimates and assumptions pertaining to regulatory events and sales targets. The most significant unobservable inputs are the probabilities of achieving regulatory approval of the development projects and subsequent commercial success.

As part of the Progenics Acquisition, the Company issued CVRs and recorded the fair value as part of consideration transferred. Each CVR entitles its holder to receive a pro rata share of aggregate cash payments equal to 40% of U.S. net sales generated by PYLARIFY in 2022 and 2023 in excess of $100.0 million and $150.0 million, respectively, subject to a maximum cap. Refer to Note 1, “Basis of Presentation” for further details on the CVRs. The Company considers the contingent consideration liabilities relating to the CVRs a Level 3 instrument (one with significant unobservable inputs) in the fair value hierarchy. The estimated fair value of these had been determined based on Monte Carlo simulation models that included significant estimates and assumptions pertaining to commercialization events and sales targets. Because of revised revenue forecasts for the balance of 2022, the Company updated the valuation technique for the CVRs from the Monte Carlo simulation model to a probability adjusted discounted cash flow model as the Company currently expects to pay out the full amount of the CVRs from available cash in the first half of 2023 based on U.S. net sales generated by PYLARIFY in 2022 and, under either valuation technique, the estimated liability would be approximately the same.

The Company also assumed contingent consideration liabilities related to a previous acquisition completed by Progenics in 2013 (“2013 Acquisition”). These contingent consideration liabilities include potential payments of up to $70.0 million if the Company attains certain net sales targets primarily for AZEDRA and 1095 and a $5.0 million 1095 commercialization milestone. Additionally, there is a potential payment of up to $10.0 million related to a 1404 commercialization milestone. The Company’s total potential payments related to the 2013 Acquisition are approximately $85.0 million. The Company considers the contingent consideration liabilities relating to the 2013 Acquisition each a Level 3 instrument (one with significant unobservable inputs) in the fair value hierarchy. The estimated fair value of these was determined based on probability adjusted discounted cash flows and Monte Carlo simulation models that included significant estimates and assumptions pertaining to commercialization events and sales targets. The most significant unobservable inputs with respect to 1095 and 1404 are the probabilities of achieving regulatory approval of those development projects and subsequent commercial success.

Significant changes in any of the probabilities of success, the probabilities as to the periods in which sales targets and milestones will be achieved, discount rates or underlying revenue forecasts would result in a significantly higher or lower fair value measurement. The Company records the contingent consideration liability at fair value with changes in estimated fair values recorded in general and administrative expenses in the condensed consolidated statements of operations. The Company can give no assurance that the actual amounts paid, if any, in connection with the contingent consideration liabilities, including the CVRs, will be consistent with any recurring fair value estimate of such contingent consideration liabilities.

The following tables summarize quantitative information and assumptions pertaining to the fair value measurement of assets and liabilities using Level 3 inputs at September 30, 2022.

	Fair Value at				Assumptions	
(in thousands)	September 30, 2022	December 31, 2021	Valuation Technique	Unobservable Input	September 30, 2022	December 31, 2021
Contingent receivable:						
Regulatory milestone	$ 2,400	$ 2,500	Probability adjusted discounted cash flow model	Period of expected milestone achievement	2023	2022
				Probability of success	70 %	70 %
				Discount rate	19 %	17 %
Royalties	5,800	6,800	Probability adjusted discounted cash flow model			
				Probability of success	10% - 60%	10% - 60%
				Discount rate	19 %	17 %
Total	$ 8,200	$ 9,300				

(in thousands)	Fair Value at September 30, 2022	Fair Value at December 31, 2021	Valuation Technique	Unobservable Input	Assumptions September 30, 2022	Assumptions December 31, 2021
Contingent consideration liability:						
Net sales targets - PYLARIFY (CVRs)			Probability adjusted discounted cash flow model (as of 9/30/2022)	Period of expected milestone achievement and sales targets		
	$ 99,700	$ 73,200	Monte Carlo simulation (as of 12/31/2021)		2022 - 2023	2022 - 2023
				Probability of success	100 %	N/A
				Discount rate	N/A	17 %
1095 commercialization milestone	1,700	1,900	Probability adjusted discounted cash flow model			
				Period of expected milestone achievement	2026	2026
				Probability of success	40 %	40 %
				Discount rate	3.7 %	1.3 %
Net sales targets - AZEDRA and 1095	9,100	11,100	Monte Carlo simulation			
				Probability of success and sales targets	20% - 100%	40% - 100%
				Discount rate	18% - 19%	16% - 17%
Total	$ 110,500	$ 86,200				

For those financial instruments with significant Level 3 inputs, the following table summarizes the activities for the periods indicated:

(in thousands)	Financial Assets Nine Months Ended September 30, 2022	Financial Assets Nine Months Ended September 30, 2021	Financial Liabilities Nine Months Ended September 30, 2022	Financial Liabilities Nine Months Ended September 30, 2021
Fair value, beginning of period	$ 9,300	$ 11,300	$ 86,200	$ 15,800
Changes in fair value included in net income (loss)	(1,100)	2,500	24,300	31,000
Fair value, end of period	$ 8,200	$ 13,800	$ 110,500	$ 46,800

The change in fair value of the contingent financial asset and contingent financial liabilities, including the CVRs, resulted in an expense of $25.4 million for the nine months ended September 30, 2022 and was primarily due to changes in revenue forecasts, changes in market conditions, an increase in discount rates (excluding the CVRs) and the passage of time. The Company expects to make all applicable cash payments related to the CVRs in the first half of 2023. As of September 30, 2022, the Company had $99.7 million in current liabilities to account for the expected payments related to the CVRs.

5. Income Taxes

The Company calculates income taxes at the end of each reporting period based on the estimated effective tax rate for the full year, adjusted for any discrete events which are recorded in the period they occur. Cumulative adjustments to the tax provision are

recorded in the reporting period in which a change in the estimated annual effective tax rate is determined. The Company's income tax expense is presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
Income tax expense (benefit)	$ 21,784	$ (6,422)	$ 55,710	$ (2,967)

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. The Company assessed the need for a valuation allowance against certain state tax credit carryforwards added through the Progenics Acquisition. The Company continues to retain other immaterial valuation allowances against the net deferred tax assets of certain of its foreign subsidiaries.

In connection with the Company's acquisition of the medical imaging business from Bristol-Myers Squibb ("BMS") in 2008, the Company recorded a liability for uncertain tax positions related to the acquired business and simultaneously entered into a tax indemnification agreement with BMS under which BMS agreed to indemnify the Company for any payments made to settle those uncertain tax positions with the state taxing authorities. Accordingly, a long-term receivable is recorded to account for the expected value to the Company of future indemnification payments to be paid on behalf of the Company by BMS, net of actual tax benefits received by the Company. The tax indemnification receivable is recorded within other long-term assets.

In accordance with the Company's accounting policy, the change in the tax liabilities, penalties and interest associated with these obligations (net of any offsetting federal or state benefit) is recognized within income tax expense. As these reserves change adjustments are included in income tax expense while the offsetting adjustment is included in other income. Assuming that the remaining receivable from BMS continues to be considered recoverable by the Company, there will be no effect on net income and no net cash outflows related to these liabilities.

During the third quarter of 2022, the Company entered into a settlement agreement with one state and accordingly reduced the amount of the uncertain tax positions by $2.2 million. The Company continues to accrue interest on the outstanding uncertain tax positions.

The Company finalized the accounting for the Progenics Acquisition for income taxes in the first quarter of 2021 resulting in a reduction of deferred tax assets, primarily related to state research credit carryforwards and an increase to goodwill of $2.6 million.

6. Inventory

Inventory consisted of the following:

(in thousands)	September 30, 2022	December 31, 2021
Raw materials	$ 17,699	$ 15,505
Work in process	8,203	13,042
Finished goods	8,891	6,582
Total inventory	$ 34,793	$ 35,129

Inventory costs associated with products that have not yet received regulatory approval are capitalized if the Company believes there is probable future commercial use of the product and future economic benefit of the asset. If future commercial use of the product is not probable, then inventory costs associated with such product are expensed during the period the costs are incurred. As of December 31, 2021, the Company had $6.1 million of such product costs included in inventories related to DEFINITY that had been manufactured through the Company's in-house manufacturing capabilities. The Company received regulatory approval for the manufacture of DEFINITY at its new in-house manufacturing facility during the first quarter of 2022 and has no inventory pending regulatory approval as of September 30, 2022.

7. Property, Plant and Equipment, Net

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

(in thousands)	September 30, 2022	December 31, 2021
Land	$ 13,450	$ 13,450
Buildings	72,497	73,559
Machinery, equipment and fixtures	88,507	83,608
Computer software	25,740	24,384
Construction in progress	17,918	10,686
	218,112	205,687
Less: accumulated depreciation and amortization	(97,286)	(88,915)
Total property, plant and equipment, net	$ 120,826	$ 116,772

Depreciation and amortization expense related to property, plant and equipment, net, was $3.9 million and $3.6 million for the three months ended September 30, 2022 and 2021, respectively, and $10.3 million and $9.8 million for the nine months ended September 30, 2022 and 2021, respectively.

8. Accrued Expenses and Other Liabilities and Other Long-Term Liabilities

Accrued expenses and other liabilities and other long-term liabilities are comprised of the following:

(in thousands)	September 30, 2022	December 31, 2021
Compensation and benefits	$ 26,205	$ 22,730
Freight, distribution and operations	35,619	16,157
Accrued rebates, discounts and chargebacks	13,247	10,977
Accrued professional fees	4,562	2,850
Short-term contingent liability (Note 4)	99,700	—
Other	11,144	5,354
Total accrued expenses and other liabilities	$ 190,477	$ 58,068
Operating lease liabilities (Note 16)	$ 15,354	$ 16,546
Long-term contingent liability (Note 4)	10,800	86,200
Other long-term liabilities	20,335	22,148
Total other long-term liabilities	$ 46,489	$ 124,894

9. Sale of Puerto Rico Subsidiary

During the fourth quarter of 2020, the Company entered into a stock purchase agreement (the "SPA") with one of its existing radiopharmacy customers to sell all the stock of its Puerto Rico radiopharmacy subsidiary. The assets were classified as held for sale and the Company determined that the fair value of the net assets being sold significantly exceeded the carrying value as of December 31, 2020. The transaction was consummated on January 29, 2021.

The purchase price for the stock sale was $18.0 million in cash, including a holdback amount of $1.8 million which the Company received during the first quarter of 2022; the purchase price also included a working capital adjustment. The SPA contains customary representations, warranties and covenants by each of the parties. Subject to certain limitations, the buyer will be indemnified for damages resulting from breaches or inaccuracies of the Company's representations, warranties and covenants in the SPA.

The Company determined that this sale of certain net assets did not constitute a strategic shift that had a major effect on the Company's operations or financial results. As a result, this transaction was not classified as discontinued operations in the Company's accompanying condensed consolidated financial statements.

The following table summarizes the major classes of assets and liabilities sold as of January 29, 2021, the date of sale:

(in thousands)	January 29, 2021
Current Assets:	
Cash and cash equivalents	$ 540
Accounts receivable, net	1,959
Inventory	530
Other current assets	65
Total current assets	3,094
Non-Current Assets:	
Property, plant & equipment, net	780
Intangibles, net	96
Other long-term assets	774
Total assets held for sale	$ 4,744
Current Liabilities:	
Accounts payable	$ 185
Accrued expense and other liabilities	369
Total current liabilities	554
Non-Current Liabilities:	
Asset retirement obligations	306
Other long-term liabilities	588
Total liabilities held for sale	$ 1,448

The sale resulted in a pre-tax book gain of $15.3 million, which was recorded within operating income in the condensed consolidated statements of operations for the six months ended June 30, 2021.

10. 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 production facilities which manufacture and process radioactive materials at its North Billerica, Massachusetts and Somerset, New Jersey sites. As of September 30, 2022, the liability is measured at the present value of the obligation expected to be incurred, of approximately $25.5 million.

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

(in thousands)	Amount
Balance at January 1, 2022	$ 20,833
Accretion expense	1,296
Accelerated costs	1,229
Balance at September 30, 2022	$ 23,358

In December 2021, the Company evaluated the accretion timeline of an asset group due to a revision in the planned period of use at the North Billerica site. As a result of the accelerated timeline, the Company determined the asset group's present value exceeded the current value recorded as of December 31, 2021. Accordingly, the Company recorded a non-cash adjustment of $5.3 million in December 2021 to anticipate a revision in the end of useful life by the end of 2022.

The Company is required to provide the Massachusetts Department of Public Health and New Jersey Department of Environmental Protection financial assurance demonstrating the Company's ability to fund the decommissioning of its North Billerica, Massachusetts and Somerset, New Jersey production facilities upon closure, although the Company has no current plans to close the facilities. The Company has provided this financial assurance in the form of a $30.3 million surety bond.

11. Intangibles, Net

Intangibles, net, consisted of the following:

(in thousands)	Useful Lives (in years)	Amortization Method	September 30, 2022 Cost	Accumulated Amortization	Net
Trademarks	15 - 25	Straight-Line	$ 13,540	$ (11,924)	$ 1,616
Customer relationships	15 - 25	Accelerated	96,682	(94,866)	1,816
Currently marketed products	9 - 15	Straight-Line	275,700	(41,557)	234,143
Licenses	11 - 16	Straight-Line	85,800	(17,214)	68,586
Developed technology	9	Straight-Line	2,400	(610)	1,790
IPR&D	N/A	N/A	15,640	—	15,640
Total			$ 489,762	$ (166,171)	$ 323,591

(in thousands)	Useful Lives (in years)	Amortization Method	December 31, 2021 Cost	Accumulated Amortization	Net
Trademarks	15 - 25	Straight-Line	$ 13,540	$ (11,510)	$ 2,030
Customer relationships	15 - 25	Accelerated	96,880	(94,630)	2,250
Currently marketed product	9 - 15	Straight-Line	275,700	(23,345)	252,355
Licenses	11 - 16	Straight-Line	85,800	(11,555)	74,245
Developed technology	9	Straight-Line	2,400	(410)	1,990
IPR&D	N/A	N/A	15,640	—	15,640
Total			$ 489,960	$ (141,450)	$ 348,510

The Company recorded amortization expense for its intangible assets of $8.3 million and $8.4 million for the three months ended September 30, 2022 and 2021, respectively, and $24.9 million and $19.1 million for the nine months ended September 30, 2022 and 2021, respectively.

In May 2021, PyL (18F-DCFPyL) was approved by the FDA under the name PYLARIFY. Accordingly, the Company reclassified the associated asset of $132.8 million from IPR&D to currently marketed products and commenced amortization of the asset.

The below table summarizes the estimated aggregate amortization expense expected to be recognized on the above intangible assets:

(in thousands)	Amount
Remainder of 2022	$ 8,310
2023	32,634
2024	32,563
2025	32,508
2026	32,497
2027 and thereafter	169,439
Total	$ 307,951

12. Long-Term Debt, Net, and Other Borrowings

As of September 30, 2022, the Company's maturities of principal obligations under its long-term debt and other borrowings are as follows:

(in thousands)	Amount
Remainder of 2022	$ 3,750
2023	15,000
2024	148,750
Total principal outstanding	167,500
Unamortized debt discount	(348)
Unamortized debt issuance costs	(301)
Finance lease liabilities	578
Total	167,429
Less: current portion	(15,372)
Total long-term debt, net and other borrowings	$ 152,057

At September 30, 2022, the Company's interest rate under the five-year secured term loan facility, which matures on June 30, 2024 (the "2019 Term Facility" and the loans thereunder, the "2019 Term Loans") was 4.6%.

On March 31, 2021, the Company voluntarily repaid in full the entire outstanding principal on its $50.0 million loan agreement (the "Royalty-Backed Loan") with a fund managed by HealthCare Royalty Partners III, L.P. in the amount of $30.9 million, which included a prepayment amount of $0.5 million, and terminated the agreement governing the Royalty-Backed Loan. The Company recorded a gain on extinguishment of debt of $0.9 million related to the write-off of an unamortized debt premium offset by the prepayment amount.

13. Derivative Instruments

The Company uses interest rate swaps to reduce the variability in cash flows associated with a portion of the Company's forecasted interest payments on its variable rate debt. In March 2020, the Company entered into interest rate swap contracts to fix the LIBOR rate on a notional amount of $100.0 million through May 31, 2024. The average fixed LIBOR rate on the interest rate swaps is approximately 0.82%. This agreement involves the receipt of floating rate amounts in exchange for fixed rate interest payments over the life of the agreement without an exchange of the underlying principal amount. The interest rate swaps were designated as cash flow hedges. In accordance with hedge accounting, the interest rate swaps are recorded on the Company's condensed consolidated balance sheets at fair value, and changes in the fair value of the swap agreements are recorded to other comprehensive loss and reclassified to interest expense in the period during which the hedged transaction affected earnings or it will become probable that the forecasted transaction would not occur. At September 30, 2022, accumulated other comprehensive income included $3.5 million of pre-tax deferred gains that are expected to be reclassified to earnings during the next 12 months.

The following table presents the location and fair value amounts of derivative instruments reported in the condensed consolidated balance sheets:

(in thousands)		September 30, 2022	December 31, 2021
Derivatives type	**Classification**		
Assets:			
Interest rate swap	Other long-term assets	$ 5,660	$ 357

14. Accumulated Other Comprehensive Income (Loss)

The components of accumulated other comprehensive income (loss), net of tax of $1.5 million and $0.2 million for the nine months ended September 30, 2022 and 2021, respectively, consisted of the following:

(in thousands)	Foreign currency translation	Unrealized loss on cash flow hedges	Accumulated other comprehensive income (loss)
Balance at January 1, 2022	$ (754)	$ 269	$ (485)
Other comprehensive (loss) income before reclassifications	(463)	4,112	3,649
Amounts reclassified to earnings	—	(170)	(170)
Balance at September 30, 2022	$ (1,217)	$ 4,211	$ 2,994
Balance at January 1, 2021	$ (630)	$ (1,418)	$ (2,048)
Other comprehensive income before reclassifications	55	312	367
Amounts reclassified to earnings	—	539	539
Balance at September 30, 2021	$ (575)	$ (567)	$ (1,142)

15. Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
Cost of goods sold	$ 1,268	$ 144	$ 3,263	$ 1,672
Sales and marketing	1,745	684	4,433	1,726
General and administrative	3,991	2,330	10,777	6,641
Research and development	1,099	709	2,665	1,733
Total stock-based compensation expense	$ 8,103	$ 3,867	$ 21,138	$ 11,772

16. Leases

Operating and finance lease assets and liabilities are as follows:

(in thousands)	Classification	September 30, 2022	December 31, 2021
Assets			
Operating	Other long-term assets	$ 8,293	$ 8,788
Finance	Property, plant and equipment, net	679	556
Total leased assets		$ 8,972	$ 9,344
Liabilities			
Current			
Operating	Accrued expenses and other liabilities	$ 1,677	$ 1,599
Finance	Current portion of long-term debt and other borrowings	372	392
Noncurrent			
Operating	Other long-term liabilities	15,354	16,546
Finance	Long-term debt, net and other borrowings	206	299
Total leased liabilities		$ 17,609	$ 18,836

The Company entered into an agreement in February 2022 to lease additional office space in Bedford, Massachusetts. The facility is currently being renovated and the associated right-of-use asset and liability will be recorded once renovations are substantially complete. The lease payments are expected to commence in the fourth quarter of 2022 when renovation of the facility is completed.

17. Net Income (Loss) Per Common Share

A summary of net income per common share is presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	**2022**	**2021**	**2022**	**2021**
Net income (loss)	$ 61,232	$ (13,415)	$ 147,252	$ (31,064)
Basic weighted-average common shares outstanding	68,756	67,623	68,482	67,409
Effect of dilutive stock options	455	—	452	—
Effect of dilutive restricted stock	1,864	—	1,735	—
Diluted weighted-average common shares outstanding	71,075	67,623	70,669	67,409
Basic income (loss) per common share	$ 0.89	$ (0.20)	$ 2.15	$ (0.46)
Diluted income (loss) per common share	$ 0.86	$ (0.20)	$ 2.08	$ (0.46)
Antidilutive securities excluded from diluted net income (loss) per common share	52	3,051	226	3,051

18. Other Income

Other income consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**	**2022**	**2021**
Foreign currency losses	$ 145	$ 127	$ 189	$ 156
Tax indemnification loss, net	1,460	3,823	668	3,092
Interest income	(504)	(11)	(551)	(39)
Other	—	1	—	—
Total other income	$ 1,101	$ 3,940	$ 306	$ 3,209

19. Commitments and Contingencies

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 costs and 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 and could have a material adverse effect on the Company's results of operations or financial condition. 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. If a matter is both probable to result in material liability and the amount of loss can be reasonably estimated, the Company estimates and discloses the possible material loss or range of loss. If such loss is not probable or cannot be reasonably estimated, a liability is not recorded in its condensed consolidated financial statements.

As of September 30, 2022, the Company did not have any material ongoing litigation to which the Company was a party.

20. Segment Information

In the first quarter of fiscal year 2021, the Company completed the evaluation of its operating and reporting structure, including the impact on the Company's business of the acquisition of Progenics described in Note 1, and the sale of the Puerto Rico subsidiary in the first quarter of fiscal year 2021, which resulted in a change in operating and reportable segments. The Company now operates as one business segment: the development, manufacture and sale of innovative imaging diagnostics, radiotherapeutics, and artificial intelligence solutions designed to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. This conclusion reflects the Company's focus on the performance of the business on a consolidated worldwide basis. The results of this operating segment are regularly reviewed by the Company's chief operating decision maker, the President and Chief Executive

Officer. The Company's chief operating decision maker does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company's consolidated operating results.

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 (the "Securities Act"), 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 can generally be identified by words such as "anticipates," "believes," "can," "could," "designed," "estimates," "expects," "hopes," "intends," "launch," "may," "pipeline," "plans," "predicts," "seeks," "should," "target," "will," "would" and similar expressions, or by express or implied discussions regarding potential marketing approvals or new indications for the collaborations, products candidates or approved products described in this Quarterly Report on Form 10-Q, or regarding potential future revenues from such collaborations, product candidates and products. Examples of forward-looking statements include statements we make relating to our outlook and expectations including, without limitation, in connection with: (i) our ability to continue to grow PYLARIFY as a commercial product, including (A) our ability to obtain FDA approval for additional positron emission tomography ("PET") manufacturing facilities ("PMFs") to manufacture PYLARIFY, (B) the ability of PMFs to manufacture PYLARIFY to meet product demand, (C) our ability to sell PYLARIFY to customers, (D) our ability to obtain and maintain adequate coding, coverage and payment for PYLARIFY, and (E) our ability to establish PYLARIFY as a leading PSMA PET imaging agent in an increasingly competitive environment in which other PSMA PET imaging agents have been approved and additional ones are in development; (ii) continued market expansion and penetration for our established commercial products, particularly DEFINITY, in the face of segment competition and potential generic competition, including as a result of patent and regulatory exclusivity expirations and challenges; (iii) the global Molybdenum-99 ("Mo-99") supply; (iv) our ability to have third party manufacturers manufacture our products and our ability to manufacture DEFINITY in our in-house manufacturing facility; (v) our ability to successfully launch PYLARIFY AI as a commercial product; (vi) the continuing impact of the global COVID-19 pandemic on our business, supply chain, financial condition and prospects; (vii) the efforts and timing for clinical development and regulatory approval of our product candidates and new clinical applications and territories for our products, in each case, that we may develop, including 1095 and NM-01, or that our strategic partners may develop, including piflufolastat F 18 in Europe and flurpiridaz fluorine-18 ("F 18"); (viii) our ability to identify and acquire or in-license additional diagnostic and therapeutic product opportunities in oncology and other strategic areas; and (ix) the potential reclassification by the FDA of certain of our products and product candidates from drugs to devices with the expense, complexity and potentially more limited competitive protection such reclassification could cause. 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. These 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. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, and in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q.

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.

Available Information

Our global Internet site is www.lantheus.com. We routinely make available important information, including copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after those reports are electronically filed with, or furnished to, the SEC, free of charge on our website at 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.

Our reports filed with, or furnished to, the SEC are also available on the SEC's website at www.sec.gov, and for Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, in an iXBRL (Inline Extensible Business Reporting Language) format. iXBRL is an electronic coding language used to create interactive financial statement data over the Internet. The information on our website is neither part of nor incorporated by reference into this Quarterly Report on Form 10-Q.

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, 2021, and in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q.

Overview

Our Business

We are an established leader and fully integrated provider committed to improving patient outcomes through diagnostics, radiotherapeutics and artificial intelligence solutions that enable clinicians to Find, Fight and Follow disease. We classify our products in three categories: precision diagnostics, radiopharmaceutical oncology, and strategic partnerships and other revenue. Our leading precision diagnostic products assist healthcare professionals ("HCPs") Find and Follow diseases in non-oncologic conditions. Our radiopharmaceutical oncology diagnostics and therapeutics help HCPs Find, Fight and Follow cancer. Our strategic partnerships and other revenue category focuses on facilitating precision medicine through the use of biomarkers, artificial intelligence solutions and radiotherapeutic platforms, and also includes royalty revenue from our license of RELISTOR.

Our commercial products are used by cardiologists, urologists, oncologists, internal medicine physicians, nuclear medicine physicians, radiologists, sonographers and technologists working in a variety of clinical settings. We believe that our diagnostic products provide improved diagnostic information that enables HCPs to better detect and characterize, or rule out, disease, with the potential to achieve better patient outcomes, reduce patient risk and limit overall costs for payors and throughout the healthcare system.

We produce and market our products throughout the United States (the "U.S."), selling primarily to clinics, group practices, hospitals, integrated delivery networks, and radiopharmacies. We sell our products outside the U.S. through a combination of direct distribution in Canada and third party distribution relationships in Europe, Canada, Australia, Asia-Pacific, Central America and South America.

Our headquarters are located in North Billerica, Massachusetts, with additional offices in Somerset, New Jersey; Montreal, Canada and Lund, Sweden.

Key Factors Affecting Our Results

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

PYLARIFY, Ongoing Commercial Launch and Revenue Growth

On May 27, 2021, we announced that the FDA had approved PYLARIFY, an F 18-labeled PET imaging agent targeting prostate-specific membrane antigen ("PSMA"). PYLARIFY is a product in our radiopharmaceutical oncology product category. We commercially launched PYLARIFY in the U.S. in June 2021.

PYLARIFY is a radioactive diagnostic agent indicated for PET imaging of PSMA-positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy and with suspected recurrence based on elevated serum prostate-specific antigen ("PSA") levels. PYLARIFY works by binding to PSMA, a protein that is overexpressed on the surface of more than 90% of primary and metastatic prostate cancer cells. PYLARIFY works with PET/computed tomography ("CT") technology to produce a combined PET/CT scan that enables the reader of the PET/CT scan to detect and locate the disease.

According to the American Cancer Society, prostate cancer is the second most common cancer in American men -- one in eight American men will be diagnosed with prostate cancer in their lifetimes and over 3.0 million American men are living with prostate cancer today. Based on estimates from third party sources regarding the incidence of prostate cancer in men in the U.S., we believe the market potential for all PSMA PET imaging agents in the U.S. could be up to 250,000 annual scans, comprised of 90,000 scans for patients with intermediate unfavorable or high/very high risk of suspected metastases of prostate cancer; 130,000 scans for patients with suspected recurrence of prostate cancer; and 30,000 scans for patients with metastatic castration-resistant prostate cancer ("mCRPC") who may be under consideration for PSMA-targeted therapy for the treatment of adult patients with PSMA-positive mCRPC who have already been treated with other anticancer treatments (androgen receptor pathway inhibition and taxane-based chemotherapy). However, because we are still early in the commercialization of PYLARIFY, we can give no assurance as to how clinical practice may evolve or our ultimate market penetration.

In March 2022, we announced a strategic collaboration with Novartis to include PYLARIFY in prostate cancer trials with Pluvicto, Novartis' recently approved PSMA-targeted therapeutic. As part of the agreement with Novartis, we will supply PYLARIFY

for the selection of patients with prostate cancer for the trials, and Novartis will provide all PYLARIFY-related clinical imaging data to us. In addition, the National Comprehensive Cancer Center updated its guidelines and the Society for Nuclear Medicine and Molecular Imaging updated its appropriate use criteria earlier this year, both noting that PSMA PET imaging agents, including PYLARIFY, can be used for patient selection for PSMA-targeted radioligand therapy.

Upon commercial launch in June 2021, PYLARIFY was immediately available in select parts of the U.S. Over the course of the remainder of 2021 and into 2022, PYLARIFY availability expanded into additional regions and is now broadly available nationwide. We continue to expand the U.S. footprint for PYLARIFY with new PMFs, increased capacity at existing PMFs and added redundancy in key geographic areas, while broadening our customer base and market access coverage to serve our customers and the U.S. prostate cancer community.

The commercial launch of PYLARIFY has been complex and expensive. Throughout 2021, we hired additional employees to assist us with the commercialization of PYLARIFY, including in sales, marketing, reimbursement, quality and medical affairs. To manufacture PYLARIFY, we assembled and qualified a nationwide network of PMFs with radioisotope-producing cyclotrons that make F 18, which has a 110-minute half-life, so PYLARIFY is manufactured and distributed rapidly to end-users. After being made on a cyclotron at a PMF, the F 18 is then combined with certain chemical ingredients in specially designed chemistry synthesis boxes to manufacture PYLARIFY. The finished PYLARIFY is then quality control tested and transferred to a radiopharmacist who prepares and dispenses patient-specific doses of the final product. Because each of the PMFs manufacturing these products is deemed by the FDA to be a separate manufacturing site, each has to be separately approved by the FDA. Although PYLARIFY is now broadly available nationwide and we continue to seek qualification for additional PMFs, we can give no assurance that the FDA will continue to approve PMFs in accordance with our planned roll-out schedule. If FDA approval of manufacturing sites is delayed or withdrawn, our future business, results of operations, financial condition and cash flows could be adversely affected.

In addition to the network of PMFs, we have also been working with academic medical centers in the U.S. that have radioisotope-producing cyclotrons and which have expressed an interest in manufacturing PYLARIFY. For this initiative, we enter into a fee-for-service arrangement under which the academic medical center's PMF manufactures and supplies batches of PYLARIFY, and its radiopharmacy prepares patient-ready unit doses, in each case for and on behalf of us. We then sell those unit doses to the academic medical center's hospitals and clinics, and in some instances, to additional customers in the academic medical center's geographic area, in each case, under separate purchase agreements. The academic medical center's PMF's ability to manufacture and supply batches of PYLARIFY is subject to FDA approval, and we can give no assurance that the FDA will approve such PMFs in accordance with our planned roll-out schedule.

Our commercial launch also required obtaining adequate coding, coverage and payment for PYLARIFY, including not only coverage from Medicare, Medicaid and other government payors, as well as private payors, but also appropriate payment levels, to adequately cover our customers' costs of using PYLARIFY in PSMA PET/CT imaging procedures. We received notification that our Healthcare Procedure Coding System ("HCPCS") code, which enables streamlined billing, went into effect as of January 1, 2022. In addition, effective January 1, 2022, the Centers for Medicare and Medicaid Services ("CMS") granted Transitional Pass-Through Payment Status in the hospital outpatient setting ("TPT Status") for PYLARIFY, enabling traditional Medicare to provide an incremental payment for PET/CT scans performed with PYLARIFY in that setting. TPT Status for PYLARIFY is expected to expire on December 31, 2024. After TPT Status expires, under current Medicare rules, PYLARIFY, similar to other diagnostic radiopharmaceuticals, would not be separately reimbursed in the hospital outpatient setting, but rather would be included as part of the facility fee a hospital otherwise receives for a PET/CT imaging procedure, and the facility fee does not always adequately cover the total cost of the procedure. We can give no assurance that any CMS reimbursement in the hospital outpatient setting that follows the expiration of TPT Status will be adequate to cover the cost of a PYLARIFY PET/CT imaging procedure.

The successful growth of PYLARIFY is also dependent on our ability to establish PYLARIFY as a leading PSMA PET imaging agent in an increasingly competitive environment in which other PSMA PET imaging agents have been approved and additional ones are in development. PYLARIFY's competition is primarily two commercially available gallium-68-based PSMA imaging agents, as well as other non-PSMA-based imaging agents. We also could face potential competition from an F 18 PSMA PET imaging agent currently under review by the FDA. To the extent we lose market share to existing or future competitors, such loss of market share could have an adverse impact on our future business, results of operations, financial condition and cash flows. Moreover, because we are still early in the commercialization of PYLARIFY, we can give no assurance as to how clinical practice may evolve or our ultimate market penetration or market share.

We actively pursue patents in connection with PYLARIFY, both in the U.S. and internationally. In the U.S. for PYLARIFY, we have four Orange Book-listed patents, including composition of matter patents, the last of which expires in 2037. Outside of the U.S., we have and are currently pursuing additional PYLARIFY patents to obtain similar patent protection as in the U.S.

In connection with the Progenics Acquisition in June 2020, we issued to the Progenics stockholders at the time the transaction was consummated CVRs entitling them to receive a pro rata share of aggregate cash payments equal to 40% of U.S. net sales

generated by PYLARIFY in 2022 and 2023 in excess of $100.0 million and $150.0 million, respectively. In no event will our aggregate payment obligations in respect of the CVRs, together with any other non-stock consideration treated as paid in connection with the Progenics Acquisition, exceed 19.9% of the total consideration we paid in the Progenics Acquisition. Based on our 2022 PYLARIFY net sales, we believe that all of our aggregate payment obligations under the CVRs (which we currently estimate will be approximately $99.7 million) will become payable in the first half of 2023.

PYLARIFY AI Clearance and Use

During 2021, we also announced that our subsidiary, EXINI, was granted 510(k) clearance by the FDA in the U.S. and received CE marking in Europe for aPROMISE. We commercially launched aPROMISE under the name PYLARIFY AI in the U.S. in November 2021. During the second quarter of 2022, we received a new 510(k) clearance for an updated version of our PYLARIFY AI platform.

PYLARIFY AI is artificial intelligence medical device software developed to assist with the reading and quantification of PYLARIFY scans. The technology automatically analyzes a PSMA PET/CT image to segment anatomical regions – 51 bones and 12 soft tissue organs. This image segmentation enables automated localization, detection and quantification of potential PSMA-avid lesions in a PSMA PET/CT image, which data is then incorporated into the reporting system used by physicians.

Anticipated Continued Growth of DEFINITY and Expansion of Our Ultrasound Microbubble Franchise

We believe the market opportunity for our microbubble ultrasound enhancing agent, DEFINITY, continues to be significant and that DEFINITY sales will continue to grow in the future, subject to the challenges discussed in "COVID-19 Pandemic and Other Challenges" below. As we continue to educate the physician and healthcare provider community about the benefits and risks of DEFINITY, we believe we will be able to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms. In a U.S. market with three echocardiography ultrasound enhancing agents approved by the FDA, we estimate that DEFINITY continues to hold over 80% of the market.

As we continue to pursue expanding our microbubble franchise, our activities include:

- *Patents* - We continue to actively pursue additional patents in connection with DEFINITY and DEFINITY RT, both in the U.S. and internationally. In the U.S. for DEFINITY, we have five Orange Book-listed method of use patents, one of which expires in 2035 and four of which expire in 2037, as well as additional manufacturing patents that are not Orange Book-listed expiring in 2023 and 2037. In the U.S. for DEFINITY RT, we have six Orange Book-listed patents, including a composition of matter patent which expires in 2035. Outside of the U.S., we have and are currently pursuing additional DEFINITY and DEFINITY RT patents to obtain similar patent protection as in the U.S. The Orange Book-listed patents include a patent on the use of VIALMIX RFID which expires in 2037; we have submitted additional VIALMIX RFID patent applications in major markets throughout the world.

  Hatch-Waxman Act - Even though our longest duration Orange Book-listed DEFINITY patent extends until March 2037, because our Orange Book-listed composition of matter patent expired in June 2019, we may face generic DEFINITY challengers in the near to intermediate term. Under the Hatch-Waxman Act, the FDA can approve Abbreviated New Drug Applications ("ANDAs") for generic versions of drugs if the ANDA applicant demonstrates, among other things, that (i) its generic candidate is the same as the innovator product by establishing bioequivalence and providing relevant chemistry, manufacturing and product data, and (ii) either the marketing of that generic candidate does not infringe the Orange Book-listed patent(s) or the Orange Book-listed patent(s) is invalid. Similarly, the FDA can approve a Section 505(b)(2) New Drug Application ("505(b)(2)") from an applicant that relies on some of the information required for marketing approval to come from studies which the applicant does not own or have a legal right of reference. With respect to the Orange Book-listed patent(s) covering an innovator product, the ANDA applicant or the Section 505(b)(2) applicant (if relying on studies related to the innovator product) (together, the "Applicant") must give a notice (a "Notice") to the innovator of its certification that its generic candidate will not infringe the innovator's Orange Book-listed patent(s) or that the Orange Book-listed patent(s) is invalid. The innovator can then file suit against the Applicant within 45 days of receiving the Notice, and FDA approval to commercialize the generic candidate will be stayed (that is, delayed) for up to 30 months (measured from the date on which a Notice is received) while the patent dispute between the innovator and the Applicant is resolved in court. The 30-month stay could potentially expire sooner if the courts determine that no infringement had occurred or that the challenged Orange Book-listed patent is invalid or if the parties otherwise settle their dispute.

  As of the date of filing of this Quarterly Report on Form 10-Q, we have not received any Notice from an Applicant. If we were to (i) receive any such Notice in the future, (ii) bring a patent infringement suit against the Applicant within 45 days of receiving that Notice, and (iii) successfully obtain the full 30-month stay, then the Applicant would be precluded from commercializing a generic version of DEFINITY prior to the expiration of that 30-month stay and, potentially, thereafter, depending on how the patent dispute is resolved. Solely by way of example and not based on any knowledge we currently have, if we received a Notice from an Applicant in November 2022 and the full 30-month stay were obtained, then the

Applicant would be precluded from commercialization until at least May 2025. If we received a Notice some number of months in the future and the full 30-month stay were obtained, the commercialization date would roll forward in the future by the same number of months. In the event a 505(b)(2) applicant does not rely on studies related to the innovator product, the 30-month stay would not apply, but additional clinical studies may be required.

- *DEFINITY RT* - DEFINITY RT became commercially available in the fourth quarter of 2021. A modified formulation of DEFINITY that allows both storage and shipment at room temperature, DEFINITY RT provides clinicians an additional choice and allows for greater utility of this formulation in broader clinical settings. Given its physical characteristics, we believe DEFINITY RT is also well-suited for inclusion in kits requiring microbubbles for other indications and applications (including in kits developed by third parties of the type described in the paragraph entitled *Microbubble Franchise* below).
- *VIALMIX RFID* – VIALMIX RFID, our next-generation activation device designed specifically for both DEFINITY and DEFINITY RT, became commercially available in the fourth quarter of 2021. The activation rate and time are controlled by VIALMIX RFID through the use of radio-frequency identification technology ("RFID") to ensure reproducible activation of DEFINITY and DEFINITY RT. The RFID tag, which is affixed to the vial label, enables the DEFINITY or DEFINITY RT vial to be appropriately activated with the VIALMIX RFID activation device.

Global Mo-99 Supply

We currently have Mo-99 supply agreements with Institute for Radioelements ("IRE"), running through December 31, 2023, with auto-renewal provisions that are terminable upon notice of non-renewal, and with NTP Radioisotopes ("NTP"), acting for itself and on behalf of its subcontractor, the Australian Nuclear Science and Technology Organisation ("ANSTO"), running through December 31, 2024.

Although we have a globally diverse Mo-99 supply with IRE in Belgium, NTP in South Africa, and ANSTO in Australia, we still face supplier and logistical challenges in our Mo-99 supply chain. When one supplier experiences outages, we generally rely on Mo-99 supply from the other suppliers to limit the impact of the outages. We believe we effectively manage these various supply chain challenges, but depending on reactor and processor schedules and operations, at times we have not been able to fill some or all of the demand for our TechneLite generators on certain manufacturing days. A prolonged disruption of service from one of our three Mo-99 processing sites or one of their main Mo-99-producing reactors could have a substantial negative effect on our business, results of operations, financial condition and cash flows.

To augment our current supply of Mo-99, we have a strategic arrangement with SHINE Medical Technologies LLC ("SHINE") for the future supply of Mo-99. Under the terms of the supply agreement, entered into in November 2014, SHINE will provide Mo-99 produced using its proprietary LEU-solution technology for use in our TechneLite generators once SHINE's facility becomes operational and receives all necessary regulatory approvals, which SHINE now estimates will occur in 2024. The term of this arrangement provides for three years of supply of Mo-99. However, we cannot assure you that SHINE will be able to produce commercial quantities of Mo-99 for our business, or that SHINE, together with our current suppliers, will be able to deliver a sufficient quantity of Mo-99 to meet our needs.

Inventory Supply

We obtain a substantial portion of our imaging agents from a third party supplier. Jubilant HollisterStier ("JHS") is currently a significant supplier of DEFINITY and our sole source manufacturer of NEUROLITE, Cardiolite and evacuation vials, the latter being an ancillary component for our TechneLite generators. On February 23, 2022, our wholly-owned subsidiary, LMI, entered into a Manufacturing and Supply Agreement (the "MSA") with JHS, effective as of February 23, 2022, pursuant to which JHS will manufacture, and LMI will purchase, DEFINITY, NEUROLITE, Cardiolite and evacuation vial products. The new MSA supersedes all of the prior agreements of the parties. The initial term of the MSA runs through December 31, 2027 and can be further extended by mutual agreement of the parties. The MSA requires LMI to purchase from JHS specified percentages of its total requirements for DEFINITY, as well as specified quantities of NEUROLITE, Cardiolite and evacuation vial products, each year during the contract term. Either party can terminate the MSA upon the occurrence of certain events, including the material breach or bankruptcy of the other party. In addition to JHS, we rely on Samsung BioLogics as our sole source manufacturer of DEFINITY RT.

In 2021, we completed the construction of a specialized in-house manufacturing facility at our North Billerica campus to produce DEFINITY and, potentially, other sterile vial products. On February 22, 2022, we received FDA approval of our supplemental new drug application authorizing commercial manufacturing of DEFINITY at our new facility, and inventory that we had previously manufactured at this facility became commercially saleable. We believe this facility will allow us to better manage DEFINITY manufacturing and inventory, reduce our costs in a potentially more price competitive environment, and provide us with supply chain redundancy.

Radiopharmaceuticals are decaying radioisotopes with half-lives ranging from a few hours to several days. Radiopharmaceutical finished goods 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 facilities in North Billerica, Massachusetts and Somerset, New Jersey, as well as at our PMF partner manufacturing facilities across the U.S.

COVID-19 Pandemic and Other Challenges

The global COVID-19 pandemic has had, and could still have, a future negative impact on our business, particularly if there are additional resurgences as a result of new variants of the virus that further increase its communicability or its impact on certain populations, geographic regions and the healthcare system, including elective procedures and hospital access. In addition, our business has been impacted by hospital staffing challenges and a decline in the volume of certain procedures and treatments using our products. For example, we believe sales of DEFINITY during the third quarter of 2022 were impacted by ongoing staffing challenges for nurses at U.S. healthcare institutions, as well as there being fewer in-person U.S. cardiology visits during the quarter as compared to the third quarter of 2021.

Research and Development Expenses

To remain a leader in the marketplace, we have historically made and will continue to make substantial investments in new product development and lifecycle management for existing products, including:

- For PYLARIFY, our development of PYLARIFY resulted in approval by the FDA in May 2021.
- For PYLARIFY AI, our development of PYLARIFY AI resulted in a 510(k) clearance granted by the FDA in the third quarter of 2021 and an additional 510(k) clearance granted during the second quarter of 2022.
- For 1095, we completed an interim analysis of the ARROW Phase 2 study in mCRPC patients in the fourth quarter of 2021 and continued that study without modifications. During the second quarter of 2022, we enrolled the last patient in this study. In total, 120 patients have been randomized -- 80 in the 1095 plus enzalutamide combination group and 40 in the enzalutamide alone group. This study is a multicenter, randomized, open-label, controlled Phase 2 clinical study evaluating the efficacy and safety of 1095, our PSMA-targeted I-131 therapeutic, in combination with enzalutamide compared to enzalutamide alone in patients with metastatic castration resistant prostate cancer who are PSMA-avid, chemotherapy naïve, and have progressed on abiraterone. The primary endpoint in this study is PSA response rate. Key secondary endpoints include time to radiographic free progression, progression free survival, and overall survival. Patients in this study will be followed for one year after their first treatment for all efficacy endpoints and survival and safety data will be collected for an additional year.
- For LMI 1195, we have decided not to make any further investment at this time based on recent feedback from the FDA that we would not be granted a pediatric voucher upon successful approval of the product. We are currently exploring alternative options for this asset.
- We are also exploring additional lifecycle management opportunities for some of our current products, including AZEDRA.

Our investments in these additional clinical activities and lifecycle management opportunities will increase our operating expenses and impact our results of operations and cash flow, and we can give no assurances as to whether any of our clinical development candidates or lifecycle management opportunities will be successful.

Strategic Partnerships, Collaborations, and other Initiatives

We continue to seek ways to further increase the overall value of our portfolio of products and product candidates. We are evaluating a number of different opportunities to collaborate, in-license or acquire additional products, product candidates, businesses and technologies to drive our future growth. In particular, we are focused on late-stage diagnostic and therapeutic product opportunities in oncology and other strategic areas that will complement our existing portfolio.

Oncology

As we continue to pursue expanding our strategic partnerships, our Pharma Services activities and strategic partnerships in oncology include:

- *Prostate Cancer* - We collaborate with pharmaceutical companies developing therapies and diagnostics in prostate cancer.
    - In March 2022, we announced a collaboration with Novartis to include PYLARIFY in prostate cancer trials with Pluvicto. As part of the agreement with Novartis, we will provide PYLARIFY for the selection of patients with prostate cancer for the trials, and Novartis will provide all PYLARIFY related clinical imaging data to us.
    - In January 2022, we announced a collaboration with the Prostate Cancer Clinical Trial Consortium (“PCCTC”), a premier multicenter clinical research organization that specializes in prostate cancer research. The intent of the strategic collaboration is to integrate our AI platform into PCCTC studies to advance the development and validation of novel AI-enabled biomarkers.

- In September 2021, we entered into a development and commercialization collaboration with RefleXion Medical, Inc. to evaluate the use of piflufolastat F 18 to enable real-time therapeutic guidance of biology-guided radiotherapy in prostate cancer using the RefleXion X1TM platform.
- Prior to 2021, we also entered into several other separate agreements, including with POINT Biopharma US Inc. ("POINT Biopharma") and Regeneron Pharmaceuticals, Inc., under which we supply piflufolastat F 18 in connection with their clinical studies, and Curium, under which we licensed exclusive rights to Curium to develop and commercialize piflufolastat F 18 in Europe. In June 2022, Curium announced that it had submitted its marketing authorization application to the European Medicines Agency seeking approval for piflufolastat F 18 in Europe. In addition, in 2022, we entered into an agreement with Curium to add PYLARIFY to its U.S. Eclipse trial, a multi-center, open-label, randomized Phase 3 trial comparing the safety and efficacy of Curium's PSMA-targeted therapeutic versus hormone therapy in patients with metastatic castration-resistant prostate cancer. PYLARIFY will be used to determine PSMA-avidity as part of patient selection.

- *Immuno-Oncology* - In May 2019, we entered into a strategic collaboration and license agreement with NanoMab Technology Limited ("NanoMab"), a privately-held biopharmaceutical company focused on the development of next generation radiopharmaceuticals for cancer precision medicine. In May 2022, we announced that the first patient had been dosed in a Phase 2 clinical trial of NM-01, a novel technetium-99m SPECT imaging agent that we are developing to assess PD-L1 expression in cancer cells. The Phase 2 clinical trial is an open-label, single-arm trial in non-small cell lung cancer patients. The primary endpoint is the assessment of PD-L1 expression in primary tumor and metastatic lesions by NM-01 compared to immunohistochemistry. Other objectives are aimed at quantifying intra- and inter-tumoral heterogeneity of PD-L1 expression by NM-01, as well as establishing correlations with other diagnostic procedures. The trial is being conducted by NanoMab at King's College London and is expected to complete enrollment later in 2022.
- *Pan-Oncology* - In March 2021, we acquired from Ratio Therapeutics LLC (previously Noria Therapeutics, Inc.) exclusive, worldwide rights to NTI-1309, an innovative imaging biomarker that targets fibroblast activation protein, an emerging target with broad potential imaging applicability and use in oncology. Upon further clinical development, we will assess options to bring NTI-1309 to market as a diagnostic or potentially a therapeutic product.

Microbubble Franchise

In addition, we continue to expand our microbubble franchise. In April 2021, we announced a strategic collaboration with Allegheny Health Network ("AHN"), which will use our microbubbles in combination with AHN's ultrasound-assisted non-viral gene transfer technology for the development of a proposed treatment of xerostomia. Xerostomia is a lack of saliva production leading to dry mouth and has a variety of causes, including radiotherapy and chemotherapy, the chronic use of drugs and rheumatic and dysmetabolic diseases. Prior to 2021, we entered into microbubble collaborations with the following parties: (i) Cerevast Medical, Inc. ("Cerevast"), in which our microbubbles will be used in connection with Cerevast's ocular ultrasound device to improve blood flow in occluded retinal veins in the eye; (ii) CarThera SAS, for the use of our microbubbles in combination with SonoCloud, a proprietary implantable device in development for the treatment of recurrent glioblastoma; and (iii) Insightec Ltd. ("Insightec"), which will use our microbubbles in connection with the development of Insightec's transcranial guided focused ultrasound device for the treatment of glioblastoma as well as other neurodegenerative conditions.

Flurpiridaz F 18

In September 2022, we announced with our strategic partner GE Healthcare Limited ("GE Healthcare") that the recent Phase III clinical trial of our investigational radiotracer, flurpiridaz F 18, had met its co-primary endpoints of exceeding a 60% threshold for both sensitivity and specificity for detecting coronary artery disease ("CAD"). The findings, shared at an American Society of Nuclear Cardiology conference, also demonstrated that cardiac PET imaging with flurpiridaz F 18 has higher diagnostic efficacy and image quality in patients with suspected CAD, compared with single photon emission computed tomography ("SPECT") Myocardial Perfusion Imaging ("MPI"), the predominant procedure currently used in nuclear cardiology. We believe SPECT MPI represents approximately 6 million procedures per year in the U.S.

Under a Collaboration and License Agreement we entered into with GE Healthcare in 2017, GE Healthcare has led the funding and development of flurpiridaz F 18, and, if the imaging agent is approved, will have the global commercialization rights for it. We have collaborated on the development and will also collaborate on potential commercialization through a joint steering committee. If flurpiridaz F 18 receives regulatory approval and is commercially successful, we will receive:

- up to $60 million in regulatory and sales milestone payments,
- tiered double-digit royalties on U.S. sales., and
- mid-single digit royalties on sales outside of the U.S.

Generally, our costs in connection with the strategic partnerships relate to the supply of drug and other ancillary expenses and the benefits can include possible supply, milestone and royalty payments, additional intellectual property rights and strategic relationships. For flurpiridaz F 18, under the Collaboration and License Agreement, we retained ownership of all of the licensed intellectual property and bear the cost of patent prosecution and maintenance. We can give no assurance as to if or when or if any of these collaborations and other new initiatives, including our collaboration for flurpiridaz F 18, will be successful or accretive to earnings.

Results of Operations

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	**2022**	**2021**	**Change $**	**Change %**	**2022**	**2021**	**Change $**	**Change %**
Revenues	$ 239,292	$ 102,073	$ 137,219	134.4 %	$ 671,895	$ 295,646	$ 376,249	127.3 %
Cost of goods sold	91,859	59,404	32,455	54.6 %	257,363	165,859	91,504	55.2 %
Gross profit	147,433	42,669	104,764	245.5 %	414,532	129,787	284,745	219.4 %
Operating expenses								
Sales and marketing	25,414	17,195	8,219	47.8 %	73,260	48,999	24,261	49.5 %
General and administrative	23,759	28,550	(4,791)	(16.8)%	93,945	87,865	6,080	6.9 %
Research and development	12,517	11,252	1,265	11.2 %	39,455	33,673	5,782	17.2 %
Total operating expenses	61,690	56,997	4,693	8.2 %	206,660	170,537	36,123	21.2 %
Gain on sale of assets	—	—	—	N/A	—	15,263	(15,263)	N/A
Operating income (loss)	85,743	(14,328)	100,071	(698.4)%	207,872	(25,487)	233,359	(915.6)%
Interest expense	1,626	1,569	57	3.6 %	4,604	6,224	(1,620)	(26.0)%
Gain on extinguishment of debt	—	—	—	N/A	—	(889)	889	N/A
Other income	1,101	3,940	(2,839)	(72.1)%	306	3,209	(2,903)	(90.5)%
Income (loss) before income taxes	83,016	(19,837)	102,853	(518.5)%	202,962	(34,031)	236,993	(696.4)%
Income tax expense (benefit)	21,784	(6,422)	28,206	(439.2)%	55,710	(2,967)	58,677	(1,977.7)%
Net income (loss)	$ 61,232	$ (13,415)	$ 74,647	(556.4)%	$ 147,252	$ (31,064)	$ 178,316	(574.0)%

Comparison of the Periods Ended September 30, 2022 and 2021

Revenues

We classify our revenues into three product categories: precision diagnostics, radiopharmaceutical oncology, and strategic partnerships and other revenue. Precision diagnostics includes DEFINITY, TechneLite and other diagnostic imaging products. Radiopharmaceutical oncology consists primarily of PYLARIFY and AZEDRA. Strategic partnerships and other revenue includes out-licensing arrangements, which includes $24.0 million of revenue recognized pursuant to the Novartis Agreement, partnerships that focus on facilitating precision medicine through the use of biomarkers, digital solutions and radiotherapeutic platforms, and on our other products, such as RELISTOR.

Revenues are summarized by product category on a net basis as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	**2022**	**2021**	**Change $**	**Change %**	**2022**	**2021**	**Change $**	**Change %**
DEFINITY	$ 60,740	$ 57,636	$ 3,104	5.4 %	$ 181,374	$ 173,448	$ 7,926	4.6 %
TechneLite	22,094	22,680	(586)	(2.6)%	64,139	69,252	(5,113)	(7.4)%
Other precision diagnostics	6,175	7,563	(1,388)	(18.4)%	16,803	21,289	(4,486)	(21.1)%
Total precision diagnostics	89,009	87,879	1,130	1.3 %	262,316	263,989	(1,673)	(0.6)%
PYLARIFY	143,754	7,724	136,030	N/A	366,763	7,997	358,766	N/A
Other radiopharmaceutical oncology	928	1,166	(238)	(20.4)%	3,183	5,206	(2,023)	(38.9)%
Total radiopharmaceutical oncology	144,682	8,890	135,792	1,527.5 %	369,946	13,203	356,743	2,702.0 %
Strategic partnerships and other revenue	5,601	5,304	297	5.6 %	39,633	18,454	21,179	114.8 %
Total revenues	$ 239,292	$ 102,073	$ 137,219	134.4 %	$ 671,895	$ 295,646	$ 376,249	127.3 %

The increase in revenues for the three months ended September 30, 2022, as compared to the prior year period, is primarily driven by the commercial launch of PYLARIFY, an increase in DEFINITY sales volume and higher strategic partnership revenue from the RELISTOR royalty stream. The increase is offset, in part, by lower sales volumes from TechneLite driven by opportunistic sales in the prior year and lower volumes of other precision diagnostics.

The increase in revenues for the nine months ended September 30, 2022, as compared to the prior year period, is primarily driven by the commercial launch of PYLARIFY and $24.0 million of revenue recognized pursuant to the Novartis Agreement, and an increase in DEFINITY sales volume. The increase is offset, in part, by lower sales volumes from TechneLite driven by the strategic decisions to exit a customer contract and opportunistic sales in the prior year, lower volumes of other precision diagnostics, lower volume of other radiopharmaceutical oncology products and lower strategic partnerships and other revenue due primarily to a sale of cREPO in the prior period.

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 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 expected purchases and the resulting applicable contractual rebate to be earned over a contractual period.

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

(in thousands)	**Rebates and Allowances**
Balance, January 1, 2022	$ 10,977
Provision related to current period revenues	20,334
Adjustments relating to prior period revenues	70
Payments or credits made during the period	(18,134)
Balance, September 30, 2022	$ 13,247

Gross Profit

The increase in gross profit for the three months ended September 30, 2022, as compared to the prior year period, is primarily due to PYLARIFY sales volume, as well as an increase in DEFINITY sales volume.

The increase in gross profit for the nine months ended September 30, 2022, as compared to the prior year period, is primarily due to PYLARIFY sales volume, the $24.0 million pursuant to the Novartis Agreement, and an increase in DEFINITY sales volume, which is partially offset by amortization expense of acquired intangible assets in the Progenics Acquisition.

Sales and Marketing

Sales and marketing expenses consist primarily of salaries and other related costs for personnel in field sales, marketing 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.

Sales and marketing expenses increased $8.2 million and $24.3 million for the three and nine months ended September 30, 2022 as compared to the prior year period. This was primarily driven by the continued commercialization activities following the launch of PYLARIFY and increased employee-related costs (including the hiring of new employees throughout 2021 in connection with the commercialization activities for PYLARIFY), as well as an increase in the level of marketing promotional programs and travel during this period which was reduced during the prior year due to the impact of the COVID-19 pandemic.

General and Administrative

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.

General and administrative expenses decreased $4.8 million for the three months ended September 30, 2022 compared to the prior period. This was primarily driven by a $9.5 million sublease impairment charge in the prior year. In addition, there was a $1.5 million net reduction for the fair value adjustments to the contingent asset and liabilities in the third quarter of 2022 (a decrease of $4.1 million from the prior year period) (refer to Note 4, “Fair Value of Financial Instruments”, for further details on contingent consideration liabilities, including CVRs). These decreases are partially offset by increased employee-related costs and professional fees.

General and administrative expenses increased $6.1 million for the nine months ended September 30, 2022 compared to the prior period. This was primarily driven by increased employee-related costs and professional fees. This amount was offset by a $3.1 million net reduction for the fair value adjustments to the contingent asset and liabilities. (refer to Note 4, “Fair Value of Financial Instruments”, for further details on contingent consideration liabilities, including CVRs).

Research and Development

Research and development expenses relate primarily to the development of new products to add to our portfolio and costs related to our medical affairs, medical information and regulatory functions.

Research and development expenses increased $1.3 million for the three months ended September 30, 2022 as compared to the prior year period. This was primarily driven by higher overall headcount related costs and the investment in medical affairs related to PYLARIFY, offset, in part, by the expenses related to the preparation activities for the launch of PYLARIFY during the prior year period.

Research and development expenses increased $5.8 million for the nine months ended September 30, 2022 as compared to the prior year period. This was primarily driven by the level of activity of the ARROW Phase 2 study of 1095, investment in medical affairs related to PYLARIFY and higher overall headcount related costs, offset by the expenses related to filing fees for the PYLARIFY New Drug Application and preparation activities for the launch of PYLARIFY during the prior year period.

Interest Expense

Interest expense decreased by approximately $1.6 million for the nine months ended September 30, 2022 as compared to the prior year period due to the repayment of the Royalty-Backed Loan on March 31, 2021.

Income Tax Expense

The income tax expense recorded for the three and nine months ended September 30, 2022 was primarily due to pre-tax profits reported during the period, partially offset by the benefit associated with stock compensation deductions.

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 evaluate all

available positive and negative evidence, and weigh the objective evidence and expected impact. We continue to record a valuation allowance against certain of our foreign net deferred tax assets and a small component of our domestic deferred tax assets.

Our effective tax rate for each reporting period is presented as follows:

	Nine Months Ended September 30,	
	2022	**2021**
Effective tax rate	27.4%	8.7%

Our effective tax rate in fiscal 2022 differs from the U.S. statutory rate of 21% principally due to the accrual of state taxes and the impact of non-deductible contingency reserve expense.

The increase in the effective income tax rate for the nine months ended September 30, 2022 is primarily due to our increased pre-tax profits in high population states that generally have higher tax rates.

Liquidity and Capital Resources

Cash Flows

The following table provides information regarding our cash flows:

	Nine Months Ended September 30,	
(in thousands)	2022	2021
Net cash provided by operating activities	$ 176,429	$ 40,027
Net cash (used in) provided by investing activities	$ (11,823)	$ 8,227
Net cash used in financing activities	$ (6,149)	$ (37,232)

Net Cash Provided by Operating Activities

Net cash provided by operating activities of $176.4 million in the nine months ended September 30, 2022 was primarily comprised of net income adjusted for the net effect of non-cash items such as depreciation, amortization and accretion expense, the change in fair value of contingent assets and liabilities of $25.4 million (refer to Note 4, “Fair Value of Financial Instruments”, for further details on contingent consideration liabilities, including CVRs), and stock-based compensation expense. The primary working capital sources of cash were the increase in billings associated with PYLARIFY sales and the timing of payments to large vendors. The primary working capital uses of cash were an increase in trade receivables associated primarily with the increase in PYLARIFY revenues.

Net cash provided by operating activities of $40.0 million in the nine months ended September 30, 2021 was driven primarily by depreciation, amortization and accretion expense of $30.1 million, a change in fair value of contingent assets and liabilities of $28.5 million (refer to Note 4, “Fair Value of Financial Instruments”, for further details on contingent consideration liabilities, including CVRs), stock-based compensation expense of $11.8 million, impairment of long-lived assets of $9.5 million and a net increase of $2.4 million related to movements in our working capital accounts during the period. The overall increases in cash from our working capital accounts were primarily driven by an increase in sales collections, the timing of payments to large vendors, and an increase in fees related to PYLARIFY sales. These net sources of cash were offset by a net loss of $31.1 million and a gain on sale of assets of $15.3 million.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2022 was primarily due to $13.6 million of capital expenditures offset by cash proceeds of $1.8 million received from the sale of our Puerto Rico subsidiary.

Net cash provided by investing activities during the nine months ended September 30, 2021 was primarily due to cash proceeds of $15.8 million received from the sale of our Puerto Rico subsidiary, which was offset by $7.6 million of capital expenditures.

Net Cash Used in Financing Activities

Net cash used in financing activities during the nine months ended September 30, 2022 is primarily attributable to the payments on long-term debt and other borrowings of $7.9 million related to the 2019 Term Facility and payments for minimum statutory tax withholding related to net share settlement of equity awards of $7.2 million offset by proceeds of $7.5 million from stock option exercises.

Net cash used in financing activities during the nine months ended September 30, 2021 is primarily attributable to the payments on long-term debt and other borrowings of $40.8 million related to the 2019 Term Facility and Royalty-Backed Loan, including a voluntary repayment of the outstanding principal on the Royalty-Backed Loan and payments for minimum statutory tax withholding related to net share settlement of equity awards of $1.9 million offset by proceeds of $4.6 million from stock option exercises.

External Sources of Liquidity

In June 2019, we refinanced our 2017 $275.0 million five-year term loan facility with the 2019 Term Facility. In addition, we replaced our $75.0 million revolving facility with our current five-year revolving credit facility (the “2019 Revolving Facility” and together with the 2019 Term Facility, the “2019 Facility”). The terms of the 2019 Term Facility are set forth in the Credit Agreement, dated as of June 27, 2019, by and among us, the lenders from time to time party thereto and Wells Fargo Bank, N.A., as administrative agent and collateral agent, which was amended on June 19, 2020 (as amended, the “2019 Credit Agreement”). We have the right to request an increase to the 2019 Term Facility or request the establishment of one or more new incremental term loan facilities, in an aggregate principal amount of up to $100.0 million, plus additional amounts, in certain circumstances.

We are permitted to voluntarily repay the 2019 Term Loans, in whole or in part, without premium or penalty. The 2019 Term Facility requires us to make mandatory prepayments of the outstanding 2019 Term Loans in certain circumstances. The 2019 Term Facility amortizes at 5.0% per year through September 30, 2022 and 7.5% thereafter, until its June 27, 2024 maturity date.

Under the terms of the 2019 Revolving Facility, the lenders thereunder agreed to extend credit to us from time to time until June 27, 2024 consisting of revolving loans in an aggregate principal amount not to exceed $200.0 million at any time outstanding. The 2019 Revolving Facility includes a $20.0 million sub-facility for the issuance of letters of credit (the "Letters of Credit"). The 2019 Revolving Facility includes a $10.0 million sub-facility for swingline loans (the "Swingline Loans"). The Letters of Credit, Swingline Loans and the borrowings under the 2019 Revolving Facility are expected to be used for working capital and other general corporate purposes.

Under the 2019 Credit Agreement, loans bear interest at LIBOR plus a spread that ranges from 1.50% to 3.00% or the Base Rate (as defined in the 2019 Credit Agreement) plus a spread that ranges from 0.50% to 2.00%, and the commitment fee ranges from 0.15% to 0.40%, in each case based on our Total Net Leverage Ratio (as defined in the 2019 Credit Agreement).

The maximum total net leverage ratio and interest coverage ratio permitted by the financial covenant in our 2019 Credit Agreement is displayed in the table below:

2019 Credit Agreement

Period	Total Net Leverage Ratio
Q3 2021 and thereafter	3.50 to 1.00

Period	Interest Coverage Ratio
Q2 2021 and thereafter	3.00 to 1.00

As of September 30, 2022, we were in compliance with all financial and other covenants under the 2019 Credit Agreement.

Please refer to our Annual Report on Form 10-K for fiscal year ended December 31, 2021 for further details on the 2019 Facility and the 2019 Credit Agreement.

On June 19, 2020, as a result of the Progenics Acquisition, we assumed Progenics outstanding debt as of such date in the amount of $40.2 million. On November 4, 2016, Progenics, through its wholly-owned subsidiary, MNTX Royalties Sub LLC, entered into the Royalty-Backed Loan. The Royalty-Backed Loan bore interest at an annual rate of 9.5% and was scheduled to mature on June 30, 2025.

On March 31, 2021, we voluntarily repaid in full the entire outstanding principal on the Royalty-Backed Loan in the amount of $30.9 million, which included a prepayment amount of $0.5 million, and terminated the agreement.

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, could be material and 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:

- The amount and timing of the expected cash payment related to the CVRs;
- The level of product sales and the pricing environment of our currently marketed products, particularly PYLARIFY and DEFINITY, as well as any additional products that we may market in the future, including decreased product sales resulting from the COVID-19 pandemic;
- Revenue mix shifts and associated volume and selling price changes that could result from contractual status changes with key customers, and additional competition;
- The continued costs of the ongoing commercialization of PYLARIFY and PYLARIFY AI;

- The costs of acquiring or in-licensing, developing, obtaining regulatory approval for, and commercializing, new products, businesses or technologies, together with the costs of pursuing opportunities that are not eventually consummated;
- Our investment in the further clinical development and commercialization of products and development candidates, including AZEDRA, 1095 and NM-01;
- The costs of investing in our facilities, equipment and technology infrastructure;
- The costs and timing of establishing or amending manufacturing and supply arrangements for commercial supplies of our products and raw materials and components;
- Our ability to have products manufactured and released from manufacturing sites in a timely manner in the future, or to manufacture products at our in-house manufacturing facilities in amounts sufficient to meet our supply needs;
- The costs of further commercialization of our existing products, including product marketing, sales and distribution and whether we obtain local partners to help share such commercialization costs;
- 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, intellectual property or other claims;
- The cost of interest on any additional borrowings which we may incur under our financing arrangements; and
- The impact of sustained inflation on our costs of goods sold and operating expenses.

We are vulnerable to future supply chain shortages, disruptions or delays, especially for our single sourced products, raw materials and components. Disruption in our financial performance could also occur if we experience significant adverse changes in product or customer mix, broad economic downturns, sustained inflation, adverse industry or company conditions or catastrophic external events, including pandemics such as COVID-19, natural disasters and political or military conflict. If we experience one or more of these events in the future, we may be required to implement 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, debt financings, assets securitizations, sale-leasebacks or other financing or strategic alternatives, to the extent such transactions are permissible under the covenants of our 2019 Credit Agreement. 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 our 2019 Credit Agreement, 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 September 30, 2022, our only current committed external source of funds is our borrowing availability under our 2019 Revolving Facility. We had $257.3 million of cash and cash equivalents at September 30, 2022. Our 2019 Facility, as amended, contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. Incremental borrowings under the 2019 Revolving Facility, as amended, may affect our ability to comply with the covenants in the 2019 Facility, as amended, including the financial covenants restricting consolidated net leverage and interest coverage. Accordingly, we may be limited in utilizing the full amount of our 2019 Revolving Facility, as amended, as a source of liquidity.

The CVRs we issued in the Progenics Acquisition entitle holders thereof to future cash payments of 40% of PYLARIFY net sales over (i) $100.0 million in 2022 and (ii) $150.0 million in 2023, which we currently intend to fund from our then-available cash. In no event will our aggregate payments under the CVRs, together with any other non-stock consideration treated as paid in connection with the Progenics Acquisition, exceed 19.9% of the total consideration we pay in the Progenics Acquisition. Refer to Note 4, “Fair Value of Financial Instruments”, for further details on contingent consideration liabilities.

Based on our current operating plans, we believe our balance of cash and cash equivalents, which totaled $257.3 million as of September 30, 2022, along with cash generated by ongoing operations and continued access to our 2019 Revolving Facility, will be sufficient to satisfy our cash requirements over the next twelve months and beyond.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are 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 requires us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. 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 significant changes to our critical accounting policies or in the underlying accounting assumptions and estimates used in such policies in the nine months ended September 30, 2022. 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, 2021.

Off-Balance Sheet Arrangements

We are required to provide the Massachusetts Department of Public Health and New Jersey Department of Environmental Protection financial assurance demonstrating our ability to fund the decommissioning of our North Billerica, Massachusetts and Somerset, New Jersey production facilities upon closure, though we do not intend to close the facilities. We have provided this financial assurance in the form of a $30.3 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, 2021. Our exposures to market risk have not changed materially since December 31, 2021.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

The Company’s management, with the participation of the Company’s Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), 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. Based on that evaluation, the Company’s CEO and CFO 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 the period covered by this report.

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting during the nine months ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

We are continually monitoring and assessing the pandemic status and geopolitical environment to determine any potential impact on the design and operating effectiveness of our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Information with respect to certain legal proceedings is included in Note 19, “Commitments and Contingencies”, to the condensed consolidated financial statements contained in Part I, Item 1. Financial Statements of this Quarterly Report on Form 10-Q and is incorporated herein by reference.

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, 2021, except as set forth below:

Our ability to continue to grow PYLARIFY as a commercial product is dependent on (A) our ability to obtain FDA approval for additional PMFs to manufacture PYLARIFY, (B) the ability of PMFs to manufacture PYLARIFY to meet product demand, (C) our ability to sell PYLARIFY to customers, (D) our ability to obtain and maintain adequate coding, coverage and payment for PYLARIFY, and (E) our ability to establish PYLARIFY as a leading PSMA PET imaging agent in an increasingly competitive environment in which other PSMA PET imaging agents have been approved and additional ones are in development.

The commercial launch of PYLARIFY has been complex and expensive. To manufacture PYLARIFY, we assembled and qualified a nationwide network of PMFs with radioisotope-producing cyclotrons that make F 18, which has a 110-minute half-life, so PYLARIFY is manufactured and distributed rapidly to end-users. Because each of the PMFs manufacturing these products is deemed by the FDA to be a separate manufacturing site, each has to be separately approved by the FDA. Although we successfully qualified 21 PMFs in 2021 and continue to seek qualification for additional PMFs in 2022, such that PYLARIFY is broadly available across the U.S., we can give no assurance that the FDA will continue to approve PMFs in accordance with our planned roll-out schedule. If FDA approval of manufacturing sites is delayed or withdrawn, our future business, results of operations, financial condition and cash flows could be adversely affected.

PYLARIFY is sold in the U.S. to hospitals, independent imaging centers and government facilities and sales are generated through a PYLARIFY direct sales team as well as a sales team at some of our PMF partners. We generally do not use group purchasing arrangements to sell PYLARIFY and require each customer to enter into a contract directly with us or our PMFs. Throughout 2021, we hired additional employees to assist us with this commercialization of PYLARIFY. Our ability to continue to successfully grow PYLARIFY depends, in part, on our ability to continue to enter into arrangements directly with the hospitals, independent imaging centers and government facilities that we serve. Any delay or inability to enter into these arrangements could have an adverse impact on our future business, results of operations, financial condition and cash flows.

Obtaining adequate coding, coverage and payment for PYLARIFY is critical, including not only coverage from Medicare, Medicaid and other government payors, as well as private payors, but also appropriate payment levels to adequately cover our customers' costs of using PYLARIFY in PET/CT imaging procedures. We received notification that our HCPCS code, which enables streamlined billing, went into effect as of January 1, 2022. In addition, effective January 1, 2022, CMS granted TPT Status for PYLARIFY, enabling traditional Medicare to provide an incremental payment for PET/CT scans performed with PYLARIFY in the hospital outpatient setting. TPT Status for PYLARIFY is expected to expire on December 31, 2024. After TPT Status expires, under current Medicare rules, PYLARIFY, similar to other diagnostic radiopharmaceuticals, would not be separately reimbursed in the hospital outpatient setting but rather would be included as part of the facility fee a hospital otherwise receives for a PET/CT imaging procedure, and the facility fee does not always adequately cover the total cost of the procedure. We can give no assurance that any CMS reimbursement in the hospital outpatient setting that follows the expiration of TPT Status will be adequate to cover the cost of a PYLARIFY PET/CT imaging procedure. In addition, if other government payors or private payors do not provide adequate reimbursement for the use of PYLARIFY, our future business, results of operations, financial condition and cash flows could be adversely affected.

The successful growth of PYLARIFY is also dependent on our ability to establish PYLARIFY as a leading PSMA PET imaging agent in an increasingly competitive environment in which other PSMA PET imaging agents have been approved and additional ones are in development. PYLARIFY currently competes with two commercially available gallium-68-based PSMA PET imaging agents from Telix Pharmaceuticals Limited and Novartis AG, as well as other non-PSMA PET imaging agents. We also face potential competition from an F 18 PSMA PET imaging agent for which Bracco is currently seeking FDA approval, which we believe could be granted by the FDA in 2023. To the extent we lose market share to existing or future competitors (including during any period of time in which our TPT Status has expired but TPT Status for a later-approved competitive product still exists), such loss of market share could have an adverse impact on our future business, results of operations, financial condition and cash flows. Moreover, because we are still early in the commercialization of PYLARIFY, we can give no assurance as to how clinical practice may evolve or our ultimate market penetration or market share.

Our success in growing PYLARIFY also depends, in part, on our successfully establishing the use of PYLARIFY for approved indications and potentially for additional indications, including for patient selection for PSMA-targeted therapeutics. For example, we believe the approval of Pluvicto for the treatment of adult patients with PSMA-positive mCRPC who have already been treated with other anticancer treatments (androgen receptor pathway inhibition and taxane-based chemotherapy) creates a new addressable market for the use of PSMA PET imaging in patient selection for PSMA-targeted therapy that increases the total addressable market in the U.S. by an additional 30,000 new scans per year for patients with mCRPC. However, the prescribing

information for Pluvicto specifies that a PSMA-11 based PSMA PET imaging agent be used for patient selection, and PYLARIFY is not a PSMA-11 based imaging agent. In March 2022, we announced a strategic collaboration with Novartis to include PYLARIFY in prostate cancer trials with Pluvicto. While we note that FDA-approved labels for F 18 based and PSMA-11 based PSMA PET imaging agents have generally been treated as a class of drugs, including recently by the National Comprehensive Cancer Center in its guidelines and the Society for Nuclear Medicine and Molecular Imaging in its appropriate use criteria, we can give no assurances that the Novartis prostate cancer trials using PYLARIFY will be successful, that the Pluvicto prescribing information will be expanded to incorporate F 18 based PSMA PET imaging agents like PYLARIFY, or how clinical practice may evolve. To the extent we are unsuccessful in establishing the use of PYLARIFY for approved or new indications, such lack of success could have an adverse impact on our future business, results of operations, financial condition and cash flows.

We face significant competition in our business and may not be able to compete effectively.

The markets for our products are highly competitive and continually evolving. Our principal competitors for our current commercial products and leading clinical development candidates include large, global companies that are more diversified than we are and that have substantial financial, manufacturing, sales and marketing, distribution and other resources:

- For PYLARIFY, our competitors currently include approved imaging agents from Telix Pharmaceuticals Limited, Novartis AG and Bracco, and may in the future include an F 18 PSMA PET imaging agent that Bracco has in late stage clinical development, which we believe could be approved by the FDA for commercialization later in 2023. In addition, the University of California, San Francisco and the University of California, Los Angeles have approved NDAs for a gallium-68 PSMA-11 injection for PSMA PET imaging, which we believe will primarily be used within their hospital systems.
- For DEFINITY, our competitors currently include GE Healthcare and Bracco.
- For a number of our radiopharmaceutical commercial products, our competitors currently include Curium, GE Healthcare, Bracco and Jubilant Life Sciences, an affiliate of JHS and Jubilant Radiopharma, as well as other competitors, including NorthStar Medical Radioisotopes, LLC and potentially BWXT Medical Ltd.
- For RELISTOR, our principal competitors include Nektar Therapeutics, in collaboration with AstraZeneca PLC; Cubist Pharmaceuticals, a subsidiary of Merck & Co., Inc.; Mallinckrodt plc, in collaboration with Takeda Pharmaceutical Company Limited; and BioDelivery Sciences International, Inc.; together with other prescription, as well as over-the-counter, laxatives used as first line therapy for opioid-induced constipation.
- For AZEDRA, there are currently no FDA approved anticancer treatments in the U.S. for malignant, recurrent, and/or unresectable pheochromocytoma and paraganglioma.
- For 1095, our principal competitors in the field of radiopharmaceutical therapeutics for mCRPC include Novartis AG, which received FDA approval for its PSMA-targeted therapeutic earlier this year; and may include POINT Biopharma, Telix Pharmaceuticals Limited, and Bayer HealthCare Pharmaceuticals Inc., each of which have product candidates in development.
- For flurpiridaz, our principal competitors may include rubidium generators from Bracco and Jubilant Radiopharma.

We cannot anticipate the actions of our current or future competitors in the same or competing diagnostic modalities, such as significant price reductions on products that are comparable to our own, development of new products that are more cost-effective or have superior performance than our current products or the introduction of generic versions after our proprietary products lose their patent protection. In addition, distributors of our products could attempt to shift end-users to competing diagnostic modalities and products, or bundle the sale of a portfolio of products, in either case to the detriment of our specific products. Our current or future products could be rendered obsolete or uneconomical as a result of these activities.

Further, the radiopharmaceutical industry continues to evolve strategically, with several market participants either recently sold or for sale. In addition, the supply-demand dynamics of the industry are complex because of large market positions of some participants, legacy businesses, government subsidies (in particular, relating to the manufacture of radioisotopes), and group purchasing arrangements. We cannot predict what impact new owners and new operators may have on the strategic decision-making of our competitors, customers and suppliers, and such decision-making could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We may be adversely affected by prevailing economic conditions and financial, business and other factors beyond our control.

Our ability to attract and retain customers, invest in and grow our business, maintain our desired levels of costs of goods sold and operating expenses and meet our financial obligations depends on our operating and financial performance, which, in turn, is

subject to numerous factors, including the prevailing economic conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the U.S. and inflationary pressures, including escalating energy prices. We cannot anticipate all the ways in which the current or future economic climate and financial market conditions could adversely impact our business. We are exposed to risks associated with reduced profitability and the potential financial instability of our customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, our customers may experience reductions in revenues, profitability and/or cash flow that could lead them to modify, delay or cancel orders for our products. If customers are not successful in generating sufficient revenue or are precluded from securing financing, they may not be able to pay, or may delay payment of, accounts receivable that are owed to us. This, in turn, could adversely affect our financial condition and liquidity. To the extent prevailing economic conditions result in fewer procedures being performed, our business, results of operations, financial condition and cash flows could be adversely affected.

Similarly, we would expect our costs of goods sold and other operating expenses to change in the future in line with periodic inflationary changes in price levels. Because we intend to retain and continue to use our property and equipment, we believe that the incremental inflation related to the replacement costs of those items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation, contract services, and transportation costs, which could increase our level of expenses and the rate at which we use our resources. While we generally believe that we will be able to offset the effect of price-level changes by adjusting our product prices and implementing operating efficiencies, any material unfavorable changes in price levels could have a material adverse effect on our financial condition, results of operations and cash flows.

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 three months ended September 30, 2022. The Company does not currently have a share repurchase program in effect. The 2015 Equity Incentive Plan, adopted by the Company on June 24, 2015, as amended on April 26, 2016 and as further amended on April 27, 2017, April 24, 2019, April 28, 2021 and April 28, 2022 (the "2015 Plan"), provides for the withholding of shares to satisfy minimum statutory tax withholding 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 2.

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
July 2022**	5,064	$ 70.65	*	*
August 2022**	1,434	$ 82.58	*	*
September 2022**	4,434	$ 82.67	*	*
Total	10,932		*	

* 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 or 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 finance the growth and development of our business and to repay indebtedness. Our ability to pay dividends is 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

EXHIBIT NUMBER	DESCRIPTION OF EXHIBITS	INCORPORATED BY REFERENCE			
		FORM	FILE NUMBER	EXHIBIT	FILING DATE
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).				
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).				
32.1**	Certification pursuant to 18 U.S.C. Section 1350.				
101.INS*	Inline XBRL Instance Document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith.

** Furnished herewith.

+ Indicates management contract or compensatory plan or arrangements

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:	November 3, 2022

LANTHEUS HOLDINGS, INC.

By:	/s/ ROBERT J. MARSHALL, JR.
Name:	Robert J. Marshall, Jr.
Title:	*Chief Financial Officer and Treasurer (Principal Financial Officer)*
Date:	November 3, 2022

Exhibit 31.1

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: November 3, 2022

/s/ MARY ANNE HEINO

Name: Mary Anne Heino

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

Exhibit 31.2

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

I, Robert J. Marshall, Jr., 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: November 3, 2022

/s/ ROBERT J. MARSHALL, JR.

Name: Robert J. Marshall, Jr.

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

Exhibit 32.1

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 Robert J. Marshall, Jr., 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 September 30, 2022 (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: November 3, 2022

/s/ MARY ANNE HEINO
Name: Mary Anne Heino
Title: *President and Chief Executive Officer*
(Principal Executive Officer)

Date: November 3, 2022

/s/ ROBERT J. MARSHALL, JR.
Name: Robert J. Marshall, Jr.
Title: *Chief Financial Officer and Treasurer*
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.