LANTHEUS™

2023 ANNUAL REPORT

>6.2M patient lives impacted in 2023

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

☐ **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)	**(I.R.S. Employer Identification No.)**
201 Burlington Road, South Building, Bedford, MA	**01730**
(Address of principal executive offices)	**(Zip Code)**

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

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, $0.01 par value per share	LNTH	NASDAQ Global Market

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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 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, or a smaller reporting company. See 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on June 30, 2023 was approximately $5,672.5 million based on the last reported sale price of the registrant's common stock on the NASDAQ Global Market on June 30, 2023 of $83.92 per share.

As of February 15, 2024 the registrant had 68,525,556 shares of common stock, $0.01 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Listed hereunder are the documents, portions of which are incorporated by reference, and the parts of this Form 10-K into which such portions are incorporated:

The Registrant's Definitive Proxy Statement for use in connection with the Annual Meeting of Stockholders to be held on April 25, 2024, portions of which are incorporated by reference into Parts II and III of this Form 10-K. The 2024 Proxy Statement will be filed with the Securities and Exchange Commission no later than 120 days after the close of our year ended December 31, 2023.

LANTHEUS HOLDINGS, INC.
ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this Annual Report on Form 10-K 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," "potential," "predicts," "seeks," "should," "target," "will," "would" and similar expressions, or by express or implied discussions regarding potential marketing approvals or new indications for the product candidates or approved products described in this Annual Report on Form 10-K, or regarding potential future revenues from such 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:

- Continued market expansion and penetration for our established commercial products, particularly PYLARIFY and DEFINITY, in a competitive environment in which other imaging agents have been approved and are being commercialized, and our ability to clinically and commercially differentiate our products;
- Our ability to have third parties manufacture our products and our ability to manufacture DEFINITY in our in-house manufacturing facility;
- The global availability of Molybdenum-99 ("Mo-99") and other raw materials and key components;
- Our strategies, future prospects, and projected growth, including revenue related to our collaboration agreements with POINT Biopharma Global Inc. ("POINT"), including our ability to obtain FDA approval for PNT2002 and PNT2003;
- Our ability to satisfy our obligations under our existing clinical development partnerships using MK-6240 as a research tool and under the license agreement through which we have rights to MK-6240, and to further develop and commercialize it as an approved product;
- Our ability to successfully execute on our agreements with Perspective Therapeutics, Inc. ("Perspective"), including finalizing the license agreements in the event we exercise our options to do so, and satisfying the closing conditions for the sale of the Somerset, NJ manufacturing facility and related assets, the value of our current and any future equity interest in Perspective, and Perspective's ability to successfully develop its alpha-particle therapy and innovative platform technology;
- The efforts and timing for clinical development, regulatory approval and successful commercialization of our product candidates and new clinical applications and territories for our products, in each case, that we or our strategic partners may undertake; and
- Our ability to identify and acquire or in-license additional radiopharmaceutical therapeutic and diagnostic product opportunities in oncology and other strategic areas to grow our pipeline of products.

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 Annual Report on Form 10-K 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 this Annual Report on Form 10-K.

Any forward-looking statement made by us in this Annual Report on Form 10-K 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.

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to a number of risks, including risks that may adversely affect our business, results of operations, cash flows, and prospects. These risks are discussed more fully below and include, but are not limited to, risks related to:

Risks Related to Our Portfolio of Commercial Products

- Our ability to continue to grow PYLARIFY including (A) the ability of positron emission tomography ("PET") manufacturing facilities ("PMFs") to manufacture PYLARIFY to meet product demand, (B) our ability to promote

PYLARIFY to customers, (C) our ability to obtain and maintain adequate coding, coverage, and payment for PYLARIFY, (D) our ability to maintain PYLARIFY as the leading prostate-specific membrane antigen ("PSMA") PET imaging agent, including after the potential expiration of Transitional Pass-Through Payment Status ("TPT Status") at the end of 2024, and (E) our ability to clinically and commercially differentiate PYLARIFY from other products.

- Our ability to continue to (A) grow the appropriate use of DEFINITY in suboptimal echocardiograms in a competitive environment and in the face of potential generic competition as a result of patent and regulatory exclusivity expirations, (B) maintain DEFINITY as the leading ultrasound enhancing agent, and (C) have third parties manufacture our products and our ability to manufacture the formulation of DEFINITY that requires refrigerated storage in our in-house manufacturing facility.
- Our dependence on a limited number of third party suppliers for Mo-99, which is a critical ingredient of TechneLite.
- Risks related to PYLCLARI, commercialized by Curium, including that the revenues generated for us thereby may not meet expectations.

Risks Related to Reimbursement and Regulation

- The dependence of many of our customers upon third party healthcare payors and the uncertainty of third party coverage and reimbursement rates.
- Uncertainties regarding the impact of U.S. and state healthcare reform measures and proposals on our business, including measures and proposals related to reimbursement for our current and potential future products, controls over drug pricing, drug pricing transparency, generic drug competition and the potential that efforts to extend or secure separate or otherwise adequate payment for radiopharmaceutical diagnostics are unsuccessful.
- Our being subject to extensive government regulation and oversight, our ability to comply with those regulations and the costs of compliance.

Risks Related to our Business Operations and Financial Results

- Our ability to hire or retain the number of qualified personnel, particularly scientific, medical and sales personnel, required for our business.
- Our ability to introduce new products and adapt to an evolving technology and medical practice landscape.
- Our ability to influence and manage the decision-making process with our collaboration partners, in particular where our partners are responsible for the performance of certain key tasks or functions, for example related to manufacturing or regulatory strategy, or where decisions may be controlled by, or subject to the approval of our collaboration partners, who may have views that differ from ours

Risks Related to Our and our Strategic Partners' Portfolios of Clinical Development Candidates

- Risks associated with the development and commercialization of PNT2002, including (A) the outcome of the Phase 3 registrational clinical trial for PNT2002, which we refer to as SPLASH, after full data becomes available, (B) our ability to obtain regulatory approval for PNT2002; (C) the additional costs and risks associated with our ability to successfully launch PNT2002 as a commercial product; (D) the market and patient receptivity to PNT2002 as a radiopharmaceutical therapy; (E) the existence, availability and profile of competing products and therapies; (F) our ability to gain post-approval market acceptance and adequate coding, coverage and payment for PNT2002; and (G) POINT's ability to successfully develop and scale the manufacturing capabilities to support the launch of PNT2002.
- Risks associated with the commercialization of PNT2003, including (A) the outcome of the patent infringement claim by Advanced Accelerator Applications USA, Inc. and Advanced Accelerator Applications SA, each a Novartis entity, in response to our filing of our Abbreviated New Drug Application ("ANDA"); (B) our ability to obtain regulatory approval for PNT2003, including the 180-day period of generic marketing exclusivity in the U.S. market as the "first applicant", as provided under the Hatch-Waxman Act; (C) our ability to gain post-approval market acceptance and adequate coding, coverage and payment for PNT2003; and (D) POINT's ability to successfully develop and scale the manufacturing capabilities to support the launch of PNT2003.
- Risks associated with MK-6240, including (A) our ability to satisfy our obligations under our existing clinical development partnerships using MK-6240 as a research tool and under the license agreement through which we have rights to MK-6240, and (B) our ability to further develop and commercialize it as an approved product, including obtaining regulatory approval and gaining post-approval market acceptance and adequate coding, coverage and payment.

- Risks associated with [18F] flurpiridaz ("flurpiridaz"), which we out-licensed to GE Healthcare Limited ("GE Healthcare") in 2017, including GE Healthcare's ability to (A) obtain regulatory approval, and (B) gain post-approval market acceptance and adequate coding, coverage and payment.
- Risks associated with our agreements with Perspective, including finalizing the license agreements in the event we exercise our options to do so, and satisfying the closing conditions for the sale of the Somerset, NJ manufacturing facility and related assets, the value of our current and any future equity interest in Perspective, and Perspective's ability to successfully develop its alpha-particle therapy and innovative platform technology.

Risks Related to our Capital Structure

- Risks related to our outstanding indebtedness and our ability to satisfy those obligations, including the 2.625% Convertible Senior Notes due 2027 (the "Notes").
- Risks related to the ownership of our common stock.

NOTE REGARDING COMPANY REFERENCES

Unless the context requires otherwise, references to "Lantheus," "the Company," "our company," "we," "us" and "our" refer to Lantheus Holdings, Inc. and, as the context requires, its direct and indirect subsidiaries; references to "Lantheus Holdings" refer to Lantheus Holdings, Inc.; references to "LMI" refer to Lantheus Medical Imaging, Inc., a wholly-owned subsidiary; references to "Cerveau," "Lantheus Alpha," "Lantheus Two," "Lantheus Three" and "Progenics" refer to Cerveau Technologies, Inc.; Lantheus Alpha Therapy, LLC; Lantheus Two, LLC; Lantheus Three, LLC; and Progenics Pharmaceuticals, Inc., respectively, each a wholly-owned subsidiary of LMI, and references to "EXINI" refer to EXINI Diagnostics AB, a wholly-owned subsidiary of Progenics.

NOTE REGARDING TRADEMARKS

We own or have the rights to various trademarks, service marks and trade names, including, among others, the following: PYLARIFY®, DEFINITY®, and Find Fight and Follow® referred to in this Annual Report on Form 10-K. Solely for convenience, we refer to trademarks and service marks in this Annual Report on Form 10-K without the TM, SM and ® symbols. Those references are not intended to indicate, in any way, that we will not assert, to the fullest extent permitted under applicable law, our rights to our trademarks and service marks. Each trademark, trade name or service mark of any other company appearing in this Annual Report on Form 10-K is, to our knowledge, owned by that other company.

PART I

Item 1. Business

Overview

We are the leading radiopharmaceutical-focused company, delivering life-changing science to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. We classify our products in three categories: Radiopharmaceutical Oncology, Precision Diagnostics, and Strategic Partnerships and Other Revenue. Our Radiopharmaceutical Oncology diagnostics and therapeutic candidates help healthcare professionals ("HCPs") Find, Fight and Follow cancer, with a focus in prostate cancer. Our leading Precision Diagnostic products assist HCPs to Find and Follow diseases, with a focus in cardiology. Our Strategic Partnerships focus on enabling precision medicine through the use of biomarkers, digital solutions and pharma solutions platforms.

Our commercial products are used by cardiologists, internal medicine physicians, nuclear medicine physicians, oncologists, radiologists, sonographers, technologists, and urologists 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 throughout the healthcare system.

We produce and market our products throughout the United States (the "United States" or the "U.S."), selling primarily to hospitals, independent diagnostic testing facilities, 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 executive offices are located in Bedford, Massachusetts, with additional offices in North Billerica, Massachusetts; Somerset, New Jersey (subject to the satisfaction of closing conditions for the sale of the Somerset facility and related assets to Perspective anticipated in the first half of 2024); Montreal, Canada and Lund, Sweden.

CEO Succession Plan

On January 23, 2024, we announced that, effective March 1, 2024, Brian Markison, our current Chair of the Board of Directors ("Board"), will become our Chief Executive Officer, and Mary Anne Heino, our current Chief Executive Officer, will retire and become the Chair of the Board. As part of this leadership transition, Mr. Markison assumed the role of Executive Chair of the Board as of January 23, 2024 until the effectiveness of his Chief Executive Officer appointment in March, and Board Member Julie McHugh became Lead Independent Director.

Strategic Agreements with Perspective Therapeutics

On January 9, 2024, we announced that we entered into multiple strategic agreements with Perspective, a radiopharmaceutical company that is pursuing advanced treatment applications for cancers throughout the body. Under the agreements, we obtained an option to exclusively license Perspective's Pb212-VMT- α-NET, a clinical stage alpha therapy in development for the treatment of neuroendocrine tumors, and an option to co-develop certain early-stage therapeutic candidates targeting prostate cancer using Perspective's innovative platform technology for an aggregate upfront payment of $28 million in cash. We also agreed to purchase up to 19.9% of Perspective's outstanding shares of common stock for up to approximately $33 million, subject to Perspective's completion of a qualified third-party financing transaction and certain other closing conditions. In addition, Perspective agreed to acquire the assets and associated lease of our radiopharmaceutical manufacturing facility in Somerset, New Jersey. Following satisfaction of the closing conditions, on January 22, 2024, our subsidiary, Lantheus Alpha purchased 56,342,355 shares of Perspective's common stock at a purchase price of $0.37 per share in a private placement transaction. The total consideration for the purchase was approximately $20.8 million in cash, which resulted in Lantheus Alpha holding approximately 10.74% of Perspective's common stock as of the purchase date and retaining the right to purchase additional shares to bring its ownership up to an aggregate of 19.9%.

Exclusive License for PNT2002 & PNT2003

On December 20, 2022, we announced the closing of a set of strategic collaborations with POINT, in which we were granted a license to exclusive worldwide rights (excluding Japan, South Korea, China (including Hong Kong, Macau and Taiwan), Singapore and Indonesia) to co-develop and commercialize POINT's PNT2002 and PNT2003 product candidates. PNT2002 is a PSMA-targeted radiopharmaceutical therapy in development for the treatment of metastatic castration-resistant prostate cancer ("mCRPC"). PNT2003 is a somatostatin receptor ("SSTR") therapy with non-carrier added lutetium-177, which is in registration to treat patients with SSTR-positive neuroendocrine tumors.

On December 27, 2023, Eli Lilly and Company announced the completion of its acquisition of POINT. The acquisition is not expected to impact the status of the license agreements related to these product candidates or the work being performed in connection with those license agreements and our collaboration with POINT.

PNT2002

With respect to PNT2002, POINT is generally responsible for funding and development activities required for FDA approval, including generating all clinical and nonclinical data, analysis and other information, and we are responsible for preparing for and seeking regulatory approval, as well as performing and funding all future development and commercialization following such approval. POINT will be responsible for all manufacturing of PNT2002, subject to certain exceptions described in the license and collaboration agreement between Lantheus Two and POINT, dated November 11, 2022 (the "PNT2002 License Agreement").

In April 2023, we announced with POINT that the FDA had granted Fast Track designation for PNT2002. Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and address unmet needs.

On December 18, 2023, we announced positive topline results from SPLASH. SPLASH is designed to evaluate the efficacy and safety of PNT2002 in patients with mCRPC who have progressed following treatment with an androgen receptor pathway inhibitor ("ARPI"). The SPLASH trial met its primary endpoint, demonstrating a median radiographic progression-free survival (rPFS) per blinded independent central review of 9.5 months for patients treated with PNT2002, compared to 6.0 months for patients treated with ARPI in the control arm, a statistically significant 29% reduction in the risk of radiographic progression or death (hazard ratio ("HR") 0.71; p=0.0088). At the time of the analysis, interim overall survival ("OS") results were immature (46% of protocol-specified target OS events reached), and the HR was 1.11. We expect more mature overall survival data in 2024 prior to the potential submission of a New Drug Application ("NDA").

PNT2002 demonstrated a favorable safety profile with grade ≥3 treatment-emergent adverse events ("TEAEs") per Common Terminology Criteria for Adverse Events, serious TEAEs, and TEAEs leading to discontinuation occurring at lower rates in the PNT2002 arm than in the ARPI arm (30.1%, 17.1%, and 1.9% versus 36.9%, 23.1%, and 6.2%, respectively).

The open-label study randomized 412 patients with PSMA-expressing mCRPC who had progressed on ARPI therapy and either refused or were not eligible for chemotherapy, in a 2:1 randomization ratio. At the time of the analysis, 84.6% of patients who experienced progressive disease in the control arm subsequently crossed over to receive PNT2002. SPLASH was conducted across the United States, Canada, Europe, and the United Kingdom. Eighty percent of SPLASH patients resided in North America and approximately ten percent of all participants were Black or African American.

During 2023, we worked on establishing an Expanded Access Program, ("EAP"), for PNT2002. EAPs, which are also referred to as compassionate use programs, provide a potential pathway for patients with serious or life-threatening conditions to gain access to an investigational drug for treatment outside of a clinical trial. We expect to enroll the first patient in the EAP for PNT2002 during the first quarter of 2024.

PNT2003

With respect to PNT2003, POINT is responsible for curating all data, analysis and other information necessary for regulatory approval, and supporting us in the preparation of regulatory filings. We are responsible for preparing for and seeking regulatory approval of all such applications, as well as performing and funding all future development and commercialization of PNT2003 following such approval. POINT will be responsible for all manufacturing of PNT2003, subject to certain exceptions described in the license and collaboration agreement between Lantheus Three and POINT, dated November 11, 2022 (the "PNT2003 License Agreement").

On January 11, 2024, we announced that our ANDA for Lutetium Lu 177 Dotatate (177Lu-PNT2003) had been accepted for filing by the FDA. On January 26, 2024, we were sued in the District Court for the District of Delaware by Advanced Accelerator Applications USA, Inc. and Advanced Accelerator Applications SA, each a Novartis entity, for patent infringement in response to the Company's ANDA filing. Based on the most recent update to the FDA's online paragraph IV database listings, we believe we are the first applicant to have filed a substantially complete ANDA for Lutetium Lu 177 Dotatate containing a Paragraph IV certification under the provisions of the Hatch-Waxman Act. As the first applicant, we believe we will be eligible for 180 days of generic marketing exclusivity in the U.S.

Under the Hatch-Waxman Act, any company submitting an ANDA must make certain certifications with respect to the patent status of the drug for which it is seeking approval. In the event that such applicant plans to challenge the validity or enforceability of an existing listed patent or asserts that the proposed product does not infringe an existing listed patent, it files a "Paragraph IV" certification. We filed a Paragraph IV certification in connection with PNT2003. In the case of ANDAs, the Hatch-Waxman Act provides for a potential 180-day period of generic exclusivity for the first company to submit an ANDA with a Paragraph IV certification. This filing triggers a regulatory process in which the FDA is required to delay the final approval of subsequently filed ANDAs containing Paragraph IV certifications until 180 days after the first commercial marketing. When litigation is brought by the

patent holder in response to a Paragraph IV certification (like the Novartis entities did for our ANDA for PNT2003), the FDA generally may not approve the ANDA until the earlier of 30 months or a court decision finding the patent invalid, not infringed or unenforceable. The submission of our ANDA for PNT2003 could result in protracted and expensive patent litigation and the outcome of such litigation is uncertain.

Acquisition of Cerveau

On February 6, 2023, we announced that we acquired Cerveau. Cerveau holds the rights under a license agreement to develop and commercialize MK-6240, an investigational second-generation F 18-labeled PET imaging agent that targets Tau tangles in Alzheimer's disease. Under the terms of our purchase agreement, we paid the stockholders of Cerveau (the "Selling Stockholders") an upfront payment of $35.0 million in February 2023 and an additional $10.0 million in May 2023 upon the successful completion of a technology transfer. The Selling Stockholders are also eligible to receive additional development and commercial milestone payments. Additionally, we will pay double-digit royalty payments for research revenue and commercial sales. Research revenue is derived from existing partnerships with pharmaceutical companies that use MK-6240 in clinical trials and includes milestone and dose-related payments. Pursuant to the terms of the stock purchase agreement for Cerveau, certain members of the Selling Stockholders will also provide transition and clinical development services for a prescribed time following the closing of the transaction.

Our Portfolio of Commercial Products

Radiopharmaceutical Oncology

Our commercial product in our Radiopharmaceutical Oncology category includes the following:

- PYLARIFY (also known as piflufolastat F 18, 18F-DCFPyL or PyL) is an F 18-labelled PSMA-targeted PET imaging agent used with PET/computed tomography ("CT"). PYLARIFY is indicated in the U.S. for PET imaging of PSMA-positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy and in men with suspected recurrence based on elevated serum prostate-specific antigen ("PSA") levels. Piflufolastat F 18 is approved under the name PYLCLARI in Europe and licensed by us to Curium.

Precision Diagnostics

Our commercial products in our Precision Diagnostics category include the following:

- DEFINITY is an injectable ultrasound enhancing agent with perflutren-containing lipid microspheres, or microbubbles, that is used in echocardiography exams. We offer two formulations of DEFINITY, one of which requires refrigerated storage (branded DEFINITY) and one which allows both storage and shipment at room temperature and provides clinicians an additional choice for greater utility of this formulation in broader clinical settings (branded DEFINITY RT). The indication for both formulations in the U.S. is for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. We believe we are currently the leading worldwide provider of ultrasound enhancing agents for use in echocardiography.
- TechneLite is a Technetium ("Tc-99m") generator that provides the essential nuclear material used by radiopharmacies to radiolabel NEUROLITE, CARDIOLITE and other Tc-99m-based radiopharmaceuticals used in nuclear medicine procedures. TechneLite uses Mo-99 as its active ingredient.
- NEUROLITE is an injectable, Tc-99m-labeled imaging agent used with single-photon emission computed tomography ("SPECT") technology to identify the area within the brain where blood flow has been blocked or reduced due to stroke.
- Xenon-133 ("Xenon") is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also to image cerebral blood flow. Our Xenon is manufactured by a third party as a bi-product of Mo-99 production and is processed and finished by us.
- CARDIOLITE, also known by its generic name sestamibi, is an injectable, Tc-99m-labeled imaging agent used in myocardial perfusion imaging ("MPI") procedures to assess blood flow to the muscle of the heart using SPECT. Included in CARDIOLITE revenues are branded CARDIOLITE and generic sestamibi revenues.

Strategic Partnerships and Other Revenue

Our commercial products in our Strategic Partnerships and Other Revenue product category include the following:

- RELISTOR (methylnaltrexone bromide) is a treatment for opioid-induced constipation ("OIC") that decreases the constipating side effects induced by opioid pain medications such as morphine and codeine without diminishing their ability to relieve pain. RELISTOR is approved in two forms: a subcutaneous injection and an oral tablet. In 2011 Progenics licensed methylnaltrexone (MNTX) along with products containing MNTX, including both approved forms of RELISTOR, to Salix Pharmaceuticals, Inc., a Bausch Health company ("Bausch") and on August 2, 2023, we sold the right to the RELISTOR net sales royalties under that license agreement and retained the rights to future sales-based milestone payments.

- Automated Bone Scan Index ("aBSI") automatically calculates the disease burden of prostate cancer by detecting and classifying bone scan tracer uptakes as metastatic or benign lesions using an artificial neural network. aBSI is FDA cleared and CE marked. The software is currently used as one of the correlative objectives of the DORA trial, an open-labeled, randomized, Phase 3 study of docetaxel versus docetaxel in combination with radium-223 (Ra-223) in subjects with mCRPC. aBSI is also approved in Japan and part of the JSMO guidelines (Japanese Society of Medical Oncology) in support of clinicians with patient treatment selection. The Japanese non-exclusive rights to aBSI have been transferred and sold to FUJIFILM Toyama Chemical Co. Ltd. ("FUJIFILM") under the name BONENAVI®.
- aPROMISE, which is currently commercialized as PYLARIFY AI in the U.S., is artificial intelligence medical device software that is designed to allow HCPs and researchers to perform standardized quantitative assessment of PSMA PET/CT images in prostate cancer, including those images obtained by using PYLARIFY.

Additional Information about our Product Categories

Radiopharmaceutical Oncology

Continued Growth of PYLARIFY

PYLARIFY is the leading radiopharmaceutical 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 in men with suspected recurrence based on elevated 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/CT technology to produce a combined scan that enables the scan reader 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 3.3 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 current market potential for PSMA PET imaging agents in the U.S. for 2024 could be about 445,000 scans, and the total addressable market by 2029 could be over 700,000 annual scans.

PYLARIFY is manufactured on a diverse, F 18 distributor supply network of PMFs, ensuring convenient and reliable supply. 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 PMF manufacturing PYLARIFY is deemed by the FDA to be a separate manufacturing site, each is separately approved by the FDA. As of December 31, 2023, we had activated 54 PMF manufacturing sites in our PMF network, up from 37 activated sites as of December 31, 2022. These additional sites provide geographic breadth, out-the-door time flexibility and added optionality within our existing PMF network. Overall, we have achieved broad national distribution of PYLARIFY with customers in 47 of 50 states, the District of Columbia and Puerto Rico.

In addition to our network of commercial PMFs, we also work with academic medical centers in the U.S. that have radioisotope-producing cyclotrons and that have expressed an interest in manufacturing PYLARIFY. For this initiative, we enter into a fee-for-service arrangement under which the academic medical center manufactures F 18 on its cyclotron and completes the manufacturing process for PYLARIFY. PYLARIFY can then be used by the academic medical center itself, and in some cases distributed to other customers under separate purchase agreements.

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 TPT Status in the hospital outpatient setting 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.

In July 2023, CMS proposed possible changes to its regulations covering payment for diagnostic radiopharmaceuticals. This included, for the first time since 2008, options for separate payment for diagnostics instead of the current packaged payment following expiration of TPT Status. We, along with numerous industry organizations, submitted comments to CMS. In completing its 2023 rulemaking for the 2024 payment calendar year, CMS recognized the challenges of patient access to diagnostic radiopharmaceuticals and requested feedback on various payment alternatives that could provide separate reimbursement for these items, but the agency did not adopt any of these proposals in the final rule, while stating that it would continue to evaluate this issue in subsequent rulemaking. We plan to submit additional comments to CMS in connection with its 2024 rulemaking for the 2025 payment calendar year.

Our continued growth of PYLARIFY will depend on our ability to clinically and commercially differentiate PYLARIFY from other products on the market and to maintain PYLARIFY as the leading PSMA PET imaging agent in a competitive marketplace. PYLARIFY's current competition is primarily two Gallium-68 ("Ga-68")-based PSMA imaging agents, a fluorine-18-based PSMA

imaging agent, and other non-PSMA-based imaging agents commonly referred to as conventional imaging. Continued growth and revenue contribution from PYLARIFY will also depend on our ability to differentiate PYLARIFY in light of the potential loss of TPT Status, including through flexible and dependable access to PYLARIFY nationally, a best in class customer experience and through long-term strategic contracts.

We actively pursue patents in connection with PYLARIFY, both in the U.S. and internationally. In the U.S. for PYLARIFY, we have five 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.

See Part I, Item 1A. "Risk Factors" for information regarding certain risks associated with PYLARIFY and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Comparison of the Periods Ended December 31, 2023 and 2022 - Revenues" for further information on total revenue contributed by PYLARIFY since its approval.

Precision Diagnostics

Continued Growth of DEFINITY

DEFINITY is the leading ultrasound enhancing agent in the U.S. and is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. Numerous patient conditions can decrease the quality of images of the left ventricle, the primary pumping chamber of the heart. The term DEFINITY includes its activated and non-activated forms and the two formulations it is commercially available in; one that requires refrigerated storage and one that we have branded as DEFINITY RT that may be stored at room temperature.

DEFINITY is a clear, colorless, sterile liquid that, upon activation in a VIALMIX or VIALMIX RFID, medical devices specifically designed for DEFINITY, becomes a homogenous, opaque, milky white injectable suspension of perflutren-containing lipid microspheres. After activation and intravenous injection, DEFINITY opacifies the left ventricular chamber and improves the delineation of the left ventricular endocardial border, or innermost layer of tissue that lines the chamber of the left ventricle. Better visualization of the left ventricle allows clinicians to make more informed decisions about disease status.

Based on estimates from third party sources, we believe there were approximately 29 to 30 million echocardiograms performed in the U.S. in 2022 (the latest time period for which full year data is available). Assuming that between 20% and 30% of echocardiograms produce suboptimal images, as stated in the clinical literature, we estimate that approximately 6 to 9 million echocardiograms in 2022 produced suboptimal images.

Since its launch in 2001, DEFINITY has been used in imaging procedures in more than 25 million studies throughout the world. We estimate that, as of December 31, 2023, DEFINITY had over 80% share of the U.S. segment for ultrasound enhancing agents in echocardiography procedures. DEFINITY currently competes with two other FDA-approved ultrasound enhancing agents, as well as echocardiography without the use of ultrasound enhancing agents and non-echocardiography imaging modalities. DEFINITY and the other FDA-approved ultrasound enhancing agents all carry an FDA-required boxed warning, which has been modified over time, to notify physicians and patients about potentially serious safety concerns or risks posed by the products. See Part I, Item 1A. "Risk Factors-Ultrasound enhancing agents may cause side effects which could limit our ability to sell DEFINITY."

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 six Orange Book-listed method-of-use patents, one of which expires in 2035 and five of which expire in 2037, as well as additional manufacturing patents that are not Orange Book-listed expiring in 2037. In the U.S. for DEFINITY RT, we have eight Orange Book-listed patents, including two composition of matter patents which expire in 2035. The Orange Book-listed patents include a patent on the use of VIALMIX RFID (see below), which expires in 2037; we have submitted additional VIALMIX RFID patent applications in major markets throughout the world.

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 challenges in the near to intermediate term. See "Intellectual Property – Patents" below.

As noted above, DEFINITY is activated through the use of medical devices branded as VIALMIX and VIALMIX RFID. 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. The RFID tag, which is affixed to the vial label, enables the DEFINITY vial to be appropriately activated with the VIALMIX RFID activation device.

To manufacture DEFINITY that requires refrigeration, historically, we have relied on Jubilant HollisterStier ("JHS") as a significant supplier. We constructed a specialized in-house manufacturing facility at our North Billerica campus for purposes of

producing this formulation of DEFINITY and, potentially, other sterile vial products. On February 22, 2022, we received FDA approval of our supplemental new drug application ("sNDA"), authorizing commercial manufacturing of this formulation of DEFINITY at our new facility. We believe this investment provides supply chain redundancy, improved flexibility and reduced costs in a potentially more price competitive environment.

See Part I, Item 1A. "Risk Factors" for information regarding certain risks associated with DEFINITY and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Comparison of the Periods Ended December 31, 2023 and 2022 - Revenues" for further information on revenue contributed by DEFINITY.

TechneLite

TechneLite is a self-contained system or generator of Tc-99m, a radioactive isotope with a six hour half-life, used by radiopharmacies to prepare various nuclear imaging agents. Tc-99m results from the radioactive decay of Mo-99, itself a radioisotope with a 66-hour half-life sourced in our supply chain in nuclear research reactors located in Belgium, South Africa and Australia from enriched uranium. The TechneLite generator is a self-contained system that houses a vertical glass column at its core that contains Mo-99, which degrades to Tc-99m. During our manufacturing process, Mo-99 is added to the column within the generator where it is adsorbed onto alumina powder. The column is sterilized, enclosed in a lead shield and further sealed in a cylindrical plastic container, which is then immediately shipped to our radiopharmacy customers. Because of the short half-lives of Mo-99 and Tc-99m, radiopharmacies typically purchase TechneLite generators on a weekly basis pursuant to standing orders.

The Tc-99m produced by our TechneLite generator is the medical radioisotope that can be attached to a number of imaging agents, including our own NEUROLITE and CARDIOLITE products, during the radiolabeling process. To radiolabel a Tc-99m-based radiopharmaceutical, a vial of sterile saline and a vacuum vial are each affixed to the top of a TechneLite generator. The sterile saline is pulled through the generator where it attracts Tc-99m resulting from the radioactive decay of Mo-99 within the generator column. The Tc-99m-containing radioactive saline is then pulled into a vacuum vial and subsequently combined by a radiopharmacist with the applicable imaging agent, which allows the preparation of individual patient-specific radiolabeled imaging agent doses. When administered, the imaging agent binds to specific tissues or organs for a period of time, enabling the Tc-99m to illuminate the functional health of the imaged tissues or organs in a diagnostic image. Our ability to produce and market TechneLite is highly dependent on our supply of Mo-99. See "Raw Materials and Supply Relationships—Molybdenum-99" below.

TechneLite is currently marketed primarily in the U.S., Canada, Central America and South America, largely to radiopharmacies that prepare unit doses of radiopharmaceutical imaging agents and ship these preparations directly to hospitals for administration to patients. In the U.S., we have supply contracts with large radiopharmacy groups, including PharmaLogic Holdings Corp ("PharmaLogic"), Cardinal Health ("Cardinal"), RLS (USA) Inc. (previously GE Healthcare) ("RLS") and United Pharmacy Partners ("UPPI"). We also supply generators on a purchase order basis to other customers. We estimate that TechneLite had approximately one third of the U.S. generator market as of December 31, 2023, competing primarily with Tc-99m-based generators produced by Curium.

We believe that our substantial capital investments in our TechneLite production line and our extensive experience in complying with the stringent regulatory requirements for the handling of nuclear materials, create significant and sustainable competitive advantages for us in generator manufacturing and distribution. Given our significant know-how and trade secrets associated with the methods of manufacturing and assembling the TechneLite generator, we believe we have a substantial amount of valuable and defensible proprietary intellectual property associated with the product. In addition, TechneLite has patent protection in the U.S. and various foreign countries on certain component technology currently until 2029, and we are pursuing additional patent protection in the U.S. and world-wide on other component technology that, if granted, would expire in 2040.

See Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Comparison of the Periods Ended December 31, 2023 and 2022 - Revenues" for further information on revenue contributed by TechneLite.

Strategic Partnerships and Other Revenue

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 radiopharmaceutical therapeutic and diagnostic product opportunities in oncology and other strategic areas that complement our existing portfolio. Our Pharma Solutions business focuses on advancing innovative imaging biomarker solutions, such as MK-6240, through collaborations with pharmaceutical companies and academic centers. Our Digital Solutions business focuses on developing and commercializing 510(k) cleared and CE marked digital applications to enhance the performance of imaging agents; our Digital Solutions portfolio currently includes aBSI, aPROMISE and PYLARIFY AI.

Oncology

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

- *Prostate Cancer* – We collaborate with pharmaceutical companies developing therapies and diagnostics in prostate cancer.
    - In July 2023, Curium (our licensee that is developing and commercializing piflufolastat F 18 in Europe) announced that it received marketing authorization for piflufolastat F 18, under the name PYLCLARI, from the European Commission. In addition, we previously 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 mCRPC. PYLARIFY will be used to determine PSMA-avidity as part of patient selection.
    - We have also entered into several other separate agreements, including with RefleXion Medical, Inc., POINT and Regeneron Pharmaceuticals, Inc., under which we supply PYLARIFY in connection with their clinical trials and 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 with PCCTC is to integrate our artificial intelligence ("AI") platform into PCCTC studies to advance the development and validation of novel AI-enabled biomarkers.
- *Immuno-Oncology* - 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, to develop NM-01, a novel technetium-99m SPECT imaging agent under development to assess PD-L1 expression in cancer cells. In connection with the collaboration, NanoMab recently completed a Phase 2 clinical trial at King's College London. The Phase 2 clinical trial was an open-label, single-arm trial in non-small cell lung cancer patients. The primary endpoint was the assessment of PD-L1 expression in primary tumor and metastatic lesions by NM-01 compared to immunohistochemistry. Other objectives were aimed at quantifying intra- and inter-tumoral heterogeneity of PD-L1 expression by NM-01, as well as establishing correlations with other diagnostic procedures. We expect results from the clinical trial to be presented at an upcoming medical congress.
- *Pan-Oncology* - In collaboration with Ratio Therapeutics LLC ("Ratio") (previously Noria Therapeutics, Inc.), we are developing LNTH-1363S, a novel copper-64 labeled PET imaging agent, targeting fibroblast activation protein alpha. We believe this diagnostic agent candidate could have broad potential applicability and use in oncology and also in inflammatory diseases. Recently, in collaboration with Ratio, we completed a Phase 1 study for LNTH-1363S to evaluate the pharmacokinetics, biodistribution and radiation dosimetry in adult healthy volunteers. We plan to initiate a Phase 1/2a study in patients in 2024.

Microbubble Franchise

In addition, we continue to seek to optimize our microbubble platform through new collaborations. Some of our microbubble collaborations are 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 ("CarThera"), for the use of our microbubbles in combination with SonoCloud, a proprietary implantable device in development for the treatment of recurrent glioblastoma; (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; (iv) 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; and (v) SonoThera, Inc. ("SonoThera"), who will use our microbubbles in combination with their ultrasound-guided, non-viral, gene therapy platform and treatments.

In March 2012, we entered into a development and distribution arrangement with China Resources Double-Crane ("Double-Crane") for DEFINITY in China, Hong Kong and Macau. Double-Crane has conducted on our behalf three confirmatory clinical trials in pursuit of cardiac, liver and kidney imaging indications, as well as one small pharmacokinetic study. In November 2022, we announced the approval of our Import Drug License application with the National Medical Products Administration ("NMPA") for the use of DEFINITY in patients with suboptimal conventional echocardiography and to better identify the left ventricular endocardial border. Double-Crane is responsible for obtaining adequate coding, coverage and payment and commercializing DEFINITY in China under a local brand name. Double-Crane is also in the process of analyzing the clinical results relating to liver and kidney indications and will also work with us to prepare an Import Drug License application for those indications, as appropriate.

MK-6240

MK-6240 is an investigational clinical stage F 18-labeled PET imaging development candidate designed to detect Tau protein in the form of neurofibrillary tangles in the brains of patients with known or suspected Alzheimer's disease. MK-6240 is being used as a

biomarker in more than 90 active clinical trials for Alzheimer's disease therapeutic candidates. Research revenue related to MK-6240 is derived from the use of MK-6240 in those clinical trials and includes milestone and dose-related payments.

RELISTOR

- On August 2, 2023, we sold our right to our RELISTOR net sales royalties under our license agreement with Bausch; we retained the rights to future sales-based milestone payments. Pursuant to our license agreement with Bausch, we are eligible to receive one-time sales milestone payments upon achievement of specified U.S. net sales targets, including:

U.S. Net Sales Levels in any Single Calendar Year	Payment ($)
	(In thousands)
In excess of $150 million	15,000
In excess of $200 million	20,000
In excess of $300 million	30,000
In excess of $750 million	50,000
In excess of $1 billion	75,000

Each sales milestone payment is payable one time only, regardless of the number of times the condition is satisfied, and all five remaining payments could be made within the same calendar year. During the fourth quarter of 2023, the Company earned the $15.0 million sales-based milestone payment listed above.

aBSI

- aBSI automatically calculates the disease burden of prostate cancer by detecting and classifying bone scan tracer uptakes as metastatic or benign lesions using an artificial neural network. The cloud based aBSI was made available for clinical use in the U.S. on August 5, 2019. In February 2020, Progenics received European Conformity Marking ("CE marking") for the standalone workstation model of aBSI, meeting the quality standards set by the European Economic Area. In September 2020, the FDA granted 510(k) clearance for the use of aBSI as software-as-a-medical device on a GE Healthcare imaging system.

PYLARIFY AI

- PYLARIFY AI is artificial intelligence medical device software that is designed to allow healthcare professionals and researchers to perform standardized quantitative assessment of PSMA PET/CT images in prostate cancer, including those images obtained by using PYLARIFY. PYLARIFY AI has demonstrated improved consistency, accuracy and efficiency in quantitative assessment of PSMA PET/CT. The technology analyzes the PET/CT image to segment anatomical regions, including 51 bones and 12 soft tissue organs. This image segmentation enables automated localization, detection and quantification of potential PSMA-avid lesions in the PET/CT image, which is incorporated into a standardized report for physicians. PYLARIFY AI can be deployed either as a secure web cloud application or within the secure firewall of the institution on a local server. Once deployed, the adaptive application can be integrated into an institution's existing clinical workflow, delivering a unique combination of clinical utility and technical flexibility. Our subsidiary, EXINI, was granted 510(k) clearance by the FDA in the U.S. and received a CE marking in Europe for aPROMISE. We commercially launched aPROMISE under the name PYLARIFY AI in the U.S. in November 2021 and the FDA granted us an additional 510(k) clearance during the second quarter of 2022.

[^{18}F] flurpiridaz

- **GE Healthcare Agreement –** In 2017, we entered into a definitive, exclusive Collaboration and License Agreement with GE Healthcare for the continued Phase 3 development and worldwide commercialization of flurpiridaz, a fluorine 18-based PET MPI agent designed to assess blood flow to the heart in patients suspected of coronary artery disease ("CAD"). Under our agreement, GE Healthcare will complete the development of flurpiridaz, pursue worldwide regulatory approvals, and, if successful, lead a worldwide launch and commercialization of the agent, with us collaborating on both development and commercialization through a joint steering committee. We also have retained the right to co-promote the agent in the U.S. GE Healthcare's development plan initially focuses on obtaining regulatory approval in the U.S., Japan, Europe and Canada. Under the agreement, we received an upfront cash payment of $5.0 million and are eligible to receive up to $60.0 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. In September 2022, we announced with GE Healthcare that the second Phase 3 clinical trial had met its co-primary endpoints of exceeding a 60% threshold for both sensitivity and specificity for detecting CAD. The findings,

shared at an American Society of Nuclear Cardiology conference, also indicated that cardiac PET imaging with flurpiridaz demonstrated higher diagnostic efficacy and image quality in patients with suspected CAD, compared with SPECT MPI, the predominant procedure currently used in nuclear cardiology. GE Healthcare recently announced that it had filed an NDA with the FDA for flurpiridaz. Assuming regulatory approval, we anticipate commercialization by GE Healthcare beginning in the second half of 2024.

See Part I, Item 1A. "Risk Factors" for information regarding certain risks associated with our strategic activities.

Our Clinical Development Candidates

In addition to our commercial products and strategic partnerships with third parties, we also have ongoing clinical development programs, including, among others, the following:

- **PNT2002** is an investigational PSMA-targeted radiopharmaceutical therapy for the treatment of mCRPC. On December 18, 2023, we announced positive topline results from SPLASH, the Phase 3 registrational trial for PNT2002 designed to evaluate superiority to the standard of care in mCRPC pre-chemotherapy patients who have failed one androgen receptor pathway inhibitor.
- **PNT2003** is an investigational SSTR therapy with non-carrier added lutetium-177, which is in registration to treat patients with SSTR-positive neuroendocrine tumors. On January 11, 2024, we announced that our ANDA for PNT2003 was accepted for filing by the FDA. On January 26, 2024, we were sued in the United States District Court for the District of Delaware by Advanced Accelerator Applications USA, Inc. and Advanced Accelerator Applications SA, each a Novartis entity, for patent infringement in response to the filing of our ANDA and Paragraph IV certification, consistent with the process established by the Hatch-Waxman Act.
- **MK-6240** is an investigational second-generation F 18-labeled PET imaging agent that targets Tau tangles in Alzheimer's disease. MK-6240 is currently being used in more than 90 active clinical trials for several Alzheimer's disease therapeutic candidates being developed.
- **LNTH-1363S** is an investigational fibroblast activation protein, alpha targeted, copper-64 labeled PET imaging agent candidate that we believe could have broad potential imaging applicability and use in oncology. Recently, we completed a Phase 1 study for LNTH-1363S to evaluate the pharmacokinetics, biodistribution and radiation dosimetry in adult healthy volunteers.
- **1095** (also known as 131 I-MIP-1095) is an investigational PSMA-targeted iodine-131-labeled small molecule that is designed to deliver a dose of beta radiation directly to prostate cancer cells with minimal impact on the surrounding healthy tissues. We enrolled the last patient in our ARROW Phase 2 study during the second quarter of 2022. 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 the years ended December 31, 2023, 2022 and 2021, we invested $77.7 million, $311.7 million and $45.0 million in research and development ("R&D"), respectively, primarily related to our clinical development candidates. In addition to our clinical development group, our R&D team also includes our Medical Affairs and Medical Information functions, which educate physicians on the scientific aspects of our commercial products and the approved indications.

See Part I, Item 1A. "Risk Factors" for information regarding certain risks associated with our strategic partnerships and clinical development programs.

Distribution, Marketing and Sales

The following table sets forth certain key market information for each of our commercial pharmaceutical products within each product category:

Product	Approved Markets
Radiopharmaceutical Oncology	
PYLARIFY	European Union*, United States
Precision Diagnostics	
DEFINITY (or LUMINITY)	Australia, Canada, China, European Union, European Economic Area, Israel, New Zealand, United Kingdom, United States
DEFINITY RT	United States
TechneLite	Australia, Canada, Colombia, Costa Rica, South Korea, Taiwan, United States
NEUROLITE	Australia, Belgium, Canada, Costa Rica, Denmark, France, Hong Kong, Italy, Japan, Luxembourg, South Korea, Spain, Taiwan, United States
Xenon	United States
CARDIOLITE	Australia, Canada, Israel, Japan, New Zealand, South Korea, Taiwan, United States
Strategic Partnerships and Other Revenue	
RELISTOR (Solution for Injection 12 mg/0.6 mL vial)	Austria, Belgium, Bulgaria, Canada, Switzerland, Cypress, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, United Kingdom, United States
RELISTOR (Solution for Injection in pre-filled syringe 8mg and pre-filled syringe 12 mg)	Austria, Belgium, Bulgaria, Canada, Cypress, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, United Kingdom, United States
RELISTOR (methylnaltrexone bromide) Oral Tablet 140 mg	United States

*Approved under the name PYLCLARI and licensed to Curium.

With respect to our medical devices:

- Progenics received CE marking for the standalone workstation model of aBSI, meeting the quality standards set by the European Economic Area. In September 2020, the FDA granted 510(k) clearance for the use of aBSI as software-as-a-medical device on a GE Healthcare imaging system.
- EXINI was granted 510(k) clearance by the FDA in the U.S. and received CE marking in Europe for aPROMISE. We launched aPROMISE under the name PYLARIFY AI in the U.S.

PYLARIFY sales are generated in the U.S. through an internal PYLARIFY sales team, as well as a sales team at some of our PMF partners. Sales of DEFINITY are generated in the U.S. through an internal DEFINITY sales team. While a small portion of our nuclear imaging product sales in the U.S. are generated through our internal sales force to hospitals and clinics that maintain their own in-house radiopharmaceutical preparation capabilities, we primarily sell our nuclear imaging products, including TechneLite, NEUROLITE, Xenon, and CARDIOLITE, to large radiopharmacy chains. We have licensed RELISTOR to Bausch, and while we have sold the right to our RELISTOR net sales royalties under our license agreement, we have retained the rights to future sales-based milestone payments generated by Bausch.

Seasonality

We have some modest seasonality for our products as patients may seek to schedule diagnostic imaging and other procedures less frequently during the summer vacation months and over the year-end holidays.

Customers

No customer accounted for greater than 10% of revenues for the years ended December 31, 2023, 2022, and 2021.

Backlog

Our backlog consists of orders for which a delivery schedule within the next twelve months has been specified. Orders included in backlog may be canceled or rescheduled by customers at any time with the exception of TechneLite orders. For TechneLite, customers must provide us with four weeks advanced notice to cancel an order. We do not believe that our backlog at any particular time is meaningful because it has historically been immaterial relative to our consolidated revenues and is not necessarily indicative of future revenues for any given period.

Competition

We believe that our key product characteristics, such as proven efficacy, reliability and safety, coupled with our core competencies, such as our efficient manufacturing processes, our established distribution network, our experienced field sales organization and our customer service focus, are important factors that distinguish us from our competitors.

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 principal competitors are currently Telix Pharmaceuticals Limited, Novartis AG, and Blue Earth Diagonstics Ltd. ("Blue Earth"), a subsidiary of Bracco Diagnostics Inc. ("Bracco").
- For DEFINITY, our competitors currently include GE Healthcare and Bracco.
- For a number of our SPECT radiopharmaceutical commercial products, our competitors currently include Curium, GE Healthcare, Bracco and Jubilant Life Sciences, an affiliate of JHS and Jubilant Radiopharma, and potentially BWXT Medical.

The markets into which any of our product candidates would be launched, if approved, are also highly competitive and continually evolving.

- For PNT2002 and 1095, our principal competitors may include Novartis AG; Telix Pharmaceuticals Limited; and Curium, each of which has commercialized products or product candidates in advanced clinical stage of development.
- For PNT2003, our principal competitor may include Novartis AG; ITM Radiopharma; and RayzeBio (under agreement to be acquired by Bristoll Meyers Squibb), each of which has commercialized products or product candidates in advanced clinical stage development.
- For MK-6240, our principal competitors may include Eli Lilly and Company and Life Molecular Imaging, each of which has commercialized products or product candidates in advanced clinical stage of development.
- For LNTH-1363S, our principal competitors may include Sofie Bioscience; GE Healthcare; and Novartis AG, each of which has product candidates in clinical stage of development.

We cannot anticipate the actions of our current or future competitors in the same or competing therapeutic and diagnostic modalities, such as significant price reductions on products that are comparable to our own, development of new products or other technologies 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 modalities and products, or bundle the sale of a portfolio of products, 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 and biopharmaceutical industry continues to evolve strategically, with several market participants recently sold. 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), government reimbursement policies, such as TPT Status, 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.

Raw Materials and Supply Relationships

We rely on certain raw materials and supplies to produce our products. Due to the specialized nature of our products and the limited, and sometimes intermittent, supply of raw materials available in the market, we have established relationships with several key suppliers. For the year ended December 31, 2023, our largest suppliers of raw materials and supplies were Institute for Radioelements ("IRE"), the Australian Nuclear Science and Technology Organisation ("ANSTO") and NTP Radioisotopes ("NTP"), which, in the aggregate, accounted for approximately 9.3% of our total purchases.

Molybdenum-99

Our TechneLite, CARDIOLITE and NEUROLITE products all rely on Mo-99, the radioisotope which is produced by bombarding uranium with neutrons in research reactors. With a 66-hour half-life, Mo-99 decays into, among other things, Tc-99m, another radioisotope with a half-life of six hours. Tc-99m is the isotope that is attached to radiopharmaceuticals, including our own NEUROLITE and CARDIOLITE, during the labeling process and is the most common radioisotope used for medical diagnostic imaging purposes.

We currently purchase finished Mo-99 from three of the four main processing sites in the world, namely IRE in Belgium, NTP in South Africa and ANSTO in Australia. These processing sites provide us Mo-99 from five of the six main Mo-99-producing reactors in the world, namely BR2 in Belgium, LVR-15 in the Czech Republic, HFR in The Netherlands, SAFARI in South Africa and OPAL in Australia.

Our agreement with IRE (the "IRE Agreement") contains minimum percentage volume requirements and unit pricing. The IRE Agreement also requires IRE to provide certain favorable allocations of Mo-99 during periods of supply shortage or failure. The IRE Agreement allows for termination upon the occurrence of certain events, including failure by IRE to provide our required amount of Mo-99, material breach of any provision by either party, bankruptcy by either party or force majeure events. The IRE Agreement expires on December 31, 2024, and automatically renews on an annual basis thereafter, subject to prior notice of non-renewal by either party.

Our agreement with NTP (the "NTP Agreement"), with NTP acting for itself and on behalf of its subcontractor ANSTO, specifies our percentage purchase requirements and unit pricing, and provides for the supply of Mo-99. The NTP Agreement allows for termination upon the occurrence of certain events, including failure by NTP to provide our required amount of Mo-99, material breach of any provision by either party, bankruptcy by either party or force majeure events. The NTP Agreement expires on 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.

Xenon

Xenon is a by-product of the Mo-99 production process. Under a strategic agreement entered into in 2021, we receive from IRE bulk unprocessed Xenon, which we process and finish for our customers at our North Billerica, Massachusetts manufacturing facility. That contract runs through December 31, 2025, with auto-renewal provisions and is terminable upon notice of non-renewal. Until we can qualify an additional source of bulk unprocessed Xenon, we will rely on IRE as a sole source provider.

Other Materials

We have additional supply arrangements for active pharmaceutical ingredients, excipients, packaging materials and other materials and components, none of which are exclusive, but a number of which are sole source, and all of which we currently believe are either in good standing or replaceable without any material disruption to our business.

See Part I, Item 1A. "Risk Factors" for information regarding certain risks associated with our raw materials and supply arrangements.

Manufacturing

The commercial manufacture of PYLARIFY required us to create a field-based network of specialized PMFs with radioisotope-producing cyclotrons. The radioisotope used in PYLARIFY is F 18, which has a 110 minute half-life, requiring that this agent be 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 from the final product. Because each of the PMFs manufacturing PYLARIFY is deemed by the FDA to be a separate manufacturing site, each requires separate FDA approval.

We have a specialized in-house manufacturing facility at our North Billerica campus for purposes of producing the formulation of DEFINITY that requires refrigerated storage and, potentially, other sterile vial products. On February 22, 2022, we received FDA

approval of our sNDA, authorizing commercial manufacturing of DEFINITY at our new facility. DEFINITY manufactured at this facility became commercially available on February 23, 2022. We believe this investment provides supply chain redundancy, improved flexibility and reduced costs in a potentially more price competitive environment.

We also manufacture TechneLite on an automated production line and we process and finish Xenon on a hot cell line at our North Billerica, Massachusetts facility.

We manufacture, finish and distribute our radiopharmaceutical products on a just-in-time basis, and supply our customers with these products either by next day delivery services or by either ground or air custom logistics. We believe that our substantial capital investments in our automated generator production line and our other manufacturing assets, which we have made over the years, and our extensive experience in complying with the stringent regulatory requirements for the handling of nuclear materials and operations in a highly regulated environment, create significant and sustainable competitive advantages for us.

In addition to our in-house manufacturing capabilities, a substantial portion of our products are manufactured by third party contract manufacturing organizations, and in certain instances, we rely on them for sole source manufacturing. To ensure the quality of the products that are manufactured by third parties, the key raw materials used in those products are first sent to our North Billerica, Massachusetts facility, where we test them prior to the third party manufacturing of the final product. For many of our products, after the final products are manufactured, they are sent back to us for final quality control testing, and then we ship them to our customers. We have expertise in the design, development and validation of complex manufacturing systems and processes, and our strong execution and quality control culture supports the just-in-time manufacturing model at our facilities.

Manufacturing and Supply Arrangements

We currently have the following technology transfer and manufacturing and supply agreements in place for some of our major products:

- *PYLARIFY*—We have entered into commercial supply agreements with different PMF networks. Our agreements with our PMF networks allow for the termination upon the occurrence of specified events, including material breach or bankruptcy by either party, and have various termination dates generally terminating between 2025 and 2030 and are subject to renewal provisions.
- *DEFINITY, CARDIOLITE and NEUROLITE*—In February 2022, we entered into a Manufacturing and Supply Agreement with JHS, for the manufacture of DEFINITY, CARDIOLITE, NEUROLITE and evacuation vials, the latter being an ancillary component for our TechneLite generators. The agreement expires on December 31, 2027, and can be renewed upon mutual consent. The agreement allows for termination upon the occurrence of certain events such as a material breach or default by either party, or bankruptcy by either party. The agreement also requires us to order from JHS a specified minimum percentage of our requirements for DEFINITY and fixed quantities of CARDIOLITE and NEUROLITE each year during the contract term.

See Part I, Item 1A. “Risk Factors” for information regarding certain risks associated with our manufacturing and supply relationships.

Intellectual Property

Patents, trademarks and other intellectual property rights, both in the U.S. and foreign countries, are very important to our business. We also rely on trade secrets, manufacturing know-how, technological innovations, licensing agreements and confidentiality agreements to maintain and improve our competitive position. We review third party proprietary rights, including patents and patent applications, as available, in an effort to develop an effective intellectual property strategy, avoid infringement of third party proprietary rights, identify licensing opportunities and monitor the intellectual property owned by others. Our ability to enforce, defend and protect our intellectual property rights may be limited in certain countries outside the U.S., which could make it easier for competitors to capture market position in those countries by utilizing technologies that are similar to those developed or licensed by us. Competitors also may harm our sales by designing products that mirror the capabilities of our products or technology without infringing our intellectual property rights. If we do not obtain sufficient protection for our intellectual property, or if we are unable to effectively enforce or defend our intellectual property rights or our freedom to operate, our competitiveness could be impaired, which would limit our growth and future revenue. If we elect to enforce our intellectual property rights, or are required to defend our rights, we could incur significant litigation expense.

Trademarks, Service Marks and Trade Names

We own various trademarks, service marks and trade names, including, among others, PYLARIFY, DEFINITY and Find Fight and Follow. We have generally registered these trademarks, as well as others, in the U.S. and/or numerous foreign jurisdictions.

Patents

We actively seek to protect the proprietary technology that we consider important to our business, including chemical species, compositions and formulations, their methods of use and processes for their manufacture, as new intellectual property is developed. In addition to seeking patent protection in the U.S., we file patent applications in numerous foreign countries in order to further protect the inventions that we consider important to the development of our international business. We also rely upon trade secrets and contracts to protect our proprietary information.

We have patent protection on certain of our commercial products and clinical development candidates. We typically seek patent protection in major markets around the world, including, among others, the U.S., Canada, Western Europe, Asia, Central America and South America. All patent terms described below are presented without giving effect to any applicable patent term adjustments or regulatory extensions.

PYLARIFY - We actively pursue patents in connection with PYLARIFY, both in the U.S. and internationally. In the U.S. for PYLARIFY, we have five Orange Book-listed patents, including composition of matter patents, the last of which expire 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.

DEFINITY - 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 six Orange Book-listed method-of-use patents, one of which expires in 2035 and five of which expire in 2037, as well as additional manufacturing patents that are not Orange Book-listed expiring in 2037. In the U.S. for DEFINITY RT, we have eight Orange Book-listed patents, including two composition of matter patents which expire in 2035. Outside of the U.S., we 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; additional VIALMIX RFID patent applications have been submitted in major markets throughout the world.

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 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) NDA 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. Submission of an ANDA with a Paragraph IV certification can result in protracted and expensive patent litigation.

As of the date of filing of this Annual Report on Form 10-K, 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 period 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 March 2024 and the full 30-month stay were obtained, then the Applicant would be precluded from commercialization until at least September 2026. 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 trials may be required.

TechneLite - We currently own patents in the U.S. and various foreign countries on certain component technology expiring in 2029, and we are pursuing additional patent protection in the U.S. and world-wide on other component technology that, if granted, would expire in 2040. In addition, given the significant know-how and trade secrets associated with the methods of manufacturing and assembling the TechneLite generator, we believe we have a substantial amount of valuable and defensible proprietary intellectual property associated with the product.

PYLARIFY AI - U.S. Patents and pending patent applications worldwide relating to automated medical image analysis, have expiration ranging from 2037 to 2041.

Other Nuclear Products - Neither CARDIOLITE nor NEUROLITE is covered any longer by patent protection in either the U.S. or the rest of the world. We have patent protection in the U.S. that expires in October 2035 for an improved container for Xenon, and are pursuing similar patent protection outside the U.S.

aBSI - We own patents relating to automated detection of bone cancer metastases. The patents on this technology expire in the U.S. in 2032 and outside of the U.S. in 2028. Further, we own a U.S. patent and have patent applications that are pending in the U.S. and worldwide relating to aBSI improvements, which have expiration ranging from 2040 to 2041.

flurpiridaz - We own patents and patent applications in numerous jurisdictions covering composition, use, formulation and manufacturing, including in the U.S. a composition of matter patent expiring in 2026, a formulation patent expiring in 2032, a method-of-use patent expiring in 2028, and manufacturing-related patents expiring in 2031 and 2033, and various patent applications, some of which, if granted, will expire in 2033.

PNT2002 - We exclusively license granted U.S. patents and pending U.S. patent applications as well as pending patent applications in jurisdictions outside of the U.S. directed to formulations, use and manufacturing of PNT2002. The granted U.S. patents expire in 2041.

PNT2003 - We exclusively license pending U.S. patent applications as well as pending patent applications in jurisdictions outside of the U.S. directed to formulations, use and manufacturing of PNT2003 which, if granted, would expire in 2041.

MK-6240 - We exclusively license patents directed to composition of matter and methods of use of MK-6240 which expire in 2035.

1095 - We own patents relating to 1095, with the composition of matter patent as well as radiolabeled forms patent in the U.S. and Europe expiring in 2027. Additional U.S. patents that we own for stable compositions and radiolabeling processes expire, respectively, in 2030 and 2031.

LNTH-1363S - We exclusively license patent applications directed to compositions of matter and methods of use of LNTH-1363S. If granted, the last patent will expire in 2043.

NM-01- We exclusively license in the field of imaging, patents and applications directed to compositions of matter of NM-01. The granted U.S. patents expire in 2037.

1404 - We own patents relating to composition of matter, as well as technetium-99 labeled forms of 1404 expiring in the U.S. from 2029 to 2030, and expiring worldwide in 2029.

In addition to patents, we rely, where necessary, upon unpatented trade secrets and know-how, proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees, consultants and other third parties and invention assignment agreements with our employees.

In addition, we license third-party technologies and other intellectual property rights that are incorporated into some elements of our drug discovery and development efforts. Some of these licenses are material to our business – for example, the licenses on the PYLARIFY patent family from Johns Hopkins University ("JHU").

See Part I, Item 1A. "Risk Factors" for information regarding certain risks associated with our intellectual property.

Regulatory Matters

Food and Drug Laws

The development, manufacture and commercialization of our products are subject to comprehensive governmental regulation both within and outside the U.S. A number of factors substantially increase the time, difficulty and costs incurred in obtaining and maintaining the approval to market newly developed and existing products. These factors include governmental regulation, such as detailed inspection of and controls over research and laboratory procedures, clinical trials, manufacturing, marketing, advertising and promotion, sampling, distribution, import and export, record keeping and storage and disposal practices, together with various post-marketing requirements. Governmental regulatory actions can result in the seizure or recall of products, suspension or revocation of the authority necessary for their production and sale as well as other civil or criminal sanctions.

Our activities related to the development, manufacture, packaging or repackaging of our products subject us to a wide variety of laws and regulations. We are required to register for permits and/or licenses with, seek approvals from and comply with operating and security standards of, the FDA, the U.S. Nuclear Regulatory Commission ("NRC"), the U.S. Department of Health and Human Services ("HHS"), Health Canada, the European Medicines Agency ("EMA"), the U.K. Medicines and Healthcare Products Regulatory Agency ("MHRA"), the NMPA and various state and provincial boards of pharmacy, state and provincial controlled substance agencies, state and provincial health departments and/or comparable state and provincial agencies, as well as foreign agencies, and certain accrediting bodies depending upon the type of operations and location of product distribution, manufacturing and sale.

The FDA and various state regulatory authorities regulate the research, testing, manufacture, safety, labeling, storage, recordkeeping, premarket approval, marketing, advertising and promotion, import and export, and sales and distribution of pharmaceutical products in the U.S. Prior to marketing a pharmaceutical product, we must first receive FDA approval. In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and implementing regulations. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Currently, the process required by the FDA before a drug product may be marketed in the U.S. generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to current Good Laboratory Practices regulations;
- Submission to the FDA of an investigational new drug application ("IND") which must become effective before human clinical trials may begin, including review and approval by any institutional review board ("IRB"), serving any of the institutions participating in the clinical trials;
- Performance of adequate and well-controlled human clinical trials according to current Good Clinical Practices and other requirements, to establish the safety and efficacy of the proposed drug product for its intended use;
- Submission to the FDA of an NDA for a new drug;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug product is produced to assess compliance with current Good Manufacturing Practices ("cGMPs") regulations; and
- FDA review and approval of the NDA.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for our products in development will be granted on a timely basis, if at all. Once a pharmaceutical product is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation, and stability, as well as animal studies to assess its potential safety and efficacy. This testing culminates in the submission of the IND to the FDA.

Once the IND becomes effective, including review and approval by any IRB serving any of the institutions participating in the clinical trial, the clinical trial program may begin. Each new clinical trial protocol must be submitted to the FDA before the trial may begin. The person, entity or organization taking responsibility for the trial is referred to as the clinical trial sponsor. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with those diseases.
- *Phase 2.* Involves trials in a limited patient population to identify possible adverse effects and safety risks, to evaluate preliminarily the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These trials are intended to collect sufficient safety and efficacy data to support the NDA for FDA approval.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. Submissions must also be made to inform the FDA of certain changes to the clinical trial protocol. Federal law also requires the sponsor to register the trials on public databases when they are initiated, and to disclose the results of the trials on public databases upon completion. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being

exposed to an unacceptable health risk. Similarly, any IRB serving any of the institutions participating in the clinical trial can suspend or terminate approval of a clinical trial at an institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to patients. Failure to register a clinical trial or disclose study results within the required time periods could result in penalties, including civil monetary penalties.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life.

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug product, proposed labeling, and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product. The submission of an NDA is subject to the payment of a substantial user fee. A waiver of that fee may be obtained under certain limited circumstances. The approval process is lengthy and difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied. The FDA has substantial discretion in the product approval process, and it is impossible to predict whether and when the FDA will grant marketing approval. The FDA may on occasion require the sponsor of an NDA to conduct additional clinical trials or to provide other scientific or technical information about the product, and these additional requirements may lead to unanticipated delay or expense. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug product's safety and effectiveness after NDA approval. The FDA also may impose one or more Risk Evaluation and Mitigation Strategies ("REMS") to ensure that the benefits of a product outweigh its risks. A REMS could add training requirements for healthcare professionals, safety communications efforts and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be. Whether a REMS would be imposed on any of our products and any resulting financial impact is uncertain at this time.

Under the Orphan Drug Act, the FDA may designate a product as an Orphan Drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

In the United States, Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has Orphan Drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to Orphan Drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on drug products that are placed on the market. Drugs may be promoted only for the approved indications and consistent with the provisions of the approved label and promotional claims must be appropriately balanced with important safety information and otherwise be adequately substantiated. Further, manufacturers of drugs must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Drug product manufacturers and other entities involved in the manufacturing and distribution of approved drugs products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain other agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release. In addition, manufacturers of commercial PET products such as PYLARIFY, including radiopharmacies, hospitals and academic medical centers, are required to submit either an NDA or ANDA in order to produce PET drugs for clinical use, or produce the drugs under an IND.

The FDA also regulates the preclinical and clinical testing, design, manufacture, safety, efficacy, labeling, storage, record keeping, sales and distribution, post-market adverse event reporting, import/export and advertising and promotion of any medical devices that we distribute pursuant to the FDCA and FDA's implementing regulations. The Federal Trade Commission shares jurisdiction with the FDA over the promotion and advertising of certain medical devices. The FDA can also impose restrictions on the sale, distribution or use of medical devices at the time of their clearance or approval, or subsequent to marketing. Currently, medical devices comprise only a small portion of our revenues.

The FDA may withdraw marketing authorization for a product if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously-unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, civil monetary penalties, warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions, or civil or criminal penalties.

Regulations are subject to change as a result of legislative, administrative or judicial action, which may also increase our costs or reduce sales or otherwise adversely impact our products. For example, on April 16, 2021 in the case Genus Medical Technologies LLC v. Food and Drug Administration, the U.S. Court of Appeals for the D.C. Circuit held that a product (other than a combination product) that meets the definitions of both "drug" and "device" under the FDCA must be regulated as a device. On August 9, 2021, the FDA announced that, as part of its implementation of this court decision, the FDA intended to regulate products that meet both the device and drug definition as devices, except where Congress intended a different classification. The FDA further indicated that it intended to bring previously classified products into line with the court decision and would reexamine whether individual imaging agents meet the device definition, which raised uncertainty as to how our some of our products would be regulated. Congress subsequently resolved this issue when it passed the Consolidated Appropriations Act of 2023, which amended the FDCA by adding a provision that deemed any contrast agent or radioactive drug to be a drug.

Because our operations include the manufacture and distribution of medical radioisotopes and other medical products, we are subject to regulation by the NRC and the departments of health of each state in which we operate and the applicable state boards of pharmacy. In addition, the FDA is also involved in the regulation of cyclotron facilities where PET products are produced in compliance with cGMP requirements and U.S. Pharmacopeia requirements for PET drug compounding.

Drug laws also are in effect in many of the non-U.S. markets in which we or our partners conduct business. These laws range from comprehensive drug approval requirements to requests for product data or certifications. In addition, inspection of and controls over manufacturing, as well as monitoring of adverse events, are components of most of these regulatory systems. Most of our business is subject to varying degrees of governmental regulation in the countries in which we or our partners operate, and the general trend is toward increasingly stringent regulation. The exercise of broad regulatory powers by the FDA continues to result in increases in the amount of testing and documentation required for approval or clearance of new drugs and devices, all of which add to the expense of product introduction. Similar trends also are evident in major non-U.S. markets, including Canada, the European Union, Australia and Japan.

To assess and facilitate compliance with applicable FDA, NRC and other state, federal and foreign regulatory requirements, we regularly review our quality systems to assess their effectiveness and identify areas for improvement. As part of our quality review, we perform assessments of our suppliers of the raw materials that are incorporated into products and conduct quality management reviews designed to inform management of key issues that may affect the quality of our products. From time to time, we may determine that products we manufactured or marketed do not meet our specifications, published standards, such as those issued by the International Standards Organization, or regulatory requirements. When a quality or regulatory issue is identified, we investigate the issue and take appropriate corrective action, such as withdrawal of the product from the market, correction of the product at the customer location, notice to the customer of revised labeling and other actions.

Hatch-Waxman Act

The Hatch-Waxman Act added two pathways for FDA drug approval. First, the Hatch-Waxman Act permits the FDA to approve ANDAs for generic versions of drugs if the ANDA applicant demonstrates, among other things, that its product is bioequivalent to the innovator product and provides relevant chemistry, manufacturing and product data. See "Item 1. Business - Patents." Second, the Hatch-Waxman Act created what is known as a Section 505(b)(2) NDA, which requires the same information as a full NDA (known as a Section 505(b)(1) NDA), including full reports of clinical and preclinical studies but allows some of the information from the reports required for marketing approval to come from studies which the applicant does not own or have a legal right of reference. A Section 505(b)(2) NDA permits a manufacturer to obtain marketing approval for a drug without needing to conduct or obtain a right of reference for all of the required studies. The Hatch-Waxman Act also provides for: (1) restoration of a portion of a product's patent term that was lost during clinical development and application review by the FDA; and (2) statutory protection, known as exclusivity, against the FDA's acceptance or approval of certain competitor applications.

Under U.S. law, patent term extension can compensate for time lost during product development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. This period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Patent term extensions, however, are subject to a maximum extension of five years, and the patent term extension cannot extend the remaining term of a patent beyond a total of 14 years. The application for patent term extension is subject to approval by the U.S. Patent and Trademark Office in conjunction with the FDA.

The Hatch-Waxman Act also provides for a period of statutory protection for new drugs that receive NDA approval from the FDA. If the FDA approves a Section 505(b)(1) NDA for a new drug that is a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety, then the Hatch-Waxman Act prohibits the submission or approval of an ANDA or a Section 505(b)(2) NDA for a period of five years from the date of approval of the NDA, except that the FDA may accept an application for review after four years under certain circumstances, specifically a patent challenge for one or more patents listed by the NDA holder in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), submitted in a "Paragraph IV" Certification. The Hatch-Waxman Act will not prevent the filing or approval of a full NDA, as opposed to an ANDA or Section 505(b)(2) NDA, for any drug, but the competitor would be required to conduct its own clinical trials, and any use of the drug for which marketing approval is sought could not violate another NDA holder's patent claims. The Hatch-Waxman Act provides for a three-year period of exclusivity for an NDA for a new drug containing an active moiety that was previously approved by the FDA, but also includes new clinical data (other than bioavailability and bioequivalence studies) to support an innovation over the previously-approved drug and those studies were conducted or sponsored by the applicant and were essential to approval of the application. This three-year exclusivity period does not prohibit the FDA from accepting an application from a third party for a drug with that same innovation, but it does prohibit the FDA from approving that application for the three-year period. The three-year exclusivity does not prohibit the FDA, with limited exceptions, from approving generic drugs containing the same active ingredient but without the new innovation.

Reimbursement

The successful commercialization of our products is also subject to the availability of appropriate third-party coding, coverage and payment for our customers. Third-party payors in the U.S. include private payors, including managed care providers, and State and Federal healthcare programs, such as Medicare and Medicaid. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product. Coverage of a product does not ensure there will be an appropriate reimbursement amount for such product and the process to ensure appropriate reimbursement is outside our control. For private payors, coverage and reimbursement of our products vary from private payor to private payor. Many private payors, such as managed care providers, manage access to products, and may use medical policies (which may include specific coverage requirements such as prior authorization, re-authorization and achieving performance metrics under value-based contracts) to control utilization. Exclusion from or restriction in coverage can reduce product use. For government payors, we participate, as required, in the Medicaid drug rebate program, the Federal Supply Schedule (FSS) and the Public Health Service Act 340B program, which each require discounts for participation and may be subject to change. For Medicare, reimbursement to customers for our products is generally established through the rulemaking process or in discussion with Medicare Administrative Contractors (MACs). We have ongoing conversations with third-party payors to advocate for appropriate coding, coverage and payment for our portfolio of products.

Medicare Outpatient TPT Status

Part B of the Medicare program generally reimburses medical services and supplies, including drugs, provided to beneficiaries by physicians and other qualified healthcare professionals. Generally, drugs furnished "incident to" a physician's service in the hospital outpatient setting of care are reimbursed at Average Sales Price ("ASP") plus a certain additional percent, unless the product is treated as a "supply" in the performance of the procedure and "packaged" and paid as part of bundled payment for the procedure.

Novel drugs, however, may apply for TPT Status in which case they are provided a separate payment at ASP plus a certain additional percent for two to three years, regardless of whether they would ordinarily be packaged.

PYLARIFY has received TPT Status effective January 1, 2022 through December 31, 2024, thereby providing separate reimbursement to customers using PYLARIFY in the hospital outpatient setting during this specified period. The reimbursement rate for PYLARIFY was initially based on the wholesale acquisition cost (WAC) plus three percent until ASP could be established. In 2023, CMS established an ASP for PYLARIFY and reimbursed at a rate equal to ASP plus an add-on percentage that varied throughout the year.

PYLARIFY has been assigned Healthcare Common Procedure Coding System code A9595 (piflufolastat F 18, diagnostic, 1 millicurie) for identification in claims and can be used by both public and private payors. Under existing Medicare policy for the hospital outpatient setting of care, non-pass-through diagnostic radiopharmaceuticals are not separately paid and are instead packaged into payment for the underlying procedure. Therapeutic radiopharmaceuticals are paid separately by Medicare OPPS regardless of TPT Status. We plan to continue our advocacy efforts with CMS and private insurers so that PYLARIFY customers will have appropriate and adequate reimbursement following the expiration of TPT Status. We are also supporting trade associations in their efforts to have Congress pass the Facilitating Innovative Nuclear Diagnostics (FIND) Act, which would allow for separate payment for certain diagnostic radiopharmaceuticals, including PYLARIFY, similar to the way Medicare OPPS currently pays for other drugs, biologics, and therapeutic radiopharmaceuticals instead of under the current TPT structure of a separate payment that is limited to three years.

Healthcare Reform and Other Laws Affecting Payment

We operate in a highly regulated industry. The U.S. and state governments continue to propose and pass legislation that may affect the availability and cost of healthcare. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Healthcare Reform Act"), substantially changes the way in which healthcare is financed by both governmental and private insurers and has a significant impact on the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that affect coverage, reimbursement and/or delivery of drug products and the medical imaging procedures in which our drug products are used. Key provisions that currently affect our business include the following:

- increasing the presumed utilization rate for imaging equipment costing $1.0 million or more in the physician office and free-standing imaging facility setting which reduces the Medicare per procedure medical imaging reimbursement; which rate was further increased by subsequent legislation effective January 1, 2014;
- increasing drug rebates paid to state Medicaid programs under the Medicaid Drug Rebate Program for brand name prescription drugs and extending those rebates to Medicaid managed care organizations;
- expanding access to the 340B program by allowing additional covered entities to participate in the program; and
- imposing a non-deductible annual fee on pharmaceutical manufacturers or importers who sell brand name prescription drugs to specified federal government programs.

The Healthcare Reform Act also amended the federal self-referral laws, requiring referring physicians to inform patients under certain circumstances that the patients may obtain services, including PET, CT, MRI and certain other diagnostic imaging services, from a provider other than that physician, another physician in his or her group practice, or another individual under direct supervision of the physician or another physician in the group practice. The referring physician must provide each patient with a written list of other suppliers who furnish those services in the area in which the patient resides. These requirements could have the effect of shifting where certain diagnostic medical imaging procedures are performed.

The Healthcare Reform Act has been subject to political and judicial challenges, but it has generally withstood such challenges, and the main provisions of the Healthcare Reform Act remain in effect. More recently, Congress enacted the Inflation Reduction Act of 2022 (the "IRA") which significantly impacts the pharmaceutical industry. Among other provisions, the IRA authorizes Medicare to negotiate pricing for the highest Medicare-spend drugs, as determined by their Medicare Part B and D spend, that have been on the market for an extended period of time without market competition. Although the IRA provides for a limited number of categorical exclusions from Medicare negotiation, radiopharmaceuticals are not among those categorical exclusions. CMS plans to begin implementing the first year of Medicare negotiation, which will be restricted to Part D drugs, starting in calendar years 2026 and 2027. We are currently focused on drugs that are covered under Part B, therefore we do not expect the Part D benefit redesign to have an impact on our portfolio. Part B drugs will be considered for Medicare negotiation beginning in calendar year 2028, and CMS will begin the process of identifying Part B drugs for negotiation as early as calendar year 2026. We are monitoring the implementation of the IRA to determine what impact, if any, this would have on our current products and product candidates in development.

The IRA also introduces rebate obligations for manufacturers of Part B and D drugs that take price increases which exceed the rate of inflation, similar to the longstanding Medicaid inflation rebates. Under these new Medicare inflation rebates, each Part B and D

single-source drug/biological and biosimilar will have an "inflation adjusted" payment amount calculated by CMS. If the manufacturer's price increases for the relevant product exceeds the inflation adjusted payment amount, as trended forward by the rate of inflation, the manufacturer will be required to reimburse Medicare the difference between what Medicare paid for the product and what it would have paid based on the inflation adjusted payment amount.

Recent state legislative efforts seek to address drug costs and generally have focused on increasing transparency around drug costs or limiting drug prices. Some of those efforts have been subject to legal challenge.

General legislative cost control measures may also affect reimbursement for our products or services provided with our products. The Budget Control Act, as amended by the Bipartisan Budget Act of 2019, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers beginning in 2013 and will remain in effect through fiscal year 2030 unless additional Congressional action is taken. The imposition of the 2% payment adjustment had been suspended through March 31, 2022 and went into effect as of April 1, 2022. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our business results of operations, financial condition and cash flows.

Healthcare Fraud and Abuse Laws

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and/or exclusion from federal health care programs (including Medicare and Medicaid). Federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry, and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the federal False Claims Act ("FCA"). Violations of international fraud and abuse laws could result in similar penalties, including exclusion from participation in health programs outside the U.S. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed.

The federal Anti-Kickback Statute generally prohibits, among other things, a pharmaceutical manufacturer from directly or indirectly soliciting, offering, receiving, or paying any remuneration in cash or in kind where one purpose is either to induce the referral of an individual for, or the purchase or prescription of a particular drug that is payable by a federal health care program, including Medicare or Medicaid. The Healthcare Reform Act clarifies the intent requirements of the federal Anti-Kickback Statute, providing that a person or entity does not need to have actual knowledge of the statute or a specific intent to violate the statute. Violations of the federal Anti-Kickback Statute can result in exclusion from Medicare, Medicaid or other governmental programs as well as civil and criminal fines and penalties of up to $104,330 per violation and three times the amount of the unlawful remuneration. In addition, the Healthcare Reform Act revised the FCA to provide that a claim arising from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The majority of states also have anti-kickback, false claims, and similar fraud and abuse laws and although the specific provisions of these laws vary, their scope is generally broad, and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices. There is, therefore, a possibility that our practices might be challenged under the anti-kickback statutes or similar laws.

Federal and state false claims laws generally prohibit anyone from knowingly and willfully, among other activities, presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid) claims for drugs or services that are false or fraudulent (which may include claims for services not provided as claimed or claims for medically unnecessary services). As discussed, a claim arising from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. False or fraudulent claims for purposes of the FCA carry fines and civil penalties for violations ranging from $11,665 to $23,331 for each false claim, plus up to three times the amount of damages sustained by the federal government and, most critically, may provide the basis for exclusion from federally funded healthcare programs. There is also a criminal FCA statute by which individuals or entities that submit false claims can face criminal penalties. In addition, under the federal Civil Monetary Penalty Law, the Department of Health and Human Services Office of Inspector General has the authority to exclude from participation in federal health care programs or to impose civil penalties against any person who, among other things, knowingly presents, or causes to be presented, certain false or otherwise improper claims. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws.

Laws and regulations have also been enacted by the U.S. federal government and various states, as well as by countries outside of the U.S., to regulate the sales and marketing practices of certain entities including pharmaceutical and device manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers; require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government; and/or require disclosure by pharmaceutical and device manufacturers to the government and/or public of financial interactions or other financial relationships with health care providers and other entities such as teaching hospitals (so-called "sunshine laws"). The Healthcare Reform Act requires manufacturers to submit information to the FDA on the identity and quantity of drug samples requested and distributed by a manufacturer during each year. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. The laws and regulations include requirements that can be unclear in their scope, nature, and required implementation by regulated entities. If we fail to comply with such laws and regulations, we could be subject to penalties and administrative actions under such laws and regulations.

Data Privacy, Security and Breach Notification

We are subject to data protection laws and regulations that set forth data privacy, security, and breach notification requirements. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on data protection and other data privacy and security issues. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. In addition to establishing restrictions on how personal information may be collected, used, and disclosed, these laws and regulations provide various rights to data subjects with respect to their personal information and establish requirements for how personal information must be secured. In addition, every state in the United States now has a data breach notification law that requires regulated entities to report certain security breaches to affected data subjects, regulators, or other entities. Failure to comply with data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties and requirements to take corrective actions), private litigation (which may result in the award of damages against us), and/or adverse publicity, and could negatively affect our operating results, business, and reputation. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are themselves subject to privacy, security, and breach notification requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "HIPAA"). While we believe that we are neither a "covered entity" nor "business associate" subject directly to regulation under HIPAA, HIPAA's criminal provisions can apply to entities other than "covered entities" or "business associates" in certain circumstances. Accordingly, we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted.

In addition, a growing number of jurisdictions outside of the United States have enacted robust data protection laws. Certain of these laws have extraterritorial application. For example, the processing of personal data in the European Union is governed by the provisions of the General Data Protection Regulation, or GDPR, which came into effect on May 25, 2018. The GDPR applies to an entity established in the EU and extraterritorially to an entity outside of the EU that offers goods or services to, or monitors the behavior of, individuals located in the EU. Certain "special categories" of personal data, including data concerning health, are subject to enhanced protections under the GDPR. This regulation imposes several requirements on the controllers and processors of personal data, including the obligation to comply with various rights that individuals have with respect to their personal data and restrictions on the processing of personal data, and to provide notice of data processing obligations to the competent national data protection authorities. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States may result in significant fines and other administrative penalties.

In the United States, several state legislatures are considering enacting new data privacy legislation. One example of such legislation that has already been passed is the California Consumer Privacy Act ("CCPA"), which took effect on January 1, 2020 and imposes many requirements on certain for-profit businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects various rights, such as the right to request access to their personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of the "sale" of their personal information. In addition, the CCPA requires regulated businesses to implement reasonable security procedures and practices to protect personal information. The CCPA contains significant penalties for companies that violate its requirements. It also provides California residents a private right of action, including the ability to seek statutory damages, in the event of a breach involving their personal information resulting from a business's failure to implement and maintain reasonable security procedures and practices. Compliance with the CCPA, and similar laws implemented in other states, is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

On November 3, 2020, California passed the California Privacy Rights Act ("CPRA") through a ballot initiative. The CPRA amends the CCPA and expands its protections for personal information, including by establishing a new California Privacy Protection Agency to enforce the CPRA and by providing California consumers various rights such as the right to restrict the processing of their "sensitive personal information." The CPRA's amendments to the CCPA took effect on January 1, 2023, and generally apply to personal information collected by regulated businesses on or after January 1, 2022.

Antitrust and Competition Laws

The federal government and most states have enacted antitrust laws that prohibit specific types of anti-competitive conduct, including price fixing, wage fixing, concerted refusals to deal, price discrimination and tying arrangements, as well as monopolization and acquisitions of competitors that have, or may have, a substantial adverse effect on competition. Violations of federal or state antitrust laws can result in various sanctions, including criminal and civil penalties. We believe we are in compliance with such federal and state laws, but courts or regulatory authorities may reach a determination in the future that could adversely affect our business, results of operations, financial condition and cash flows. In addition, we are subject to similar antitrust and anti-competition laws in foreign countries. We believe we are in compliance with such laws, however, any violation could create a substantial liability for us and also cause a loss of reputation in both foreign and domestic markets.

Laws Relating to Foreign Trade

We are subject to various federal and foreign laws that govern our international business practices with respect to payments to government officials. Those laws include the Foreign Corrupt Practices Act ("FCPA") which prohibits U.S. companies and their representatives from paying, offering to pay, promising, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity. In many countries, the healthcare professionals we regularly interact with may meet the FCPA's definition of a foreign government official. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls.

Those laws also include the U.K. Bribery Act ("Bribery Act") which proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official, and failing to have adequate procedures to prevent employees and other agents from giving bribes. U.S. companies that conduct business in the United Kingdom generally will be subject to the Bribery Act. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances.

Our policies mandate compliance with these anti-bribery laws. Our operations reach many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents.

We are also subject to trade control regulations and trade sanctions laws that restrict the movement of certain goods, currency, products, materials, services and technology to, and certain operations in, various countries or with certain persons. Our ability to transfer people and products among certain countries may be subjected to these laws and regulations.

Health and Safety Laws

We are also subject to various federal, state and local laws, regulations and recommendations, both in the U.S. and abroad, relating to safe working conditions, laboratory and manufacturing practices and the use, transportation and disposal of hazardous or potentially hazardous substances.

See Part I, Item 1A. "Risk Factors" for information regarding certain risks related to reimbursement and regulation.

Environmental Matters

We are subject to various federal, state and local laws and regulations relating to the protection of the environment, human health and safety in the U.S. and in other jurisdictions in which we operate. Our operations, like those of other medical product companies, involve the transport, use, handling, storage, exposure to and disposal of materials and wastes regulated under environmental laws, including hazardous and radioactive materials and wastes. If we violate these laws and regulations, we could be fined, criminally charged or otherwise sanctioned by regulators. We believe that our operations currently comply in all material respects with applicable environmental laws and regulations.

Certain environmental laws and regulations assess liability on current or previous owners or operators of real property for the cost of investigation, removal or remediation of hazardous materials or wastes at those formerly owned or operated properties or at third party properties at which they have disposed of hazardous materials or wastes. In addition to cleanup actions brought by governmental authorities, private parties could bring personal injury, property damage or other claims due to the presence of, or exposure to, hazardous materials or wastes. We currently are not party to any claims or any obligations to investigate or remediate any material contamination at any of our facilities, however, if we were found to be liable under one or more of these laws or regulations, it could create a substantial liability.

We are required to maintain a number of environmental permits and nuclear licenses for our North Billerica, Massachusetts campus, which includes our primary manufacturing, packaging and distribution facility. In particular, we must maintain a nuclear byproducts materials license issued by the Commonwealth of Massachusetts. This license requires that we provide financial assurance demonstrating our ability to cover the cost of decommissioning and decontaminating ("D&D") the Billerica site at the end of its use as a nuclear facility. In addition, we have a radioactive production facility in Somerset, NJ where we must also maintain a number of environmental permits and nuclear licenses. We store low level radioactive waste at our facilities until the materials are below regulatory limits, as allowed by our licenses and permits. As of December 31, 2023, we currently estimate the D&D cost of all of our manufacturing sites to be approximately $25.1 million. As of December 31, 2023 and 2022, we have a liability of approximately $22.9 million and $22.5 million, respectively associated with our asset retirement obligations. We currently provide this financial assurance in the form of surety bonds.

We also actively monitor and seek to reduce our solid waste, energy and water usage, waste water discharge and greenhouse gas emissions. We generally contract with third parties for the disposal of wastes generated by our operations. In 2020, we developed a stormwater management operations and maintenance plan to minimize stormwater pollution from high impact activities. Improvements we made include (i) the regular inspection and cleaning of catch basins and piping to reduce sediment and debris wash out to adjacent wetlands; (ii) increasing street and parking lot cleaning to reduce pollutant run off; (iii) updating our snow removal plan at our North Billerica campus to reduce the impact to adjacent wetlands; and (iv) using salt brine as a pretreatment for winter storms to reduce the amount of salt use and run off.

With respect to sustainability, we track and monitor our energy use, water use, a limited scope of greenhouse gas emissions, and waste generation. We use an Energy Star Portfolio Manager to track energy and water use and have calculated scope 1 and 2 greenhouse gas emissions for our North Billerica Campus, with plans to expand these activities to other Lantheus properties. We will continue to compare our usage data against annual baselines, national medians, and similar buildings.

Environmental laws and regulations are complex, change frequently and have become more stringent over time. While we have budgeted for future capital and operating expenditures to maintain compliance with these laws and regulations, we cannot assure you that our costs of complying with current or future environmental protection, health and safety laws and regulations will not exceed our estimates or adversely affect our results of operations and financial condition. Further, we cannot assure you that we will not be subject to additional environmental claims for personal injury or cleanup in the future based on our past, present or future business activities. While it is not feasible to predict the future costs of ongoing environmental compliance, it is possible that there will be a need for future provisions for environmental costs that, in management's opinion, are not likely to have a material effect on our financial condition, but could be material to the results of operations in any one accounting period.

See Part I, Item 1A. "Risk Factors" for information regarding certain risks associated with environmental matters.

Human Capital Management

As of December 31, 2023, we had 834 employees, of which 808 were located in the U.S. and 26 were located internationally. None of our employees are represented by a collective bargaining agreement, and we believe that our relationship with our employees is good.

Diversity, Inclusion, Ethics and Compliance

We believe that supporting our local community and instilling a diverse, inclusive, ethical and compliant culture makes us an employer of choice, allows us to maintain good standing with the regulatory authorities and our customers, and benefits our stockholders in the long run.

We have a female Chief Executive Officer who, effective March 1, 2024, will transition to Chair of the Board, over half of our Vice Presidents and above (including our senior management team, which we refer to as our "Expanded Executive Team") are women, and approximately 50% of our employees are women. We continue to strive to improve our diversity and inclusion with a strategic emphasis beyond gender, and we require recruiters working with us to present diverse candidates. We also sponsor three Employee Resource Groups ("ERGs"), the Lantheus Diversity Connection ERG, the Women Leaders of Lantheus ERG, and the Professional Networking at Lantheus ERG.

We are committed to promoting a culture of ethics and compliance. Our Code of Conduct and Ethics reflects our commitment to corporate integrity and the underlying business practices and principles of behavior that support this commitment. Each year our employees complete mandatory training that includes anti-bribery/anti-corruption rules, insider trading prohibitions, confidentiality obligations, as well as specialized training in healthcare industry marketing practices. We have a formal Ethics and Compliance Committee that develops, implements and oversees our ethics and compliance programs. We also have a Supplier Code of Conduct, and we seek to do business with minority-owned, female-owned and other diverse businesses and organizations (including those owned or operated by veterans and disabled veterans) that appropriately reflect the communities in which we operate and the customer base we serve.

Compensation and Benefits

We seek to provide pay, benefits, and services that are competitive to market and create incentives to attract and retain employees. Our compensation package includes, among other things, market-competitive pay, cash bonuses, healthcare and defined contribution plan benefits, paid time off and family leave, and restricted stock and other equity grants to certain levels of employees. We are focused on pay equity and regularly assess pay among similar roles and responsibilities throughout our organization and in comparison to our peer group.

Communication and Engagement

We believe that our success depends on employees understanding how their work contributes to our overall strategy. To this end, we utilize a variety of channels to facilitate open and direct communication, including: (i) quarterly town hall meetings for our entire company; (ii) regular ongoing update communications, including through monthly newsletters and our recently launched intranet site; and (iii) an externally administered whistleblower hotline and website that is prominently advertised to our employees, and a whistleblower's anonymity is protected, if so requested. We also established various employee recognition award programs to recognize and reward employees for specific outstanding accomplishments and to foster a positive employee relations climate.

Health, Wellness and Safety

We are committed to the health and safety of our employees, patients and other partners in the healthcare community. We work to promote an environment of awareness and shared responsibility for safety and regulatory compliance throughout the Company, in order to minimize risks of injury, exposure, or business impact.

Corporate History

Founded in 1956 as New England Nuclear Corporation, our medical imaging diagnostic business was purchased by E.I. du Pont de Nemours and Company ("DuPont") in 1981. Bristol Myers Squibb ("BMS") subsequently acquired our diagnostic medical imaging business as part of its acquisition of DuPont Pharmaceuticals in 2001. In January 2008, Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P. and ACP-Lantern Co-Invest, LLC formed Lantheus Holdings and acquired our medical imaging business from BMS. On June 30, 2015, we completed an initial public offering of our common stock. We completed our acquisition of Progenics on June 19, 2020 (the "Progenics Acquisition"). We completed our acquisition of Cerveau Technologies, Inc. on February 6, 2023 (the "Cerveau Acquisition"). Our common stock is traded on the NASDAQ Global Market under the symbol "LNTH".

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 Annual Report on Form 10-K, 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 Inline Extensible Business Reporting Language ("iXBRL") format. iXBRL is an electronic coding language used to create interactive financial statement data over the Internet.

Item 1A. Risk Factors

You should carefully consider the following risks. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. These risks could materially affect our business, results of operations or financial condition, cause the trading price of our outstanding common stock to decline materially or cause our actual results to differ materially from those expected or those expressed in any forward-looking statements made by us or on our behalf. See "Cautionary Note Regarding Forward-Looking Statements" and the risks of our businesses described elsewhere in this Annual Report on Form 10-K.

Risks Related to Our Portfolio of Commercial Products

Our ability to continue to grow PYLARIFY as a commercial product is dependent on (A) the ability of PMFs to manufacture PYLARIFY to meet product demand, (B) our ability to promote PYLARIFY to customers, (C) our ability to obtain and maintain adequate coding, coverage and payment for PYLARIFY, (D) our ability to maintain PYLARIFY as the leading PSMA PET imaging agent, including after the potential expiration of TPT Status at the end of 2024 and (E) our ability to clinically and commercially differentiate PYLARIFY from other products.

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 PYLARIFY is broadly available across the U.S., we continue to seek qualification for additional PMFs in 2024 and 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 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 an internal PYLARIFY 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. 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 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 would not be separately reimbursed in the hospital outpatient setting but rather would be bundled into the facility payment a hospital receives for a PET/CT imaging procedure, and the facility payment may 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 business, results of operations, financial condition and cash flows could be adversely affected. We plan to continue our advocacy efforts with CMS and private insurers so that PYLARIFY customers will have appropriate and adequate reimbursement following the expiration of TPT Status and we are also supporting trade associations in their efforts to have Congress pass the Facilitating Innovative Nuclear Diagnostics (FIND) Act, which would allow for separate payment for certain diagnostic radiopharmaceuticals, including PYLARIFY, similar to the way Medicare OPPS currently pays for other drugs, biologics, and therapeutic radiopharmaceuticals instead of under the current TPT structure of a separate payment that is limited to three years, however, we can give no assurances that we will be successful in those efforts or that the availability of TPT Status for other diagnostic radiopharmaceuticals will not impact clinical decision making regarding which product to use, which could have an adverse effect on our business, results of operations, financial condition and cash flows.

The successful growth of PYLARIFY is also dependent on our ability to clinically and commercially differentiate PYLARIFY from other products on the market and to maintain PYLARIFY as the leading PSMA PET imaging agent in a competitive environment in which other PSMA PET imaging agents have been approved. PYLARIFY currently competes with two commercially available Ga-68-based PSMA PET imaging agents from Telix Pharmaceuticals Limited and Novartis AG and an F 18 PSMA PET imaging agent from Blue Earth, as well as other non-PSMA PET imaging agents. 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 products still exists), such loss of market share could have an adverse impact on our business, results of operations, financial condition and cash flows. Continued growth and revenue contribution from PYLARIFY will also depend on our ability to differentiate

PYLARIFY in light of the potential loss of TPT Status, including through flexible and dependable access to PYLARIFY nationally, a best in class customer experience and through long-term strategic contracts.

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) created a new addressable market for the use of PSMA PET imaging in patient selection for PSMA-targeted therapy. 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. 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 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 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 business, results of operations, financial condition and cash flows.

The near-term growth of our business is also dependent on our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms in the face of competition from other existing echocardiography agents and potential generic competitors as a result of patent and regulatory exclusivity expirations.

The growth of our business is also dependent on our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms. DEFINITY currently competes with ultrasound enhancing agents produced by GE Healthcare and Bracco, as well as echocardiography without ultrasound enhancing agents and other non-echocardiography agents.

We launched DEFINITY in 2001, and 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 six Orange Book-listed method-of-use patents, one of which expires in 2035 and five of which expire in 2037, as well as additional manufacturing patents that are not Orange Book-listed expiring in 2037. In the U.S. for DEFINITY RT, we have eight Orange Book-listed patents, including two composition of matter patents that expire in 2035. Outside of the U.S., we 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; additional VIALMIX RFID patent applications have been submitted in major markets throughout the world.

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 ANDAs for generic versions of drugs before the expiration of an Orange Book-listed patent covering the innovator product 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) NDA 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. The ANDA applicant or the Section 505(b)(2) applicant (if relying on studies related to the innovator product) (together, the "Applicant") must also give Notice to the innovator, which would then enable the innovator to file suit against the Applicant within 45 days of receiving the Notice. If the innovator challenges the Applicant in court in a timely manner, then FDA approval to commercialize the generic candidate will be stayed (that is, delayed) for up to 30 months while the dispute between the innovator and the Applicant is resolved in court. The 30 month stay can be shortened if the patent infringement suit is resolved in the Applicant's favor before the 30 month stay expires, and this may involve a successful challenge of the patent's validity in U.S. Patent and Trademark Office ("USPTO") proceedings and appeals process. 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 trials may be required. We can give no assurance that we would have grounds to file a patent infringement suit, that we would obtain the full 30 month stay, that we would be successful on the merits asserting that an Applicant infringes our Orange Book-listed patent, or that we would be successful defending the validity of our Orange Book-listed patent in court or in a USPTO adversarial proceeding.

As of the date of filing of this Annual Report on Form 10-K, we have not received any such Notice from any Applicant, but we can give no assurance that we will not receive a Notice in the future. If we were to receive any such Notice in the future, we would review the Notice, evaluate the strength of any potential patent infringement claims, and be prepared to challenge the Applicant in a timely fashion, which would thereby trigger the stay of up to 30 months. We can give no assurance that we would have grounds to file a patent infringement suit, that we would obtain the full 30 month stay, that we would be successful on the merits asserting that an Applicant infringes our Orange Book-listed patent, or that we would be successful defending the validity of our Orange Book-listed patent in court or in a USPTO adversarial proceeding. If we were to receive such a Notice and to challenge the Applicant, patent litigation is complex and can be protracted and expensive, which could also have a negative effect on our business, results of operations and financial condition.

As part of our microbubble franchise strategy, (i) we have developed and received FDA approval for DEFINITY RT, a modified formulation of DEFINITY, (ii) we look for other opportunities to expand our microbubble franchise, including new applications beyond echocardiography and ultrasound enhancing agent imaging generally such as our strategic arrangements with Cerevast, CarThera, Insightec, AHN and SonoThera, and (iii) we have constructed a specialized in-house manufacturing facility at our North Billerica campus for purposes of producing the formulation of DEFINITY that requires refrigerated storage and, potentially, other sterile vial products. On February 22, 2022, we received FDA approval of our sNDA, authorizing commercial manufacturing of DEFINITY at our new facility. However, we can give no assurance that our microbubble franchise strategy will be successful or that the modified formulation, new applications or new manufacturing capabilities will grow our microbubble franchise.

If we are not able to continue to (i) grow DEFINITY and DEFINITY RT sales, which depend on one or more of the growth of echocardiograms, the growth in the appropriate use of ultrasound enhancing agents in suboptimal echocardiograms, and our ability to sustain and grow our leading position in the U.S. echocardiography ultrasound enhancing agent market, or (ii) be successful with our microbubble franchise strategy, we may not be able to continue to grow the revenue and cash flow of our business, which could have a negative effect on our business, results of operations and financial condition.

Our dependence upon third parties for the manufacture and supply of a substantial portion of our products and certain key components and raw materials and upon our in-house manufacturing for DEFINITY could prevent us from delivering our products to our customers in the required quantities, within the required timeframes, or at all, which could result in order cancellations and decreased revenues.

We obtain a substantial portion of our products from third party manufacturers and suppliers.

PYLARIFY is manufactured by a nationwide network of PMFs with radioisotope-producing cyclotrons. The radioisotope in PYLARIFY is fluorine-18, which has a 110-minute half-life, so PYLARIFY is manufactured and distributed rapidly to end-users. Because each of the PMFs manufacturing PLYARIFY is deemed by the FDA to be a separate manufacturing site, each has to be separately approved by the FDA. Although we have qualified and continue to qualify additional PMFs, we can give no assurance that the FDA will continue to approve PMFs in accordance with our planned roll-out schedule or that the PMFs will not experience issues with their ability to manufacture and deliver PYLARIFY to our customers. If FDA approval of manufacturing sites is delayed or withdrawn or our PMF sites experience manufacturing issues, our business, results of operations, financial condition and cash flows could be adversely affected.

We rely on JHS as a substantial supplier of DEFINITY, as well as our sole source manufacturer of NEUROLITE, CARDIOLITE and evacuation vials. We rely on Samsung Biologics Co., Ltd. (“SBL”) as our sole source manufacturer of DEFINITY RT. In addition, for reasons of quality assurance or cost-effectiveness, we purchase certain components and raw materials from sole suppliers (including, for example, the specially designed chemistry synthesis boxes and consumables used in the manufacturing of PYLARIFY, the lipid blend material and perflutren gas used in the manufacturing of DEFINITY and the lead casing for our TechneLite generators). Because we do not control the actual production of many of the products we sell and many of the raw materials and components that make up the products we sell, we may be subject to delays caused by interruption in production based on events and conditions outside of our control.

If we or one of our manufacturing partners or suppliers experiences an event, including a supply chain disruption, shortage or delay, logistics issue, labor dispute, natural disaster, fire, power outage, machinery breakdown, security problem, failure to meet regulatory requirements, product quality issue, technology transfer issue, cybersecurity breach or other issue, we or one of our manufacturing partners or suppliers may be unable to manufacture the relevant products at previous levels or on the forecasted schedule, if at all. Due to the stringent regulations and requirements of the governing regulatory authorities regarding the manufacture of our products, we may not be able to quickly restart manufacturing at a third party or our own facility or establish additional or replacement sources for certain products, components or materials.

In addition to our existing manufacturing relationships, we are also pursuing new manufacturing relationships to establish and secure additional or alternative suppliers for our commercial products. We also constructed a specialized in-house manufacturing facility at our North Billerica, Massachusetts campus for purposes of producing the formulation of DEFINITY that requires refrigerated storage and, potentially, other sterile vial products. On February 22, 2022, we received FDA approval of our sNDA, authorizing commercial manufacturing of DEFINITY at our new facility. This project provides a certain amount of supply chain redundancy for DEFINITY (other than DEFINITY RT, which is supplied solely by SBL). However, we cannot assure you that these activities or any of our additional supply activities will be successful or that we will be able to avoid or mitigate interim supply shortages before new sources of product are fully functional and qualified. In addition, we cannot assure you that our existing manufacturers or suppliers or any new manufacturers or suppliers can adequately maintain either their financial health, technical capabilities or regulatory compliance to allow continued production and supply. A reduction or interruption in manufacturing, or an inability to secure alternative sources of raw materials or components, could eventually have a material adverse effect on our business, results of operations, financial condition and cash flows.

The global supply of Mo-99 is fragile and not stable. Our dependence on a limited number of third party suppliers for Mo-99 could prevent us from delivering some of our products to our customers in the required quantities, within the required timeframe, or at all, which could result in order cancellations and decreased revenues.

A critical ingredient of TechneLite is Mo-99. We currently purchase finished Mo-99 from three of the four main processing sites in the world, namely IRE in Belgium, NTP in South Africa and ANSTO in Australia. These processing sites provide us Mo-99 from five of the six main Mo-99-producing reactors in the world, namely BR2 in Belgium, LVR-15 in the Czech Republic, HFR in The Netherlands, SAFARI in South Africa and OPAL in Australia.

Our agreement with NTP, acting for itself and on behalf of its subcontractor ANSTO, expires on 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.

U.S., Canadian and international governments have encouraged the development of a number of alternative Mo-99 production projects with existing reactors and technologies as well as new technologies. However, we cannot say when, or if, the Mo-99 produced from these projects will become available. As a result, there is a limited amount of Mo-99 available which could limit the quantity of TechneLite that we could manufacture, sell and distribute, resulting in a substantial negative effect on our business, results of operations, financial condition and cash flows.

Most of the global suppliers of Mo-99 rely on Framatone-CERCA in France to fabricate uranium targets and in some cases fuel for research reactors from which Mo-99 is produced. Absent a new supplier, a supply disruption relating to uranium targets or fuel could have a substantial negative effect on our business, results of operations, financial condition and cash flows.

We can give no assurance that Curium will be successful with its commercialization of piflufolastat F 18 in Europe.

We have licensed exclusive rights to Curium to develop and commercialize piflufolastat F 18 in Europe. Under the terms of the collaboration, Curium is responsible for the development, regulatory approvals and commercialization of piflufolastat F 18 in Europe, and we are entitled to double-digit royalties on net sales of piflufolastat F 18. In July 2023, Curium announced that the EMA approved piflufolastat F 18 in Europe, under the name PYLCLARI. We cannot assure that Curium will be successful in commercializing it in Europe. Any failure or significant delay in Curium's ability to successfully launch PYLCLARI in Europe may harm our business and delay or prevent us from being able to generate additional future royalty revenue from product sales.

We may not be able to successfully launch PYLARIFY AI as a commercial product.

We announced in November 2021 that PYLARIFY AI, our FDA-cleared medical device software, was commercially available in the United States. Our ability to successfully launch PYLARIFY AI as a commercial product depends in part on, among other things:

- the market receptivity to PYLARIFY AI as a new digital application for quantitative assessment of PSMA PET/CT images in prostate cancer;
- our ability, and our distributors' abilities, to secure customers' internal approvals and sell and deploy PYLARIFY AI at customer locations;
- interruptions or performance problems associated with our digital application, including a service outage; and
- a network or data security incident that allows unauthorized access to our network or data or our customers' data.

Our just-in-time manufacturing of radiopharmaceutical products relies on the reliability of our equipment and processes, the timely receipt of radioactive raw materials and the timely shipment of finished goods, and any disruption of our supply or distribution networks could have a negative effect on our business.

At the facility on our North Billerica, Massachusetts campus, we manufacture TechneLite on an automated production line. As with all manufacturing facilities, equipment and infrastructure age and become subject to increasing maintenance and repair. If we experience an event, including a labor dispute, natural disaster, fire, power outage, machinery breakdown, security problem, failure to meet regulatory requirements, product quality issue, technology transfer issue or other issue, we may be unable to manufacture the relevant products at previous levels or on the forecasted schedule, if at all. Due to the stringent regulations and requirements of the

governing regulatory authorities regarding the manufacture of our products, we may not be able to quickly restart manufacturing at our facilities or establish additional or replacement sources for certain products, components or materials.

In addition, because a number of our radiopharmaceutical products, including PYLARIFY and our TechneLite generators rely on radioisotopes with limited half-lives, we or our partners must manufacture, finish and distribute these products on a just-in-time basis, because the underlying radioisotope is in a constant state of decay. For example, the radioisotope used in PYLARIFY is F 18, which has a 110 minute half-life, requiring that this product be manufactured and distributed within the same day 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 from the final product. Similarly, with respect to our TechneLite generators, if we receive Mo-99 in the morning of a manufacturing day for TechneLite generators, then we will generally ship finished generators to customers by the end of that same business day. Shipment of generators may be by next day delivery services or by either ground or air custom logistics. Any delay in us receiving radioisotopes from suppliers or being able to have finished products delivered to customers because of weather or other unforeseen transportation issues could have a negative effect on our business, results of operations, financial condition and cash flows.

In the U.S., we are heavily dependent on a few large customers to generate a majority of our revenues for our single-photon emission computerized tomography (SPECT) nuclear medical imaging products in our Precision Diagnostic product category. For PYLARIFY, we depend in part on some of our PMF partners to generate sales and collect revenue. Outside of the U.S., we rely primarily on distributors to generate a substantial portion of our revenue.

In the U.S., we have historically relied on a limited number of radiopharmacy customers, primarily Cardinal, RLS, UPPI, PharmaLogic and Jubilant Radiopharma, to purchase our nuclear imaging products in our Precision Diagnostic product category. Among the existing radiopharmacies in the U.S., continued consolidations, divestitures and reorganizations may have a negative effect on our business, results of operations, financial condition and cash flows. Our contractual arrangements with these radiopharmacy customers generally specify pricing levels and requirements to purchase minimum percentages of certain products during certain periods. The agreements generally may be terminated upon the occurrence of specified events, including a material breach by the other party and certain force majeure events. If these contracts are terminated prior to the expiration of their term, or are not renewed, or are renewed on terms that are less favorable to us, then such an event could have a material adverse effect on our business, results of operations, financial condition and cash flows.

For PYLARIFY, we depend in part on some of our PMF partners to generate sales and collect revenue. To the extent our PMF partners are unsuccessful in generating sales or in collecting revenue, such an event could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We also continue to experience significant pricing pressures from our competitors, large customers and group purchasing organizations, and any significant, additional pricing pressures could lead to a reduction in revenue which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Outside of the U.S., we have no sales force and, consequently, rely on third party distributors, either on a country-by-country basis or on a multi-country, regional basis, to market, sell and distribute our products. In certain circumstances, distributors may also sell competing products to our own or products for competing diagnostic modalities and may have incentives to shift sales towards those competing products. As a result, we cannot assure you that our international distributors will increase or maintain current levels of unit sales or that we will be able to increase or maintain our current unit pricing, which, in turn, could have a material adverse effect on our 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 Blue Earth, a subsidiary of Bracco.
- 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, and potentially BWXT Medical.
- For PNT2002 and 1095, our principal competitors may include Novartis AG; Telix Pharmaceuticals Limited; and Curium, each of which has commercialized products or product candidates in advanced clinical stage of development.

- For PNT2003, our principal competitor may include Novartis AG; ITM Radiopharma; and RayzeBio (under agreement to be acquired by Bristoll Meyers Squibb), each of which has commercialized products or product candidates in advanced clinical stage of development.
- For MK-6240, our principal competitors may include Eli Lilly and Company and Life Molecular Imaging, each of which has commercialized products or product candidates in advanced clinical stage of development. .
- For LNTH-1363S, our principal competitors may include Sofie Bioscience; GE Healthcare; and Novartis AG, each of which has product candidates in clinical stage of development.

We cannot anticipate the actions of our current or future competitors in the same or competing modalities, such as significant price reductions on products that are competitive with our own, development of new products that are more cost-effective or have superior performance than our current products or potential future 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 recently sold. 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.

Ultrasound enhancing agents may cause side effects which could limit our ability to sell DEFINITY.

DEFINITY is an ultrasound enhancing agent based on perflutren lipid microspheres. In 2007, the FDA received reports of deaths and serious cardiopulmonary reactions following the administration of ultrasound enhancing agents used in echocardiography. Four of the 11 reported deaths were caused by cardiac arrest occurring either during or within 30 minutes following the administration of the ultrasound enhancing agent; most of the serious but non-fatal reactions also occurred in this time frame. As a result, in October 2007, the FDA requested that we and GE Healthcare, which distributes Optison, a competitor to DEFINITY, add a boxed warning to these products emphasizing the risk for serious cardiopulmonary reactions and that the use of these products was contraindicated in certain patients. In a strong reaction by the cardiology community to the FDA's new position, a letter was sent to the FDA, signed by 161 doctors, stating that the benefit of these ultrasound enhancing agents outweighed the risks and urging that the boxed warning be removed. In May 2008, the FDA substantially modified the boxed warning. On May 2, 2011, the FDA held an advisory committee meeting to consider the status of ultrasound enhancing agents and the boxed warning. In October 2011, we received FDA approval of further modifications to the DEFINITY label, including: further relaxing the boxed warning; eliminating the sentence in the Indication and Use section "The safety and efficacy of DEFINITY with exercise stress or pharmacologic stress testing have not been established" (previously added in October 2007 in connection with the imposition of the box warning); and including summary data from the post-approval CaRES (Contrast echocardiography Registry for Safety Surveillance) safety registry and the post-approval pulmonary hypertension study. Further, in January 2017, the FDA approved an additional modification to the DEFINITY label, removing the contraindication statement related to use in patients with a known or suspected cardiac shunt. Bracco's ultrasound enhancing agent, Lumason, has substantially similar safety labeling as DEFINITY and Optison. In April 2021, after reviewing certain adverse events that occurred in patients with a prior history of allergic reactions to polyethylene glycol ("PEG"), an inactive excipient in both DEFINITY and Lumason, the FDA and the marketing authorization holders of these products agreed to an additional contraindication for use of these products, including advising clinicians to assess patients for prior PEG hypersensitivity before administering these products. In June 2023, after reviewing adverse events that occurred in patients with history of sickle cell disease, we agreed with the FDA to amend the label to advise clinicians that if a patient with sickle cell disease experiences acute pain episodes following DEFINITY administration, use of DEFINITY in that patient should be discontinued. If additional safety issues arise (not only with DEFINITY but also potentially with Optison and Lumason), this may result in unfavorable changes in labeling or result in restrictions on the approval of our product, including removal of the product from the market. Lingering safety concerns about DEFINITY among some healthcare providers or future unanticipated side effects or safety concerns associated with DEFINITY could limit expanded use of DEFINITY and have a material adverse effect on the unit sales of this product and our financial condition and results of operations.

Risks Related to Reimbursement and Regulation

Many of our customers are highly dependent on payments from third-party payors, including government sponsored programs, particularly Medicare, in the U.S. and other countries in which we operate, and reductions in third party coverage and reimbursement rates for our products (or services provided with our products) could adversely affect our business and results of operations.

A substantial portion of our revenue depends on the extent to which the costs of our products purchased by our customers (or services provided with our products) are reimbursed by third party payors, including Medicare, Medicaid, other U.S. government sponsored programs, non-U.S. governmental payors and private payors. These third-party payors exercise significant control over patient access and increasingly use their enhanced bargaining power to secure discounted rates and impose other requirements that may reduce demand for our products. Our customers' ability to obtain adequate reimbursement for products and services from these third-party payors affects the selection of products they purchase and the prices they are willing to pay. If Medicare and other third party payors do not provide adequate reimbursement for the costs of our products (or services provided using our products), deny the coverage of the products (or those services), or reduce current levels of reimbursement, healthcare professionals may not prescribe our products and providers and suppliers may not purchase our products.

In addition, demand for new products may be limited unless we obtain favorable reimbursement (including coding, coverage and payment) from governmental and private third party payors at the time of the product's introduction, which will depend, in part, on our ability to demonstrate that a new agent has a positive impact on clinical outcomes. Third-party payors continually review their coverage policies for existing and new products and procedures and can deny coverage for products or procedures that include the use of our products or revise payment policies such that payments do not adequately cover the cost of our products. Even if third-party payors make coverage and reimbursement available, that reimbursement may not be adequate or these payors' reimbursement policies may have an adverse effect on our business, results of operations, financial condition and cash flows.

For example, effective January 1, 2022, the CMS granted TPT Status in the hospital outpatient setting 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 December 31, 2024. After TPT Status expires, under current Medicare rules, PYLARIFY would not be separately reimbursed in the hospital outpatient setting but rather would be bundled into the facility payment a hospital receives for a PET/CT imaging procedure, and the facility payment may not always cover the total cost of the procedure. In 2023 rulemaking for the 2024 payment calendar year, CMS recognized the challenges of patient access to diagnostic radiopharmaceuticals and requested feedback on various payment alternatives that could provide separate reimbursement for these items, but the agency did not adopt any of these proposals in the final rule, while stating that it would continue to evaluate this issue in subsequent rulemaking. 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 a PYLARIFY PET/CT imaging procedure or that the availability of TPT Status for other diagnostic radiopharmaceuticals will not impact clinical decision making regarding which product to use, which could have an adverse effect on our business, results of operations, financial condition and cash flows.

Over the past several years, Medicare has implemented numerous changes to payment policies for imaging procedures in both the hospital setting and non-hospital settings (which include physician offices and freestanding imaging facilities). Some of these changes have had a negative impact on utilization of imaging services. Examples of these changes include:

- Reducing payments for certain imaging procedures when performed together with other imaging procedures in the same family of procedures on the same patient on the same day in the physician office and free-standing imaging facility setting;
- Making significant revisions to the methodology for determining the practice expense component of the Medicare payment applicable to the physician office and free-standing imaging facility settings which results in a reduction in payment;
- Revising payment policies and reducing payment amounts for imaging procedures performed in the hospital outpatient settings; and
- Reducing prospective payment levels for applicable diagnosis-related groups in the hospital inpatient setting.

In the physician office and free-standing imaging facility setting, services provided using our products are reimbursed under the Medicare physician fee schedule. Payment rates under the Medicare physician fee schedule are regularly subject to updates to effectuate various policy goals of CMS and Congress. For example, in 2022, CMS reduced Medicare fee schedule payments rates in the agency's final rulemaking, while a larger cut was put forth in the proposed rulemaking earlier that year. For 2023, CMS had finalized a reduction in the Medicare fee schedule payments rates, which was revised by Congress, pursuant to the Consolidated Appropriations Act, 2023, to a lesser reduction. Additionally, since 2019, fee schedule payments have been adjusted for certain physicians based on their performance under a consolidated measurement system (that measures performance with respect to quality, resource utilization, meaningful use of certified electronic health records technology, and clinical practice improvement activities).

From 2019 through payment year 2024, physicians may be eligible for a bonus based on the use of certain alternative payment models designated as "advanced" by CMS. The ongoing and future impact of these changes cannot be determined at this time.

We believe that Medicare changes to payment policies for imaging procedures applicable to non-hospital settings will continue to result in certain physician practices ceasing to provide these services and a further shifting of where certain medical imaging procedures are performed, from the physician office and free-standing imaging facility settings to the hospital outpatient setting. Changes applicable to Medicare payment in the hospital outpatient setting could also influence the decisions by hospital outpatient physicians to perform procedures that involve our products. Within the hospital outpatient setting, CMS payment policy is such that the use of many of our products are not separately payable by Medicare, although certain new drug products are eligible for separate (incremental) payment for the first three years after approval. Changes to the Medicare hospital outpatient prospective payment system payment rates, including reductions implemented for certain hospital outpatient sites, could influence the decisions by hospital outpatient physicians to perform procedures that involve our products.

We also believe that all of these changes and their resulting pressures may incrementally reduce the overall number of diagnostic medical imaging procedures performed. These changes overall could slow the acceptance and introduction of next-generation imaging equipment into the marketplace, which, in turn, could adversely impact the future market adoption of certain of our imaging agents already in the market or currently in development. We expect that there will continue to be proposals to reduce or limit Medicare and Medicaid payment for diagnostic services, which could impact our current or potential future diagnostic and other types of products and have a material adverse effect on our business, results of operations, financial condition and cash flows.

We also expect increased regulation and oversight of advanced diagnostic testing in which our products are used, although the timing of such regulation is uncertain after a recent pause by CMS. Under section 218(b) of the Protecting Access to Medicare Act, beginning January 1, 2020, a professional who is ordering advanced diagnostic imaging services (which include MRI, CT, nuclear medicine (including PET) and other advanced diagnostic imaging services that the Secretary of HHS may specify, but not currently including echocardiography) must consult a qualified clinical decision support mechanism, as identified by HHS, to determine whether the ordered service adheres to specified appropriate use criteria ("AUC") developed or endorsed by CMS-qualified "provider led entities". Medicare claims for such services must include information indicating whether services ordered would adhere to specified applicable AUC. Denial of claims for failure to include AUC consultation information on the claim form was set to begin on January 1, 2022, but was not implemented by CMS. In the CY 2024 Physician Fee Schedule Final Rule, CMS determined that it was not feasible to fully operationalize the AUC program consistent with the statute within the required time frame. Accordingly, the agency finalized an indefinite pause to the AUC program and the recission of the regulations promulgated thus far to implement the AUC program. While it is unclear when CMS will resume implementation of the AUC program, to the extent that these types of changes have the effect of reducing the aggregate number of diagnostic medical imaging procedures performed in the U.S., our business, results of operations, financial condition and cash flows would be adversely affected.

Medicare coverage of PET radiopharmaceuticals has been the subject of a large number of National Coverage Determinations ("NCDs") by CMS since 2000. Specific indications for PET imaging were covered, some through Coverage with Evidence Development. CMS's longtime policy, however, was that a particular use of PET scans is not covered unless an NCD specifically provided that such use was covered. Effective March 7, 2013, CMS revised its policy through an NCD to allow local Medicare Administrative Contractors ("MACs") to determine coverage within their respective jurisdictions for PET using radiopharmaceuticals for their FDA-approved labeled indications for oncologic imaging. Effective January 1, 2022, non-coverage in the absence of an NCD has also been removed for non-oncologic indications of PET radiopharmaceuticals, allowing MACs to determine coverage for these indications within their respective jurisdictions. To the extent that CMS or the MACs impose more restrictive coverage, our business, results of operations, financial condition and cash flows would be adversely affected.

Reforms to the U.S. healthcare system may adversely affect our business.

A significant portion of our patient volume is derived from U.S. government healthcare programs, principally Medicare, which are highly regulated and subject to frequent and substantial changes. The Healthcare Reform Act substantially changed the way healthcare is financed by both governmental and private insurers. The law contains a number of provisions that affect coverage and reimbursement of drug products and medical imaging procedures in which our drug products are used and/or that could potentially reduce the aggregate number of diagnostic medical imaging procedures performed in the U.S. Subsequently, the Medicare Access and CHIP Reauthorization Act of 2015 significantly revised the methodology for updating the Medicare physician fee schedule. In 2017, Congress enacted legislation that effectively eliminated the Healthcare Reform Act's "individual mandate" beginning in 2019. Congress continues to consider other healthcare reform legislation. There is no assurance that the Healthcare Reform Act, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the Healthcare Reform Act was enacted. The Budget Control Act of 2011 and subsequent Congressional actions includes provisions to reduce the federal deficit. These provisions have resulted in the imposition of 2% reductions in Medicare payments to providers, which went into effect on April 1, 2013 and will remain in effect through fiscal year 2030. The imposition of the 2% payment adjustment had been suspended through March 31, 2022 and went into effect as of April 1, 2022. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our business, results of operations, financial condition and cash flows.

Further, changes in payor mix and reimbursement by private third-party payors may also affect our business. Rates paid by some private third-party payors are based, in part, on established physician, clinic and hospital charges and are generally higher than Medicare payment rates. Reductions in the amount of reimbursement paid for diagnostic medical imaging procedures, including the elimination of any additional payment such as TPT Status, and changes in the mix of our patients between non-governmental payors and government sponsored healthcare programs and among different types of non-government payor sources, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

The full impact on our business of healthcare reforms and other new laws, or changes in existing laws, is uncertain. Nor is it clear whether additional legislative changes will be adopted or how those changes would affect our industry in general or our ability to successfully commercialize our products or develop or commercialize new products.

Our business and industry are subject to complex and costly regulations. If government regulations are interpreted or enforced in a manner adverse to us or our business, we may be subject to enforcement actions, penalties, exclusion and other material limitations on our operations.

Both before and after the approval of our products in development, we, our products, development products, operations, facilities, suppliers, distributors, contract manufacturers, contract research organizations and contract testing laboratories are subject to extensive and, in certain circumstances, expanding regulation by federal, state and local government agencies in the U.S. as well as non-U.S. and transnational laws and regulations, with regulations differing from country to country and even state to state, including, among other things, anti-trust and competition laws and regulations, and data privacy laws and regulations such as the General Data Protection Regulation in the European Union and the CCPA and the CPRA. In the U.S., the FDA regulates, among other things, the pre-clinical testing, clinical trials, manufacturing, safety, efficacy, potency, labeling, storage, record keeping, quality systems, advertising, promotion, sale, distribution, and import and export of drug products. We are required to register our business for permits and/or licenses with, and comply with the stringent requirements of the FDA, the NRC, the HHS, Health Canada, the EMA, the MHRA, the NMPA, state and provincial boards of pharmacy, state and provincial health departments and other federal, state and provincial agencies. Violation of any of these regulatory schemes, individually or collectively, could disrupt our business and have a material adverse effect on our business, results of operations, financial condition and cash flows.

Under U.S. law, for example, we are required to report certain adverse events and production problems, if any, to the FDA or other federal or state regulators. We also have similar adverse event and production reporting obligations outside of the U.S., including to the EMA and MHRA. Additionally, we must comply with requirements concerning advertising and promotion for our products, including the prohibition on the promotion of our products for indications for which they have not been approved by the FDA or a so-called "off-label use" or promotion that is inconsistent with the approved labeling. If the FDA determines that our promotional materials constitute unlawful promotion, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions. Also, quality control and manufacturing procedures at our own facility and at third-party suppliers must conform to cGMP regulations and other applicable law after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs and other applicable law, and, from time to time, makes those cGMPs more stringent. Accordingly, we and others with whom we work must expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. If in the future issues arise at our own manufacturing facility or at a third-party manufacturer, the FDA could take regulatory action which could limit or suspend the ability to manufacture our products or have any additional products approved at the relevant facility for manufacture until the issues are resolved and remediated. Such a limitation or suspension could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We are also subject to laws and regulations that govern financial and other arrangements between pharmaceutical manufacturers and healthcare providers, including federal and state anti-kickback statutes, federal and state false claims laws and regulations, federal and state "sunshine" laws and regulations and other fraud and abuse laws and regulations.

We must offer discounted pricing or rebates on purchases of pharmaceutical products under various federal and state healthcare programs, such as the Medicaid drug rebate program, the 340B drug pricing program and the Medicare Part D Program. We must also report specific prices to government agencies under healthcare programs, such as the Medicaid drug rebate program and Medicare Part B. Our Medicaid Drug Rebate agreements require us to report certain price information to the federal government. Determination of

the rebate amount that we pay to state Medicaid programs for our products, of prices charged to government and certain private payors for our products, or of amounts paid for our products under government healthcare programs, depends upon information reported by us to the government. If we provide customers or government officials with inaccurate information about the products' pricing or eligibility for coverage, or the products fail to satisfy coverage requirements, we could be terminated from the rebate program, be excluded from participation in government healthcare programs, or be subject to potential liability under the False Claims Act or other laws and regulations.

Failure to comply with other requirements and restrictions placed upon us or our third-party manufacturers or suppliers by laws and regulations can result in fines, civil and criminal penalties, exclusion from federal healthcare programs and debarment. Possible consequences of those actions could include:

- Substantial modifications to our business practices and operations;
- Significantly reduced demand for our products (if products become ineligible for reimbursement under federal and state healthcare programs);
- A total or partial shutdown of production in one or more of the facilities where our products are produced while the alleged violation is being remediated;
- Delays in or the inability to obtain future pre-market clearances or approvals; and
- Withdrawals or suspensions of our current products from the market.

Our marketing and sales practices may contain risks that could result in significant liability, require us to change our business practices, and restrict our operations in the future.

We are subject to numerous domestic (federal, state and local) and foreign laws addressing fraud and abuse in the healthcare industry, including the FCA and federal Anti-Kickback Statute, self-referral laws, the FCPA, the Bribery Act, FDA promotional restrictions, the federal disclosure (sunshine) law and state marketing and disclosure (sunshine) laws. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid as well as health programs outside the U.S., and even settlement of alleged violations can result in the imposition of corporate integrity agreements that could subject us to additional compliance and reporting requirements and impact our business practices. These laws and regulations are complex and subject to changing interpretation and application, which could restrict our sales or marketing practices. Even minor and inadvertent irregularities could potentially give rise to a charge that the law has been violated. Although we believe we maintain an appropriate compliance program, we cannot be certain that the program will adequately detect or prevent violations and/or the relevant regulatory authorities may disagree with our interpretation. Additionally, if there is a change in law, regulation or administrative or judicial interpretations, we may have to change one or more of our business practices to be in compliance with these laws. Required changes could be costly and time consuming.

If our operations are found to be in violation of these laws or any other government regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, imprisonment, the curtailment or restructuring of our operations, or exclusion from state and federal healthcare programs including Medicare and Medicaid, any of which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Risks Related to Our Business Operations and Financial Results

We may not be able to hire or retain the number of qualified personnel, particularly scientific, medical and sales personnel, required for our business, which would harm the development and sales of our products and limit our ability to grow.

Competition in our industry for highly skilled scientific, healthcare and sales personnel is intense. In connection with the launch and continued growth of PYLARIFY, we hired additional employees to assist us with the commercialization of PYLARIFY, including in sales, marketing, reimbursement, quality and medical affairs. Although we were successful in hiring and onboarding those employees and we have not had any material difficulty in the past in hiring or retaining qualified personnel, if we are unable to retain our existing personnel, or attract and train additional qualified personnel, either because of competition in our industry for these personnel or insufficient financial resources, then our growth may be limited and it could have a material adverse effect on our business.

If we lose the services of our key personnel, our business could be adversely affected.

Our success is substantially dependent upon the performance, contributions and expertise of our chief executive officer, executive leadership and senior management team. Mary Anne Heino, our Chief Executive Officer, and other members of our executive leadership and senior management team play a significant role in formulating and executing on our long-term strategy, generating business and overseeing operations. We have employment agreements with Ms. Heino, Brian Markison, who will succeed Ms. Heino as Chief Executive Officer effective March 1, 2024, and a limited number of other individuals on our executive leadership

team, although we cannot prevent them from terminating their employment with us. We do not maintain key person life insurance policies on any of our executive officers. While we have experienced some turnover on our executive leadership team, we have generally been able to fill positions by either promoting existing employees or attracting new, qualified individuals to lead key functional areas. For example, on January 23, 2024, we announced that effective March 1, 2024, Brian Markison, our current Chair of the Board, will become our Chief Executive Officer, and Mary Anne Heino, our current Chief Executive Officer, will retire and become the Chair of the Board. Our inability to retain our existing executive leadership and senior management team, maintain an appropriate internal succession program or attract and retain additional qualified personnel could have a material adverse effect on our business.

Our business depends on our ability to successfully introduce new products and adapt to a changing technology and medical practice landscape.

The healthcare industry is characterized by continuous technological development resulting in changing customer preferences and requirements. The success of new product development depends on many factors, including our ability to fund development of new products or new indications for existing products, anticipate and satisfy customer needs, obtain timely regulatory approval based on performance of our products in development versus their clinical trial comparators, develop and manufacture products in a cost-effective and timely manner, maintain advantageous positions with respect to intellectual property and differentiate our products from our competitors. To compete successfully in the marketplace, we must make substantial investments in new product development, whether internally or externally through licensing or acquisitions. Our failure to introduce new and innovative products in a timely manner would have an adverse effect on our business, results of operations, financial condition and cash flows.

Even if we are able to develop, manufacture and obtain regulatory approvals for our new products, the success of these products would depend upon market acceptance and adequate coding, coverage and payment. Levels of market acceptance for our new products could be affected by a number of factors, including:

- The availability of alternative products from our competitors;
- The breadth of indications in which alternative products from our competitors can be marketed;
- The price of our products relative to those of our competitors;
- The timing of our market entry;
- Our ability to enter into commercial contracts to sell our products;
- Our ability to market and distribute our products effectively;
- Market acceptance of our products; and
- Our ability to obtain adequate coding, coverage and payment, including the availability of TPT Status.

The field of diagnostic medical imaging is dynamic, with new products, including equipment, software and products, continually being developed and existing products continually being refined. Our own diagnostic imaging agents compete not only with other similarly administered imaging agents but also with imaging agents employed in different and often competing diagnostic modalities, and in the case of DEFINITY, echocardiography procedures without ultrasound enhancing agents. New hardware, software or products in a given diagnostic modality may be developed that provide benefits superior to the then-dominant hardware, software and products in that modality, resulting in commercial displacement of the products. Similarly, changing perceptions about comparative efficacy and safety including, among other things, comparative radiation exposure, as well as changing availability of supply or the availability of additional payments for new devices such as TPT Status, may favor one product over another or one modality over another. In addition, new or revised appropriate use criteria developed by professional societies, to assist physicians and other health care providers in making appropriate imaging decisions for specific clinical conditions, can and have reduced the frequency of and demand for certain imaging modalities and imaging agents. To the extent there is technological obsolescence in any of our products that we manufacture, resulting in lower unit sales or decreased unit sales prices, we will have increased unit overhead allocable to the remaining market share, which could have a material adverse effect on our business, results of operations, financial condition and cash flows. Similar risks could apply to therapeutic products, including products we are developing.

Our future growth may depend on our ability to identify and acquire or in-license additional products, businesses or technologies, and if we do not successfully do so, or otherwise fail to integrate any new products, lines of business or technologies into our operations, we may have limited growth opportunities and it could result in significant impairment charges or other adverse financial consequences.

We seek to acquire or in-license products, businesses or technologies that we believe are a strategic fit with our business strategy. Future acquisitions or in-licenses, however, may entail numerous operational and financial risks, including:

- A reduction of our current financial resources;

- Incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- Difficulty or inability to secure financing to fund development activities for those acquired or in-licensed technologies;
- Higher than expected acquisition and integration costs;
- Disruption of our business, customer base and diversion of our management's time and attention to develop acquired products or technologies; and
- Exposure to unknown liabilities.

We may not have sufficient resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than we do and may have greater expertise in identifying and evaluating new opportunities. Furthermore, there may be an overlap between our products or customers and the companies which we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses. Additionally, the time between our expenditures to acquire or in-license new products, technologies or businesses and the subsequent generation of revenues from those acquired products, technologies or businesses (or the timing of revenue recognition related to licensing agreements and/or strategic collaborations) could cause fluctuations in our financial performance from period to period. Finally, if we devote resources to potential acquisitions or in-licensing opportunities that are never completed, or if we fail to realize the anticipated benefits of those efforts, we could incur significant impairment charges or other adverse financial consequences.

Challenges with product quality or product performance, including defects, caused by us or our manufacturers or suppliers could result in a decrease in customers and revenues, unexpected expenses and loss of market share.

The manufacture of our products is highly exacting and complex and must meet stringent quality requirements, due in part to strict regulatory requirements, including the FDA's cGMPs. Problems may be identified or arise during manufacturing, quality review, packaging or shipment for a variety of reasons including equipment malfunction, failure to follow specific protocols and procedures, defective raw materials and environmental factors. Additionally, manufacturing flaws, component failures, design defects, off-label uses or inadequate disclosure of product-related information could result in an unsafe condition or the injury or death of a patient. Those events could lead to a recall of, or issuance of a safety alert relating to, our products or could harm our reputation and our ability to market our products in the future. We also may undertake voluntarily to recall products or temporarily shut down production lines based on internal safety and quality monitoring and testing data.

Quality, regulatory and recall challenges could cause us to incur significant costs, including costs to replace products, lost revenue, damage to customer relationships, time and expense spent investigating the cause and costs of any possible settlements or judgments related thereto and potentially cause similar losses with respect to other products. These challenges could also divert the attention of our management and employees from operational, commercial or other business efforts. If we deliver products with defects, or if there is a perception that our products or the processes related to our products contain errors or defects, we could incur additional recall and product liability costs, and our credibility and the market acceptance and sales of our products could be materially adversely affected. Due to the strong name recognition of our brands, an adverse event involving one of our products could result in reduced market acceptance and demand for all products within that brand, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our applications for new product approvals. These challenges could have a material adverse effect on our business, results of operations, financial condition and cash flows.

In the ordinary course of business, we may be subject to product liability claims and lawsuits, including potential class actions, alleging that our products have resulted or could result in an unsafe condition or injury.

Any product liability claim brought against us, with or without merit, could be time consuming and costly to defend and could result in an increase of our insurance premiums. Although we have not had any such claims to date, claims that could be brought against us might not be covered by our insurance policies. Furthermore, although we currently have product liability insurance coverage with policy limits that we believe are customary for pharmaceutical companies in the diagnostic medical imaging industry and adequate to provide us with insurance coverage for foreseeable risks, even where the claim is covered by our insurance, our insurance coverage might be inadequate and we would have to pay the amount of any settlement or judgment that is in excess of our policy limits. We may not be able to obtain insurance on terms acceptable to us or at all, since insurance varies in cost and can be difficult to obtain. Our failure to maintain adequate insurance coverage or successfully defend against product liability claims could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

Our operations use hazardous materials and produce hazardous wastes, including radioactive, chemical and, in certain circumstances, biological materials and wastes. We are subject to a variety of federal, state and local laws and regulations as well as non-U.S. laws and regulations relating to the transport, use, handling, storage, exposure to and disposal of these materials and wastes. Environmental laws and regulations are complex, change frequently and have generally become more stringent over time. We are required to obtain, maintain and renew various environmental permits and nuclear licenses. Although we believe that our safety procedures for transporting, using, handling, storing and disposing of, and limiting exposure to, these materials and wastes comply in all material respects with the standards prescribed by applicable laws and regulations, the risk of accidental contamination or injury cannot be eliminated. We place a high priority on these safety procedures and seek to limit any inherent risks. We generally contract with third parties for the disposal of wastes generated by our operations. We store low level radioactive waste at our facility and dispose of the materials in accordance with applicable laws and regulations. A majority of our low level radioactive waste is held to decay until materials are no longer considered radioactive. Although we believe we have complied in all material respects with all applicable environmental, health and safety laws and regulations, we cannot assure you that we have been or will be in compliance with all such laws at all times. If we violate these laws, we could be fined, criminally charged or otherwise sanctioned by regulators. We may be required to incur further costs to comply with current or future environmental and safety laws and regulations. In addition, in the event of accidental contamination or injury from these materials, we could be held liable for any damages that result and any such liability could exceed our resources.

We previously leased a small portion of our North Billerica, Massachusetts campus to PerkinElmer for the manufacturing, finishing and packaging of certain radioisotopes, including Strontium-90, which has physical characteristics that make it more challenging to work with and dispose of than our own commercial radioisotopes, including a much longer half-life. PerkinElmer decommissioned its space and vacated the premises as of December 30, 2021. We are fully indemnified by PerkinElmer under our lease for any property damage or personal injury resulting from their activities in our facility. If any release or excursion of radioactive materials took place from their leased space that resulted in property damage or personal injury, the indemnification obligations were not honored, and we were forced to cover any related remediation, clean-up or other expenses, depending on the magnitude, the cost of such remediation, clean-up or other expenses could have a material adverse effect on our business, results of operations, financial condition and cash flows.

While we have budgeted for current and future capital and operating expenditures to maintain compliance with these laws and regulations, we cannot assure you that our costs of complying with current or future environmental, health and safety laws and regulations will not exceed our estimates or adversely affect our results of operations and financial condition. Further, we cannot assure you that we will not be subject to additional environmental claims for personal injury, investigation or cleanup in the future based on our past, present or future business activities.

If we are unable to protect our intellectual property, our competitors could develop and market products with features similar to our products, and demand for our products may decline.

Our commercial success will depend in part on obtaining and maintaining patent and trade secret protection of our commercial products and technologies and products in development as well as successfully enforcing and defending these patents and trade secrets against third parties and their challenges, both in the U.S. and in foreign countries. We will only be able to protect our intellectual property from unauthorized use by third parties to the extent that we maintain the secrecy of our trade secrets and can enforce our valid patents and trademarks.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. In addition, changes in either the patent laws or in interpretations of patent laws in the U.S. or other countries may diminish the value of our intellectual property and we may not receive the same degree of protection in every jurisdiction. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- We might not have been the first to make the inventions covered by each of our pending patent applications and issued patents, and we could lose our patent rights as a result;
- We might not have been the first to file patent applications for these inventions or our patent applications may not have been timely filed, and we could lose our patent rights as a result;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies;
- It is possible that none of our pending patent applications will result in any further issued patents;
- Our issued patents may not provide a basis for commercially viable drugs, may not provide us with any protection from unauthorized use of our intellectual property by third parties, and may not provide us with any competitive advantages;

- The validity or enforceability of our patent applications or patents may be subject to challenge through interferences, oppositions, post-grant review, ex-parte re-examinations, inter partes review or similar administrative proceedings;
- While we generally apply for patents in those countries where we intend to make, have made, use or sell patented products, we may not be able to accurately predict all of the countries where patent protection will ultimately be desirable and may be precluded from doing so at a later date;
- We may choose not to seek patent protection in certain countries where the actual cost outweighs the perceived benefit at a certain time;
- Patents issued in foreign jurisdictions may have different scopes of coverage than our U.S. patents and so our products may not receive the same degree of protection in foreign countries as they would in the U.S.;
- We may not develop additional proprietary technologies that are patentable;
- The patents of others may have an adverse effect on our business; or
- The cost to defend our patents may be significant and may result in litigation which could be costly and time consuming.

Moreover, the issuance of a patent is not conclusive as to its validity or enforceability. A third party may challenge the validity or enforceability of a patent even after its issuance by the USPTO or the applicable foreign patent office. It is also uncertain how much protection, if any, will be afforded by our patents if we attempt to enforce them and they are challenged in court or in other proceedings, which may be brought in U.S. or non-U.S. jurisdictions to challenge the validity of a patent.

The initiation, defense and prosecution of intellectual property suits (including Hatch-Waxman related litigation), interferences, oppositions and related legal and administrative proceedings are costly, time consuming to pursue and result in a diversion of resources, including a significant amount of management time. The outcome of these proceedings is uncertain and could significantly harm our business. If we are not able to enforce and defend the patents of our technologies and products, then we will not be able to exclude competitors from marketing products that directly compete with our products, which could have a material and adverse effect on our business, results of operations, financial condition and cash flows.

We also rely on trade secrets and other know-how and proprietary information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We use reasonable efforts to protect our trade secrets, but our employees, consultants, contractors, outside scientific partners and other advisors may unintentionally or willfully disclose our confidential information to competitors or other third parties. Enforcing a claim that a third party improperly obtained and is using our trade secrets is expensive, time consuming and resource intensive, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. We rely on confidentiality agreements with our collaborators, employees, consultants and other third parties and invention assignment agreements with our employees to protect our trade secrets and other know-how and proprietary information concerning our business. These confidentiality agreements may not prevent unauthorized disclosure of trade secrets and other know-how and proprietary information, and there can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our trade secrets, other technical know-how or proprietary information, or that we can detect such an unauthorized disclosure. We may not have adequate remedies for any unauthorized disclosure. This might happen intentionally or inadvertently. It is possible that a competitor will make use of that information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making those unauthorized disclosures, which could have a material and adverse effect on our business, results of operations, financial condition and cash flows.

We rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. We cannot assure you that any pending trademark applications will be approved. Third parties may also oppose our trademark applications, or otherwise challenge our use of the trademarks. If our trademarks are successfully challenged, we could be forced to re-brand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot assure you that competitors will not infringe our trademarks, or that we will have adequate resources to enforce our trademarks.

Our patents are subject to generic challenge, and the validity, enforceability and commercial value of these patents are highly uncertain.

Our ability to obtain and defend our patents impacts the commercial value of our products and product candidates. Third parties have challenged and are likely to continue challenging the patents that have been issued or licensed to us. Patent protection involves complex legal and factual questions and, therefore, enforceability is uncertain. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented, which could negatively impact their commercial value. Furthermore, patent applications filed outside the United States may be challenged by other parties, for example, by filing third-party observations that argue against patentability or an opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend.

We may be subject to claims that we have infringed, misappropriated or otherwise violated the patent or other intellectual property rights of a third party. The outcome of any of these claims is uncertain and any unfavorable result could adversely affect our business, financial condition and results of operations.

We may be subject to claims by third parties that we have infringed, misappropriated or otherwise violated their intellectual property rights. We are aware of intellectual property rights held by third parties that relate to products or technologies we are developing. For example, we are aware of other groups investigating PSMA or related compounds and monoclonal antibodies directed at PSMA, PSMA-targeted imaging agents and therapeutics, and methylnaltrexone and other peripheral opioid antagonists, and of patents held, and patent applications filed, by these groups in those areas. While the validity of these issued patents, the patentability of pending patent applications and the applicability of any of them to our products and programs are uncertain, if asserted against us, any related patent or other intellectual property rights could adversely affect our ability to commercialize our products.

We may be subject to litigation over infringement claims regarding the products we manufacture or distribute or intend to manufacture or distribute. For example, on January 26, 2024, we were sued in the United States District Court for the District of Delaware by Advanced Accelerator Applications USA, Inc. and Advanced Accelerator Applications SA, each a Novartis entity, for patent infringement in response to the filing of our ANDA for PNT2003 and Paragraph IV certification, consistent with the process established by the Hatch-Waxman Act. This type of litigation can be costly and time consuming and could divert management's attention and resources, generate significant expenses, damage payments (potentially including treble damages) or restrictions or prohibitions on our use of our technology, which could adversely affect our business, results of operations, financial condition and cash flows. In addition, if we are found to be infringing on proprietary rights of others, we may be required to develop non-infringing technology, obtain a license (which may not be available on reasonable terms, or at all), make substantial one-time or ongoing royalty payments, or cease making, using and/or selling the infringing products, any of which 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.

Our business is subject to international economic, political and other risks that could negatively affect our results of operations or financial position.

For the year ended December 31, 2023, we derived approximately 2.6% of our revenues and sourced approximately 11.2% of our costs of goods sold outside of the United States. Accordingly, our business is subject to risks associated with doing business internationally, including:

- Less stable political and economic environment and changes in a specific country's or region's political or economic conditions;

- Changes in trade policies, regulatory requirements and other barriers, including, for example, U.S. trade sanctions against Iran and those countries and entities doing business with Iran, which could adversely impact international isotope production and, indirectly, our global supply chain;
- Potential global disruptions in air transport, which could adversely affect our international supply chains for radioisotopes and DEFINITY RT as well as international distribution channels for our commercial products;
- Entering into, renewing or enforcing commercial agreements with international governments or provincial authorities or entities directly or indirectly owned or controlled by such governments or authorities, such as our Belgian, Australian and South African isotope suppliers, IRE, ANSTO and NTP, and our Chinese development and commercialization partner, Double-Crane;
- International customers which are agencies or institutions owned or controlled by foreign governments;
- Local business practices which may be in conflict with the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act;
- Currency fluctuations;
- Unfavorable labor regulations;
- Greater difficulties in relying on non-U.S. courts to enforce either local or U.S. laws, particularly with respect to intellectual property;
- Greater potential for intellectual property piracy;
- Greater difficulties in managing and staffing non-U.S. operations, including our EXINI operations in Sweden;
- The need to ensure compliance with the numerous in-country and international regulatory and legal requirements applicable to our business in each of these jurisdictions and to maintain an effective compliance program to ensure compliance with these requirements, including in connection with the GDPR in the EU;
- Changes in public attitudes about the perceived safety of nuclear facilities;
- Civil unrest or other catastrophic events; and
- Longer payment cycles of non-U.S. customers and difficulty collecting receivables in non-U.S. jurisdictions.

These factors are beyond our control. The realization of any of these or other risks associated with operating outside the United States could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We face currency and other risks associated with international sales.

We generate revenue from export sales, as well as from operations conducted outside the United States. Operations outside the U.S. expose us to risks including fluctuations in currency values, trade restrictions, tariff and trade regulations, U.S. export controls, U.S. and non-U.S. tax laws, shipping delays and economic and political instability. For example, violations of U.S. export controls, including those administered by the U.S. Treasury Department's Office of Foreign Assets Control, could result in fines, other civil or criminal penalties and the suspension or loss of export privileges which could have a material adverse effect on our business, results of operations, financial conditions and cash flows.

Many of our customer relationships outside of the U.S. are, either directly or indirectly, with governmental entities, and we could be adversely affected by violations of the FCPA and similar worldwide anti-bribery laws outside the U.S.

The FCPA, the Bribery Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business.

The FCPA prohibits us from providing anything of value to foreign officials for the purposes of obtaining or retaining business or securing any improper business advantage. It also requires us to keep books and records that accurately and fairly reflect our transactions. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the U.S. are, either directly or indirectly, with governmental entities and are therefore subject to the FCPA and similar anti-bribery laws in non-U.S. jurisdictions. In addition, the provisions of the Bribery Act extend beyond bribery of foreign public officials and are more onerous than the FCPA in a number of other respects, including jurisdiction, non-exemption of facilitation payments and penalties.

Our policies mandate compliance with these anti-bribery laws. We operate in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of those violations, could disrupt our business and result in a material adverse effect on our results of operations, financial condition and cash flows.

Our business depends on the continued effectiveness and availability of our information technology infrastructure, and failures of this infrastructure could harm our operations.

To remain competitive in our industry, we must employ information technologies to support manufacturing processes, quality processes, distribution, R&D and regulatory applications and that capture, manage and analyze large streams of data in compliance with applicable regulatory requirements. We rely extensively on technology, some of which is managed by third-party service providers, to allow the concurrent conduct of work sharing around the world. As with all information technology, our equipment and infrastructure age and become subject to increasing maintenance and repair and our systems generally are vulnerable to potential damage or interruptions from fires, natural disasters, power outages, blackouts, machinery breakdown, telecommunications failures and other unexpected events, as well as to break-ins, sabotage, increasingly sophisticated intentional acts of vandalism or cybersecurity threats which, due to the nature of such attacks, may remain undetected for a period of time. As these threats continue to evolve, we may be required to expend additional resources to enhance our information security measures or to investigate and remediate any information security vulnerabilities. Given the extensive reliance of our business on technology, any substantial disruption or resulting loss of data that is not avoided or corrected by our backup measures could harm our business, reputation, operations and financial condition.

A disruption in our computer networks, including those related to cybersecurity, could adversely affect our operations or financial position.

We believe that our cybersecurity program is designed to effectively mitigate the risks of material cybersecurity incidents. However, our management does not expect that our cybersecurity program will prevent or detect all occurrences of cybersecurity incidents, material or otherwise, and there is potential risk that certain cybersecurity breaches may go undetected for a period of time. The design of our cybersecurity program is based, in part, upon certain assumptions about the likelihood of future incidents, and there can be no assurance that any design will prevent or detect all cybersecurity breaches. Over time, certain aspects of cybersecurity programs may become inadequate because of changes in technology, sophistication of cybersecurity attacks, emerging threats or other conditions, or the degree of compliance with our policies and procedures may deteriorate.

We rely on our computer networks and systems, some of which are managed by third parties, to manage and store electronic information (including sensitive data such as confidential business information, personally identifiable data and personal health information), and to manage or support a variety of critical business processes and activities. We may face threats to our networks from unauthorized access, security breaches and other system disruptions. Despite our security measures, our infrastructure may be vulnerable to external or internal attacks. Any such security breach may compromise information stored on our networks and may result in significant data losses or theft of sensitive or proprietary information. A cybersecurity breach could hurt our reputation by adversely affecting the perception of customers and potential customers about the security of their orders and personal information, as well as the perception of our manufacturing partners of the security of their proprietary information. In addition, a cybersecurity attack could result in other negative consequences, including disruption of our internal operations, increased cybersecurity protection costs, lost revenue, regulatory actions or litigation. Any disruption of internal operations could also have a material adverse impact on our results of operations, financial condition and cash flows. To date, we have not experienced any known material cybersecurity attacks.

We may be limited in our ability to utilize, or may not be able to utilize, net operating loss carryforwards to reduce our future tax liability.

As of December 31, 2023, we had U.S. federal income tax loss carryforwards of $297.6 million, $157.9 million of which will expire between 2027 and 2037, $139.6 million of which can be carried forward indefinitely, and state income tax loss carryforwards of $12.5 million, tax-effected. We may be limited in our ability to use these tax loss carryforwards to reduce our future U.S. federal and state income tax liabilities if our future income is not sufficient to absorb the losses, or if we were to experience another "ownership change" as specified in Section 382 of the Internal Revenue Code including if we were to issue a certain amount of equity securities, certain of our stockholders were to sell shares of our common stock, or we were to enter into certain strategic transactions.

We are involved in various legal proceedings that are uncertain, costly and time-consuming and could have a material adverse impact on our business, financial condition and results of operations.

From time to time we are involved in legal proceedings and disputes and may be involved in litigation in the future. For example, on January 26, 2024, we were sued in the United States District Court for the District of Delaware by Advanced Accelerator Applications USA, Inc. and Advanced Accelerator Applications SA, each a Novartis entity, for patent infringement in response to the

filing of our ANDA for PNT2003 and Paragraph IV certification, consistent with the process established by the Hatch-Waxman Act. These proceedings are complex and extended and occupy the resources of our management and employees.

Legal proceedings are also costly to prosecute and defend and may involve substantial awards or damages payable by us if not found in our favor. We may also be required to pay substantial amounts or grant certain rights on unfavorable terms in order to settle such proceedings.

Defending against or settling legal proceedings and any unfavorable legal decisions, settlements or orders could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common stock to decline.

In particular, the pharmaceutical and medical device industries historically have generated substantial litigation concerning the manufacture, use and sale of products, and we expect this litigation activity to continue. As a result, we expect that patents related to our products will routinely be challenged, and our patents may not be upheld. In order to protect or enforce patent rights, we may initiate litigation against third parties. If we are not successful in defending an attack on our patents and maintaining exclusive rights to market one or more of our products still under patent protection, we could lose a significant portion of sales in a very short period. We may also become subject to infringement claims by third parties and may have to defend against charges that we violated patents or the proprietary rights of third parties. If we infringe the intellectual property rights of others, we could lose our right to develop, manufacture or sell products, or could be required to pay monetary damages or royalties to license proprietary rights from third parties.

In addition, in the U.S., it has become increasingly common for patent infringement actions to prompt claims that antitrust laws have been violated during the prosecution of the patent or during litigation involving the defense of that patent. Such claims by direct and indirect purchasers and other payors are typically filed as class actions. The relief sought may include treble damages and restitution claims. Similarly, antitrust claims may be brought by government entities or private parties following settlement of patent litigation, alleging that such settlements are anti-competitive and in violation of antitrust laws. In the U.S. and Europe, regulatory authorities have continued to challenge as anti-competitive so-called "reverse payment" settlements between branded and generic drug manufacturers. We may also be subject to other antitrust litigation involving competition claims unrelated to patent infringement and prosecution. A successful antitrust claim by a private party or government entity against us could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common stock to decline.

Risks Related to our and our Strategic Partners' Portfolios of Clinical Development Candidates

We may not, or may take longer to, realize the expected benefits and opportunities related to, the POINT License Agreements.

On December 20, 2022, we announced the closing of a set of strategic collaborations with an affiliate of POINT, in which we were granted a license to exclusive worldwide rights (excluding Japan, South Korea, China (including Hong Kong, Macau and Taiwan), Singapore and Indonesia) to co-develop and commercialize POINT's PNT2002 and PNT2003 product candidates (the "POINT License Agreements"). The expected benefits and opportunities related to the POINT License Agreements may not be realized or may take longer to realize than expected due to, for example, challenges and uncertainties inherent in product research, development, manufacturing, regulatory approval, marketing and competition. In particular, activities under the POINT License Agreements may not result in viable products suitable for commercialization in a timely manner or at all, due to a variety of reasons, including any inability of the relevant parties to perform their commitments and obligations under the POINT License Agreements. The POINT License Agreements impose various development, regulatory filing, commercialization and other obligations on us, and require us to meet development timelines or to exercise commercially reasonable efforts to develop and commercialize licensed products. We, along with our counterparty in the POINT License Agreements, may not be able to meet expected or planned regulatory milestones and timelines due to a number of factors, including, with respect to PNT2003, potential litigation under the Hatch-Waxman Act that could impose a stay on FDA approval of up to 30 months. Even if the licensed products are suitable for commercialization in a timely manner, we may not achieve the expected revenues from the sale of such products, and our revenue, ability to achieve profitability and return on investment may be adversely affected.

With respect to PNT2002, on December 18, 2023, we announced positive topline results from SPLASH, the Phase 3 registrational trial for PNT2002. Although the topline results indicated that the SPLASH trial met its primary endpoint, at the time of our topline analysis, interim OS results were immature. We expect additional, follow-up data in 2024 prior to the potential submission of an NDA; however, we can give no assurance that, as additional data become available, such data will not be materially different from the topline data we previously published, or that such data will support an NDA filing, FDA approval, or successful commercialization of PNT2002.

In addition, we are dependent on POINT to develop commercial product capacity and manufacture clinical and commercial supply for both PNT2002 and PNT2003, as well as supply for our EAP for PNT2002.

Disagreements with the counterparty in the POINT License Agreements over proprietary rights, contract interpretation or the preferred course of product research, development or marketing, might cause delays in performance of the POINT License Agreements or termination of the POINT License Agreements, or might result in litigation or arbitration, which could be time-consuming and expensive.

In spite of our efforts, if we fail to comply with our obligations under the POINT License Agreements, the counterparty in the POINT License Agreements may conclude that we have materially breached and may terminate one or both of the POINT License Agreements, in which event we may lose our rights to develop and market PNT2002 and PNT2003 or incur liability for damages.

Any of the foregoing risks could materially and adversely affect our business, results of operations and prospects and the trading price of our common stock.

We may not, or may take longer to, realize the expected benefits and opportunities related to, the Cerveau Acquisition.

On February 6, 2023, we announced that we acquired Cerveau. Cerveau holds the rights under a license agreement to develop and commercialize MK-6240, an investigational second-generation F 18-labeled PET imaging agent that targets Tau tangles in Alzheimer's disease. MK-6240 is currently being used in more than 90 active clinical trials for several Alzheimer's disease therapeutic candidates being developed. While we believe that MK-6240, as a Tau imaging agent, has the potential to play an important role in patient staging, selection, and monitoring for future treatments and could be a surrogate endpoint for treatment efficacy, we can give no assurance that we will be successful with continued development, regulatory approval and commercialization of the product candidate or that disagreements with the counterparty to our license agreement for MK-6240 or the Selling Stockholders will not arise over proprietary rights, contract interpretation or the preferred course of product research, development or marketing that might cause delays or termination of the license agreement, or might result in litigation or arbitration, which could be time-consuming and expensive.

The process of developing new drugs and obtaining regulatory approval is complex, time-consuming and costly, and the outcome is not certain.

We currently have clinical development programs in the U.S., including those related to PNT2002, PNT2003, MK-6240 and LNTH-1363S, and are exploring additional lifecycle management opportunities for some of our current products, including PYLARIFY. We also have a number of strategic partnerships relating to obtaining additional indications for existing commercial products or regulatory approval for clinical development candidates. To obtain regulatory approval for these products in the indications being pursued, we must conduct extensive human tests, which are referred to as clinical trials, as well as meet other rigorous regulatory requirements, as further described in Part I, Item 1. "Business—Regulatory Matters." Satisfaction of all regulatory requirements typically takes many years and requires the expenditure of substantial resources. A number of other factors may cause significant delays in the completion of our clinical trials, including unexpected delays in the initiation of clinical sites, slower than projected enrollment, competition with ongoing clinical trials and scheduling conflicts with participating clinicians, regulatory requirements, limits on manufacturing capacity and failure of an investigational product to meet required standards for administration to humans. In addition, it may take longer than we project to achieve study endpoints and complete data analysis for a clinical trial or we may decide to slow down the enrollment in a trial in order to conserve financial resources or for other reasons.

Our products in development are also subject to the risks of failure inherent in drug development, drug testing and regulatory approval. The results of preliminary studies do not necessarily predict clinical success, and larger and later stage clinical trials may not produce the same results as earlier stage trials. Sometimes, products that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. Products in later stage clinical trials may fail to show desired safety and efficacy traits, despite having progressed through initial clinical testing. In addition, the data collected from clinical trials of our products in development may not be sufficient to support regulatory approval, or regulators could interpret the data differently and less favorably than we do. Further, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. Regulatory authorities may require us or our partners to conduct additional clinical testing, in which case we would have to expend additional time and resources. Depending on the regulatory pathway selected for drug approval, such as by filing an ANDA or Section 505(b)(2) NDA that requires sending notice to the innovator of a drug, regulatory approval may also be delayed by litigation brought under the Hatch-Waxman Act. For example, on January 26, 2024, we were sued in the United States District Court for the District of Delaware by Advanced Accelerator Applications USA, Inc. and Advanced Accelerator Applications SA, each a Novartis entity, for patent infringement in response to the filing of our ANDA for PNT2003 and Paragraph IV certification, consistent with the process established by the Hatch-Waxman Act. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in regulatory policy that occur prior to or during regulatory review. The failure to provide clinical and preclinical data that are adequate to demonstrate to the satisfaction of the regulatory authorities that our products in development are safe and effective for their proposed use will delay or preclude approval and will prevent us from marketing those products.

We are not permitted to market our products in development in the U.S. or other countries until we have received requisite regulatory approvals. For example, securing FDA approval for a new drug requires the submission of an NDA to the FDA for our products in development. The NDA must include extensive nonclinical and clinical data and supporting information to establish the product's safety and effectiveness for each indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. The FDA review process can take many years to complete, and approval is never guaranteed. If a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling, impose restricted distribution programs, require expedited reporting of certain adverse events, or require costly ongoing requirements for post-marketing clinical trials and surveillance or other risk management measures to monitor the safety or efficacy of the product. In some instances, products in development may also be approved by filing an ANDA or Section 505(b)(2) NDA with the FDA (as further described in Part I, Item 1. "Business—Regulatory Matters—Hatch-Waxman Act."); provided, however, that seeking regulatory approval under such pathways may subject the product candidate to delays caused by litigation brought by an innovator of similar drugs under the Hatch-Waxman Act, as is the case with our ANDA application and Paragraph IV certification for PNT2003. Markets outside of the U.S. also have requirements for approval of products with which we must comply prior to marketing. Obtaining regulatory approval for marketing of a product in one country does not ensure we will be able to obtain regulatory approval in other countries, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. Also, any regulatory approval of any of our products in development, once obtained, may be withdrawn. Approvals might not be granted on a timely basis, if at all.

We can give no assurance that GE Healthcare will be successful with the further clinical development of flurpiridaz.

In May 2015, we announced complete results from the first of two planned Phase 3 clinical trials for flurpiridaz. Although the development candidate appeared to be well-tolerated from a safety perspective and outperformed SPECT in a highly statistically significant manner in the co-primary endpoint of sensitivity and in the secondary endpoints of image quality and diagnostic certainty, flurpiridaz did not meet its other co-primary endpoint of non-inferiority for identifying subjects without disease. In April 2017, we entered into the License Agreement with GE Healthcare for the continued Phase 3 development and worldwide commercialization of flurpiridaz. Under the License Agreement, GE Healthcare agreed, among other things, to complete the worldwide development of flurpiridaz by conducting a second Phase 3 trial and pursue worldwide regulatory approvals. In September 2022, we announced with GE Healthcare that the second Phase 3 clinical trial had met its co-primary endpoints of exceeding a 60% threshold for both sensitivity and specificity for detecting CAD. The findings, shared at an American Society of Nuclear Cardiology conference, also demonstrated that cardiac PET imaging with flurpiridaz had higher diagnostic efficacy and image quality in patients with suspected CAD, compared with SPECT MPI, the predominant procedure currently used in nuclear cardiology. Notwithstanding these findings, we cannot assure that any of the data generated in either our or GE Healthcare's sponsored Phase 3 study will be sufficient to support an NDA approval or that flurpiridaz will ever be approved as a PET MPI imaging agent by the FDA. While GE Healthcare recently announced that it had filed an NDA with the FDA for flurpiridaz, any failure or significant delay in receiving regulatory approval for the sale of flurpiridaz may harm our business and delay or prevent us from being able to generate additional future royalty revenue from product sales.

Even if clinical development candidates receive regulatory approval, we can give no assurance that they can be successfully commercialized.

Even if our clinical development candidates proceed through their clinical trials and ultimately receive regulatory approval, there is no guarantee that an approved product can be manufactured in commercial quantities at a reasonable cost or that such a product will be successfully marketed or distributed. For example, the manufacturing, marketing and distribution of a radiopharmaceutical like flurpiridaz and MK-6240 will require the creation of a field-based network of specialized PET manufacturing facilities, or PMFs, with radioisotope-producing cyclotrons, similar to what we created for PYLARIFY, and will need to be manufactured and distributed rapidly to end-users.

In addition, obtaining adequate coding, coverage and payment at appropriate payment levels for any clinical development candidate will be critical, including not only coverage from Medicare, Medicaid, and other government payors, but also from private payors. We can give no assurance, even if a clinical development candidate were to obtain regulatory approval, that adequate coding, coverage and payment could be secured to allow the approved products to become successfully commercialized.

We have been and expect to continue to be dependent on partners for the development of certain product candidates, which expose us to the risk of reliance on these partners.

In connection with our ongoing development activities, we currently depend, and expect to continue to depend, on numerous collaborators. For example, in addition to our collaboration with Curium on PYLCLARI in Europe, GE Healthcare on flurpiridaz and POINT on PNT2002 and PNT2003, we have other collaborations to develop and commercialize products. In addition, certain clinical trials for our product candidates may be conducted by government-sponsored agencies, and consequently will be dependent on governmental participation and funding. These arrangements expose us to the same considerations we face when contracting with third parties for our own trials.

If any of our collaborators breach or terminate its agreement with us or otherwise fail to conduct successfully and in a timely manner the collaborative activities for which they are responsible, the preclinical or clinical development or commercialization of the affected product candidate or research program could be delayed or terminated. We generally do not control the amount and timing of resources that our collaborators devote to our programs or product candidates. We also do not know whether current or future collaboration partners, if any, might pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors, as a means for developing treatments for the diseases or conditions targeted by our collaborative arrangements. Our collaborators are also subject to similar development, regulatory, manufacturing, cyber-security and competitive risks as us, which may further impede their ability to successfully perform the collaborative activities for which they are responsible. Setbacks of these types to our collaborators could have a material adverse effect on our business, results of operations and financial condition.

We depend on licenses from third parties for our rights to develop and commercialize certain product candidates. If we fail to achieve milestone requirements or to satisfy other conditions, we may lose those rights under those license agreements, and our business, results of operations and financial condition could be adversely affected.

Many of our products or product candidates incorporate rights licensed by third parties -- for example, we license patent rights on PYLARIFY, PNT2002, PNT2003, MK-6240, LNTH-1363S and NM-01. We could lose the rights to develop or commercialize these products and product candidates if the related license agreement is terminated due to a breach by us or otherwise. In addition, we are required to make substantial cash payments, achieve milestones and satisfy other conditions, including filing for and obtaining marketing approvals and introducing products, sometimes in accordance with established timelines, to maintain rights under our license agreements. Due to the nature of these agreements and the uncertainties of development, we may not be able to achieve milestones or satisfy conditions to which we have contractually committed, and as a result may be unable to maintain our rights under these licenses. If we do not comply with our license agreements, the licensors may terminate them, which could result in our losing our rights to, and therefore being unable to commercialize, related products. This loss could have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Our Capital Structure

The conditional conversion feature of the 2.625% Convertible Senior Notes due 2027, if triggered, may adversely affect our financial condition and operating results.

On December 8, 2022, we issued $575.0 million in aggregate principal amount of 2.625% Convertible Senior Notes due 2027 (the "Notes"), which included $75.0 million in aggregate principal amount of Notes sold pursuant to the full exercise of the initial purchasers' option to purchase additional Notes. The Notes were issued under an indenture, dated as of December 8, 2022 (the "Indenture"), among Holdings, LMI, and U.S. Bank Trust Company, National Association ("U.S. Bank"), as Trustee. Prior to the close of business on the business day immediately preceding September 15, 2027, the Notes may be converted at the option of the holders upon occurrence of specified events and during certain periods, and thereafter until the close of business on the business day immediately preceding the maturity date, the Notes may be converted at any time. If one or more holders elect to convert their Notes, we would be required to settle any converted principal amount of such Notes through the payment of cash and by paying or delivering, at our election, cash, shares of our common stock, or a combination of cash and shares, with respect to the remainder of our conversion obligation in excess of the aggregate principal amount of the Notes being converted, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The issuance or sale of shares of our common stock, or rights to acquire shares of our common stock, could depress the trading price of our common stock.

We may conduct future offerings of our common stock, preferred stock or other securities that are convertible into or exercisable for our common stock to finance our operations or fund acquisitions, or for other purposes. In addition, we expect to continue to grant equity awards to directors, officers and employees under our equity incentive plans. If we issue additional shares of our common stock or rights to acquire shares of our common stock, if any of our existing stockholders sells a substantial amount of our common stock, or if the market perceives that such issuances or sales may occur, then the trading price of our common stock may significantly decrease. In addition, our issuance of additional shares of common stock will dilute the ownership interests of our existing common stockholders.

Repurchases by us of our common stock may affect the value of our common stock.

In December 2022, our Board authorized the repurchase of up to $150.0 million in aggregate amount of our common stock under certain circumstances. We used approximately $75.0 million of the net proceeds from the Notes to repurchase shares of our common stock from purchasers of Notes in privately negotiated transactions effected with or through one of the initial purchasers or its affiliate. The purchase price per share of the common stock repurchased in such transactions was equal to the closing sale price per share of our

common stock on December 5, 2022, which was $56.01 per share. Following this initial repurchase, we may from time to time repurchase additional shares of our common stock. Such repurchases could increase, or prevent a decrease in, the market price of our common stock.

We have indebtedness which may limit our financial and operating activities and may adversely affect our ability to incur additional debt to fund future needs.

As of December 31, 2023, we had approximately $575.0 million of total principal indebtedness remaining under the Notes and availability of $350.0 million under our five-year 2022 Revolving Facility. Our indebtedness and any future indebtedness we incur could:

- Require us to dedicate a substantial portion of cash flow from operations to the payment of interest on and principal of our indebtedness, thereby reducing the funds available for other purposes, including for working capital, capital expenditures and acquisitions;
- Make it more difficult for us to satisfy and comply with our obligations with respect to our outstanding indebtedness, namely the payment of interest and principal;
- Make it more difficult to refinance the outstanding indebtedness;
- Subject us to increased sensitivity to interest rate increases;
- Make us more vulnerable to economic downturns, adverse industry or company conditions or catastrophic external events;
- Limit our ability to withstand competitive pressures;
- Reduce our flexibility in planning for or responding to changing business, industry and economic conditions; and
- Place us at a competitive disadvantage to competitors that have relatively less debt than we have.

In addition, our level of indebtedness could limit our ability to obtain additional financing on acceptable terms, or at all, for working capital, capital expenditures and general corporate purposes. Our liquidity needs could vary significantly and may be affected by general economic conditions, industry trends, performance and many other factors outside our control.

We may not be able to generate sufficient cash flow to meet our debt service obligations.

Our ability to generate sufficient cash flow from operations to make scheduled payments on our debt obligations will depend on our future financial performance, which will be affected by a range of economic, competitive and business factors, many of which are outside of our control. If we do not generate sufficient cash flow from operations to satisfy our debt obligations, including interest and principal payments, our credit ratings could be downgraded, and we may have to undertake alternative financing plans, such as refinancing or restructuring our debt, selling assets, entering into additional corporate collaborations or licensing arrangements for one or more of our products in development, reducing or delaying capital investments or seeking to raise additional capital. We cannot assure you that any refinancing would be possible, that any assets could be sold, licensed or partnered, or, if sold, licensed or partnered, of the timing of the transactions and the amount of proceeds realized from those transactions, that additional financing could be obtained on acceptable terms, if at all, or that additional financing would be permitted under the terms of our various debt instruments then in effect. Furthermore, our ability to refinance would depend upon the condition of the financial and credit markets. Our inability to generate sufficient cash flow to satisfy our debt obligations, or to refinance our obligations on commercially reasonable terms or on a timely basis, would have an adverse effect on our business, results of operations and financial condition.

Despite our indebtedness, we may incur more debt, which could exacerbate the risks described above.

We and our subsidiaries may be able to incur substantial additional indebtedness in the future subject to the limitations contained in the agreements governing our debt, including the 2022 Revolving Facility. Although these agreements restrict us and our restricted subsidiaries from incurring additional indebtedness, these restrictions are subject to important exceptions and qualifications. For example, we are generally permitted to incur certain indebtedness, including indebtedness arising in the ordinary course of business, indebtedness among restricted subsidiaries and us and indebtedness relating to hedging obligations. If we or our subsidiaries incur additional debt, the risks that we and they now face as a result of our leverage could intensify. In addition, the 2022 Revolving Facility will not prevent us from incurring obligations that do not constitute indebtedness under that agreement.

Our 2022 Revolving Facility contains restrictions that will limit our flexibility in operating our business.

Our 2022 Revolving Facility contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our and our restricted subsidiaries' ability to, among other things:

- Maintain net leverage above certain specified levels;

- Maintain interest coverage below certain specified levels;
- Incur additional debt;
- Pay dividends or make other distributions;
- Redeem stock;
- Issue stock of subsidiaries;
- Make certain investments;
- Create liens;
- Enter into transactions with affiliates; and
- Merge, consolidate or transfer all or substantially all of our assets.

A breach of any of these covenants could result in a default under the 2022 Revolving Facility. We may also be unable to take advantage of business opportunities that arise because of the limitations imposed on us by the restrictive covenants under our indebtedness.

U.S. credit markets may impact our ability to obtain financing or increase the cost of future financing, including interest rate fluctuations based on macroeconomic conditions that are beyond our control.

During periods of volatility and disruption in the U.S., European, or global credit markets, obtaining additional or replacement financing may be more difficult and the cost of issuing new debt or replacing or repaying our 2022 Facility could be higher than under our current 2022 Facility. Higher cost of new debt may limit our ability to have cash on hand for working capital, capital expenditures and acquisitions on terms that are acceptable to us. Additionally, our 2022 Facility has variable interest rates. By its nature, a variable interest rate will move up or down based on changes in the economy and other factors, all of which are beyond our control. If interest rates increase, our interest expense could increase, affecting earnings and reducing cash flows available for working capital, capital expenditures and acquisitions.

Our stock price could fluctuate significantly, which could cause the value of your investment to decline, and you may not be able to resell your shares at or above your purchase price.

Securities markets worldwide have experienced, and may continue to experience, significant price and volume fluctuations. This market volatility, as well as general economic, market or political conditions, could reduce the market price of our common stock regardless of our operating performance. The high and low closing sales prices of our common stock during the twelve months ended December 31, 2023 were $99.65 and $47.76, respectively. The trading price of our common stock is likely to be volatile and subject to wide price fluctuations in response to various factors, including:

- Market conditions in the broader stock market;
- Actual or anticipated fluctuations in our quarterly financial and operating results;
- Issuance of new or changed securities analysts' reports or recommendations;
- Investor perceptions of us and the pharmaceutical and medical device industries;
- Sales, or anticipated sales, of large blocks of our stock;
- Acquisitions or introductions of new products or services by us or our competitors;
- Positive or negative results from our clinical development programs;
- Additions or departures of key personnel;
- Regulatory or political developments;
- Loss of intellectual property protections;
- Litigation and governmental investigations;
- Geopolitical events; and
- Changing economic conditions.

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management from our business, which could significantly harm our profitability and reputation.

If securities or industry analysts do not publish research or reports about our business, if they adversely change their recommendations regarding our stock, or if our results of operations do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if one or more of the analysts who cover us downgrades our stock, or if our results of operations do not meet their expectations, our stock price could also decline.

We do not anticipate paying any cash dividends for the foreseeable future, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain our future earnings, if any, for the foreseeable future, to repay indebtedness and to fund the development and growth of our business. We do not intend to pay any dividends to holders of our common stock and the agreements governing our senior secured credit facilities limit our ability to pay dividends. As a result, capital appreciation in the price of our common stock, if any, will be your only source of gain on an investment in our common stock.

Anti-takeover provisions in our charter documents and Delaware law and certain provisions in the Notes and Indenture may make an acquisition of us more difficult.

Our amended and restated certificate of incorporation and bylaws, as amended and restated, contain provisions that delay, defer or discourage transactions involving an actual or potential change in control of us or change in our management. These provisions may also discourage bids for our common stock at a premium over market price or adversely affect the market price of, and the voting and other rights of the holders of, our common stock. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors other than the candidates nominated by our Board. In addition, we are incorporated in Delaware and subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit large stockholders from consummating a merger with, or acquisition of, us. These provisions may deter an acquisition of us that might otherwise be attractive to stockholders.

Certain provisions in the Notes and the Indenture could make it more difficult or more expensive for a third party to acquire us. For example, if a takeover would constitute a fundamental change, holders of the Notes will have the right to require us to repurchase their Notes in cash. In addition, if a takeover constitutes a make-whole fundamental change, we may be required to increase the conversion rate for holders who convert their Notes in connection with such takeover. In either case, and in other cases, our obligations under the Notes and the Indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders of our common stock may view as favorable.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk management and strategy

With respect to cybersecurity risks, we have invested and continually invest in new cybersecurity services, technologies, and capabilities. On an ongoing basis we provide our employees with comprehensive cybersecurity awareness training around phishing, malware and other cybersecurity risks, all in a manner reasonably intended to educate employees to safely avoid cyber attacks and mitigate the risk of employee related security breaches. In support of our cybersecurity program, our systems and services undergo regular reviews by management to determine if any insufficiencies in cybersecurity exist.

If an incident is detected, the Cybersecurity team follows the incident response policy to investigate, review and determine the potential impacts of such an incident. If the Cybersecurity team determines that an incident could reasonably be expected to have an impact on the financial condition or operations of the Company, it escalates the incident to the crisis management team, which includes executive management. The crisis management team further evaluates the potential impact and materiality of an event and the

appropriate response required. The crisis management team coordinates the appropriate response effort and communicates, as applicable, to the Audit Committee. To the extent that Cybersecurity incident is determined to be material, the appropriate public disclosures are made.

We monitor material risks from cybersecurity threats relating to potential compromises of sensitive information at our third-party business partners where relevant and reevaluate these risks periodically. We also perform third-party cybersecurity audits at least annually and conduct third-party security reviews and testing of our network, processes and systems periodically.

Impact of cybersecurity risks on business strategy, results of operations or financial condition

We rely on our computer networks and systems, some of which are managed by third-parties, to manage and store electronic information (including sensitive data such as confidential business information, personally identifiable data and personal health information), and to manage or support a variety of critical business processes and activities. We may face threats to our networks from unauthorized access, security breaches and other system disruptions. Despite our security measures, our infrastructure may be vulnerable to external or internal attacks. Any such security breach may compromise information stored on our networks and may result in significant data losses or theft of sensitive or proprietary information. A cybersecurity breach could hurt our reputation by adversely affecting the perception of customers and potential customers about the security of their orders and personal information, as well as the perception of our manufacturing partners of the security of their proprietary information. In addition, a cybersecurity attack could result in other negative consequences, including disruption of our internal operations, increased cybersecurity protection costs, lost revenue, regulatory actions or litigation. Any disruption of internal operations could also have a material adverse impact on our results of operations, financial condition and cash flows.

As of the date of this report, we have not experienced any known cybersecurity incidents, or a series of related incidents, that have materially affected or are reasonably likely to affect us, including our business strategy, results of operations or financial condition. For an additional description of these cybersecurity risks and potential related impacts on us, see “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K.

Governance

Our Board actively oversees our corporate strategy and enterprise risk management (“ERM”) programs, including those relating to cybersecurity and data privacy risks.

Our Audit Committee and Nominating and Corporate Governance Committee are primarily responsible for, among other things, overseeing our compliance and ERM programs, information technology systems, and our processes and data, including cybersecurity and data privacy. These responsibilities include reviewing and discussing with management our policies and processes relating to risk assessment and risk management. Cybersecurity and data privacy are regular topics on the Audit Committee’s agenda and management reviews at least quarterly the results of cybersecurity monitoring and discusses performance metrics, any incidents identified and potential recommended modifications to our technology, organization training, awareness and governance with our Audit Committee. A summary of these results are also reported by the Audit Committee to the Board at least annually.

Management, including our Chief Information Officer (“CIO”), who has over 25 years of experience serving primarily in the life science industry and is a recognized industry leader, is responsible for monitoring and assessing cybersecurity risks. Management reviews and determines the effectiveness of both internal and third-party leveraged expertise to ensure we have the appropriate knowledge base for risk coverage.

Item 2. Properties

The following table summarizes information regarding our significant leased and owned properties, as of December 31, 2023:

Location	Purpose	Square Footage	Ownership	Lease Term End
U.S.				
North Billerica, Massachusetts	Manufacturing, Laboratory, Mixed Use and Other Office Space	431,000	Owned	N/A
Bedford, Massachusetts	Executive Offices, Laboratory, Office Space	88,200	Leased	December 2039
New York, New York	Office Space	26,000	Leased*	September 2030
Somerset, New Jersey	Manufacturing, Mixed Use and Office Space	11,400	Leased	November 2028
Somerset, New Jersey	Office Space	8,249	Leased	March 2027
Canada				
Quebec	Mixed Use and Office Space	1,106	Leased	May 2024
Quebec	Distribution Center and Office Space	1,433	Leased	May 2025
Sweden				
Lund	Office Space	4,000	Leased	December 2024

* On October 11, 2021, we entered into an agreement to sublease our office space at the World Trade Center in New York City to an unrelated third party. Please refer to Note 16, “Leases” for further details.

** On January 9, 2024, we announced that Perspective agreed to acquire the assets and associated lease of our radiopharmaceutical manufacturing facility in Somerset, New Jersey, subject to customary closing conditions, including regulatory approval.

We believe all of these facilities are well-maintained and suitable for the office, manufacturing or warehouse operations conducted in them and provide adequate capacity for current and foreseeable future needs.

Item 3. Legal Proceedings

Information with respect to certain legal proceedings is included in Note 19, “Commitments and Contingencies”, to the consolidated financial statements contained in Item 8. Financial Statements and Supplementary Data, and is incorporated herein by reference.

Item 4. Mine Safety Disclosures

Not applicable

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock trades on the NASDAQ Global Market under the symbol "LNTH".

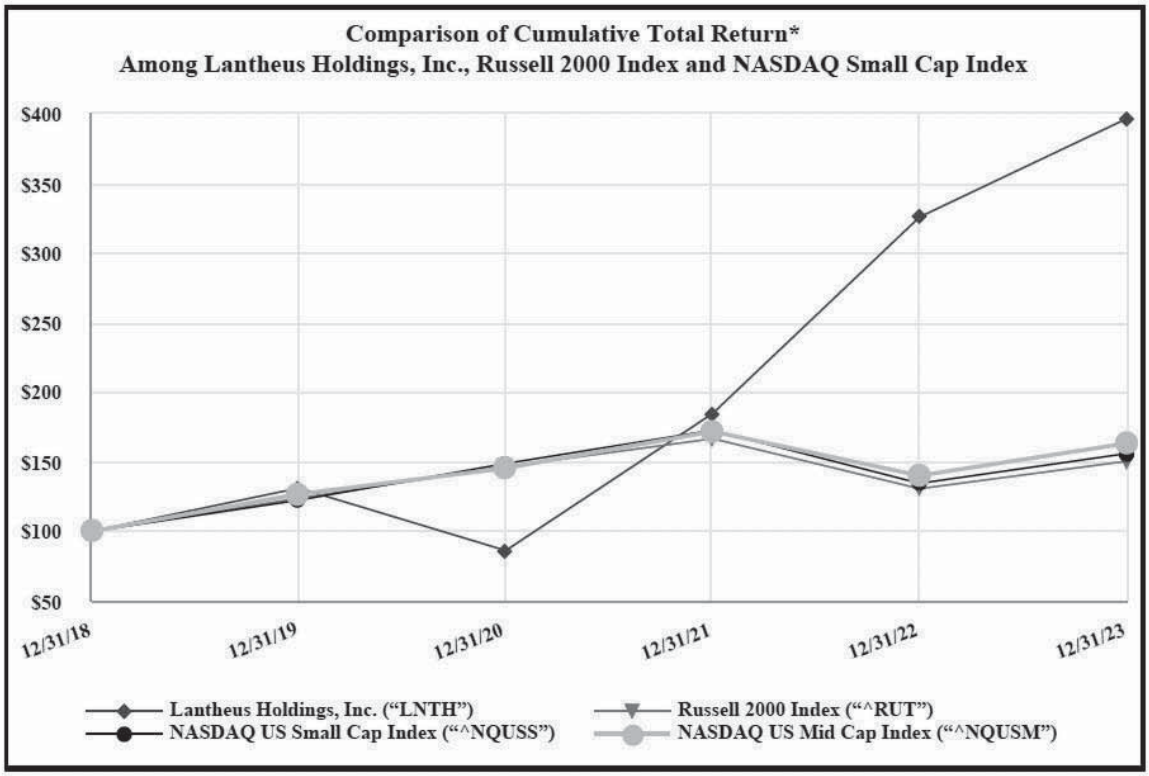
Holders of Record

On February 15, 2024, there were approximately 30 stockholders of record of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

Performance Graph

The performance graph set forth below shall not be deemed "soliciting material" or to be "filed" with the SEC. This graph will not be deemed "incorporated by reference" into any filing under the Securities Act or the Exchange Act, whether such filing occurs before or after the date hereof, except to the extent that we explicitly incorporate it by reference into in such filing.

The following graph provides a comparison of the cumulative total shareholder return on our common shares with that of the cumulative total shareholder return on the (i) Russell 2000 Index, (ii) the NASDAQ US Small Cap Index and (iii) the NASDAQ US Mid Cap Index, commencing on December 31, 2018 and ending December 31, 2023. The graph assumes a hypothetical $100 investment in our common stock and in each of the comparative indices on December 31, 2018. Our historic share price performance is not necessarily indicative of future share price performance.



** Assumes hypothetical investment of $100 in our common stock and each of the indices on December 31, 2018, including reinvestment of dividends.*

Performance Graph Data

The following table sets forth the cumulative total shareholder return on the hypothetical $100 investment in our common stock and each of the comparative indices on December 31, 2018:

Date	Lantheus Holdings, Inc. ("LNTH")	Russell 2000 Index ("^RUT")	NASDAQ US Small Cap Index ("^NQUSS")	NASDAQ US Mid Cap Index ("^NQUSM")
12/31/18	$ 100.00	$ 100.00	$ 100.00	$ 100.00
12/31/19	$ 131.05	$ 123.72	$ 122.37	$ 126.72
12/31/20	$ 86.20	$ 146.44	$ 148.64	$ 145.38
12/31/21	$ 184.60	$ 166.50	$ 172.58	$ 171.68
12/31/22	$ 325.62	$ 130.60	$ 134.43	$ 139.97
12/31/23	$ 396.17	$ 150.31	$ 155.82	$ 163.12

Dividend Policy

We did not declare or pay any dividends in 2023, 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 II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—External Sources of Liquidity" for further information.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

The following table presents information with respect to purchases of common stock we made during the three months ended December 31, 2023. In December 2022, our Board authorized the repurchase of up to $150.0 million in aggregate amount of our common stock under certain circumstances. We used approximately $75.0 million of the net proceeds from the Notes to repurchase shares of our common stock from purchasers of the Notes in privately negotiated transactions effected with or through one of the initial purchasers or its affiliate. The 2015 Equity Incentive Plan, adopted by us 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 5.

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 Purchase d Under the Program
October 2023 *	4,984	$ 71.02	0	$75.0 million
November 2023 *	3,930	$ 68.38	0	$75.0 million
December 2023 *	4,061	$ 76.04	0	$75.0 million
Total	12,975		0	$75.0 million

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

Securities Authorized for Issuance under Equity Compensations Plans

The information required with respect to this item is incorporated herein by reference to our Definitive Proxy Statement for our 2024 Annual Meeting of Stockholders to be filed with the SEC no later than 120 days after the close of our year ended December 31, 2023.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with the consolidated financial statements and the related notes included in Item 8 of this Annual Report on Form 10-K. This discussion contains forward-looking statements related to future events and our future financial performance that are based on current expectations and subject to risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those set forth in Part I—Item 1A. "Risk Factors" and "Cautionary Note Regarding Forward Looking Statements." included in this Annual Report on Form 10-K.

This section discusses 2023 and 2022 items and year-to-year comparisons between 2023 and 2022. Discussions of 2021 items and year-to-year comparisons between 2022 and 2021 have been excluded from this Form 10-K and can be found in "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on February 23, 2023.

Overview

Our Business

We are the leading radiopharmaceutical-focused company, delivering life-changing science to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. We classify our products in three categories: Radiopharmaceutical Oncology, Precision Diagnostics, and Strategic Partnerships and Other Revenue. Our Radiopharmaceutical Oncology diagnostics and therapeutics help healthcare professionals ("HCPs") Find, Fight and Follow cancer, with a focus on prostate cancer. Our leading Precision Diagnostic products assist HCPs to Find and Follow diseases, with a focus in cardiology. Our Strategic Partnerships focus on enabling precision medicine through the use of biomarkers, digital solutions and pharma solutions platforms.

Our commercial products are used by cardiologists, internal medicine physicians, nuclear medicine physicians, oncologists, radiologists, sonographers, technologists, and urologists working in a variety of clinical settings. We believe that our diagnostic products provide improved 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 throughout the healthcare system.

We produce and market our products throughout the United States (the "U.S."), selling primarily to hospitals, independent diagnostic testing facilities, 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 executive offices are located in Bedford, Massachusetts, with additional offices in North Billerica, Massachusetts; Somerset, New Jersey; Montreal, Canada; and Lund, Sweden.

Recent Developments

CEO Succession Plan

On January 23, 2024, we announced that, effective March 1, 2024, Brian Markison, our current Chair of the Board, will become our Chief Executive Officer, and Mary Anne Heino, our current Chief Executive Officer, will retire and become the Chair of the Board. As part of this leadership transition, Mr. Markison assumed the role of Executive Chair of the Board as of January 23, 2024 until the effectiveness of his Chief Executive Officer appointment in March, and Board Member Julie McHugh became Lead Independent Director.

Strategic Agreements with Perspective Therapeutics

On January 9, 2024, we announced that we entered into multiple strategic agreements with Perspective, a radiopharmaceutical company that is pursuing advanced treatment applications for cancers throughout the body. Under the agreements, we obtained an option to exclusively license Perspective's Pb212-VMT- α-NET, a clinical stage alpha therapy in development for the treatment of neuroendocrine tumors, and an option to co-develop certain early-stage therapeutic candidates targeting prostate cancer using Perspective's innovative platform technology, for an aggregate upfront payment of $28 million in cash. We also agreed to purchase up to 19.9% of Perspective's outstanding shares of common stock for up to approximately $33 million, subject to Perspective's completion of a qualified third-party financing transaction and certain other closing conditions. In addition, Perspective agreed to acquire the assets and associated lease of our radiopharmaceutical manufacturing facility in Somerset, New Jersey, subject to customary closing conditions, including regulatory approval.

On January 22, 2024, following the satisfaction of applicable closing conditions, our subsidiary, Lantheus Alpha, purchased 56,342,355 shares of Perspective's common stock at a purchase price of $0.37 per share in a private placement transaction. The total consideration for the purchase was approximately $20.8 million in cash, which resulted in Lantheus Alpha holding approximately

10.74% of Perspective's common stock as of the purchase date and retaining the right to purchase additional shares to bring its ownership up to an aggregate of 19.9%.

Exclusive License for PNT2002 and PNT2003

On December 20, 2022, we announced the closing of a set of strategic collaborations with POINT Biopharma Global Inc. ("POINT"), in which we were granted a license to exclusive worldwide rights (excluding Japan, South Korea, China (including Hong Kong, Macau, and Taiwan), Singapore, and Indonesia) to co-develop and commercialize POINT's PNT2002 and PNT2003 product candidates.

On December 27, 2023, Eli Lilly announced the completion of its acquisition of POINT. The acquisition is no expected to impact the status of the PNT2002 License Agreement, the PNT2003 License Agreement, or the work being performed in connection with those agreements and our collaboration with POINT.

PNT2002

With respect to PNT2002, POINT is generally responsible for funding and development activities required for FDA approval, including generating all clinical and nonclinical data, analysis and other information, and we are responsible for preparing for and seeking regulatory approval for PNT2002, as well as performing and funding all future development and commercialization following such approval. POINT will be responsible for all manufacturing of PNT2002, subject to certain exceptions described in the license and collaboration agreement between Lantheus Two and POINT, dated November 11, 2022 (the "PNT2002 License Agreement").

In April 2023, we announced with POINT that the FDA had granted Fast Track designation for PNT2002. Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and address unmet needs.

On December 18, 2023, we announced positive topline results from SPLASH, the Phase 3 registrational trial for PNT2002. SPLASH was designed to evaluate the efficacy and safety of PNT2002 in patients with mCRPC who have progressed following treatment with an androgen receptor pathway inhibitor ("ARPI"). The SPLASH trial met its primary endpoint, demonstrating a median radiographic progression-free survival (rPFS) per blinded independent central review of 9.5 months for patients treated with PNT2002, compared to 6.0 months for patients treated with ARPI in the control arm, a statistically significant 29% reduction in the risk of radiographic progression or death (hazard ratio ("HR") 0.71; p=0.0088). At the time of the analysis, interim overall survival (OS) results were immature (46% of protocol-specified target OS events reached), and the HR was 1.11. We expect more mature overall survival data in 2024 prior to the potential submission of a New Drug Application ("NDA").

PNT2002 demonstrated a favorable safety profile with grade ≥3 treatment-emergent adverse events (TEAEs) per Common Terminology Criteria for Adverse Events, serious TEAEs, and TEAEs leading to discontinuation occurring at lower rates in the PNT2002 arm than in the control arm (30.1%, 17.1%, and 1.9% versus 36.9%, 23.1%, and 6.2%, respectively).

The open-label study randomized 412 patients with PSMA-expressing mCRPC who had progressed on ARPI therapy and either refused or were not eligible for chemotherapy, in a 2:1 randomization ratio. At the time of the analysis, 84.6% of patients who experienced progressive disease in the control arm subsequently crossed over to receive PNT2002. SPLASH was conducted across the U.S., Canada, Europe, and the United Kingdom. Eighty percent of SPLASH patients resided in North America and approximately ten percent of all participants were Black or African American.

During 2023, we worked on establishing an EAP, for PNT2002. EAPs, which are also referred to as compassionate use programs, provide a potential pathway for patients with serious or life-threatening conditions to gain access to an investigational drug for treatment outside of a clinical trial. We expect to enroll the first patient in the EAP for PNT2002 during the first quarter of 2024.

PNT2003

With respect to PNT2003, POINT is responsible for curating all data, analysis and other information necessary for regulatory approval, and supporting us in the preparation of regulatory filings. We are responsible for preparing for and seeking regulatory approval of all such applications, as well as performing and funding all future development and commercialization following such approval. POINT will be responsible for all manufacturing of PNT2003, subject to certain exceptions described in the license and collaboration agreement between Lantheus Three and POINT, dated November 11, 2022 (the "PNT2003 License Agreement"). On January 11, 2024, we announced that our ANDA for PNT2003 had been accepted for filing by the FDA. Based on the most recent update to the FDA's online paragraph IV database listings, we believe we are the first applicant to have filed a substantially complete ANDA for Lutetium Lu 177 Dotatate containing a Paragraph IV certification under the provisions of the Hatch-Waxman Act. As the first applicant, we believe we will be eligible for 180 days of generic marketing exclusivity in the U.S. On January 26, 2024, we were sued in the District Court for the District of Delaware by Advanced Accelerator Applications USA, Inc. and Advanced Accelerator Applications SA, each a Novartis entity, for patent infringement in response to the Company's ANDA filing and Paragraph IV

certification, consistent with the process established by the Hatch-Waxman Act. Under the terms of the Hatch-Waxman Act, FDA approval of our ANDA filing could be subject to a stay of up to 30-months. If our filing is stayed for the full 30-month period and we are successful in obtaining FDA approval, we would expect to launch PNT2003 in 2026, although no assurance of that approval or timing can be assured.

For more information, see Note 21, "Acquisition of Assets" in our consolidated financial statements included herein.

Acquisition of Cerveau Technologies, Inc.

On February 6, 2023, we announced that we acquired Cerveau. Cerveau holds the rights under a license agreement to develop and commercialize MK-6240, an investigational second-generation F 18-labeled PET imaging agent that targets Tau tangles in Alzheimer's disease. Under the terms of the agreement, we paid the Selling Stockholders an upfront payment of $35.0 million in February 2023 and an additional $10.0 million in May 2023 upon the successful completion of a technology transfer. The Selling Stockholders are also eligible to receive additional development and commercial milestone payments. Additionally, we will pay double-digit royalty payments for research revenue and commercial sales. Research revenue is derived from existing partnerships with pharmaceutical companies that use MK-6240 in clinical trials and includes milestone and dose-related payments. Pursuant to the terms of the stock purchase agreement for Cerveau, certain members of the Selling Stockholders will also provide transition and clinical development services for a prescribed time following the closing of the transaction.

In September 2023, MK-6240 was granted Fast Track designation by the FDA.

For more information, see Note 21, "Acquisition of Assets" in our consolidated financial statements included herein.

Sale of RELISTOR Licensed Intangible Asset Associated with Net Sales Royalties

On August 2, 2023, we sold the right to our RELISTOR net sales royalties, which is classified as a licensed intangible asset ("RELISTOR royalty asset"), under our license agreement with Bausch; we retained the rights to future sales-based milestone payments. We received an initial payment of approximately $98.0 million in connection with the sale and we have the right to receive an additional payment from the buyer of $5.0 million if worldwide net sales of RELISTOR in 2025 exceed a specified threshold. The additional payment would be recognized upon achievement of the specified threshold. Decreases of $63.6 million of license assets and $17.5 million of associated accumulated amortization, as well as a gain of $51.8 million were recorded as a result of the sale. During the fourth quarter of 2023, the Company earned a $15 million sales-based milestone payment.

For more information, see Note 10, "Intangibles, Net and Goodwill" in our consolidated financial statements included herein.

Discontinuation of AZEDRA

On August 15, 2023, we announced our decision to discontinue the production and promotion of AZEDRA and that we would be winding down our Somerset, New Jersey manufacturing site. We will continue manufacturing AZEDRA into the first quarter of 2024, to the extent feasible, with the goal of providing doses of AZEDRA to current patients so they can complete their treatment regimen.

For more information, see Note 10, "Intangibles, Net and Goodwill" in our consolidated financial statements included herein.

Refinancing of 2019 Facility

In December 2022, we refinanced our existing credit facility, consisting of (i) a $200.0 million five-year term loan facility (the "2019 Term Facility") and (ii) a $200.0 million five-year revolving credit facility (the "2019 Revolving Facility" and, together with the 2019 Term Facility, the "2019 Facility"), with a new $100.0 million delayed draw term loan facility (the "2022 Term Facility" and, the loans thereunder, the "Term Loans") and a new $350.0 million five-year revolving credit facility (the "2022 Revolving Facility" and, together with the 2022 Term Facility, the "2022 Facility").

We used approximately $7.8 million of cash on hand to primarily repay the principal amount of the loans outstanding related to the 2019 Facility through the nine months ended September 30, 2022. In addition, we used approximately $167.6 million of cash on hand to repay in full the aggregate remaining principal amount of the loans outstanding under the 2019 Facility and to pay related interest, transaction fees and expenses.

While the 2022 Term Facility allowed for a delayed draw term loan, the loan was not drawn upon. We recorded a loss on extinguishment of debt of $0.6 million related to the write-off of unamortized debt issuance costs and debt discounts associated with the 2019 Term Facility. In addition, we incurred and capitalized $2.7 million of new deferred financing costs related to the refinancing.

Issuance of Convertible Notes

On December 8, 2022, we issued $575.0 million in aggregate principal amount of 2.625% Convertible Senior Notes due 2027 (the "Notes"), which includes $75.0 million in aggregate principal amount of the Notes sold pursuant to the full exercise of the initial purchasers' option to purchase additional Notes. The Notes were issued under an indenture, dated as of December 8, 2022 (the "Indenture"), among the Company, LMI, as Guarantor, and U.S. Bank, as Trustee. The net proceeds from the issuance of the Notes were approximately $557.8 million, after deducting the initial purchasers' discounts and offering expenses payable by us.

Key Factors Affecting Our Results

Our 2023 financial performance incorporates the results of the Cerveau Acquisition since the February 6, 2023 closing date.

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

Continued Growth of PYLARIFY

PYLARIFY, an F 18-labeled PET imaging agent targeting PSMA, was approved by the FDA in May 2021 and commercially launched in the U.S. in June 2021. PYLARIFY is indicated for PET imaging of PSMA-positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy and in men with suspected recurrence based on elevated PSA levels. Both the National Comprehensive Cancer Center guidelines and the Society for Nuclear Medicine and Molecular Imaging appropriate use criteria note that PSMA PET imaging agents, including PYLARIFY, can be used for patient selection for PSMA-targeted radioligand therapy. PYLARIFY is available through a diverse, multi-partner network of PET manufacturing facilities ("PMFs"), including both commercial and academic partners.

The successful growth of PYLARIFY is dependent on our ability to sustain PYLARIFY as the leading PSMA PET imaging agent in an increasingly competitive marketplace. PYLARIFY's competition includes two commercially available gallium-68-based PSMA imaging agents, an approved fluorine-18-based PSMA imaging agent, and other non-PSMA-based imaging agents commonly referred to as conventional imaging. We previously hired additional employees to assist us with the commercialization of PYLARIFY, including in Sales, Marketing, Reimbursement, Quality and Medical Affairs, and we will continue to make commercial investments necessary to drive PYLARIFY awareness and adoption. We believe that PYLARIFY currently has the largest dedicated field-based commercial team in the PSMA PET imaging agent space. Continued growth and revenue contribution from PYLARIFY will also depend on our ability to differentiate PYLARIFY in light of the potential loss of TPT Status, including through flexible and dependable access to PYLARIFY nationally, a best in class customer experience and through long-term strategic contracts.

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 in the hospital outpatient setting for PYLARIFY, enabling traditional Medicare to provide an incremental payment for PET/CT scans performed with PYLARIFY in that setting. TPT Status for PYLARIFY could expire on December 31, 2024.

In 2023 rulemaking for the 2024 payment calendar year, CMS recognized the challenges of patient access to diagnostic radiopharmaceuticals and requested feedback on various payment alternatives that could provide separate reimbursement for these items, but the agency did not adopt any of these proposals in the final rule, while stating that it would continue to evaluate this issue in subsequent rulemaking. We intend to submit comments in connection with CMS's 2024 rulemaking for 2025 payment calendar year to request that CMS establish separate payment for diagnostics instead of the current packaged payment following expiration of TPT Status.

Our plan to successfully grow PYLARIFY has also included highlighting its commercial and clinical value, as well as through strategic partnerships and collaborations, both for the commercialization of our product outside of the United States as well as for the use of our product potentially for additional indications or in connection with the development of PSMA-targeted therapeutics. With respect to commercializing PYLARIFY outside of the U.S., we previously licensed exclusive rights to Curium to develop and commercialize piflufolastat F 18 in Europe. In July 2023, Curium announced that it received marketing authorization for piflufolastat F 18 from the European Commission, which will be commercialized in the EU under the brand name PYLCLARI. With respect to the use of PYLARIFY in connection with the development of PSMA-targeted therapeutics, we have entered into multiple strategic collaborations with pharmaceutical companies. Additional information on collaborations using PYLARIFY are described further under Part I, Item 1. "Business - Strategic Partnerships and Other Revenue – Oncology."

In connection with the acquisition of Progenics in June 2020, we issued CVRs tied to the financial performance of PYLARIFY. We paid $99.6 million to the CVR holders during May 2023 in full satisfaction of our obligations under the CVRs.

PYLARIFY AI Use

During 2021, we announced that 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 designed 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.

During the third quarter of 2023, in collaboration with Curium, we customized and released our PYLARIFY AI platform for use in Europe. At the European Association of Nuclear Medicine meeting in Vienna, the PYLARIFY AI presentation was awarded the Top Rated Oral Presentation for response evaluation of metastatic prostate cancer patients.

Also in the third quarter of 2023, we announced a data agreement with the Prostate Cancer Clinical Trial Consortium (PCCTC) on its IRONMAN Registry for development and validation of PSMA biomarkers with PYLARIFY AI. The IRONMAN is the International Registry for Men with Advanced Prostate Cancer, the Registry is accumulating contextualized clinical and imaging data from more than 100 institutions across the globe.

During 2023, we also entered into an agreement with PIONEER (Prostate Cancer DIagnOsis and TreatmeNt Enhancement through the Power of Big Data in EuRope), led by the European Association of Urology (project Coordinator) and Bayer AG (private leader) to use our AI technology to help validate the clinical utility of PYLARIFY AI enabled PSMA biomarker to diagnose, treat and monitor prostate cancer patients. PIONEER is a European Network of Excellence for Big Data in Prostate Cancer, consisting of 34 private and public stakeholders in prostate cancer research and clinical care from across 9 countries.

Continued Growth of DEFINITY

We believe we will be able to increase use of DEFINITY through continued education of physicians and healthcare providers about the benefits of ultrasound enhancing agents in suboptimal echocardiograms. The U.S. market currently has three echocardiography ultrasound enhancing agents approved by the FDA; we estimate that DEFINITY will continue to hold at least an 80% share of the U.S. segment for ultrasound enhancing agents in echocardiography procedures.

As we continue to grow 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 six Orange Book-listed method-of-use patents, one of which expires in 2035 and five of which expire in 2037, as well as additional manufacturing patents that are not Orange Book-listed expiring in 2037. For DEFINITY RT, we have eight Orange Book-listed patents, including two composition of matter patents which expire in 2035
- *VIALMIX RFID* – DEFINITY is activated through the use of medical devices branded as VIALMIX and VIALMIX RFID. 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. The RFID tag, which is affixed to the vial label, enables the DEFINITY vial to be appropriately activated with the VIALMIX RFID activation device.
- *DEFINITY RT* - The formulation of DEFINITY that we have branded as DEFINITY RT allows both storage and shipment at room temperature and provides clinicians an additional choice and use 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 further in the paragraph entitled “Microbubble Franchise” below).

Expansion of Strategic Partnerships and Other Revenue

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 radiopharmaceutical therapeutic and diagnostic product opportunities in oncology and other strategic areas that will complement our existing portfolio.

Our Strategic Partnerships and Other Revenue category includes our Strategic Partnerships, Pharma Solutions, and Digital Solutions businesses and is focused on enabling precision medicine with biomarkers and digital solutions.

- *Strategic Partnerships* – We seek to monetize our assets through our Strategic Partnerships business, by optimizing core assets geographically and by driving value through non-core assets. For example, we have licensed the development and commercialization rights of PYLARIFY in Europe to Curium. Similarly, we licensed the commercialization rights for flurpiridaz fluorine-18 to GE Healthcare Limited.
- *Pharma Solutions* – We use our Pharma Solutions business to offer our Biomarkers and Microbubble Platforms to pharmaceutical and start-up companies to support their research and development of therapeutic drugs and devices. The strategic goal of our Pharma Solutions business is to gain early access to innovation, de-risk the development, data generation

and co-funding of our pipeline through collaborations, embed our technologies in the clinical ecosystem and establish the clinical utility of product candidates and research tools in our pipeline. Our Biomarkers are intended to support patient selection and the monitoring of disease progression. For example, piflufolastat F 18 is currently being used by Curium and Regeneron in those companies' prostate cancer therapeutic drug development programs, and was also used in the development of PNT2002. Our acquisition of Cerveau in February 2023 added MK-6240 to our biomarker portfolio. MK-6240 is currently being used in more than ninety active clinical trials for several Alzheimer's disease therapeutic candidates. Most recently, in collaboration with Ratio, we completed a Phase 1 study for LNTH-1363S, our novel fibroblast activation protein, alpha targeted, copper-64 labeled PET imaging agent candidate, to evaluate the pharmacokinetics, biodistribution and radiation dosimetry in adult healthy volunteers and plan to initiate a Phase 1/2a study in patients in 2024.

With respect to our Microbubble Platform, we generally enter into collaborations with partners that are designed to include our microbubble as part of a kit used with our partner's medical device for therapeutic applications. In these collaborations, our microbubble is intended to be used as a vehicle to deliver a therapeutic drug.

- *Digital Solutions* – Our Digital Solutions are designed to enhance imaging value and the throughput, reproducibility and reliability of image analysis, as well as to inform treatment selection and response to therapy. Our Digital Solutions include aPROMISE and aBSI (as defined below), both of which are FDA cleared and CE marked. aPROMISE, which is currently sold as PYLARIFY AI in the U.S., is artificial intelligence medical device software that is designed to allow healthcare professionals and researchers to perform standardized quantitative assessment of PSMA PET/CT images in prostate cancer, including those images obtained by using PYLARIFY. Automated Bone Scan Index ("aBSI") automatically calculates the disease burden of prostate cancer by detecting and classifying bone scan tracer uptakes as metastatic or benign lesions using an artificial neural network. The software is currently used as one of the correlative objectives of the DORA trial, an open-labeled, randomized, Phase 3 study of docetaxel versus docetaxel in combination with radium-223 (Ra-223) in subjects with mCRPC. We offer our Digital Solutions to HCPs for clinical use and to pharmaceutical companies for development purposes, and in some cases, we also obtain clinical imaging data that we may use to further develop artificial intelligence solutions.

Global Mo-99 Supply

We currently have Mo-99 supply agreements with Institute for Radioelements ("IRE"), running through December 31, 2024, 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 believe we have the most 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 negative effect on our business, results of operations, financial condition and cash flows.

Inventory Supply & Third Party Suppliers

We obtain a substantial portion of our imaging agents from third-party suppliers. Jubilant HollisterStier ("JHS") is currently a significant supplier of DEFINITY and our sole source manufacturer of NEUROLITE, CARDIOLITE and evacuation vials. Our manufacturing and supply agreement with JHS (the "JHS MSA") runs through December 31, 2027 and can be further extended by mutual agreement of the parties. The JHS MSA requires us to purchase from JHS specified percentages of our 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 JHS MSA upon the occurrence of certain events, including the material breach or bankruptcy of the other party. In addition to JHS, we rely on SBL 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 the formulation of DEFINITY that requires refrigerated storage. On February 22, 2022, we received FDA approval of our supplemental new drug application authorizing commercial manufacturing of DEFINITY at our new facility. We believe this investment provides supply chain redundancy, improved flexibility and reduced costs in a potentially more price competitive environment.

Radiopharmaceuticals are decaying radioisotopes with half-lives ranging from a few hours to several days. Radiopharmaceutical finished goods, such as doses of PYLARIFY, 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 54 PMF manufacturing sites across the U.S., with respect to PYLARIFY, and at our facilities in North Billerica, Massachusetts, with respect to our TechneLite generators and Xenon

Research and Development Expenses

To ensure we remain the leading radiopharmaceutical-focused company in our industry, we have historically made and will continue to make substantial investments in new product development and lifecycle management for existing products, including:

- For PYLARIFY, we recently enrolled the first patient in a clinical trial to determine whether PYLARIFY can accurately detect the presence or absence of prostate cancer beyond the prostate gland in patients with favorable intermediate-risk prostate cancer, as well as how it may change the patient's intended management. We are also exploring opportunities for the use of PYLARIFY beyond prostate cancer.
- For PNT2002 and PNT2003, we were granted a license to exclusive worldwide rights (excluding certain countries) for $260.0 million in upfront payments during the fourth quarter of 2022 and will potentially make additional payments as described below. We also filed an ANDA for PNT2003 as described further in the section entitled "Exclusive License for PNT2002 and PNT2003" above.
- For LNTH-1363S, in collaboration with Ratio, we recently completed a Phase 1 study for LNTH-1363S to evaluate the pharmacokinetics, biodistribution and radiation dosimetry in adult healthy volunteers. We plan to initiate a Phase 1/2a study in patients in 2024.
- For 1095, our PSMA-targeted iodine-131-labeled small molecule product candidate, we enrolled the last patient in our ARROW Phase 2 study during the second quarter of 2022. 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.

PNT2002

Under the terms of the PNT2002 License Agreement, Lantheus Two paid POINT an upfront cash payment of $250.0 million, and could pay up to an additional $281.0 million in milestone payments upon the achievement of specified U.S. and ex-U.S. regulatory milestones related to PNT2002. POINT is also eligible to receive up to $1.3 billion in sales milestone payments upon the achievement of specified annual sales thresholds of PNT2002. In addition, after Lantheus Two achieves $500.0 million in cumulative gross profit, POINT is eligible to receive royalty payments of twenty percent of net sales of PNT2002. Prior to achieving that financial recoupment threshold, POINT is eligible to receive royalty payments of twenty percent on that portion of annual net sales of PNT2002 that generate annual gross profit in excess of specified levels.

PNT2003

Under the terms of the PNT2003 License Agreement, Lantheus Three, LLC paid POINT an upfront cash payment of $10.0 million, and could pay up to an additional $34.5 million in milestone payments upon the achievement of specified U.S. and ex-U.S. regulatory milestones related to PNT2003. POINT is also eligible to receive up to $275.0 million in sales milestone payments upon the achievement of specified annual sales thresholds of PNT2003. In addition, POINT is eligible to receive royalty payments of fifteen percent of net sales of PNT2003.

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 these clinical development candidates or lifecycle management opportunities will be successful.

Strategic Partnerships and Other Revenue

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 therapeutic and diagnostic radiopharmaceutical 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 Solutions activities in oncology are designed to enable precision medicine using biomarkers and digital solutions that augment diagnostic productivity. For example, in prostate cancer, we collaborate with pharmaceutical companies by supplying them with piflufolastat F 18 for use in their therapeutic drug development programs. For immuno-oncology, we intend to offer NM-01, a novel technetium-99m SPECT imaging agent that we are developing to assess PD-L1 expression in cancer cells, for potential use as an efficacy and safety biomarker in immuno-oncology therapies. With respect to pan-oncology, we are further exploring the use of LNTH-1363S as an innovative imaging biomarker that targets fibroblast activation protein.

Microbubble Franchise

In addition, we continue to expand our microbubble franchise. Some of our microbubble collaborations are 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; (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; (iv) 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; and (v) SonoThera, which will use our microbubbles in combination with their ultrasound-guided, non-viral, gene therapy platform and treatments.

flurpiridaz

In September 2022, we announced with our strategic partner GE Healthcare Limited ("GE Healthcare") that the recent Phase 3 clinical trial of our investigational radiotracer, flurpiridaz, 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 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, and, if the imaging agent is approved, will have the global commercialization rights for it. GE Healthcare recently announced that it had filed an NDA with the FDA for flurpiridaz. Assuming regulatory approval, we anticipate commercialization by GE Healthcare beginning in the second half of 2024. If flurpiridaz 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 intellectual property, 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, 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, will be successful or accretive to earnings.

Results of Operations

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

(in thousands)	Year Ended December 31, 2023	2022	2021	2023 vs. 2022 Change $	Change %	2022 vs. 2021 Change $	Change %
Revenues	$ 1,296,429	$ 935,061	$ 425,208	$ 361,368	38.6 %	$ 509,853	119.9 %
Cost of goods sold	586,886	353,358	237,513	233,528	66.1 %	115,845	48.8 %
Gross profit	709,543	581,703	187,695	127,840	22.0 %	394,008	209.9 %
Operating expenses							
Sales and marketing	141,736	100,243	68,422	41,493	41.4 %	31,821	46.5 %
General and administrative	125,458	133,584	150,395	(8,126)	(6.1)%	(16,811)	(11.2)%
Research and development	77,707	311,681	44,966	(233,974)	(75.1)%	266,715	593.1 %
Total operating expenses	344,901	545,508	263,783	(200,607)	(36.8)%	281,725	106.8 %
Gain on sales of assets	—	—	15,263	—	N/A	(15,263)	N/A
Operating income (loss)	364,642	36,195	(60,825)	328,447	907.4 %	97,020	(159.5)%
Interest expense	20,019	7,185	7,752	12,834	178.6 %	(567)	(7.3)%
Loss (gain) on extinguishment of debt	—	588	(889)	(588)	(100.0)%	1,477	(166.1)%
Other (income) loss, net	(66,320)	1,703	7,350	(68,023)	(3,994.3)%	(5,647)	(76.8)%
Income (loss) before income taxes	410,943	26,719	(75,038)	384,224	1,438.0 %	101,757	(135.6)%
Income tax expense (benefit)	84,282	(1,348)	(3,759)	85,630	(6,352.4)%	2,411	(64.1)%
Net income (loss)	$ 326,661	$ 28,067	$ (71,279)	$ 298,594	1,063.9 %	$ 99,346	(139.4)%

Comparison of the Periods Ended December 31, 2023 and 2022

Revenues

We classify our revenues into three product categories: Radiopharmaceutical Oncology, Precision Diagnostics, and Strategic Partnerships and Other Revenue. Radiopharmaceutical Oncology consists of PYLARIFY and AZEDRA. In 2023, we announced our decision to discontinue the production and promotion of AZEDRA and we do not expect AZEDRA to contribute to the business after the first quarter of 2024. Precision Diagnostics includes DEFINITY, TechneLite and other diagnostic imaging products. Strategic Partnerships and Other Revenue primarily includes out-licensing arrangements and partnerships that focus on facilitating precision medicine through the use of biomarkers, digital solutions and radiotherapeutic platforms.

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

	Year Ended December 31,			2023 vs. 2022	
(in thousands)	2023	2022	2021	Change $	Change %
PYLARIFY	$ 851,303	$ 527,405	$ 43,414	$ 323,898	61.4 %
Other radiopharmaceutical oncology	3,130	4,102	5,473	(972)	(23.7)%
Total radiopharmaceutical oncology	854,433	531,507	48,887	322,926	60.8 %
DEFINITY	279,768	244,993	232,759	34,775	14.2 %
TechneLite	87,370	88,864	91,293	(1,494)	(1.7)%
Other precision diagnostics	22,980	22,825	26,973	155	0.7 %
Total precision diagnostics	390,118	356,682	351,025	33,436	9.4 %
Strategic Partnerships and other revenue	51,878	46,872	25,296	5,006	10.7 %
Total revenues	$ 1,296,429	$ 935,061	$ 425,208	$ 361,368	38.6 %

The increase in revenues for the year ended December 31, 2023, as compared to the prior year period, is primarily due to increased PYLARIFY and DEFINITY sales volume and RELISTOR milestone achievement of $15.0 million earned in the fourth quarter of 2023. The increase is offset, in part, by a decrease in Strategic Partnerships and Other Revenue due to the revenue recognized from the Novartis licensing agreement in the prior year described further under Note 3, "Disaggregation of Revenue" below and the sale of the RELISTOR royalty revenue asset.

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 for rebates and allowances is summarized as follows:

(in thousands)	Rebates and Allowances
Balance, January 1, 2022	$ 10,977
Provision related to current period revenues	26,683
Adjustments relating to prior period revenues	70
Payments or credits made during the period	(24,331)
Balance, December 31, 2022	13,399
Provision related to current period revenues	32,308
Adjustments relating to prior period revenues	(453)
Payments or credits made during the period	(29,184)
Balance, December 31, 2023	$ 16,070

Gross Profit

The increase in gross profit for the year ended December 31, 2023, as compared to the prior year period, is primarily due to increased PYLARIFY and DEFINITY sales volume and a RELISTOR milestone achievement, partially offset by the impairment of the AZEDRA currently marketed intangible asset, the Novartis licensing payment in the prior year, amortization of Cerveau intangible assets, and the loss of RELISTOR royalty revenue due to the sale of the asset.

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 utilization of advertising and promotional material, professional services, market research and sales meetings.

Sales and marketing expenses increased $41.5 million for the year ended December 31, 2023, as compared to the prior year period. This was primarily driven by our investment in sales and marketing efforts in support of an expansion of our PYLARIFY sales force and supporting functions intended to support and expand adoption of PYLARIFY and pre-commercialization activities for certain product candidates.

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 $8.1 million for the year ended December 31, 2023 compared to the prior year period. This was primarily driven by a $44.1 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) and an insurance settlement in 2023. These reductions were partially offset by increased employee-related costs, investments in technology, new lease expense, and increased professional fees.

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 decreased $234.0 million for the year ended December 31, 2023 as compared to the prior year period. This was primarily driven by the $260.0 million upfront payment in 2022 for the two agreements with POINT, partially offset by in-process research and development (“IPR&D”) impairment loss of $15.6 million in connection with our discontinuation of the production and promotion of AZEDRA and higher employee related costs driven by increased headcount.

Interest Expense

Interest expense for the year ended December 31, 2023 increased $12.8 million as compared to the prior year period due to the issuance of the Notes on December 8, 2022.

Loss on Extinguishment of Debt

During the year ended December 31, 2022, we realized a $0.6 million loss on extinguishment of debt related to the refinancing of our existed indebtedness. There were no extinguishments on debt for the year ended December 31, 2023.

Other (Income) Loss

Other (income) loss increased by $68.0 million for the year ended December 31, 2023 as compared to the prior year period primarily due to the gain on sale of the RELISTOR licensed intangible asset associated with net sales royalties of $51.8 million and an increase in interest income.

Income Tax Expense (Benefit)

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

	Year Ended December 31,	
	2023	2022
Effective tax rate	20.5%	(5.0)%

Our effective tax rate in fiscal 2023 differs from the U.S. statutory rate of 21% primarily due to the income tax benefits associated with stock compensation deductions, additional net operating losses available for utilization under Internal Revenue Code Section 382 as a result of the sale of our RELISTOR royalty asset, and the release of uncertain tax positions, partially offset by state income taxes.

In accordance with our accounting policy, the change in the tax liabilities, penalties and interest associated with our uncertain tax positions (net of any offsetting federal or state benefit) is recognized within income tax expense (benefit). Our uncertain tax positions include indemnified liabilities, in accordance with the Stock and Asset Purchase Agreement entered into with BMS in 2008. Changes in the liability result in offsetting changes in the indemnification receivable. As these reserves change, adjustments are included in income tax expense while the offsetting adjustment is included in other income. Assuming that the receivable from BMS continues to be considered recoverable by us, there will be no effect on net income and no net cash outflows related to these liabilities. During 2023, the Company released a significant portion of its indemnified liability due to the settlement of these positions in certain states at a cost significantly less than our accrual resulting in $5.2 million (net of federal or state benefit) income tax benefit. Refer to Note 5, Income Taxes.

Our effective tax rate in fiscal 2022 differs from the U.S. statutory rate of 21% primarily due to the income tax benefit for the release of a portion of our uncertain tax positions and the tax benefit associated with stock compensation deductions offset by tax expense from the change in fair value of contingent consideration and expense generated on the revaluation of the Company's deferred state tax rate. During 2022, the Company released a significant portion of its indemnified liability due to the settlement of these positions in various states at a cost significantly less than our accrual resulting in $9.6 million (net of federal or state benefit) income tax benefit.

Liquidity and Capital Resources

Cash Flows

The following table provides information regarding our cash flows:

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Net cash provided by operating activities	$ 305,260	$ 281,781	$ 53,916
Net cash provided by (used in) investing activities	$ 5,939	$ (276,547)	$ 3,683
Net cash (used in) provided by financing activities	$ (13,062)	$ 311,691	$ (39,332)

For a discussion of our liquidity and capital resources related to our cash flow activities for the fiscal year ended December 31, 2021, see "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of our annual report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on February 23, 2023.

Net Cash Provided by Operating Activities

Net cash provided by operating activities of $305.3 million during the year ended December 31, 2023 was primarily comprised of net income adjusted for the net effect of non-cash items such as impairment of long-lived assets, depreciation, amortization and accretion expense, gain on sale of our RELISTOR royalty asset, deferred income taxes, and stock-based compensation expense. The primary working capital sources of cash were the timing of payments to large vendors. The primary working capital uses of cash were a decrease to accruals related to the CVR payment, an increase in trade receivables associated primarily with the increase in PYLARIFY revenues, and an increase in inventory related to the timing of batch processes.

Net cash provided by operating activities of $281.8 million during the year ended December 31, 2022 was primarily comprised of net income adjusted for charges incurred in connection with acquired IPR&D and 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 $34.7 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 accruals associated with PYLARIFY sales. 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 (Used in) Investing Activities

Net cash provided by investing activities during the year ended December 31, 2023 was primarily due to net cash proceeds of $97.8 million from the sale of our RELISTOR royalty asset offset by $45.3 million for our asset acquisition of Cerveau and $46.6 million of capital expenditures.

Net cash used in investing activities during the year ended December 31, 2022 was primarily due to the $260.0 million upfront payment to POINT and the $18.3 million of capital expenditures partially offset by $1.8 million received from the sale of our Puerto Rico subsidiary.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities during the year ended December 31, 2023 is primarily attributable to the payments for minimum statutory tax withholding related to net share settlement of equity awards of $14.4 million and the CVR initial valuation as of June 30, 2020 of $3.7 million, offset by proceeds of $3.8 million from stock option exercises.

Net cash provided by financing activities during the year ended December 31, 2022 is primarily attributable to the proceeds of $557.8 million received from the issuance of the Notes, proceeds of $7.5 million from stock option exercises and proceeds of $5.6 million from the voluntarily terminated interest rate swap contracts in connection with the refinancing of debt. These amounts were offset by payments on long-term debt and other borrowings of $175.0 million, repurchase of common stock of $75.0 million and payments for minimum statutory tax withholding related to net share settlement of equity awards of $7.8 million.

External Sources of Liquidity

In December 2022, we voluntarily repaid our 2019 $200.0 million five-year term loan facility. In addition, we replaced our $200.0 million revolving facility with the 2022 Revolving Facility. The terms of the 2022 Revolving Facility are set forth in the Credit Agreement, dated as of December 2, 2022, by and among us, the lenders from time to time party thereto and Citizens Bank, N.A., as administrative agent and collateral agent (the "2022 Credit Agreement"). We have the right to request an increase to the 2022 Revolver Facility or request the establishment of one or more new incremental term loan facilities, in an aggregate principal amount of up to $335.0 million or consolidated EBITDA for the four consecutive fiscal quarters most recently ended, plus additional amounts, in certain circumstances.

The Company used approximately $7.8 million of cash on hand to primarily repay the principal amount of the loans outstanding related to the 2019 Facility through the nine months ended September 30, 2022. In addition, in December 2022, the Company used approximately $167.6 million of cash on hand to repay in full the aggregate remaining principal amount of the loans outstanding under the 2019 Facility and to pay related interest, transaction fees and expenses.

Under the terms of the 2022 Revolving Facility, the lenders thereunder agreed to extend credit to us from time to time until December 2, 2027 consisting of revolving loans in an aggregate principal amount not to exceed $350.0 million at any time. The 2022 Revolving Facility includes a $20.0 million sub-facility for the issuance of letters of credit (the "Letters of Credit"). The 2022 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 2022 Revolving Facility are expected to be used for working capital and other general corporate purposes.

Please refer to Note 12, "Long-Term Debt, Net, and Other Borrowings" for further details on the 2022 Facility.

As of December 31, 2023, we were in compliance with all financial and other covenants under the 2022 Credit Agreement.

On December 8, 2022, we issued $575.0 million in aggregate principal amount of the Notes, which includes $75.0 million in aggregate principal amount of Notes sold pursuant to the full exercise of the initial purchasers' option to purchase additional Notes. The Notes were issued under an indenture, dated as of December 8, 2022 (the "Indenture"), among the Company, LMI, as Guarantor, and U.S. Bank, as Trustee. The net proceeds from the issuance of the Notes were approximately $557.8 million, after deducting the initial purchasers' discounts and offering expenses payable by us.

On March 31, 2021, we voluntarily repaid in full the entire outstanding principal on outstanding debt of Progenics that we assumed as a result of the Progenics Acquisition. The total amount we paid was $30.9 million, which included a prepayment amount of $0.5 million.

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 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 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;
- 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 our products;
- Our investment in the further clinical development and commercialization of products and development candidates, including PNT2002, PNT2003, 1095 and MK-6240;
- The costs of acquiring or in-licensing, developing, obtaining regulatory approval for, and commercializing, new products, businesses or technologies, including any potential related milestone or royalty payments, together with the costs of pursuing opportunities that are not eventually consummated;
- 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, particularly in international markets, including product marketing, sales and distribution and whether we obtain local partners to help share such commercialization costs;
- 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, including the patent infringement claim related to the filing of our ANDA for PNT2003;
- 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.

Disruption in our financial performance could 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 further 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 2022 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 2022 Credit Agreement, which could result in additional expenses associated with obtaining the amendment or waiver, we will seek to obtain such an amendment or waiver to remain in compliance with those covenants. However, we cannot provide assurance that such an amendment or waiver would be granted, or that additional capital will be available on acceptable terms, if at all.

At December 31, 2023, our only current committed external source of funds is our borrowing availability under our 2022 Revolving Facility. We had $713.7 million of cash and cash equivalents as of December 31, 2023. Our 2022 Revolving Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. Incremental borrowings under the 2022 Revolving Facility may affect our ability to comply with the covenants including the financial covenants restricting consolidated net leverage and interest coverage. Accordingly, we may be limited in utilizing the full amount of our 2022 Revolving Facility as a source of liquidity.

Based on our current operating plans, we believe our balance of cash and cash equivalents, which totaled $713.7 million as of December 31, 2023, along with cash generated by ongoing operations and continued access to our 2022 Revolving Facility, will be sufficient to satisfy our cash requirements over the next twelve months and beyond. Our material cash requirements include the following contractual and other obligations.

Debt

We completed a sale of $575.0 million in aggregate principal amount of the Notes due in 2027. As of December 31, 2023, we had no amounts of principal due within the next twelve months. Future interest payments associated with the Notes total $60.0 million, with $15.1 million payable within twelve months.

Leases

We have operating lease arrangements for certain facilities, including corporate and manufacturing space. As of December 31, 2023, we had fixed operating lease payment obligations of $99.5 million, with $4.6 million payable within twelve months.

We have lease arrangements for certain equipment. As of December 31, 2023, we had fixed finance lease payment obligations of $1.7 million, with $0.8 million payable within twelve months.

Purchase Obligations

We have purchase obligations that primarily consist of noncancelable obligations related to minimum quantities of goods or services that have been committed to be purchased on an annual basis. As of December 31, 2023, we had minimum purchase obligations of $10.9 million, with $2.7 million due within twelve months.

License Agreements

We have entered into license agreements in which fixed payments have been committed to be paid on an annual basis. As of December 31, 2023, we had no amount of fixed license payments due within twelve months. These amounts do not include potential milestone or contractual payment obligations contingent upon the achievement or occurrence of future milestones or events under our license agreements, because they are contingent and the amounts and timing of such potential obligations are unknown or uncertain. We may be required to pay additional amounts up to approximately $264.4 million in contingent payments under our license agreements.

Asset Acquisitions

During 2022, we entered into the POINT License Agreements, in which we made upfront payments of $260.0 million, and under which we may make additional milestone payments. The additional milestone payments are based on FDA approval and net sales and commercial milestones. Under the terms of the PNT2002 License Agreement, we have the potential to pay up to an additional $281.0 million in milestone payments and up to $1.3 billion in sales milestone payments upon the achievement of specified annual sales thresholds. Under the terms of the PNT2003 License Agreement, we have the potential to pay an additional $34.5 million in milestone payments and up to $275.0 million in sales milestone payments upon the achievement of specified annual sales thresholds. In total, we may be required to pay up to approximately $1.8 billion related to the asset acquisition. As of December 31, 2023, these contingent payments were not expected to be payable due to the uncertainty around the timing of the future cash flows.

On February 6, 2023, the Company acquired Cerveau and made an upfront payment of approximately $35.3 million to the Selling Stockholders. The Company paid the Selling Stockholders an additional $10.0 million in May 2023 upon the successful completion of a technology transfer. The Company could pay up to an additional $51.0 million in milestone payments upon achievement of specified U.S. regulatory milestones related to MK-6240. The Selling Stockholders are also eligible to receive up to $1.2 billion in sales milestone payments upon the achievement of specified annual commercial sales thresholds of MK-6240 in the event the Company pursues commercialization, as well as up to $13.5 million in research revenue milestones upon achievement of specified annual research revenue thresholds. Additionally, the Company will pay to the Selling Stockholders up to double-digit royalty payments for research revenue and commercial sales. As of December 31, 2023, these contingent payments were not expected to be payable due to the uncertainty around the timing of the future cash flows.

Other Long-Term Liabilities

Our other long-term liabilities in the consolidated balance sheet include the fair values of contingent consideration liabilities including contingent consideration liabilities related to a previous acquisition completed by Progenics in 2013. We may be required to pay up to approximately $85.0 million related to the contingent consideration. As of December 31, 2023, these contingent payments were not expected to be payable within twelve months due to the uncertainty around the timing of the future cash flows.

Our other long-term liabilities in the consolidated balance sheet include unrecognized tax benefits and related interest and penalties. As of December 31, 2023, we had unrecognized tax benefits of $3.2 million, which included interest and penalties, classified as noncurrent liabilities. At this time, we are unable to make a reasonably reliable estimate of the timing of payments in individual years in connection with these tax liabilities.

Asset Retirement Obligation

We are required to provide the Massachusetts Department of Public Health and the 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, respectively, upon closure. We have provided this financial assurance in the form of a $30.3 million surety bond (the "Surety Bond"). As of December 31, 2023, the liability, which was approximately $22.9 million, was measured at the present value of the obligation expected to be incurred of approximately $25.1 million. These contingent payments are not expected to be payable within twelve months due to the uncertainty around the timing of the future cash flows related to the decommissioning of our radioactive operations.

Off-Balance Sheet Arrangements

As noted above, we have provided the Surety Bond to the Massachusetts Department of Public Health and New Jersey Department of Environmental Protection.

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

Effects of Inflation

We do not believe that inflation has had a significant impact on our revenues or results of operations. We expect our cost of product sales and other operating expenses will 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 and contract services, 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 some of 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.

Recent Accounting Standards

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying consolidated financial statements located under Item 8 of this Annual Report on Form 10-K for information regarding recently issued accounting standards that may have a significant impact on our business.

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements require 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.

We believe the following represent our critical accounting estimates used in the preparation of our financial statements.

Revenue from Contracts with Customers

Revenue is measured based on a consideration specified in a contract with a customer, and excludes any sales incentives and amounts collected on behalf of third parties. We recognize revenue when we satisfy our performance obligations by transferring control over products or services to our customers. The amount of revenue we recognize reflects the consideration to which we expect to be entitled to receive in exchange for these goods or services. To achieve this core principle, we apply the following five steps: (1) identify the contracts with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) we satisfy performance obligations.

We derive our revenues through arrangements with customers for product sales as well as licensing and royalty arrangements. We sell our products primarily to hospitals, independent diagnostic testing facilities, and radiopharmacies, and we consider customer purchase orders, which in some cases are governed by master sales or group purchasing organization agreements, to be contracts with

our customers. In addition to these arrangements, we also enter into licensing agreements under which we license certain rights to third parties. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products. We analyze various factors requiring management judgment when applying the five-step model to our contracts with customers.

Our product revenues are recorded at the net sales price (transaction price), which represents our sales price less estimates related to reserves which are established for items such as discounts, returns, rebates and allowances that may be provided for in certain contracts with our customers. Judgment is used in determining and updating our reserves on an ongoing basis, and where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which it is entitled based on the terms of the contract. Actual amounts of consideration ultimately received may differ from our estimates.

For our licensing and royalty arrangements, we use judgment in determining the number of performance obligations in a license agreement by assessing whether the license is distinct or should be combined with another performance obligation as well as the nature of the license. As part of the accounting for these arrangements, we develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in a contract. These key assumptions may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

Business Combinations

We account for business combinations using the acquisition method of accounting. We recognize the assets acquired and liabilities assumed in business combinations on the basis of their fair values at the date of acquisition. We assess the fair value of assets acquired, including intangible assets, and liabilities assumed using a variety of methods. Each asset acquired and liability assumed is measured at fair value from the perspective of a market participant. The method used to estimate the fair values of intangible assets incorporates significant assumptions regarding the estimates a market participant would make in order to evaluate an asset, including a market participant’s use of the asset and the appropriate discount rates. Acquired IPR&D is recognized at fair value and initially characterized as an indefinite-lived intangible asset, irrespective of whether the acquired IPR&D has an alternative future use. Any excess purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill. Transaction costs and restructuring costs associated with a business combination are expensed as incurred.

The fair values assigned to tangible and intangible assets acquired and liabilities assumed are based on our estimates and assumptions, as well as other information we have compiled, including valuations that utilize customary valuation procedures and techniques. If the actual results differ from the estimates and assumptions used in these estimates, it could result in a possible impairment of the intangible assets and goodwill, a required acceleration of the amortization expense of finite-lived intangible assets or the recognition of additional consideration, which would be expensed.

During the measurement period, which extends no later than one year from the acquisition date, we may record certain adjustments to the carrying value of the assets acquired and liabilities assumed with the corresponding offset to goodwill. After the measurement period, all adjustments are recorded in the consolidated statements of operations as operating expenses or income.

Intangible and Long-Lived Assets

We test intangible and long-lived assets for recoverability whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets may not be recoverable. We measure the recoverability of assets to be held and used by comparing the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If those assets are considered to be impaired, the impairment equals the amount by which the carrying amount of the assets exceeds the fair value of the assets. Any impairments are recorded as permanent reductions in the carrying amount of the assets. Long-lived assets, other than goodwill and other intangible assets, that are held for sale are recorded at the lower of the carrying value or the fair market value less the estimated cost to sell.

Intangible assets, consisting of trademarks, customer relationships, currently marketed products, licenses and developed technology are amortized in a method equivalent to the estimated utilization of the economic benefit of the asset.

Costs of IPR&D intangible assets acquired as part of an asset acquisition that have no alternative future use are expensed when incurred. Milestone payments made after regulatory approval are capitalized as an intangible asset and amortized over an estimated useful life of the product. Cash payments related to acquired IPR&D intangible assets are reflected as an investing cash flow in the Company's consolidated statement of cash flows.

Our IPR&D intangible assets include intangible assets acquired in a business combination that are used in research and development activities but have not yet reached technological feasibility, regardless of whether they have alternative future use. The primary basis for determining the technological feasibility or completion of these projects is whether we have obtained regulatory approval to market the underlying products in an applicable geographic region. Because obtaining regulatory approval can include significant risks and uncertainties, the eventual realized value of the acquired IPR&D projects may vary from their fair value at the date of acquisition. We classify IPR&D intangible assets acquired in a business combination as an indefinite-lived intangible asset until the completion or abandonment of the associated research and development efforts. Upon completion of the associated research and development efforts, we will determine the useful life and begin amortizing the assets to reflect their use over their remaining lives. Upon permanent abandonment, we write-off the remaining carrying amount of the associated IPR&D intangible asset. We test our IPR&D intangible assets at least annually or when a triggering event occurs that could indicate a potential impairment and we recognize any impairment loss in our consolidated statements of operations.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk from changes in interest rates and foreign currency exchange rates. We may from time to time use derivative financial instruments or other financial instruments to hedge these economic exposures related to foreign currencies. We do not hold or issue financial instruments for trading purposes.

Interest Rate Risk

We are subject to interest rate risk in connection with our 2022 Revolving Facility, which is variable rate indebtedness. Interest rate changes could increase the amount of our interest payments and thus negatively impact our future earnings and cash flows. As of December 31, 2023, there was availability of $350.0 million on the 2022 Revolving Facility. Any increase in the interest rate under the 2022 Revolving Facility may have a negative impact on our future earnings to the extent we have outstanding borrowings under the 2022 Revolving Facility.

We had used interest rate swaps to reduce the variability in cash flows associated with a portion of our forecasted interest payments on its variable rate debt. We voluntarily terminated our interest rate swap contracts on December 2, 2022.

Foreign Currency Risk

We face exposure to movements in foreign currency exchange rates whenever we, or any of our subsidiaries, enter into transactions with third parties that are denominated in currencies other than our, or that subsidiary's, functional currency. Intercompany transactions between entities that use different functional currencies also expose us to foreign currency risk.

During the years ended December 31, 2023, 2022 and 2021, the net impact of foreign currency changes on transactions was a loss of less than $0.1 million, $0.3 million and $0.3 million, respectively. From time to time, we enter into foreign currency forward contracts primarily to reduce the effects of fluctuating foreign currency exchange rates. We may enter into additional foreign currency forward contracts when deemed appropriate. We do not enter into foreign currency forward contracts for speculative or trading purposes.

The Canadian dollar presents the primary currency risk on our earnings. At December 31, 2023, a hypothetical 10% change in value of the U.S. dollar relative to the Canadian dollar would not have materially affected our financial instruments.

Item 8. Financial Statements and Supplementary Data

LANTHEUS HOLDINGS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Lantheus Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Lantheus Holdings, Inc. and subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive income (loss), changes in stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 22, 2024, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Intangible Assets — Non-Cash Impairment Charge for AZEDRA Intangible Asset Group — Refer to Note 10 to the financial statements

Critical Audit Matter Description

In March 2023, the Company stopped all development activities in relation to a future indication associated with AZEDRA, which was classified as an in-process research and development ("IPR&D") intangible asset. The asset group, which consisted of the IPR&D asset and a currently marketed product (the "AZEDRA intangible asset group"), was assessed for impairment. The Company considered several factors in estimating the future projections of revenues and cash flows of the AZEDRA intangible asset group as part of the impairment testing. The Company concluded that the carrying amount exceeded the fair value of the AZEDRA intangible asset group, which had no value. As a result of such assessment, the Company recorded a non-cash impairment charge in research and development expenses relating to the IPR&D asset and a non-cash impairment charge in cost of goods sold relating to the currently marketed indication of AZEDRA in the consolidated statement of operations for the year ended December 31, 2023.

We identified management's estimates of future projections of revenue and cash flows used to determine the fair value of the AZEDRA intangible asset group used to record the non-cash impairment charge as a critical audit matter because of the significant estimates made by management. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of management's estimates of future projections of revenues and cash flows.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to management's estimates of future revenues and cash flows used to record the non-cash impairment charge for the AZEDRA intangible asset group included the following, among others:

- We tested the effectiveness of controls over management's review of the estimates of future projections of revenue and cash flows used to record the non-cash impairment charge for the AZEDRA intangible asset group.
- We assessed the reasonableness of management's estimates of future projections of revenues and cash flows for the AZEDRA intangible asset group by:
    - Comparing historical results to the Company's strategic plans.
    - Making inquiries of management and corroborating inquiries with the Company's strategic planning group.
    - Reading internal communications to management and the Board of Directors.
- We evaluated whether the estimates of future projections of revenues and cash flows for AZEDRA were consistent with evidence obtained in other areas of the audit.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 22, 2024

We have served as the Company's auditor since 2007.

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

	December 31,	
	2023	2022
Assets		
Current assets		
Cash and cash equivalents	$ 713,656	$ 415,652
Accounts receivable, net	284,292	213,397
Inventory	64,029	35,475
Other current assets	16,683	13,092
Assets held for sale	7,159	—
Total current assets	1,085,819	677,616
Property, plant and equipment, net	146,697	122,166
Intangibles, net	151,985	315,285
Goodwill	61,189	61,189
Deferred tax assets, net	150,198	110,647
Other long-term assets	55,261	34,355
Total assets	$ 1,651,149	$ 1,321,258
Liabilities and stockholders' equity		
Current liabilities		
Current portion of long-term debt and other borrowings	$ 823	$ 354
Accounts payable	41,189	20,563
Short-term contingent liability	—	99,700
Accrued expenses and other liabilities	145,338	127,084
Total current liabilities	187,350	247,701
Asset retirement obligations	22,916	22,543
Long-term debt, net and other borrowings	561,670	557,712
Other long-term liabilities	63,321	46,155
Total liabilities	835,257	874,111
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; 69,863 and 68,851 shares issued as of December 31, 2023 and 2022, respectively)	699	689
Additional paid-in capital	757,727	715,875
Treasury Stock at cost - 1,339 shares as of December 31, 2023 and 2022	(75,000)	(75,000)
Retained earnings (accumulated deficit)	133,503	(193,158)
Accumulated other comprehensive loss	(1,037)	(1,259)
Total stockholders' equity	815,892	447,147
Total liabilities and stockholders' equity	$ 1,651,149	$ 1,321,258

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

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

	Year Ended December 31,		
	2023	**2022**	**2021**
Revenues	$ 1,296,429	$ 935,061	$ 425,208
Cost of goods sold	586,886	353,358	237,513
Gross profit	709,543	581,703	187,695
Operating expenses			
Sales and marketing	141,736	100,243	68,422
General and administrative	125,458	133,584	150,395
Research and development	77,707	311,681	44,966
Total operating expenses	344,901	545,508	263,783
Gain on sales of assets	—	—	15,263
Operating income (loss)	364,642	36,195	(60,825)
Interest expense	20,019	7,185	7,752
Loss (gain) on extinguishment of debt	—	588	(889)
Other (income) loss, net	(66,320)	1,703	7,350
Income (loss) before income taxes	410,943	26,719	(75,038)
Income tax expense (benefit)	84,282	(1,348)	(3,759)
Net income (loss)	$ 326,661	$ 28,067	$ (71,279)
Net income (loss) per common share:			
Basic	$ 4.79	$ 0.41	$ (1.06)
Diluted	$ 4.65	$ 0.40	$ (1.06)
Weighted-average common shares outstanding:			
Basic	68,266	68,487	67,486
Diluted	70,239	70,671	67,486

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

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

	Year Ended December 31,		
	2023	2022	2021
Net income (loss)	$ 326,661	$ 28,067	$ (71,279)
Other comprehensive income:			
Foreign currency translation	222	(505)	(124)
Realized loss on cash flow hedges, net of tax	—	(269)	—
Unrealized gain on cash flow hedges, net of tax	—	—	1,687
Total other comprehensive income (loss)	222	(774)	1,563
Comprehensive income (loss)	$ 326,883	$ 27,293	$ (69,716)

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

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

	Common Stock		Treasury Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance, January 1, 2021	66,875	$ 669	—	$ —	$ 665,530	$ (149,946)	$ (2,048)	$ 514,205
Net loss	—	—	—	—	—	(71,279)	—	(71,279)
Other comprehensive loss	—	—	—	—	—	—	1,563	1,563
Stock option exercises and employee stock plan purchases	360	3	—	—	6,059	—	—	6,062
Vesting of restricted stock awards	611	6	—	—	(6)	—	—	—
Shares withheld to cover taxes	(107)	(1)	—	—	(2,045)	—	—	(2,046)
Stock-based compensation	—	—	—	—	15,934	—	—	15,934
Balance, December 31, 2021	67,739	677	—	—	685,472	(221,225)	(485)	464,439
Net income	—	—	—	—	—	28,067	—	28,067
Other comprehensive income	—	—	—	—	—	—	(774)	(774)
Stock option exercises and employee stock plan purchases	411	4	—	—	8,908	—	—	8,912
Vesting of restricted stock awards	845	9	—	—	(9)	—	—	—
Shares withheld to cover taxes	(144)	(1)	—	—	(7,758)	—	—	(7,759)
Repurchase of common stock	—	—	1,339	(75,000)	—	—	—	(75,000)
Stock-based compensation	—	—	—	—	29,262	—	—	29,262
Balance, December 31, 2022	68,851	689	1,339	(75,000)	715,875	(193,158)	(1,259)	447,147
Net income	—	—	—	—	—	326,661	—	326,661
Other comprehensive loss	—	—	—	—	—	—	222	222
Stock option exercises and employee stock plan purchases	245	2	—	—	5,747	—	—	5,749
Vesting of restricted stock awards and units	962	10	—	—	(10)	—	—	—
Shares withheld to cover taxes	(195)	(2)	—	—	(14,392)	—	—	(14,394)
Stock-based compensation	—	—	—	—	50,507	—	—	50,507
Balance, December 31, 2023	69,863	$ 699	1,339	$ (75,000)	$ 757,727	$ 133,503	$ (1,037)	$ 815,892

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

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

	Year Ended December 31,		
	2023	2022	2021
Operating activities			
Net income (loss)	$ 326,661	$ 28,067	$ (71,279)
Adjustments to reconcile net income (loss) to net cash flows from operating activities:			
Depreciation, amortization and accretion	60,043	47,929	42,288
Impairment of long-lived assets	138,050	—	9,729
Asset retirement obligation acceleration	—	280	5,259
Gain on interest rate swap termination	—	(5,494)	—
Amortization of debt related costs	4,300	1,249	676
Changes in fair value of contingent assets and liabilities	(9,275)	34,700	72,400
Charges incurred in connection with acquired IPR&D	—	260,000	—
Loss (gain) on extinguishment of debt	—	588	(889)
Provision for excess and obsolete inventory	7,914	7,145	4,057
Stock-based compensation	50,507	29,262	15,934
Gain on disposal of assets	(51,789)	—	(15,263)
Deferred taxes	(55,632)	(48,016)	4,437
Long-term indemnification receivable	3,929	9,554	7,121
Long-term income tax payable and other long-term liabilities	(3,103)	(12,477)	(7,912)
Other	4,855	4,059	2,512
Changes in assets and liabilities which provided (used) cash:			
Accounts receivable	(68,637)	(128,460)	(33,102)
Inventory	(36,220)	(7,508)	(3,549)
Other current assets	(2,418)	(2,440)	(73)
Other long-term assets	—	(533)	—
Accounts payable	17,189	301	5,425
Accrued expenses and other liabilities	(81,114)	63,575	16,145
Net cash provided by operating activities	305,260	281,781	53,916
Investing activities			
Capital expenditures	(46,555)	(18,347)	(12,140)
Proceeds from sale of assets, net	97,839	1,800	15,823
Acquisition of assets	(45,345)	(260,000)	—
Net cash provided by (used in) investing activities	5,939	(276,547)	3,683
Financing activities			
Proceeds from issuance of common stock	1,933	1,375	767
Debt issuance costs	—	(95)	—
Proceeds from issuance of long-term debt, net	—	557,750	—
Contingent value rights settlement	(3,700)	—	—
Payments on long-term debt and other borrowings	(717)	(175,385)	(43,348)
Deferred financing costs	—	(2,315)	—
Proceeds from interest rate swap termination	—	5,583	—
Proceeds from stock option exercises	3,816	7,537	5,295
Payments for minimum statutory tax withholding related to net share settlement of equity awards	(14,394)	(7,759)	(2,046)
Repurchase of common stock	—	(75,000)	—
Net cash (used in) provided by financing activities	(13,062)	311,691	(39,332)
Effect of foreign exchange rates on cash and cash equivalents	(93)	(335)	(310)
Net increase in cash and cash equivalents and restricted cash	298,044	316,590	17,957
Cash and cash equivalents and restricted cash, beginning of year	417,241	100,651	82,694
Cash and cash equivalents and restricted cash, end of year	$ 715,285	$ 417,241	$ 100,651

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

	Year Ended December 31,		
	2023	2022	2021
Reconciliation to amounts within the consolidated balance sheets			
Cash and cash equivalents	$ 713,656	$ 415,652	$ 98,508
Restricted cash included in other long-term assets	1,629	1,589	2,143
Cash, cash equivalents and restricted cash at end of period	$ 715,285	$ 417,241	$ 100,651

	Year Ended December 31,		
	2023	2022	2021
Supplemental disclosure of cash flow information			
Cash paid during the period for:			
Interest	$ 15,387	$ 5,064	$ 6,284
Income taxes, net of refunds of $25, $50 and $315, respectively	$ 151,579	$ 54,049	$ 215
Schedule of non-cash investing and financing activities			
Additions of property, plant and equipment included in liabilities	$ 6,978	$ 2,370	$ 1,262
Right-of-use asset obtained in exchange for operating lease liabilities	$ 29,396	$ 11,019	$ 683

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

Lantheus Holdings, Inc.
Notes to Consolidated Financial Statements

1. Description of Business

Lantheus Holdings, Inc., a Delaware corporation, is the parent company of Lantheus Medical Imaging, Inc. ("LMI") and LMI is the parent company of Progenics Pharmaceuticals, Inc., a Delaware corporation ("Progenics"), and Cerveau Technologies, Inc. ("Cerveau"). See "Progenics Acquisition" and "Acquisition of Assets", respectively.

The Company develops, manufactures and commercializes innovative diagnostic and therapeutic products that assist clinicians in the diagnosis and treatment of cancer, heart disease and other diseases. The Company believes its diagnostic products result in improved diagnostic information that enables healthcare providers to better detect and characterize, or rule out, disease, potentially achieving improved patient outcomes, reducing patient risk and limiting overall costs throughout the healthcare system.

The Company's commercial products are used by cardiologists, internal medicine physicians, nuclear medicine physicians, oncologists, radiologists, sonographers, technologists, and urologists working in a variety of clinical settings.

The Company produces and markets its products throughout the U.S., selling primarily to hospitals, independent diagnostic testing facilities, and radiopharmacies. The Company sells its 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.

Sales of the Company's prostate cancer diagnostic imaging agent, PYLARIFY (as defined below), are generated in the U.S. through an internal PYLARIFY sales team, as well as a sales team at some of the Company's positron emission tomography ("PET") manufacturing facilities ("PMF") partners. Sales of the Company's ultrasound enhancing agent, DEFINITY, are generated in the U.S. through an internal DEFINITY sales team. In the U.S., the Company's other nuclear imaging products, including TechneLite, Xenon, NEUROLITE and CARDIOLITE, are primarily sold to commercial radiopharmacies, the majority of which are controlled by or associated with PharmaLogic, Cardinal, RLS, UPPI, and Jubilant Radiopharma. Research revenue is derived from existing partnerships with pharmaceutical companies that use our products and product candidates in clinical trials and includes milestone and dose-related payments. A small portion of the Company's nuclear imaging product sales in the U.S. are generated through the Company's internal sales force to hospitals and clinics that maintain their own in-house radiopharmaceutical preparation capabilities.

In Europe, Australia, Asia-Pacific, Central America and South America, the Company generally relies on third-party distributors to market, sell and distribute its nuclear imaging and ultrasound enhancing agent products, either on a country-by-country basis or on a multi-country regional basis. The Company's executive offices are located in Bedford, MA, with additional offices in North Billerica, MA, Somerset, NJ, Montreal, Canada and Lund, Sweden.

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").

In connection with the Progenics Acquisition, Lantheus Holdings issued 26,844,877 shares of Lantheus Holdings common stock and 86,630,633 contingent value rights (each a "CVR") tied to the financial performance of PYLARIFY to former Progenics stockholders and option holders. Each CVR entitled its holder to receive a pro rata share of aggregate cash payments equal to 40% of United States ("U.S.") net sales generated by PYLARIFY in 2022 and 2023 in excess of $100.0 million and $150.0 million, respectively. 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, was capped at 19.9% of the total consideration the Company paid in the Progenics Acquisition. Based on the Company's 2022 PYLARIFY net sales, the Company determined that the aggregate payment obligation under the CVRs was $99.6 million, which was the maximum amount payable. The Company paid out this amount in May 2023 in full satisfaction of the CVRs.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with U.S. GAAP. The consolidated financial statements include the accounts of the Company and its direct and indirect wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. The estimates reflected in the Company's consolidated financial statements include, but are not limited to, certain judgments regarding revenue recognition, goodwill, tangible and intangible asset valuation, inventory valuation, asset retirement obligations, contingent assets and liabilities, income tax liabilities and related indemnification receivable, deferred tax assets and liabilities and accrued expenses. Actual results could materially differ from those estimates or assumptions.

Revenue Recognition

The Company recognizes revenue when it transfers control of promised goods or services to its customers in an amount that reflects the consideration to which the Company expects to be entitled to in exchange for those goods and services. See Note 3, "Revenue from Contracts with Customers" for further discussion on revenues.

Accounts Receivable, net

Accounts receivable consist of amounts billed and currently due from customers. The Company maintains an allowance for doubtful accounts for estimated losses. In determining the allowance, consideration includes the probability of recoverability based on past experience and general economic factors. Certain accounts receivable may be fully reserved when the Company becomes aware of any specific collection issues. The Company periodically reviews the aging of receivables, payment history and customer creditworthiness to determine if adjustments to the allowance for doubtful accounts is necessary. Allowance for doubtful accounts has been immaterial for all years presented.

Income Taxes

The Company accounts for income taxes using an asset and liability approach. Income tax (benefit) expense represents income taxes paid or payable for the current year plus the change in deferred taxes during the year. Deferred taxes result from differences between the financial and tax bases of the Company's assets and liabilities. Deferred tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those tax attributes are expected to be recovered or paid, and are adjusted for changes in tax rates and tax laws when such changes are enacted.

The Company recognizes deferred tax assets to the extent that the Company believes that these assets are more-likely-than-not to be realized. Valuation allowances are recorded to reduce deferred tax assets when it is more-likely-than-not that the future tax benefit will not be realized. The assessment of whether or not a valuation allowance is required involves weighing both positive and negative evidence, including both historical and prospective information, with greater weight given to evidence that is objectively verifiable. A history of recent losses is negative evidence that is difficult to overcome with positive evidence. In evaluating prospective information there are four sources of taxable income: reversals of taxable temporary differences, items that can be carried back to prior tax years (such as net operating losses), pre-tax income, and prudent and feasible tax planning strategies. Adjustments to the deferred tax valuation allowances are made in the period when those assessments are made.

The Company accounts for uncertain tax positions using a two-step recognition threshold and measurement analysis method to determine the financial statement impact of uncertain tax positions taken or expected to be taken in a tax return. Differences between tax positions taken in a tax return and amounts recognized in the financial statements are recorded as adjustments to other long-term assets and liabilities, or adjustments to deferred taxes, or both. The Company records the related interest and penalties to income tax (benefit) expense.

Net Income (Loss) per Common Share

The Company computes earnings per share using the two-class method. Basic earnings per common share is computed by dividing net income by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per common share is computed by dividing net income by the weighted-average number of shares of common stock outstanding during the period, plus the potential dilutive effect of other securities as if those securities were converted or exercised. The Company's potentially dilutive shares, which could include shares issuable upon conversion of the 2.625% Convertible Senior Notes due 2027 (the "Notes"), are considered to be common stock equivalents and are only included in the calculation of diluted net income per share when their effect is dilutive. The Company has the option to settle the Notes through cash settlement or a combination of cash and share settlement provided that the principal is settled in cash and the conversion spread is settled in cash or shares as elected by the Company. The Company applies the if-converted method for diluted earnings in order to reflect the conversion spread. During periods in which the Company incurs net losses, both basic and diluted loss per common share is calculated by dividing the net loss by the weighted-average shares of common stock outstanding and potentially dilutive securities are excluded from the calculation because their effect would be antidilutive.

Cash and Cash Equivalents

Cash and cash equivalents include savings deposits, certificates of deposit and money market funds that have original maturities of three months or less when purchased.

Restricted Cash

Restricted cash as of December 31, 2023 and 2022, represents primarily collateral for a letter of credit securing a lease obligation and a security deposit. The Company believes the carrying value of these assets approximates fair value.

Concentration of Risks and Limited Suppliers

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of trade accounts receivable. The Company periodically reviews its accounts receivable for collectability and provides for an allowance for doubtful accounts to the extent that amounts are not expected to be collected. The Company sells primarily to hospitals, independent diagnostic testing facilities, and radiopharmacies.

As of December 31, 2023 and 2022, no customer accounted for greater than 10% of accounts receivable, net. No customer accounted for greater than 10% of revenues for the years ended December 31, 2023, 2022 and 2021.

The Company relies on certain materials used in its development and manufacturing processes, some of which are procured from only one or a few sources. The failure of one of these suppliers to deliver on schedule could delay or interrupt the manufacturing or commercialization process and would adversely affect the Company's operating results. In addition, a disruption in the commercial supply of, or a significant increase in the cost of one of the Company's materials from these sources could have a material adverse effect on the Company's business, financial position and results of operations.

The Company currently relies on JHS as its significant manufacturer of DEFINITY and its sole source manufacturer of NEUROLITE, CARDIOLITE and evacuation vials for TechneLite. The Company relies on Samsung Biologics Co., Ltd. ("SBL") as its sole source manufacturer of DEFINITY RT. The Company has Mo-99 supply agreements with IRE of Belgium, running through December 31, 2024, with auto-renewal provisions and terminable upon notice of non-renewal, and with NTP and its subcontractor ANSTO, running through December 31, 2024.

The following table sets forth revenues for each of the Company's products representing 10% or more of revenues:

	Year Ended December 31,		
	2023	**2022**	**2021**
PYLARIFY	65.7 %	56.4 %	10.2 %
DEFINITY	21.6 %	26.2 %	54.7 %
TechneLite	6.7 %	9.5 %	21.5 %

Inventory

Inventory includes material, direct labor and related manufacturing overhead and is stated at the lower of cost and net realizable value on a first-in, first-out basis. The Company records inventory when the Company takes title to the product.

The Company assesses the recoverability of inventory to determine whether adjustments for excess and obsolete inventory are required. Inventory that is in excess of future requirements is written down to its estimated net realizable value based on product shelf life, forecasted demand and other factors.

Inventory costs associated with product that has not yet received regulatory approval are capitalized if the Company believes there is probable future commercial use of the product and future economic benefits of the asset. If future commercial use of the product is not probable, then inventory costs associated with such product are expensed as incurred. The Company had no inventory pending regulatory approval as of December 31, 2023.

Property, Plant and Equipment, net

Property, plant & equipment are stated at cost. Replacements of major units of property are capitalized, and replaced properties are retired. Replacements of minor components of property and repair and maintenance costs are charged to expense as incurred. Certain costs to obtain or develop computer software are capitalized and amortized over the estimated useful life of the software. Depreciation and amortization are computed on a straight-line basis over the estimated useful lives of the related assets and recorded

in costs of goods sold and operating expenses in the associated functional expense category which utilizes the associated asset. The estimated useful lives of the major classes of depreciable assets are as follows:

Class	Range of Estimated Useful Lives
Buildings	10 - 50 years
Land improvements	15 - 40 years
Machinery and equipment	3 - 15 years
Furniture and fixtures	15 years
Leasehold improvements	Lesser of lease term or 15 years
Computer software	3 - 5 years

Upon retirement or other disposal of property, plant & equipment, the cost and related amount of accumulated depreciation are removed from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds is included in operating income.

Included within machinery and equipment are spare parts. Spare parts include replacement parts relating to plant & equipment and are either recognized as an expense when consumed or reclassified and capitalized as part of the related asset and depreciated over the remaining useful life of the related asset.

Business Combinations

The Company accounts for business combinations using the acquisition method of accounting. The Company recognizes the assets acquired and liabilities assumed in business combinations on the basis of their fair values at the date of acquisition. The Company assesses the fair value of assets acquired, including intangible assets, and liabilities assumed using a variety of methods. Each asset acquired and liability assumed is measured at fair value from the perspective of a market participant. The method used to estimate the fair values of intangible assets incorporates significant assumptions regarding the estimates a market participant would make in order to evaluate an asset, including a market participant's use of the asset and the appropriate discount rates. Acquired IPR&D is recognized at fair value and initially characterized as an indefinite-lived intangible asset, irrespective of whether the acquired IPR&D has an alternative future use. Any excess purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill. Transaction costs and restructuring costs associated with a business combination are expensed as incurred.

During the measurement period, which extends no later than one year from the acquisition date, the Company may record certain adjustments to the carrying value of the assets acquired and liabilities assumed with the corresponding offset to goodwill. After the measurement period, all adjustments are recorded in the consolidated statements of operations as operating expenses or income. The Company recorded a measurement period adjustment of $2.6 million related to deferred taxes for the three months ended March 31, 2021, which finalized all measurement period adjustments related to the Progenics Acquisition.

Goodwill

Goodwill is not amortized but is instead tested for impairment at least annually and whenever events or circumstances indicate that it is more likely-than-not that it may be impaired. The Company has elected to perform the annual test for goodwill impairment as of October 31 of each year.

In performing the Company's annual assessment, the Company is permitted to first perform a qualitative test and if necessary, perform a quantitative test. If the Company is required to perform the quantitative impairment test of goodwill, the Company compares the fair value of a reporting unit to its carrying value. If the reporting unit's carrying value exceeds its fair value, the Company would record an impairment loss to the extent that the carrying value of goodwill exceeds its implied fair value. The Company estimates the fair value of its reporting units using discounted cash flow or other valuation models, such as comparative transactions and market multiples. The Company performed a qualitative assessment and did not recognize any goodwill impairment charges during the years ended December 31, 2023, 2022 or 2021.

Intangible and Long-Lived Assets

The Company tests intangible and long-lived assets for recoverability whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets may not be recoverable. The Company measures the recoverability of assets to be held and used by comparing the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If those assets are considered to be impaired, the impairment equals the amount by which the carrying amount of the assets exceeds the fair value of the assets. Any impairments are recorded as permanent reductions in the carrying amount of the assets. See Note 7, "Property, Plant and Equipment, Net" for further details on impairment. Long-lived assets, other than goodwill and other intangible assets that are held for sale are recorded at the lower of the carrying value or the fair market value less the estimated cost to sell.

Intangible assets, consisting of patents, trademarks, customer relationships, a currently marketed product, licenses and developed technology related to the Company's products are amortized in a method equivalent to the estimated utilization of the economic benefit of the asset.

Costs of IPR&D intangible assets acquired as part of an asset acquisition that have no alternative future use are expensed when incurred. Milestone payments made after regulatory approval are capitalized as an intangible asset and amortized over an estimated useful life of the product. Cash payments related to acquired IPR&D intangible assets are reflected as an investing cash flow in the Company's consolidated statement of cash flows.

The Company's IPR&D intangible assets includes intangible assets acquired in a business combination that are used in research and development activities but have not yet reached technological feasibility, regardless of whether they have alternative future use. The primary basis for determining the technological feasibility or completion of these projects is obtaining regulatory approval to market the underlying products in an applicable geographic region. Because obtaining regulatory approval can include significant risks and uncertainties, the eventual realized value of the acquired IPR&D projects may vary from their fair value at the date of acquisition. The Company classifies IPR&D intangible assets acquired in a business combination as an indefinite-lived intangible asset until the completion or abandonment of the associated research and development efforts. Upon completion of the associated research and development efforts, the Company will determine the useful life and begin amortizing the assets to reflect their use over their remaining lives. Upon permanent abandonment, the Company writes-off the remaining carrying amount of the associated IPR&D intangible asset. IPR&D intangible assets are tested at least annually as of October 31 or when a triggering event occurs that could indicate a potential impairment and any impairment loss is recognized in the Company's consolidated statements of operations. See Note 10, "Intangibles, net and Goodwill" for further details on impairment.

Contingencies

In the normal course of business, the Company is subject to loss contingencies, such as legal proceedings and claims arising out of its business, that cover a wide range of matters, including, among others, product and environmental liability. The Company records accruals for those loss contingencies when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. The Company does not recognize gain contingencies until realized.

Convertible Notes

The Company evaluates convertible notes to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for. The change in fair value of any separately recognized derivative is recorded in the consolidated statement of operations as other income or expense. Upon conversion, exercise or cancellation of a derivative instrument, the instrument is marked to fair value at the date of conversion, exercise or cancellation.

Fair Values of Financial Instruments

The estimated fair values of the Company's financial instruments, including its cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate the carrying values of these instruments due to their short term nature. The Company's long-term debt has triggering events that would impact the fair value of the instruments. The Company determined that no triggering event has occurred during the years ended December 31, 2023 and December 31, 2022. As of December 31, 2023, the fair value of the Company's convertible debt was estimated to be approximately $644.3 million based on external pricing data, including quoted market prices of these instruments and was classified as a Level 1 measurement within the fair value hierarchy. As of December 31, 2022, the carrying value of the Company's convertible debt approximated fair value and was classified as a Level 1 measurement within the fair value hierarchy. The fair value See Note 4, "Fair Value of Financial Instruments".

Contingent Consideration Liabilities

The estimated fair value of contingent consideration liabilities are initially measured and recorded on the acquisition date, are considered to be a Level 3 instrument and are reviewed quarterly, or whenever events or circumstances occur that indicate a change in fair value. The contingent consideration liabilities are recorded at fair value at the end of each reporting period with changes in estimated fair values recorded in general and administrative expenses in the consolidated statements of operations.

The estimated fair value is determined based on probability adjusted discounted cash flows and Monte Carlo simulation models that include significant estimates and assumptions pertaining to commercialization events and sales targets. The most significant unobservable inputs are the probabilities of achieving regulatory approval of the development projects and subsequent commercial success.

Significant changes in any of the probabilities of success would result in a significantly higher or lower fair value measurement. Significant changes in the probabilities as to the periods in which milestones will be achieved would result in a significantly lower or higher fair value measurement.

The Company's acquisitions accounted for as asset acquisitions may also include contingent consideration payments to be made for sales-based milestones, development and regulatory milestones. The Company assesses whether such contingent consideration meets the definition of a derivative. Contingent consideration payments in an asset acquisition not required to be accounted for as derivatives are recognized when the contingency is resolved, and the consideration is paid or becomes payable. Contingent consideration payments required to be accounted for as derivatives are recorded at fair value on the date of the acquisition and are subsequently remeasured to fair value at each reporting date. Upon recognition of the contingent consideration payment, the amount is included in the cost of the acquired asset or group of assets.

Derivative Instruments

The Company has used 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. To qualify for hedge accounting, the hedging instrument must be highly effective at reducing the risk from the exposure being hedged. Further, the Company must formally document the hedging relationship at inception and, on at least a quarterly basis, continually reevaluate the relationship to ensure it remains highly effective throughout the life of the hedge. The Company does not enter into derivative financial instruments for speculative or trading purposes.

Advertising and Promotion Costs

Advertising and promotion costs are expensed as incurred. During the years ended December 31, 2023, 2022 and 2021, the Company incurred $26.0 million, $26.0 million and $17.5 million, respectively in advertising and promotion costs, which are included in sales and marketing in the consolidated statements of operations.

Research and Development

Research and development costs are expensed as incurred and relate primarily to the development of new products to add to the Company's portfolio and costs related to its medical affairs and medical information functions. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and recognized as an expense as the goods are delivered or the related services are performed.

Foreign Currency

The consolidated statements of operations of the Company's foreign subsidiaries are translated into U.S. Dollars using weighted-average exchange rates. The net assets of the Company's foreign subsidiaries are translated into U.S. Dollars using the end of period exchange rates. The impact from translating the net assets of these subsidiaries at changing rates are recorded in the foreign currency translation adjustment account, which is included in accumulated other comprehensive loss in the consolidated balance sheets.

Remeasurement of the Company's foreign currency denominated transactions are included in net income. Transaction gains and losses are reported as a component of other loss (income) in the consolidated statements of operations.

Stock-Based Compensation

The Company's stock-based compensation cost is measured at the grant date of the stock-based award based on the fair value of the award and is recognized as expense over the requisite service period, which generally represents the vesting period, and includes an estimate of the awards that will be forfeited. The Company estimates the fair value of each stock-based award on its measurement date using either the current market price of the stock, the Black-Scholes option valuation model or the Monte Carlo simulation valuation model, whichever is most appropriate. The Black-Scholes and Monte Carlo simulation valuation models incorporate assumptions such as stock price volatility, the expected life of options or awards, a risk-free interest rate and dividend yield.

Expected volatility is based on the historical volatility of the Company's stock price. The risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the awards' expected lives. Expected lives are principally based on the Company's historical exercise experience with previously issued awards. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future.

Expense for performance restricted stock awards is recognized based upon the fair value of the awards on the date of grant and the number of shares expected to vest based on the terms of the underlying award agreement and the requisite service period(s).

Other Loss (Income)

Other loss (income) consisted of the following:

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Foreign currency losses	$ 21	$ 256	$ 274
Tax indemnification expense, net	4,943	9,554	7,121
Interest income	(19,638)	(2,613)	(45)
Interest rate swap termination	—	(5,494)	—
Gain on sale of RELISTOR licensed intangible asset associated with net sales royalties	(51,789)		
Other	143	—	—
Total other (income) loss	$ (66,320)	$ 1,703	$ 7,350

Comprehensive Income (Loss)

Comprehensive income (loss) consists of net income (loss) and other gains and losses affecting stockholders' equity that, under U.S. GAAP, are excluded from net income. For the Company, other comprehensive income (loss) consists of foreign currency translation gains and losses as well as realized and unrealized gains and losses on cash flow hedges related to the Company's interest rate swaps. The accumulated other comprehensive income (loss) balance consists entirely of foreign currency translation gains and losses and realized and unrealized gains and losses on outstanding cash flow hedges related to the Company's interest rate swaps.

Asset Retirement Obligations

The Company's compliance with federal, state, local and foreign environmental laws and regulations may require it to remove or mitigate the effects of the disposal or release of chemical substances in jurisdictions where it does business or maintains properties. The Company establishes accruals when those costs are legally obligated and can be reasonably estimated. Accrual amounts are estimated, which may include the assistance of third-party environmental specialists, and are based on currently available information, regulatory requirements, remediation strategies, historical experience, the relative shares of the total remediation costs, a relevant discount rate, and the time periods of when estimated costs can be reasonably predicted. Changes in these assumptions could impact the Company's future reported results.

The Company has production facilities which manufacture and process radioactive materials at its North Billerica, Massachusetts campus and its Somerset, New Jersey site. The Company considers its legal obligation to remediate its facilities upon a decommissioning of its radioactive-related operations as an asset retirement obligation. The fair value of a liability for asset retirement obligations is recognized in the period in which the liability is incurred. The liability is measured at the present value of the obligation expected to be incurred and is adjusted in subsequent periods as accretion expense is recorded. The corresponding asset retirement costs are capitalized as part of the carrying values of the related long-lived assets and depreciated over the assets' useful lives.

The Company has identified conditional asset retirement obligations related to the future removal and disposal of asbestos contained in certain of the buildings located on the Company's North Billerica, Massachusetts campus. The Company believes the asbestos is appropriately contained and it is compliant with all applicable environmental regulations. If these properties undergo major renovations or are demolished, certain environmental regulations are in place, which specify the manner in which asbestos must be handled and disposed. The Company is required to record the fair value of these conditional liabilities if they can be reasonably estimated. As of December 31, 2023 and 2022, sufficient information was not available to estimate a liability for such conditional asset retirement obligations as the obligations to remove the asbestos from these properties have indeterminable settlement dates. As such, no liability for conditional asset retirement obligations has been recorded in the accompanying consolidated balance sheets as of December 31, 2023 and 2022.

Self-Insurance Reserves

The Company's consolidated balance sheets at December 31, 2023 and 2022 include $1.0 million and $0.9 million of accrued liabilities associated with employee medical costs that are retained by the Company, respectively. The Company estimates the required liability of those claims on an undiscounted basis based upon various assumptions which include, but are not limited to, the Company's historical loss experience and projected loss development factors. The required liability is also subject to adjustment in the future based upon changes in claims experience, including changes in the number of incidents (frequency) and change in the ultimate cost per incident (severity).

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The guidance in this update is effective for fiscal years beginning after December 15, 2023, and interim periods after December 15, 2024. The Company is currently in the process of evaluating the effects of this pronouncement on our related disclosures.

In December 2023, the FASB also issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires enhanced income tax disclosures, including specific categories and disaggregation of information in the effective tax rate reconciliation, disaggregated information related to income taxes paid, income or loss from continuing operations before income tax expense or benefit, and income tax expense or benefit from continuing operations. The requirements of the ASU are effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently in the process of evaluating the impact of this pronouncement on our related disclosures.

3. Revenue from Contracts with Customers

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these goods or services. To achieve this core principle, the Company applies the following five steps: (1) identify the contracts with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the Company satisfies a performance obligation.

Disaggregation of Revenue

The following table summarizes revenue by revenue source as follows:

	Year Ended December 31,		
Major Products/Service Lines (in thousands)	**2023**	**2022**	**2021**
Product revenue, net[(1)]	$ 1,263,068	$ 887,038	$ 400,356
License and royalty revenues[(2)]	33,361	48,023	24,852
Total revenues	$ 1,296,429	$ 935,061	$ 425,208

(1) The Company's product revenue includes PYLARIFY and DEFINITY, among other products. This category represents the delivery of physical goods. The Company applies the same revenue recognition policies and judgments for all of 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: Radiopharmaceutical Oncology, Precision Diagnostics, and Strategic Partnerships and Other Revenue. Radiopharmaceutical Oncology includes PYLARIFY and AZEDRA. In 2023, the Company announced its decision to discontinue the production and promotion of AZEDRA and it does not expect AZEDRA to contribute to the business after the first quarter of 2024. Precision Diagnostics includes DEFINITY, TechneLite and other diagnostic imaging products. Strategic Partnerships and Other Revenue includes strategic partnerships and other arrangements related to other products of the Company, including our royalty revenue from our license of RELISTOR. On August 2, 2023, the Company sold the RELISTOR royalty asset under its license agreement with Bausch; the Company retained the rights to future sales-based milestone payments. During the fourth quarter of 2023, the Company earned a $15.0 million sales-based milestone payment.

On January 31, 2022, the Company entered into a global settlement agreement with Novartis Pharma AG ("Novartis"), Advanced Accelerator Applications USA, Inc., Endocyte, Inc. 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)	Year Ended December 31, 2023	2022	2021
PYLARIFY	$ 851,303	$ 527,405	$ 43,414
Other radiopharmaceutical oncology	3,130	4,102	5,473
Total radiopharmaceutical oncology	854,433	531,507	48,887
DEFINITY	279,768	244,993	232,759
TechneLite	87,370	88,864	91,293
Other precision diagnostics	22,980	22,825	26,973
Total precision diagnostics	390,118	356,682	351,025
Strategic Partnerships and other revenue	51,878	46,872	25,296
Total revenues	$ 1,296,429	$ 935,061	$ 425,208

Product Revenue, Net

The Company sells its products principally to hospitals, independent diagnostic testing facilities, and radiopharmacies. The Company considers customer purchase orders, which in some cases are governed by master sales or group purchasing organization agreements, to be the contracts with a customer.

For each contract, the Company considers the promise to transfer products, each of which is distinct, to be the identified performance obligations. In determining the transaction price, the Company evaluates whether the price is subject to refund or adjustment to determine the net consideration to which the Company expects to be entitled.

The Company typically invoices customers upon satisfaction of identified performance obligations. As the Company's standard payment terms are 30 to 60 days from invoicing, the Company has elected to use the significant financing component practical expedient.

The Company allocates the transaction price to each distinct product based on their relative standalone selling price. The product price as specified on the purchase order is considered the standalone selling price as it is an observable input which depicts the price as if sold to a similar customer in similar circumstances.

Revenue is recognized when control of the product is transferred to the customer (i.e., when the Company's performance obligation is satisfied), which typically occurs upon delivery to the customer. Further, in determining whether control has transferred, the Company considers if there is a present right to payment and legal title, along with risks and rewards of ownership having transferred to the customer.

Frequently, the Company receives orders for products to be delivered over multiple dates that may extend across several reporting periods. The Company invoices for each delivery upon shipment and recognizes revenues for each distinct product delivered, assuming transfer of control has occurred.

The Company generally does not separately charge customers for shipping and handling costs, but any shipping and handling costs charged to customers are included in product revenue, net. Taxes collected from customers relating to product sales and remitted to governmental authorities are excluded from revenues.

Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established for discounts, returns, rebates and allowances that are offered within contracts between the Company and its customers. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as a current liability. Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the

Company's estimates. If actual results in the future vary from the Company's estimates, the Company adjusts these estimates, which would affect product revenue and earnings in the period such variances become known.

Rebates and Allowances: The Company provides certain customers with rebates and allowances that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. The Company establishes a liability for such amounts, which is included in accrued expenses in the accompanying consolidated balance sheets. These rebates and allowances result from performance-based offers that are primarily based on attaining contractually specified sales volumes and administrative fees the Company is required to pay to group purchasing organizations. The Company estimates the amount of rebates and allowances that are explicitly stated in the Company's contracts based on a combination of actual purchases and an estimate of the customer's buying patterns.

Product Returns: The Company generally offers customers a limited right of return due to non-conforming product. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities using its historical product return information and considers other factors that it believes could significantly impact its expected returns, including product recalls. Reserves for product returns are not significant to the Company due to the nature of its products including radiopharmaceutical products with limited half-lives.

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	26,683
Adjustments relating to prior period revenues	70
Payments or credits made during the period	(24,331)
Balance, December 31, 2022	13,399
Provision related to current period revenues	32,308
Adjustments relating to prior period revenues	(453)
Payments or credits made during the period	(29,184)
Balance, December 31, 2023	$ 16,070

License and Royalty Revenues

The Company has entered into licensing agreements, under which it licenses certain rights to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products. The Company also has distribution licenses which are treated as combined performance obligations with the delivery of its products and are classified as product revenue, net.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the five-step approach stated earlier. The Company uses judgment in determining the number of performance obligations in a license agreement by assessing whether the license is distinct or should be combined with another performance obligation, as well as the nature of the license. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development or sales milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are outside the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license and royalty revenues and earnings in the period of adjustment. At December 31, 2023, the variable consideration for the milestone payments is constrained and is excluded from contract price until the milestone is achieved by the customer.

Royalty Revenues: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Contract Costs

The Company recognizes an asset for incremental costs of obtaining a contract with a customer if it expects to recover those costs. The Company's sales incentive compensation plans qualify for capitalization since these plans are directly related to sales achieved during a period of time. However, the Company has elected the practical expedient to expense the costs as they are incurred, within sales and marketing expenses, since the amortization period is less than one year.

The Company recognized certain revenues as follows:

	Year Ended December 31,	
(in thousands)	**2023**	**2022**
Amounts included in the contract liability at the beginning of the period	$ 682	$ 244

The Company did not record any revenue related to performance obligations satisfied (or partially satisfied) in previous periods during the years ended December 31, 2023 and 2022.

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 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:

	December 31, 2023			
(in thousands)	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 574,131	$ 574,131	$ —	$ —
Total assets	$ 574,131	$ 574,131	$ —	$ —
Liabilities:				
Contingent consideration liabilities	$ 2,700	$ —	$ —	$ 2,700
Total liabilities	$ 2,700	$ —	$ —	$ 2,700

	December 31, 2022			
(in thousands)	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 342,646	$ 342,646	$ —	$ —
Total assets	$ 342,646	$ 342,646	$ —	$ —
Liabilities:				
Contingent consideration liabilities	$ 111,600	$ —	$ —	$ 111,600
Total liabilities	$ 111,600	$ —	$ —	$ 111,600

During the years ended December 31, 2023 and 2022, there were no transfers into or out of Level 3. On December 2, 2022, the Company voluntarily terminated the interest rate swap contracts in connection with the refinancing of debt.

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. ("CytoDyn") 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. During the fourth quarter of 2022, the Company reduced the probability to zero as CytoDyn withdrew their regulatory application. 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 entitled 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 paid out the maximum amount payable under the CVRs from available cash in May 2023 in full satisfaction of the CVR obligation.

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 (also known as 131 I-MIP-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 consolidated statements of operations. The Company can give no assurance that the actual amounts paid, if any, in connection with the contingent consideration liabilities 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 liabilities using Level 3 inputs as of December 31, 2023.

(in thousands)	Fair Value as of December 31, 2023	Fair Value as of December 31, 2022	Valuation Technique	Unobservable Input	Assumptions December 31, 2023	Assumptions December 31, 2022
Contingent consideration liability:						
Net sales targets – PYLARIFY (CVRs)			Probability adjusted discounted cash flow model	Period of expected milestone achievement and sales targets		
	N/A	$ 99,700			N/A	2022 – 2023
				Probability of success	N/A	100 %
1095 commercialization milestone	1,800	1,700	Probability adjusted discounted cash flow model			
				Period of expected milestone achievement	2026	2026
				Probability of success	40 %	40 %
				Discount rate	4.1 %	3.8 %
Net sales targets – AZEDRA and 1095	900	10,200	Monte Carlo simulation			
				Probability of success and sales targets	0% - 40%	20% - 100%
				Discount rate	15%	16% - 17%
Total	$ 2,700	$ 111,600				

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

(in thousands)	Financial Assets Years Ended December 31, 2023	Financial Assets Years Ended December 31, 2022	Financial Liabilities Years Ended December 31, 2023	Financial Liabilities Years Ended December 31, 2022
Fair value, beginning of period	$ —	$ 9,300	$ 111,600	$ 86,200
Changes in fair value included in net income (loss)	—	(9,300)	(9,275)	25,400
Cash Payments	—	—	(99,625)	—
Fair value, end of period	$ —	$ —	$ 2,700	$ 111,600

The change in fair value of the contingent financial asset and contingent financial liabilities, including the CVRs, resulted in a general and administrative expense of $9.3 million for the year ended December 31, 2023 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 made the applicable cash payment related to the CVRs in May 2023.

5. Income Taxes

The components of income (loss) before provision (benefit) for income taxes consists of the following:

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
U.S.	$ 410,326	$ 29,012	$ (76,389)
International	617	(2,293)	1,351
Income (loss) before income taxes	$ 410,943	$ 26,719	$ (75,038)

The Company's provision (benefit) for income taxes consists of the following:

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Current			
Federal	$ 110,108	$ 42,532	$ —
State	29,806	4,302	(8,166)
International	—	(166)	(30)
	139,914	46,668	(8,196)
Deferred			
Federal	(45,252)	(39,920)	1,048
State	(10,739)	(8,315)	3,058
International	359	219	331
	(55,632)	(48,016)	4,437
Income tax expense (benefit)	$ 84,282	$ (1,348)	$ (3,759)

The reconciliation of income taxes at the U.S. federal statutory rate to the income tax expense (benefit) is as follows:

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
U.S. statutory rate	$ 86,298	$ 5,611	$ (15,758)
Permanent items	1,042	2,309	1,764
Sale of RELISTOR licensed intangible asset associated with net sales royalties	(10,817)	—	—
Section 162(m)	307	247	1,028
Uncertain tax positions	(5,045)	(12,629)	(8,952)
Tax credits	(2,118)	(4,085)	(990)
State and local taxes	18,726	67	656
Impact on deferred taxes of change in tax rate	(330)	4,169	3,049
Changes in fair value of contingent assets and liabilities	(1,948)	5,422	15,015
Foreign tax rate differential	128	68	23
Valuation allowance	(4)	(30)	(400)
Stock compensation	(3,941)	(4,612)	(1,164)
Change in indemnification deferred tax asset	1,240	2,343	1,786
Other	744	(228)	184
Income tax expense (benefit)	$ 84,282	$ (1,348)	$ (3,759)

The components of deferred income tax assets (liabilities) are as follows:

(in thousands)	December 31, 2023	2022
Deferred Tax Assets		
Federal benefit of state taxes payable	$ 263	$ 1,739
Reserves, accruals and other	18,923	31,532
Inventory obsolescence	—	919
Capitalized research and development	17,142	79,946
Stock compensation	9,266	—
Intangible assets	25,214	—
Net operating loss carryforwards	80,184	88,014
Lease liability	14,365	—
Deferred tax assets	165,357	202,150
Deferred Tax Liabilities		
Reserves, accruals and other	—	(5,354)
Right-of-use asset	(11,543)	—
Intangible assets	—	(80,770)
Amortization of intangibles other than goodwill	—	(385)
Depreciation	—	(1,469)
Deferred tax liability	(11,543)	(87,978)
Less: valuation allowance	(3,616)	(3,525)
	$ 150,198	$ 110,647
Recorded in the accompanying consolidated balance sheets as:		
Noncurrent deferred tax assets, net	$ 150,198	$ 110,647

The Tax Cuts and Jobs Act (the "Act") was enacted on December 22, 2017. Under the Act, research and experimental expenditures incurred for tax years beginning after December 31, 2021, must be capitalized and amortized ratably over five or fifteen years for tax purposes, depending on where the research activities are conducted. If the requirement to capitalize Section 174 expenditures is not modified, it may impact our cash tax liability in future years. The increase in worldwide net deferred tax assets is primarily due to the tax capitalization of the Company's current year research and development expenses that are not currently deductible in 2023 and the decrease in deferred tax liabilities related to the AZEDRA and RELISTOR royalty intangible assets, partially offset by utilization of net operating losses.

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. As of December 31, 2023 and 2022, the Company maintains a valuation allowance of $3.6 million and $3.5 million, respectively, primarily related to net deferred tax assets of certain of its foreign subsidiaries.

Utilization of net operating loss carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 ("IRC Section 382") and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change, as defined by IRC Section 382, results from transactions which impact the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period.

At December 31, 2023, the Company had U.S. federal net operating loss carryforwards of approximately $297.6 million, $157.9 million of which will expire between 2027 and 2037, and $139.6 million of which can be carried forward indefinitely. The Company's state net operating losses are $12.5 million on a tax-effected basis, which will expire between 2024 and 2040. The Company has state research credit carryforwards of $2.1 million, which will expire between 2026 and 2038. The Company has state investment tax credit carryforwards of $0.8 million which have no expiration date.

The Company's U.S. federal income tax returns are subject to examination for three years after the filing date of the return. The state and foreign income tax returns are subject to examination for periods varying from three to four years after filing, depending on the specific jurisdiction's statutes of limitation, and in the case of Sweden, up to six years after the end of the financial year.

A reconciliation of the Company's changes in uncertain tax positions for 2023 and 2022 is as follows:

(in thousands)	Amount
Balance of uncertain tax positions as of January 1, 2021	$ 5,292
Additions related to current year tax positions	—
Reductions related to prior year tax positions	(188)
Settlements	(1,446)
Lapse of statute of limitations	—
Balance of uncertain tax positions as of December 31, 2021	3,658
Additions related to current year tax positions	—
Reductions related to prior year tax positions	(1,180)
Settlements	(306)
Lapse of statute of limitations	(692)
Balance of uncertain tax positions as of December 31, 2022	1,480
Additions related to current year tax positions	3,749
Reductions related to prior year tax positions	(688)
Settlements	(442)
Lapse of statute of limitations	—
Balance of uncertain tax positions as of December 31, 2023	$ 4,099

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 an indemnification agreement with BMS for any payments made to settle those uncertain tax positions with the taxing authorities.

In accordance with the Company's accounting policy, the change in the tax liability, 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 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. Included in other (income) loss for the years ended December 31, 2023, 2022 and 2021, is tax indemnification expense (income), net of $4.9 million, $9.6 million and $7.1 million, respectively.

As of December 31, 2023 and 2022, total liabilities for uncertain tax positions including interest and penalties were $5.4 million and $8.3 million, respectively, consisting of uncertain tax positions of $4.1 million and $1.5 million, respectively, interest accruals of $1.3 million and $6.4 million, respectively, and no penalty accruals as of December 31, 2023 and $0.4 million of penalty accruals as of December 31, 2022. The increase in uncertain tax positions during the year ended December 31, 2023 was primarily related to certain acquired tax attributes. As of December 31, 2023, $1.3 million, $3.2 million, and $0.9 million of these liabilities were recorded in current liabilities, other long-term liabilities, and as a reduction of deferred tax assets, respectively. As of December 31, 2022 these liabilities were included in other long-term liabilities. Included in the 2023, 2022 and 2021 tax provisions are benefits of $5.0 million, $12.6 million and $9.0 million, respectively, relating to reversals of uncertain tax positions recognized upon settlements, effective settlements, or lapses of relevant statutes of limitation, partially offset by interest accruals.

6. Inventory

Inventory consisted of the following:

	December 31,	
(in thousands)	**2023**	**2022**
Raw materials	$ 31,259	$ 19,987
Work in process	13,807	8,234
Finished goods	18,963	7,254
Total inventory	$ 64,029	$ 35,475

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. The Company has no inventory pending regulatory approval as of December 31, 2023.

7. Property, Plant and Equipment, Net

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

	December 31,	
(in thousands)	**2023**	**2022**
Land	$ 9,480	$ 13,450
Buildings	73,441	76,329
Machinery, equipment and fixtures	102,576	92,604
Computer software	27,259	25,864
Construction in progress	40,964	14,047
	253,720	222,294
Less: accumulated depreciation and amortization	(107,023)	(100,128)
Total property, plant and equipment, net	$ 146,697	$ 122,166

Depreciation and amortization expense related to property, plant & equipment, net, was $13.2 million, $13.7 million and $13.2 million for the years ended December 31, 2023, 2022 and 2021, respectively.

The Company tests long-lived assets for recoverability whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets may not be recoverable. During the year ended December 31, 2021, the Company reviewed certain facts relating to an asset group that included the right-of-use ("ROU") asset associated with the lease of office space in the World Trade Center (the "WTC lease") in New York City and resulted in a change to the asset group due to the negotiation of a sublease. Please refer to Note 16, "Leases" for further details.

During the three months ended June 30, 2023, as a result of a decline in expected future cash flows related to a certain asset group, the Company determined certain impairment triggers had occurred. The Company reviewed revised undiscounted cash flows that were estimated to be generated by the asset group as of June 30, 2023. Based on the undiscounted cash flow analysis, the Company determined that the asset group had net carrying values that exceeded their estimated undiscounted future cash flows. The Company then estimated the fair value of the asset group based on their discounted cash flows. The carrying value exceeded the fair value and as a result, the Company recorded a noncash impairment of $6.0 million for the six months ended June 30, 2023 in cost of goods sold in the consolidated statements of operations.

Long-Lived Assets Held for Sale

During the first quarter of 2023, the Company committed to a plan to sell a portion of its land and buildings associated with its Billerica, Massachusetts campus. Effective March 16, 2023, the Company entered into a purchase and sale agreement (the "P&S") with a prospective buyer. The assets were classified as held for sale and comprised entirely of property, plant and equipment, net. The Company determined that the fair value of the net assets being sold exceeded the carrying value as of September 30, 2023. The purchase price for the campus sale is $10.0 million in cash. The transaction is expected to close in the second or third quarter of 2024.

8. 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, which included a holdback amount of $1.8 million that was remitted to the Company as of December 31, 2021, and paid in the first quarter of 2022; the purchase price also included a working capital adjustment. The SPA contained 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 consolidated financial statements.

The sale resulted in a pre-tax book gain of $15.3 million, which was recorded within operating income (loss) in the consolidated statements of operations for the year ended December 31, 2021.

9. 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 December 31, 2023, the liability is measured at the present value of the obligation expected to be incurred, of approximately $25.1 million.

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

(in thousands)	Amount
Balance, January 1, 2022	$ 20,833
Change in useful life estimate	280
Accretion expense	1,430
Balance, December 31, 2022	22,543
Accretion expense	373
Balance, December 31, 2023	$ 22,916

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, respectively, upon closure. The Company has provided this financial assurance in the form of a $30.3 million surety bond.

10. Intangibles, Net and Goodwill

Intangibles, net, consisted of the following:

	December 31, 2023				
(in thousands)	Useful Lives (in years)	Amortization Method	Cost	Accumulated Amortization	Net
Trademarks	15 – 25	Straight-Line	$ 13,540	$ (12,216)	$ 1,324
Customer relationships	15 – 25	Accelerated	157,995	(117,574)	40,421
Currently marketed product	9 – 15	Straight-Line	132,800	(38,277)	94,523
Licenses	11 – 16	Straight-Line	22,233	(7,972)	14,261
Developed technology	9	Straight-Line	2,400	(944)	1,456
Total			$ 328,968	$ (176,983)	$ 151,985

	December 31, 2022				
(in thousands)	Useful Lives (in years)	Amortization Method	Cost	Accumulated Amortization	Net
Trademarks	15 – 25	Straight-Line	$ 13,540	$ (12,061)	$ 1,479
Customer relationships	15 – 25	Accelerated	96,681	(95,009)	1,672
Currently marketed product	9 – 15	Straight-Line	275,700	(47,628)	228,072
Licenses	11 – 16	Straight-Line	85,800	(19,101)	66,699
Developed technology	9	Straight-Line	2,400	(677)	1,723
IPR&D	N/A	N/A	15,640	—	15,640
Total			$ 489,761	$ (174,476)	$ 315,285

The Company recorded amortization expense for its intangible assets of $46.4 million, $33.2 million and $27.5 million for the years ended December 31, 2023, 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.

On August 2, 2023, the Company sold the right to its RELISTOR royalty asset under its license agreement with Bausch; the Company retained the rights to future sales-based milestone payments. The Company received an initial payment of approximately $98.0 million in connection with the sale and has the right to receive an additional payment from the buyer of $5.0 million if worldwide net sales of RELISTOR in 2025 exceed a specified threshold. The additional payment would be recognized upon achievement of the specified threshold. Decreases of $63.6 million of license assets and $17.5 million of associated accumulated amortization, as well as a gain of $51.8 million were recorded as a result of the sale. During the fourth quarter of 2023, the Company earned a $15.0 million sales-based milestone payment.

In March 2023, the Company stopped all development activities in relation to a future indication associated with AZEDRA, which was classified as an IPR&D intangible asset. The asset group, which consisted of the IPR&D asset and a currently marketed product (the "AZEDRA intangible asset group"), was assessed for impairment. The Company considered several factors in estimating the future projections of revenues and cash flows of the AZEDRA intangible asset group as part of the impairment testing. The Company concluded that the carrying amount exceeded the fair value of the AZEDRA intangible asset group, which had no value. The Company recorded a non-cash impairment charge of $15.6 million in research and development expenses relating to the IPR&D asset and $116.4 million in cost of goods sold relating to the currently marketed indication of AZEDRA in the consolidated statement of operations for the year ended December 31, 2023.

On August 15, 2023, the Company announced that it had made the decision to discontinue the production and promotion of AZEDRA and would be winding down its Somerset, New Jersey manufacturing site. The Company will continue manufacturing AZEDRA into the first quarter of 2024, to the extent feasible, with the goal of providing doses of AZEDRA to current patients so they can complete their treatment regimen. See Note 7, "Property, Plant and Equipment, Net" for impairment analysis.

In February 2023, the Company entered into an agreement with the stockholders of Cerveau to purchase all of the outstanding capital stock of Cerveau for approximately $35.3 million. In May 2023, upon successful completion of a technology transfer, the Company paid $10.0 million to the selling stockholders of Cerveau. This additional contingent payment was capitalized as part of the

asset cost and increased the Company's customer relationship intangible assets. See Note 21, "Acquisition of Assets" for further discussion of the Cerveau acquisition.

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

(in thousands)	Amount
2024	$ 39,726
2025	24,409
2026	25,206
2027	19,680
2028	16,195
2029 and thereafter	26,769
Total	$ 151,985

11. 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:

	December 31,	
(in thousands)	2023	2022
Compensation and benefits	$ 36,331	$ 30,425
Freight, distribution and operations	67,529	49,067
Accrued rebates, discounts and chargebacks	16,070	13,399
Accrued professional fees	10,244	8,668
Other	15,164	25,525
Total accrued expenses and other liabilities	$ 145,338	$ 127,084
Operating lease liabilities (Note 16)	$ 54,453	$ 25,442
Long-term contingent liability (Note 4)	2,700	11,900
Other long-term liabilities	6,168	8,813
Total other long-term liabilities	$ 63,321	$ 46,155

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

As of December 31, 2023, the Company's maturities of principal obligations under its long-term debt and other borrowings are as follows:

(in thousands)	Amount
2024	$ —
2025	—
2026	—
2027	575,000
2028	—
Total principal outstanding	575,000
Unamortized debt issuance costs	(13,955)
Finance lease liabilities	1,448
Total	562,493
Less: current portion	(823)
Total long-term debt, net, and other borrowings	$ 561,670

In December 2022, the Company refinanced its existing credit facility, consisting of (i) a $200.0 million five-year term loan facility (the "2019 Term Facility") and (ii) a $200.0 million five-year revolving credit facility (the "2019 Revolving Facility" and, together with the 2019 Term Facility, the "2019 Facility"), with a new $100.0 million delayed draw term loan facility (the "2022 Term

Facility" and, the loans thereunder, the "Term Loans") and a new $350.0 million five-year revolving credit facility (the "2022 Revolving Facility" and, together with the 2022 Term Facility, the "2022 Facility").

The Company used approximately $7.8 million of cash on hand to primarily repay the principal amount of the loans outstanding related to the 2019 Facility through the nine months ended September 30, 2022. In addition, in December 2022, the Company used approximately $167.6 million of cash on hand to repay in full the aggregate remaining principal amount of the loans outstanding under the 2019 Facility and to pay related interest, transaction fees and expenses.

The Company paid off the 2019 Term Facility using available cash and did not utilize another term loan to fund the payoff. While the 2022 Term Facility allowed for a delayed draw term loan, the loan was not drawn upon. The Company recorded a loss on extinguishment of debt of $0.6 million related to the write-off of unamortized debt issuance costs and debt discounts associated with the 2019 Term Facility. In addition, the Company incurred and capitalized $2.7 million of new deferred financing costs related to the refinancing.

2022 Revolving Facility

Under the terms of the 2022 Revolving Facility, the lenders are committed to extending credit to the Company from time to time until December 2, 2027 consisting of revolving loans (the "Revolving Loans") in an aggregate principal amount not to exceed $350.0 million (the "Revolving Commitment") at any time, including a $20.0 million sub-facility for the issuance of letters of credit (the "Letters of Credit") and a $10.0 million sub-facility for swingline loans (the "Swingline Loans"). The Letters of Credit, Swingline Loans and the Revolving Loans, if used, are expected to be used for working capital and for other general corporate purposes.

The Revolving Loans bear interest, with pricing based from time to time at the Company's election, at (i) the secured overnight financing rate as published by the Federal Reserve Bank of New York on its website plus an applicable margin that ranges from 1.50% to 2.50% based on the Company's total net leverage ratio or (ii) the alternative base rate plus an applicable margin that ranges from 0.50% to 1.50% based on the Company's total net leverage ratio. The 2022 Revolving Facility also includes an unused commitment fee at a rate ranging from 0.15% to 0.35% per annum based on the Company's total net leverage ratio.

The Company is permitted to voluntarily prepay the Revolving Loans, in whole or in part, or reduce or terminate the Revolving Commitment, in each case, without premium or penalty. On any business day on which the total amount of outstanding Revolving Loans, Letters of Credit and Swingline Loans exceeds the total Revolving Commitment, the Company must prepay the Revolving Loans in an amount equal to such excess. The Company is not required to make mandatory prepayments under the 2022 Revolving Facility. As of December 31, 2023, there were no outstanding borrowings under the 2022 Revolving Facility.

The Company has the right to request an increase to the Revolving Commitment in an aggregate principal amount of up to the sum of $335.0 million or consolidated EBITDA for the four consecutive fiscal quarters most recently ended, plus additional amounts in certain circumstances (collectively, the "Incremental Cap"), minus certain incremental term loans made pursuant to specified incremental term loan commitments ("Incremental Term Loans"). The Company has the right to request Incremental Term Loans in an aggregate principal amount of up to the Incremental Cap less any incremental increases to the Revolving Commitment. Proceeds of Incremental Term Loans may be used for working capital and for other general corporate purposes and will bear interest at rates agreed between the Company and the lenders providing the Incremental Term Loans.

2022 Facility Covenants

The 2022 Facility contains a number of affirmative, negative and reporting covenants, as well as financial maintenance covenants pursuant to which the Company is required to be in quarterly compliance, measured on a trailing four quarter basis, with two financial covenants. The minimum interest coverage ratio, commencing with the fiscal quarter ended December 31, 2022, must be at least 3.00 to 1.00. The maximum total net leverage ratio permitted by the financial covenant, commencing with the fiscal quarter ending March 31, 2024, is 3.50 to 1.00.

The 2022 Facility contains usual and customary restrictions on the ability of the Company and its subsidiaries to: (i) incur additional indebtedness (ii) create liens; (iii) consolidate, merge, sell or otherwise dispose of all or substantially all of its assets; (iv) sell certain assets; (v) pay dividends on, repurchase or make distributions in respect of capital stock or make other restricted payments; (vi) make certain investments; (vii) repay subordinated indebtedness prior to stated maturity; and (viii) enter into certain transactions with its affiliates.

Upon an event of default, the Administrative Agent will have the right to declare the loans and other obligations outstanding under the 2022 Facility immediately due and payable and all commitments immediately terminated.

The 2022 Facility is guaranteed by Holdings, and certain subsidiaries of LMI, including Progenics and Lantheus MI Real Estate, LLC, and obligations under the 2022 Facility are generally secured by first priority liens over substantially all of the assets of each of

LMI, Holdings, and certain subsidiaries of LMI, including Progenics and Lantheus MI Real Estate, LLC (subject to customary exclusions set forth in the transaction documents) owned as of December 2, 2022 or thereafter acquired.

Convertible Notes

On December 8, 2022, the Company issued $575.0 million in aggregate principal amount of 2.625% Convertible Senior Notes due 2027 (the "Notes"), which includes $75.0 million in aggregate principal amount of Notes sold pursuant to the full exercise of the initial purchasers' option to purchase additional Notes. The Notes were issued under an indenture, dated as of December 8, 2022 (the "Indenture"), among the Company, LMI (the "Guarantor"), a wholly owned subsidiary of the Company, as Guarantor, and U.S. Bank Trust Company, National Association, as Trustee. The net proceeds from the issuance of the Notes were approximately $557.8 million after deducting the initial purchasers' discounts and offering expenses payable by the Company.

The Notes are senior unsecured obligations of the Company. The Notes are fully and unconditionally guaranteed on a senior unsecured basis by the Guarantor. The Notes bear interest at a rate of 2.625% per year, payable semi-annually in arrears on June 15 and December 15 of each year, beginning on June 15, 2023, and will mature on December 15, 2027 unless earlier redeemed, repurchased or converted in accordance with their terms. The initial conversion rate for the Notes is 12.5291 shares of the Company's common stock per $1,000 in principal amount of Notes (which is equivalent to an initial conversion price of approximately $79.81 per share of the Company's common stock, representing an initial conversion premium of approximately 42.5% above the closing price of $56.01 per share of the Company's common stock on December 5, 2022). In no event shall the conversation rate per $1,000 in principal amount of notes exceed 17.8539 shares of the Company's common stock. Prior to the close of business on the business day immediately preceding September 15, 2027, the Notes may be converted at the option of the holders only upon occurrence of specified events and during certain periods, and thereafter until the close of business on the business day immediately preceding the maturity date, the Notes may be converted at any time. The Company will satisfy any conversion by paying cash up to the aggregate principal amount of the Notes to be converted and by paying or delivering, as the case may be, cash, shares of the Company's common stock, or a combination of cash and shares of the Company's common stock, at its election, in respect of the remainder, if any, of its conversion obligation in excess of the aggregate principal amount of the Notes being converted. The Company may redeem for cash all or any portion of the Notes, at its option, on or after December 22, 2025 if the closing sale price per share of the Company's common stock exceeds 130% of the conversion price of the Notes for a specified period of time. The redemption price will be equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date.

The Company evaluated the Notes upon completion of the sale and concluded on the following features:

- *Conversion Feature:* The Company determined that the conversion feature qualifies for the classification of equity. As a result, the conversion feature should not be bifurcated as a derivative instrument and the Notes were accounted for as a single liability.
- *Redemption Features:* The redemption features were reviewed within the Notes and the Company determined that the redemption features are closely related to the Notes and as such should not be separately accounted for as a bifurcated derivative instrument.
- *Additional Interest Features:* The Notes may result in additional interest if the Company fails to timely file any document or report that the Company is required to file with the SEC pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. The Company will pay additional interest on the notes at a rate equal to 0.25% to 0.50% per annum based on the principal amount of notes outstanding for each day the Company failure to file has occurred or the notes are not otherwise freely tradable. Further, if the notes are assigned a restricted CUSIP number or the notes are not otherwise freely tradable pursuant to Rule 144 under the Securities Act by holders other than our affiliates or holders that were our affiliates at any time during the three months immediately preceding as of the 385th day after the last date of original issuance of the notes offered hereby, the Company will pay additional interest on the notes at a rate equal to (i) 0.25% to 0.50% per annum based on the principal amount of notes outstanding for each day until the restrictive legend has been removed from the notes, the notes are assigned an unrestricted CUSIP and the notes are freely tradable. The Company concluded that the interest feature is unrelated to the credit risk and should be bifurcated from the Notes, however, the Company assessed the probabilities of triggering events occurring under these features and does not expect to trigger the aforementioned events. These events will continue to be monitored to determine whether the interest feature will be bifurcated if it has value.

As of December 31, 2023, the carrying value of the Notes was $575.0 million, had an unamortized discount of zero, and the fair value of the liability was $575.0 million. The Company recorded interest expense of approximately $15.1 million related to the Notes for the year ended December 31, 2023.

13. Derivative Instruments

The Company has used 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 was approximately 0.82%. This agreement involved 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 consolidated balance sheets at fair value, and changes in the fair value of the swap agreements were 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.

On December 2, 2022, the Company voluntarily terminated the interest rate swap contracts in connection with the refinancing of debt. Upon termination, the Company received approximately $5.6 million in cash and the remaining balance of approximately $5.5 million in accumulated other comprehensive income (loss) related to the interest rate swap contracts were reclassified into earnings.

14. Accumulated Other Comprehensive Loss

The components of Accumulated Other Comprehensive Loss, net of tax of zero and zero for the year ended December 31, 2023 and 2022, respectively, consisted of the following:

(in thousands)	Foreign currency translation	Unrealized loss on cash flow hedges	Accumulated other comprehensive loss
Balance at January 1, 2023	$ (1,259)	$ —	$ (1,259)
Other comprehensive income (loss) before reclassifications	222	—	222
Balance at December 31, 2023	$ (1,037)	$ —	$ (1,037)
Balance at January 1, 2022	$ (754)	$ 269	$ (485)
Other comprehensive income (loss) before reclassifications	(505)	5,838	5,333
Amounts reclassified to earnings	—	(6,107)	(6,107)
Balance at December 31, 2022	$ (1,259)	$ —	$ (1,259)

15. Stock-Based Compensation

Equity Incentive Plans

As of December 31, 2023, the Company's approved equity incentive plans included the 2015 Equity Incentive Plan ("2015 Plan"), the 2013 Equity Incentive Plan ("2013 Plan"), and the 2008 Equity Incentive Plan ("2008 Plan"). These plans are administered by the Board of Directors and permit the granting of stock options, stock appreciation rights, restricted stock, restricted stock units and dividend equivalent rights to employees, officers, directors and consultants of the Company.

The Company has certain stock option and restricted stock awards outstanding under each of its equity incentive plans but, upon adoption of the 2015 Plan, no longer grants new equity awards under its 2008 and 2013 Plans. The Company adopted its 2015 Plan in June 2015 and subsequently amended the plan in April 2016, 2017, 2019, 2021 and 2022 which increased the common stock reserved for issuance under the plan to an aggregate 10,930,277 shares. The Company assumed Progenics equity plans due to the acquisition as discussed in Note 1, "Description of Business". The Company no longer grants new equity awards under the Progenics equity plans.

Stock-based compensation expense recognized in the consolidated statements of operations is summarized below:

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Cost of goods sold	$ 9,126	$ 4,422	$ 2,370
Sales and marketing	9,500	6,185	2,472
General and administrative	24,807	14,876	9,092
Research and development	7,074	3,779	2,000
Total stock-based compensation expense	$ 50,507	$ 29,262	$ 15,934

Stock Options

Stock option awards under the 2015 Plan are granted with an exercise price equal to the fair value of the Company's common stock at the date of grant. All option awards have a ten-year contractual term.

A summary of option activity for 2023 is presented below:

	Total Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at January 1, 2023	874,749	$ 30.37	5.8	19,058,224
Options granted	332,368	$ 76.41		
Options exercised	(214,619)	$ 19.02		
Options cancelled and forfeited	(35,326)	$ 51.30		
Outstanding at December 31, 2023	957,172	$ 48.13	6.7	18,283,464
Vested and expected to vest at December 31, 2023	957,172	$ 48.13	6.7	18,283,464
Exercisable at December 31, 2023	466,039	$ 26.99	4.4	16,462,767

The table below summarizes the key weighted-average assumptions used in valuing stock options granted:

	Year Ended December 31,		
	2023	**2022**	**2021**
Expected volatility	56.1 %	62.1 %	— %
Risk-free interest rate	4.0 %	2.0 %	— %
Expected life (in years)	6.0	6.0	—
Expected dividend yield	—	—	—

During the years ended December 31, 2023, 2022 and 2021, 214,619, 397,822 and 318,662 options were exercised having aggregate intrinsic values of $12.9 million, $13.1 million and $1.6 million, respectively.

As of December 31, 2023, there was $13.2 million of unrecognized compensation expense related to outstanding stock options, which is expected to be recognized over a weighted-average period of 2.0 years.

Restricted Stock

A summary of restricted stock awards and restricted stock units activity for 2023 is presented below:

	Shares	Weighted-Average Grant Date Fair Value Per Share
Nonvested balance at January 1, 2023	1,249,992	$ 34.65
Granted	710,985	$ 74.38
Vested	(612,912)	$ 29.78
Forfeited	(137,806)	$ 50.36
Nonvested balance at December 31, 2023	1,210,259	$ 58.71

Restricted stock generally vest over 3 years. As of December 31, 2023, there was $48.4 million of unrecognized compensation expense related to outstanding restricted stock, which is expected to be recognized over a weighted-average period of 2.0 years.

The weighted average grant-date fair value for restricted stock granted during the fiscal years ended December 31, 2023, 2022 and 2021 was $74.38, $51.51 and $20.14 per share, respectively. The total fair value of restricted stock vested in fiscal years 2023, 2022 and 2021 was $18.3 million, $11.9 million and $8.8 million, respectively.

Total Stockholder Return Restricted Stock Awards ("TSR Awards")

During the years ended December 31, 2023, 2022 and 2021, the Company granted total stockholder return ("TSR") Awards that include a three-year market condition where the performance measurement period is three years. Vesting of the TSR Awards is based on the Company's level of attainment of specified TSR targets relative to the percentage appreciation of a specified index of companies for the respective three-year period and is also subject to the continued employment of the grantees. The number of shares that are earned over the performance period ranges from 0% to 200% of the initial award. The fair value of these awards are based on a Monte Carlo simulation valuation model with the following assumptions:

	Year Ended December 31,		
	2023	2022	2021
Expected volatility	52.8 %	56.6 %	54.0 %
Risk-free interest rate	4.6 %	1.7 %	30.0 %
Expected life (in years)	2.8	2.8	2.8
Expected dividend yield	—	—	—

A summary of TSR Award activity for 2023 is presented below:

	Shares	Weighted-Average Grant Date Fair Value Per Share
Nonvested balance at January 1, 2023	658,875	$ 48.58
Granted	365,478	$ 127.75
Vested	(348,302)	$ 23.43
Forfeited	(45,997)	$ 57.77
Nonvested balance at December 31, 2023	630,054	$ 78.91

As of December 31, 2023, there was $26.2 million of unrecognized compensation expense related to outstanding performance restricted stock which is expected to be recognized over a weighted-average period of 2.0 years.

The weighted average grant-date fair value for TSR Awards granted during the fiscal years ended December 31, 2023, 2022 and 2021 was $127.75, $95.31 and $31.25 per share, respectively. The total fair value of TSR Awards vested in fiscal years 2023, 2022 and 2021 was $8.2 million, $8.8 million and $2.0 million, respectively.

Common Stock Repurchases

In December 2022, the Company's Board of Directors authorized the repurchase of up to $150.0 million in aggregate amount of the Company's common stock under certain circumstances. The Company used approximately $75.0 million of the net proceeds from the Notes to repurchase shares of their common stock from purchasers of the Notes in privately negotiated transactions effected with or through one of the initial purchasers or its affiliate. The purchase price per share of the common stock repurchased in such transactions was equal to the closing sale price per share of the Company's common stock on the date of the offering memorandum used for the Notes, which was $56.01 per share. Following this initial repurchase, the Company may from time to time repurchase additional shares of their common stock. In the year ended December 31, 2022, the Company purchased approximately 1.3 million shares of their outstanding common stock for $75.0 million as part of the program. The Company did not purchase any shares of its outstanding common stock in the year ended December 31, 2023.

16. Leases

The Company determines if an arrangement is a lease at inception. The Company has operating and finance leases for vehicles, corporate offices and certain equipment.

Operating lease right-of-use ("ROU") assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Lease agreements with lease and non-lease components are accounted for separately. As the Company's leases do not provide an implicit rate, the Company used the incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

The Company assumed two operating leases as a result of the Progenics acquisition related to office space at the World Trade Center in New York City, pursuant to a lease agreement expiring in September 2030 (the "WTC Lease"), and a radiopharmaceutical manufacturing facility in Somerset, New Jersey, under a sublease agreement expiring in November 2028, which were recorded as of June 19, 2020, for $18.6 million and $0.6 million, respectively. The Company entered into an operating lease related to office space in Somerset, New Jersey, under a lease agreement expiring in August 2026, which was recorded in October 2021 for $0.7 million. The Company entered into an operating lease agreement in February 2022 to lease office space in Bedford, Massachusetts, under a lease agreement expiring in June 2031, which commenced and was recorded in December 2022 for $11.0 million.

On May 4, 2023, the Company entered into a modification to the operating lease for office space in Bedford, Massachusetts, (the "Existing Premises") that was executed in February 2022. The lease commenced and was recorded in December 2022 for $11.0 million and the initial term was set to expire in June 2031. The lease modification includes a lease of additional office and laboratory space at the Bedford location (the "Additional Premises") for a term of 15 years and 4 months and extends the term of the lease for the Existing Premises to be coterminous with the term of the lease for the Additional Premises. As a result of the extended term for the Existing Premises, the Company recorded an additional right-of-use asset and liability of $6.0 million in May 2023. The modification also contains a provision to convert the rent schedule of the Existing Premises from gross to triple net in 2024, which may result in an additional adjustment to the right-of-use asset and liability. In September 2023, the landlord provided notice to the Company that its renovations of the Additional Premises were completed. As a result of the notice, the Company recorded an additional right-of-use asset and liability of $23.5 million as of September 1, 2023. To determine the value of the additional right-of-use asset and liability, the Company was required to calculate the discount rate of the lease modification. The discount rate was determined based on the expected lease term and by comparing interest rates in the market for similar borrowings with comparable credit quality of the Company. The lease for the Additional Premises allows for the extension of five years to begin immediately upon the expiration of the original term.

Leases with an initial term of 12 months or less are not recorded on the balance sheet as the Company has elected to apply the short-term lease exemption. The Company recognizes lease expense for these leases on a straight-line basis over the lease term.

Operating and finance lease assets and liabilities are as follows:

(in thousands)	Classification	December 31, 2023	December 31, 2022
Assets			
Operating	Other long-term assets	$ 45,325	$ 19,033
Finance	Property, plant and equipment, net	1,438	582
Total leased assets		$ 46,763	$ 19,615
Liabilities			
Current			
Operating	Accrued expenses and other liabilities	$ 1,904	$ 2,177
Finance	Current portion of long-term debt and other borrowings	823	354
Noncurrent			
Operating	Other long-term liabilities	54,453	25,442
Finance	Long-term debt, net and other borrowings	625	231
Total leased liabilities		$ 57,805	$ 28,204

In the third quarter of 2021, with respect to the office space in the World Trade Center, the Company negotiated a sublease agreement with an unrelated third party that was signed on October 11, 2021 (the "Sublease") and has a term of nine years, which represents the remaining term of the WTC Lease. Both the WTC Lease and the Sublease are classified by the Company as operating leases. As a result of the negotiations of the Sublease, the Company determined that an impairment triggering event had occurred. Accordingly, the Company performed an undiscounted cash flow analysis related to the asset group as of September 30, 2021. Based on the undiscounted cash flow analysis, the Company determined that the asset group, including the ROU asset, had net carrying values that exceeded their estimated undiscounted future cash flows. The Company then estimated the fair value of the asset group based on its discounted cash flows. The carrying value exceeded the fair value and, as a result, the Company recorded a non-cash impairment of $9.5 million for the year ended December 31, 2021 in general and administrative expenses in the consolidated statements of operations.

The components of lease expense were as follows:

(in thousands)	Year Ended December 31, 2023	Year Ended December 31, 2022
Operating lease expense	$ 4,627	$ 1,797
Finance lease expense		
Amortization of ROU assets	795	426
Interest on lease liabilities	81	28
Total lease expense	$ 5,503	$ 2,251

Other information related to leases were as follows:

	December 31, 2023	December 31, 2022
Weighted-average remaining lease term (Years):		
Operating leases	13.5	7.9
Finance leases	2.3	1.9
Weighted-average discount rate:		
Operating leases	7.3%	4.8%
Finance leases	6.2%	4.4%

(in thousands)	Year Ended December 31, 2023	Year Ended December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 3,462	$ 2,440
Operating cash flows from finance leases	81	28
Financing cash flows from finance leases	504	384
ROU assets obtained in exchange for lease obligations:		
Operating leases	29,396	11,019
Finance leases	1,437	582

Future minimum lease payments under non-cancellable leases as of December 31, 2023 were as follows:

(in thousands)	Operating Leases	Finance Leases
2024	$ 4,624	$ 846
2025	5,413	664
2026	7,090	151
2027	7,312	—
2028	7,453	—
Thereafter	67,642	—
Total future minimum lease payments	99,534	1,661
Less: interest	43,177	213
Total	$ 56,357	$ 1,448

17. Other Assets

Other assets are comprised of the following:

	December 31,	
(in thousands)	2023	2022
Prepaid Expenses	$ 16,437	$ 12,887
Other Current Assets	246	205
Total other current assets	$ 16,683	$ 13,092
ROU Asset (Note 16)	$ 45,325	$ 19,033
Other Long-Term Assets	9,936	15,322
Total other long-term assets	$ 55,261	$ 34,355

18. Net Income (Loss) Per Common Share

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

	Year Ended December 31,		
(in thousands, except per share amounts)	**2023**	**2022**	**2021**
Net income (loss)	$ 326,661	$ 28,067	$ (71,279)
Basic weighted-average common shares outstanding	68,266	68,487	67,486
Effect of dilutive stock options	346	439	—
Effect of dilutive restricted stock	1,428	1,745	—
Effect of convertible debt instrument	199	—	—
Diluted weighted-average common shares outstanding	70,239	70,671	67,486
Basic income (loss) per common share	$ 4.79	$ 0.41	$ (1.06)
Diluted income (loss) per common share	$ 4.65	$ 0.40	$ (1.06)
Antidilutive securities excluded from diluted net income (loss) per common share	421	358	2,893

Impact of the Convertible Notes

The Company considered whether the notes are participating securities through the two-class method. The Company determined that if a cash dividend is paid that is greater than the then stock price, the holder of Notes will receive cash on an if-converted basis. While this feature is considered to be a participating right; basic earnings per share is only impacted if the Company's earning exceeds the current share price, regardless of whether such dividend is declared. During the year ended December 31, 2023, no such dividend was declared. In addition, the Company is required to settle the principal amount of the Notes in cash upon conversion, and therefore, the Company uses the if-converted method for calculating any potential dilutive effect of the conversion option on diluted net income per share, if applicable, unless the application of the two-class method is dilutive. The conversion option will have a dilutive impact on net income per share of Common Stock when the average price per share of the Company's Common Stock for a given period exceeds the conversion price of the Notes of $79.81 per share.

19. Commitments and Contingencies

Purchase Commitments

The Company has entered into purchasing arrangements in which minimum quantities of goods or services have been committed to be purchased on an annual basis.

As of December 31, 2023, future payments required under purchase commitments are as follows:

(in thousands)	**Amount**
2024	2,716
2025	2,716
2026	2,716
2027	2,716
2028 and thereafter	—
Total	$ 10,864

The Company has entered into agreements which contain certain percentage volume purchase requirements. The Company has excluded these future purchase commitments from the table above since there are no minimum purchase commitments or payments under these agreements.

License Agreements

The Company has entered into license agreements in which fixed payments have been committed to be paid on an annual basis.

As of December 31, 2023, no future fixed payments are required under license agreements. The Company may be required to pay additional amounts up to approximately $264.4 million in contingent payments under the Company's license agreements. These

contingent payments include potential milestone or contractual payment obligations contingent upon the achievement or occurrence of future milestones or events and the amounts and timing of such potential obligations are unknown or uncertain.

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 consolidated financial statements.

As of December 31, 2023, the Company did not have any material ongoing litigation to which the Company was a party. On January 26, 2024, the Company was sued in the United States District Court for the District of Delaware by Advanced Accelerator Applications USA, Inc. and Advanced Accelerator Applications SA, each a Novartis entity, for patent infringement in response to the filing of our ANDA and Paragraph IV certification, consistent with the process established by the Hatch-Waxman Act. Because the outcome of litigation is uncertain, the Company cannot predict how or when this matter will ultimately be resolved.

20. 401(k) Plan

The Company maintains a qualified 401(k) plan (the "401(k) Plan") for its U.S. employees. The 401(k) Plan covers U.S. employees who meet certain eligibility requirements. Under the terms of the 401(k) Plan, the employees may elect to make tax-deferred contributions through payroll deductions within statutory and plan limits, and the Company may elect to make non-elective discretionary contributions. The Company may also make optional contributions to the 401(k) Plan for any plan year at its discretion.

Expense recognized by the Company for matching contributions made to the 401(k) Plan was $4.1 million, $3.1 million and $2.6 million for the years ended December 31, 2023, 2022 and 2021, respectively.

21. Acquisition of Assets

On February 6, 2023, the Company acquired Cerveau. Cerveau holds the rights under a license agreement to develop and commercialize MK-6240, an investigational second-generation F 18-labeled positron emission tomography ("PET") imaging agent that targets Tau tangles in Alzheimer's disease. The Company determined that upon review of the Cerveau acquisition, the transaction did not meet the definition of a business combination and is therefore treated as an asset acquisition.

In February 2023, the Company made an upfront payment of approximately $35.3 million to the stockholders of Cerveau (the "Selling Stockholders") and paid the Selling Stockholders an additional $10.0 million in May 2023 upon the successful completion of a technology transfer. The Company could pay up to an additional $51.0 million in milestone payments upon achievement of specified U.S. regulatory milestones related to MK-6240. The Selling Stockholders are also eligible to receive up to $1.2 billion in sales milestone payments upon the achievement of specified annual commercial sales thresholds of MK-6240 in the event the Company pursues commercialization, as well as up to $13.5 million in research revenue milestones upon achievement of specified annual research revenue thresholds. Additionally, the Company will pay to the Selling Stockholders up to double-digit royalty payments for research revenue and commercial sales. Research revenue is derived from existing partnerships with pharmaceutical companies that use MK-6240 in clinical trials and includes milestone and dose-related payments. The purchase agreement pursuant to which the Company purchased Cerveau specifies, among other things, that certain members of the Selling Stockholders will also provide transition and clinical development services for a prescribed time following the closing of the transaction.

In December 2022, the Company made upfront payments of $260.0 million to POINT as a part of an asset acquisition with the potential for additional milestone payments of approximately $1.8 billion between the two licensed assets based on U.S. Food and Drug Administration ("FDA") approval and net sales and commercial milestones.

Under the terms of the PNT2002 License Agreement, Lantheus Two paid POINT an upfront cash payment of $250.0 million, and could pay up to an additional $281.0 million in milestone payments upon the achievement of specified U.S. and ex-U.S. regulatory milestones related to PNT2002. POINT is also eligible to receive up to $1.3 billion in sales milestone payments upon the achievement of specified annual sales thresholds of PNT2002.

Under the terms of the PNT2003 License Agreement, Lantheus Three paid POINT an upfront cash payment of $10.0 million, and could pay up to an additional $34.5 million in milestone payments upon the achievement of specified U.S. and ex-U.S. regulatory milestones related to PNT2003. POINT is also eligible to receive up to $275.0 million in sales milestone payments upon the achievement of specified annual sales thresholds of PNT2003.

Additionally, the Company will pay POINT royalties on net sales, beyond certain financial thresholds and subject to conditions, of 20% for PNT2002 and 15% for PNT2003. Costs of IPR&D projects acquired as part of an asset acquisition that have no alternative future use are expensed when incurred, and therefore, a charge of $260.0 million was recognized in research and development expenses during the year ended December 31, 2022.

22. Segment Information

The Company operates as one business segment. The results of this operating segment are regularly reviewed by the Company's chief operating decision maker, the 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.

23. Subsequent Event

On January 9, 2024, the Company entered into multiple strategic agreements with Perspective Therapeutics, Inc. ("Perspective"), a radiopharmaceutical company that is pioneering advanced treatment applications for cancers throughout the body. Under the agreements:

- The Company obtained an option to exclusively license Perspective's Pb212-VMT-α-NET, a clinical stage alpha therapy in development for the treatment of neuroendocrine tumors, and an option to co-develop certain early stage therapeutic candidates targeting prostate cancer using Perspective's innovative platform technology, for an aggregate upfront payment of $28 million in cash;
- Lantheus agreed to purchase up to 19.9% of Perspective's outstanding shares of common stock for up to approximately $33 million, subject to completion of a qualified third party financing transaction and certain other closing conditions; and
- Perspective agreed to acquire the assets and associated lease of Lantheus' radiopharmaceutical manufacturing facility in Somerset, New Jersey for an undisclosed price, subject to customary closing conditions including regulatory approval.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. 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.

Management's Annual Report on Internal Control Over Financial Reporting

Our management, with the participation of our CEO and CFO, is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control system is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making its assessment of internal control over financial reporting, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013). Based on this assessment, management concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

Deloitte & Touche LLP, an independent registered public accounting firm that audited our financial statements for the fiscal year ended December 31, 2023, included in this report, has issued an attestation report on the effectiveness of our internal control over financial reporting. This report is set forth below:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Lantheus Holdings, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Lantheus Holdings, Inc. and subsidiaries (the "Company") as of December 31, 2023, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2023, of the Company and our report dated February 22, 2024, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management's Annual Report on Internal Control Over Financial Reporting*. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 22, 2024

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting for the quarter ended December 31, 2023 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.

Item 9B. Other Information

On November 7, 2023, Sam Leno, a member of our Board, entered into a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act (a "10b5-1 Plan"), providing for the potential sale of up to 2,045 shares of our common stock obtained from the exercise of vested stock options covered by the 10b5-1 Plan, between March 4, 2024 and May 15, 2024. On November 29, 2023, Mr. Leno amended his 10b5-1 Plan to add the potential sale of up to 20,344 additional shares of our common stock obtained from the exercise of vested stock options covered by the 10b5-1 Plan, between March 4, 2024 and May 15, 2024.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Pursuant to Section 406 of the Sarbanes-Oxley Act of 2002, we have adopted a code of conduct and ethics (our "Code of Conduct") for all of our employees, including our CEO, CFO and other senior financial officers, or persons performing similar functions, and each of the non-employee directors on our Board. Our Code of Conduct is currently available on our website, www.lantheus.com. The information on our web site is not part of, and is not incorporated into, this Annual Report on Form 10-K. We intend to provide any required disclosure of any amendment to or waiver from such code that applies to our CEO, CFO and other senior financial officers, or persons performing similar functions, in a Current Report on Form 8-K filed with the SEC.

The additional information required with respect to this item will be incorporated herein by reference to our Definitive Proxy Statement for our 2023 Annual Meeting of Stockholders or an amendment of this report to be filed with the SEC no later than 120 days after the close of our year ended December 31, 2023.

Item 11. Executive Compensation

The information required with respect to this item will be incorporated herein by reference to our Definitive Proxy Statement for our 2024 Annual Meeting of Stockholders or an amendment of this report to be filed with the SEC no later than 120 days after the close of our year ended December 31, 2023.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required with respect to this item will be incorporated herein by reference to our Definitive Proxy Statement for our 2024 Annual Meeting of Stockholders or an amendment of this report to be filed with the SEC no later than 120 days after the close of our year ended December 31, 2023.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required with respect to this item will be incorporated herein by reference to our Definitive Proxy Statement for our 2024 Annual Meeting of Stockholders or an amendment of this report to be filed with the SEC no later than 120 days after the close of our year ended December 31, 2023.

Item 14. Principal Accountant Fees and Services

The information required with respect to this item will be incorporated herein by reference to our Definitive Proxy Statement for our 2024 Annual Meeting of Stockholders or an amendment of this report to be filed with the SEC no later than 120 days after the close of our year ended December 31, 2023.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements

The following consolidated financial statements of Lantheus Holdings, Inc. are filed as part of this Annual Report on Form 10-K under Part II, Item 8. Financial Statements and Supplementary Data:

(a)(2) Schedules

All schedules are omitted because they are not applicable, not required, or because the required information is included in the consolidated financial statements or notes thereto.

(a)(3) Exhibits

EXHIBIT INDEX

Exhibit Number	Description of Exhibits	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Lantheus Holdings, Inc.	8-K	001-36569	3.1	April 27, 2018
3.2	Amended and Restated Bylaws of Lantheus Holdings, Inc.	8-K	001-36569	3.2	December 28, 2022
4.1	Common Stock Certificate.	8-K	001-36569	4.1	June 30, 2015
4.2*	Description of Registrant's Securities				
4.3	Indenture, dated as of December 8, 2022, between Lantheus Holdings, Inc., as Issuer, Lantheus Medical Imaging, Inc., as Guarantor, and U.S. Bank Trust Company, National Association, as Trustee	8-K	001-36569	4.1	December 8, 2022
10.1+	Lantheus Holdings, Inc. 2008 Equity Incentive Plan.	S-4	333-169785	10.18	October 6, 2010
10.2+	Amendment No. 1 to Lantheus Holdings, Inc. 2008 Equity Incentive Plan.	S-4	333-169785	10.19	October 6, 2010
10.3+	Amendment No. 2 to Lantheus Holdings, Inc. 2008 Equity Incentive Plan.	S-4	333-169785	10.20	October 6, 2010
10.4+	Form of Option Grant Award Agreement.	S-4	333-169785	10.21	October 6, 2010
10.5+	Lantheus Holdings, Inc. 2013 Equity Incentive Plan.	8-K	333-169785	10.1	May 6, 2013
10.6+	Form of Employee Option Grant Award Agreement.	8-K	333-169785	10.2	May 6, 2013
10.7+	Form of Non-Employee Director Option Grant Award Agreement.	8-K	333-169785	10.3	May 6, 2013
10.8+	2015 Equity Incentive Plan of Lantheus Holdings, Inc.	S-1	333-196998	10.37	June 24, 2015
10.9+	Form of 2015 Restricted Stock Agreement of Lantheus Holdings, Inc.	S-1	333-196998	10.38	June 24, 2015
10.10+	Form of 2015 Option Award Agreement of Lantheus Holdings, Inc.	S-1	333-196998	10.39	June 24, 2015
10.11+	Form of Amendment to the Lantheus Holdings, Inc. 2013 Equity Incentive Plan.	S-1	333-196998	10.40	June 24, 2015
10.12+	Form of Amendment to the Lantheus Holdings, Inc. 2008 Equity Incentive Plan.	S-1	333-196998	10.41	June 24, 2015
10.13+	Amendment to Lantheus Holdings, Inc. 2015 Equity Incentive Plan.	8-K	001-36569	10.1	April 28, 2016
10.14+	Second Amendment to Lantheus Holdings, Inc. 2015 Equity Incentive Plan	8-K	001-36569	10.1	April 28, 2017
10.15+	Lantheus Holdings, Inc. 2017 Employee Stock Purchase Plan	8-K	001-36569	10.2	April 28, 2017
10.16†	Collaboration and License Agreement by and between Lantheus Medical Imaging, Inc. and GE Healthcare Limited dated April 25, 2017.	10-Q	001-36569	10.1	August 1, 2017
10.17+	Second Amended and Restated Employment Agreement, effective January 25, 2019, by and between Lantheus Medical Imaging, Inc. and Mary Anne Heino.	10-K	001-36569	10.68	February 20, 2019
10.18+	Form of Severance Agreement (executives with existing employment agreements).	10-K	001-36569	10.70	February 20, 2019
10.19+	Form of Severance Agreement (executives without existing employment agreements).	10-K	001-36569	10.71	February 20, 2019
10.20+	Third Amendment to Lantheus Holdings, Inc. 2015 Equity Incentive Plan	10-Q	001-36569	10.1	April 30, 2019
10.21+	Fourth Amendment to Lantheus Holdings, Inc. 2015 Equity Incentive Plan	10-Q	001-36569	10.2	July 25, 2019

Exhibit Number	Description of Exhibits	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
10.22+	Lantheus Holdings, Inc. 2005 Stock Incentive Plan (f/k/a Progenics Pharmaceuticals, Inc. 2005 Stock Incentive Plan).	S-8	333-239491	4.4	June 26, 2020
10.23+	Lantheus Holdings, Inc. 2018 Performance Incentive Plan (f/k/a Progenics Pharmaceuticals, Inc. 2018 Performance Incentive Plan).	S-8	333-239491	4.5	June 26, 2020
10.24	Lease, dated December 31, 2015, between the Registrant and WTC TOWER 1 LLC.	8-K	000-23143	10.46 (21)	January 5, 2016
10.25+	Fifth Amendment to Lantheus Holdings, Inc. 2015 Equity Incentive Plan	8-K	001-36569	10	April 29, 2021
10.26††	Manufacturing and Supply Agreement, effective as of February 23, 2022, by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterStier LLC.	10-Q	001-36569	10.1	April 29, 2022
10.27	Form of Restricted Stock Unit Award Agreement (Employee Time-Based Vesting) of Lantheus Holdings, Inc.	10-Q	001-36569	10.2	April 29, 2022
10.28	Form of Restricted Stock Unit Award Agreement (Relative Total Shareholder Return Performance-Based Vesting) of Lantheus Holdings, Inc.	10-Q	001-36569	10.3	April 29, 2022
10.29	Form of Stock Option Award Agreement (Time Vesting) of Lantheus Holdings, Inc.	10-Q	001-36569	10.4	April 29, 2022
10.30	Sixth Amendment to Lantheus Holdings, Inc. 2015 Equity Incentive Plan	8-K	001-36569	10.1	May 2, 2022
10.31††	License and Collaboration Agreement, dated as of November 11, 2022, by and between Point Biopharma, Inc., and Lantheus Two, LLC.	8-K	000-36569	10.1	November 14, 2022
10.32	Credit Agreement dated as of December 2, 2022 by and among Citizens Bank, N.A., as administrative agent and collateral agent, each of the lenders from time to time party thereto, Lantheus Medical Imaging, Inc., as borrower, and Lantheus Holdings, Inc.	8-K	001-36569	10.1	December 5, 2022
10.33+	Lantheus Holdings, Inc. 2023 Employee Stock Purchase Plan	8-K	001-36569	10.1	May 1, 2023
10.34††	Office Lease by and between LMI and 201 Burlington Road Owner, LLC dated February 14, 2022 (the "Lease"); as amended by the First Amendment To Lease dated May 4, 2023	10-Q	001-36569	10.1	August 3, 2023
19.1*	Policy on Insider Trading and Communications with the Public				
21.1*	Subsidiaries of Lantheus Holdings, Inc.				
23.1*	Consent of Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (included as part of the signature page hereto).				
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.				
97.1*	Amended and Restated Executive Compensation Clawback Policy				
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 Labels 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.
†† Portions of this exhibit have been omitted for confidential treatment pursuant to Item 601(b)(10)(iv) of Regulation S-K.
\+ Indicates management contract or compensatory plan or arrangement.
† Confidential treatment requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: Chief Executive Officer
Date: February 22, 2024

We, the undersigned directors and officers of Lantheus Holdings, Inc., hereby severally constitute and appoint Mary Anne Heino, Robert J. Marshall, Jr. and Daniel Niedzwiecki, and each of them individually, with full powers of substitution and resubstitution, our true and lawful attorneys, with full powers to them and each of them to sign for us, in our names and in the capacities indicated below, any and all amendments to this Annual Report on Form 10-K filed with the SEC, granting unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that any such attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ MARY ANNE HEINO Mary Anne Heino	Chief Executive Officer and Director (Principal Executive Officer)	February 22, 2024
/S/ ROBERT J. MARSHALL, JR. Robert J. Marshall, Jr.	Chief Financial Officer and Treasurer (Principal Financial Officer)	February 22, 2024
/S/ ANDREA SABENS Andrea Sabens	Chief Accounting Officer (Principal Accounting Officer)	February 22, 2024
/S/ BRIAN MARKISON Brian Markison	Executive Chair of the Board of Directors	February 22, 2024
/S/ MINNIE BAYLOR-HENRY Minnie Baylor-Henry	Director	February 22, 2024
/S/ GÉRARD BER Gérard Ber	Director	February 22, 2024
/S/ SAMUEL R. LENO Samuel R. Leno	Director	February 22, 2024
/S/ HEINZ MÄUSLI Heinz Mäusli	Director	February 22, 2024
/S/ JULIE H. MCHUGH Julie H. McHugh	Director	February 22, 2024
/S/ GARY J. PRUDEN Gary J. Pruden	Director	February 22, 2024
/S/ DR. JAMES H. THRALL Dr. James H. Thrall	Director	February 22, 2024