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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, 2020

☐ **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.)**
331 Treble Cove Road, North Billerica, MA	**01862**
(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. ☑

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, 2020 was approximately $947.4 million based on the last reported sale price of the registrant's common stock on the NASDAQ Global Market on June 30, 2020 of $14.30 per share.

As of February 19, 2021 the registrant had 66,968,382 shares of common stock, $0.01 par value, issued and 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 27, 2021, portions of which are incorporated by reference into Parts II and III of this Form 10-K. The 2021 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, 2020.

LANTHEUS HOLDINGS, INC.
ANNUAL REPORT ON FORM 10-K
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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, and references to "Progenics" refer to Progenics Pharmaceuticals, Inc., a wholly-owned subsidiary of LMI.

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 include words such as "anticipates," "intends," "plans," "seeks," "believes," "estimates," "expects," "should," "could," "predicts," "hopes" and similar expressions. Examples of forward-looking statements include statements we make relating to our outlook and expectations including, without limitation, in connection with: (i) the impact of the global COVID-19 pandemic on our business, financial conditions or prospects, or on the timing and enrollment of our clinical trials; (ii) continued market expansion and penetration for our commercial products, particularly DEFINITY, in the face of segment competition and potential generic competition as a result of patent and regulatory exclusivity expirations; (iii) our efforts in new product development, including for PyL, our prostate cancer diagnostic imaging agent, including our ability to obtain U.S. Food and Drug Administration ("FDA") approval of PyL in 2021, and new clinical applications for our products; (iv) our dependence upon third parties for the manufacture and supply of PyL and the timing of that manufacturing capacity becoming available; (v) the global Molybdenum-99 ("Mo-99") supply; (vi) our products manufactured at Jubilant HollisterStier ("JHS") and our recently-approved modified formulation of DEFINITY ("DEFINITY RT") to be commercially manufactured at Samsung Biologics ("SBL"); (vii) the continued integration of the Progenics product and product candidate portfolio into our business following the June 2020 consummation of the Progenics acquisition (the "Progenics Acquisition"); (viii) our ability to use in-house manufacturing capacity; (ix) the expected timing for commercialization of products we or our strategic partners may develop, including flurpiridaz F 18; and (x) our ability to develop highly contextualized assessments of disease burden using artificial intelligence ("AI"). 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.

Trademarks

We own or have the rights to various trademarks, service marks and trade names, including, among others, the following: DEFINITY®, TechneLite®, Cardiolite®, NEUROLITE®, VIALMIX®, QUADRAMET®, Luminity®, PyL™, AZEDRA®, AZEDRA Service Connection®, RELISTOR®, Progenics®, Progenics Pharmaceuticals®, Molecular Insight®, EXINI®, Find, Fight and Follow®, PyL Research Access Program®, and Lantheus Medical Imaging® 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 an established leader and fully integrated provider of innovative imaging diagnostics, targeted therapeutics, and artificial intelligence solutions to Find, Fight and Follow serious medical conditions. For our imaging diagnostics, we believe that the resulting improved diagnostic information enables healthcare providers to better detect and characterize, or rule out, disease, potentially achieving improved patient outcomes, reducing patient risk and limiting overall costs for payers and the entire healthcare system.

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

We sell our products globally and operate our business in two reportable segments, which are further described below:

- *U.S. Segment* produces and markets our agents and products throughout the U.S. In the U.S., we primarily sell to radiopharmacies, PMFs, integrated delivery networks, hospitals, clinics and group practices.
- *International Segment* operations consist of direct distribution in Canada and Puerto Rico, as well as third-party distribution relationships in Europe, Canada, Australia, Asia-Pacific and Latin America and our EXINI business in Sweden.

We are in the process of evaluating our operating and reporting structure. We anticipate this evaluation, which we expect to complete during 2021, may result in a change to our existing operating segment reporting structure.

Progenics Acquisition

On June 19, 2020, we completed the Progenics Acquisition. Progenics is an oncology company focused on developing and commercializing innovative targeted medicines and artificial intelligence to Find, Fight and Follow cancer. Progenics' portfolio of products and product candidates includes, among other things, therapeutic agents designed to target cancer (AZEDRA, 1095 and PSMA TTC), diagnostic imaging agents designed to target PSMA for prostate cancer (PyL and 1404), RELISTOR for opioid-induced constipation ("OIC"), artificial intelligence ("AI") imaging technologies and leronlimab being developed for HIV infection and COVID-19 applications. Progenics' current revenue is generated from two principal sources: first, royalties, development and commercial milestones from strategic partnerships, including royalties from Bausch from sales of RELISTOR; and second, AZEDRA sales.

Lantheus Holdings issued 26,844,877 shares of Lantheus Holdings common stock and 86,630,633 CVRs to former Progenics stockholders in connection with the Progenics Acquisition. Lantheus Holdings also assumed 34,000 in-the-money Progenics stock options and 6,507,342 out-of-the-money Progenics stock options, each converted into Replacement Stock Options at an exchange ratio of 0.31.

As a result of the Progenics Acquisition, we added the following products and product candidates to our portfolio:

Product / Product Candidate	Description	Status	Market	Rights
Ultra-Orphan Therapeutic				
AZEDRA (iobenguane I 131) 555 MBq/mL injection	Unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma	Approved	U.S	Progenics
Prostate Cancer Diagnostics and Therapeutics				
PyL (18F-DCFPyL)	PSMA-targeted PET/CT imaging agent for prostate cancer	NDA accepted; PDUFA date of May 28, 2021	Worldwide (ex. EU, AU & NZ)	Progenics
PyL (18F-DCFPyL)	PSMA-targeted PET/CT imaging agent for prostate cancer	Late stage development	Europe	Curium
1095 (I 131 1095)	PSMA-targeted small molecule therapeutic for metastatic prostate cancer	Phase 2	Worldwide	Progenics
PSMA TTC (BAY 2315497)	PSMA-targeted antibody conjugate therapeutic for metastatic prostate cancer	Phase 1	Worldwide	Bayer
1404	Technetium-99m PSMA-targeted SPECT/CT imaging agent for prostate cancer	Discussions with European Medicines Agency (EMA)	Europe	ROTOP
Digital Solutions				
PSMA AI	AI-based imaging analysis technology that assists readers in quantification and standardized reporting of PSMA-targeted PET/CT imaging, providing an objective understanding of disease status	Investigational Use Only	Worldwide	Progenics
Automated Bone Scan Index (aBSI)	Automated reading and quantification of bone scans of prostate cancer patients using AI and deep learning	Approved in the U.S. (510(k) clearance) and in the E.U. (CE marked)	Worldwide	Progenics
Automated Bone Scan Index (BONENAVI)	Automated reading and quantification of bone scans of prostate cancer patients using AI and deep learning	Approved in Japan	Japan	FUJIFILM
Other Partnerships				
RELISTOR Subcutaneous Injection (methylnaltrexone bromide)	OIC in adults with chronic non-cancer pain or advanced-illness adult patients	Approved	Worldwide	Bausch
RELISTOR Tablets (methylnaltrexone bromide)	OIC in adults with chronic non-cancer pain	Approved	U.S.	Bausch
leronlimab (PRO 140)	HIV Infection, COVID-19	CytoDyn is working to provide information required by the FDA in order to resubmit a BLA for HIV; CytoDyn has started recruiting for a Phase 2b/3 trial for COVID-19	U.S.	CytoDyn

See Part I, Item 1A. “Risk Factors” in this Annual Report on form 10-K for the year ended December 31, 2020, for information regarding certain risks associated with our Progenics Acquisition.

Our Portfolio of Commercial Products

Our commercial products now include the following:

- DEFINITY is a microbubble ultrasound enhancing agent used in ultrasound exams of the heart, also known as echocardiography exams. DEFINITY contains perflutren-containing lipid microspheres and is indicated in the U.S. for use in patients with suboptimal echocardiograms to assist in imaging the left ventricular chamber and left endocardial border of the heart in ultrasound procedures. In November 2020, the FDA approved our supplemental new drug application ("sNDA") for DEFINITY RT. DEFINITY RT is a modified formulation of DEFINITY that allows both storage and shipment at room temperature (DEFINITY's previously approved formulation requires refrigerated storage). We believe we are currently the leading provider of ultrasound microbubble enhancing agents in the world.
- TechneLite is a Technetium ("Tc-99m") generator that provides the essential nuclear material used by radiopharmacies to radiolabel Cardiolite, Neurolite 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 SPECT technology to identify the area within the brain where blood flow has been blocked or reduced due to stroke.
- RELISTOR (methylnaltrexone bromide) is a treatment for 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.
- 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. We believe we are currently the leading provider of Xenon in the U.S.
- 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. Cardiolite was approved by the FDA in 1990 and its market exclusivity expired in July 2008. Included in Cardiolite revenues are branded Cardiolite and generic sestamibi revenues.
- Gallium-67 ("Gallium") is an injectable radiopharmaceutical imaging agent used to detect certain infections and cancerous tumors, especially lymphoma. We manufacture Gallium using cyclotron technology.
- Thallium-201 ("Thallium") is an injectable radiopharmaceutical imaging agent used in MPI studies to detect cardiovascular disease. We manufacture Thallium using cyclotron technology.
- AZEDRA (iobenguane I 131) is a radiotherapeutic, approved for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. AZEDRA is the first and only FDA-approved therapy for this indication.
- QUADRAMET is an injectable radiopharmaceutical used to treat severe bone pain associated with osteoblastic metastatic bone lesions. We serve as the direct manufacturer and supplier of QUADRAMET in the U.S.
- Automated Bone Scan Index ("aBSI") calculates the disease burden of prostate cancer by quantifying the hotspots on bone scans and automatically calculating the bone scan index value, representing the disease burden of prostate cancer shown on the bone scan. This quantifiable and reproducible calculation of the bone scan index value is intended to aid in the diagnosis and treatment of men with prostate cancer and may have utility in monitoring the course of the disease. The Japanese rights to the stand-alone aBSI have been transferred and sold to FUJIFILM Toyama Chemical Co. Ltd. ("FUJIFILM") under the name BONENAVI®. The cloud based aBSI was made available for clinical use in the U.S. on August 5, 2019. In February 2020, 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 on a GE Healthcare system.
- Cobalt (Co 57) is a non-pharmaceutical radiochemical used in the manufacture of sources for the calibration and maintenance of SPECT imaging cameras.

Sales of our microbubble ultrasound enhancing agent, DEFINITY, are made in the U.S. and Canada through a DEFINITY direct sales team. In the U.S., our nuclear imaging products, including TechneLite, Xenon, NEUROLITE and Cardiolite, are primarily distributed through commercial radiopharmacies, the majority of which are controlled by or associated with Cardinal, RLS (previously GE Healthcare), UPPI, Jubilant Radiopharma and PharmaLogic. A small portion of our nuclear imaging product sales in the U.S. are made through our direct sales force to hospitals and clinics that maintain their own in-house radiopharmaceutical preparation capabilities. AZEDRA is also sold in the U.S. through an AZEDRA direct sales team. RELISTOR was licensed to Bausch, and we collect quarterly royalties based on those sales.

We also maintain our own direct sales force in Canada for certain of our products. In Europe, Australia, Asia-Pacific and Latin America, we generally rely on third-party distributors to market, sell and distribute our nuclear imaging and ultrasound enhancing agent products, either on a country-by-country basis or on a multi-country regional basis. Our headquarters are located in North Billerica, MA with offices in New York, NY; Somerset, NJ; Montreal, Canada and Lund, Sweden.

Anticipated continued growth of DEFINITY and Expansion of Our Ultrasound Microbubble Franchise

DEFINITY is the leading ultrasound enhancing agent based on revenue and usage in the U.S., and is indicated for use in patients with suboptimal echocardiograms. 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.

DEFINITY is a clear, colorless, sterile liquid, which, upon activation in a VIALMIX apparatus, a medical device 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.

There were approximately 31.5 million echocardiograms performed in the U.S. in 2020 according to a third party source. Assuming 20% of echocardiograms produce suboptimal images, as stated in the clinical literature, we estimate that approximately 6.3 million echocardiograms in 2020 produced suboptimal images. In 2019, a year in which the volume of echocardiograms was not impacted by the COVID-19 pandemic, there were 35.1 million echocardiograms performed in the U.S. according to a third party source. Assuming the same 20% of suboptimal images, we estimate that approximately 7.0 million echocardiograms in 2019 produced suboptimal images.

Since its launch in 2001, DEFINITY has been used in imaging procedures in more than 16.1 million studies throughout the world. We estimate that DEFINITY had over 80% share of the U.S. segment for ultrasound enhancing agents in echocardiography procedures as of December 2020. DEFINITY currently competes with Optison, a GE Healthcare product, Lumason, a Bracco product (known as SonoVue outside the U.S.) as well as echocardiography without ultrasound enhancing agents and non-echocardiography imaging modalities. DEFINITY, Optison and Lumason 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.”

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

- *Patents* - We continue to actively pursue additional patents in connection with DEFINITY and DEFINITY RT, both in the U.S. and internationally. In the U.S. for DEFINITY we now own a total of four Orange Book-listed method of use patents, one of which expires in 2035 and three of which expire in 2037, as well as additional manufacturing patents that are not Orange Book-listed expiring in 2021, 2023 and 2037. In the U.S. for DEFINITY RT, we own a total of five Orange Book-listed patents, including a composition of matter patent which expires in 2035. Outside of the U.S., while our original DEFINITY patent protection and regulatory exclusivity have generally expired, we are currently prosecuting 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.
- *Hatch-Waxman Act* - Even though our longest duration Orange Book-listed DEFINITY patent extends until March 2037, because our Orange Book-listed composition of matter patent expired in June 2019, we may face generic DEFINITY challengers in the near to intermediate term. Under the Hatch-Waxman Act, the FDA can approve Abbreviated New Drug Applications (“ANDAs”) for generic versions of drugs if the ANDA applicant demonstrates, among other things, that (i) its generic candidate is the same as the innovator product by establishing bioequivalence and providing relevant chemistry, manufacturing and product data, and (ii) the marketing of that generic candidate does not infringe an Orange Book-listed patent or that an Orange Book-listed patent is invalid. With respect to any Orange Book-listed patent covering the innovator product, the ANDA applicant must give a notice to the innovator (a “Notice”) that the ANDA applicant certifies that its generic candidate will not infringe the innovator’s Orange Book-listed patent or that the Orange Book-listed patent is invalid. The innovator can then challenge the ANDA applicant in court within 45 days of receiving that 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 ANDA applicant is resolved in court. The 30 month stay could potentially expire sooner if the courts determine that no infringement had occurred or that the challenged Orange Book-listed patent is invalid or if the parties otherwise settle their dispute.

  As of the date of filing of this Annual Report on Form 10-K, we have not received any Notice from an ANDA applicant. If we were to (i) receive any such Notice in the future, (ii) bring a patent infringement suit against the ANDA applicant within 45 days of receiving that Notice, and (iii) successfully obtain the full 30 month stay, then the ANDA 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 ANDA applicant in March 2021 and the full 30 month stay was obtained, then the ANDA applicant would be precluded from commercialization until at least September 2023. If we received a Notice some number of months in the future and the full 30 month stay was obtained, the commercialization date would roll forward in the future by the same calculation.

- *DEFINITY RT* - In November 2020, the FDA approved our sNDA for DEFINITY RT. DEFINITY RT is a modified formulation of DEFINITY that allows both storage and shipment at room temperature (DEFINITY's previously approved formulation requires refrigerated storage). The modified formulation provides clinicians an additional choice and allows for greater utility of this formulation in broader clinical settings. We believe DEFINITY RT will become commercially available later in 2021, although that timing cannot be assured. Given its physical characteristics, we believe DEFINITY RT is also well-suited for inclusion in kits requiring microbubbles for other indications and applications (including in kits developed by third parties of the type described in the paragraph entitled *New Clinical Applications* below).
- *VIALMIX RFID* – In August 2020, we announced the FDA approved our sNDA for our next-generation activation device designed specifically for both DEFINITY and DEFINITY RT. The activation rate and time are controlled by VIALMIX RFID through the use of radio-frequency identification technology ("RFID") to ensure reproducible activation of DEFINITY and DEFINITY RT. The RFID tag, which is affixed to the vial label, enables the DEFINITY or DEFINITY RT vial to be appropriately activated when utilized with the VIALMIX RFID activation device.
- *New Clinical Applications* - As we continue to look for other opportunities to expand our microbubble franchise, we are evaluating new indications and clinical applications beyond echocardiography and ultrasound enhancing agent imaging generally.
    - In April 2019, we announced a strategic development and commercial collaboration with 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. Retinal vein occlusion is one of the most common causes of vision loss worldwide.
    - In December 2019, we announced a strategic commercial supply agreement with CarThera for the use of our microbubbles in combination with SonoCloud, a proprietary implantable device in development for the treatment of recurrent glioblastoma. Glioblastoma is a lethal and devastating form of brain cancer with median survival of 15 months after diagnosis.
    - In October 2020, we announced a strategic collaboration with Insightec Ltd. ("Insightec") which will use our microbubbles in connection with Insightec's transcranial guided focused ultrasound device for the treatment of glioblastoma as well as other neurodegenerative conditions.
- *In-House Manufacturing* - We have completed construction of specialized, in-house manufacturing capabilities at our North Billerica, Massachusetts facility for DEFINITY and, potentially, other sterile vial products. We believe the investment in these efforts will allow us to better control DEFINITY manufacturing and inventory, reduce our costs in a potentially more price competitive environment, and provide us with supply chain redundancy. We currently expect to make use of this in-house manufacturing capability in late 2021, although that timing cannot be assured.
- *DEFINITY in China* - In March 2020 in connection with our Chinese development and distribution arrangement with Double-Crane Pharmaceutical Company ("Double-Crane"), we filed an Import Drug License application with the National Medical Products Administration, or the NMPA, for the use of DEFINITY for the echocardiography indication. We believe this is an important milestone in our efforts to commercialize DEFINITY in China. Double-Crane is also in the process of analyzing the clinical results relating to the liver and kidney indications and will also work with us to prepare an Import Drug License application for those indications.

See Part I, Item 1A. "Risk Factors" for information regarding certain risks associated with DEFINITY and see Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations-Comparison of the Periods Ended December 31, 2020 and 2019-Revenues" for further information on total revenue contributed by DEFINITY in each of our last three fiscal years.

TechneLite

TechneLite is a self-contained system or generator of Technetium ("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 produced in nuclear research reactors around the world from enriched uranium. The TechneLite generator is a little larger than a coffee can in size, and the self-contained system houses a vertical glass column at its core that contains Mo-99. 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 Cardiolite products and NEUROLITE, 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 the vacuum vial and subsequently combined by a radiopharmacist with the applicable imaging agent, and individual patient-specific radiolabeled imaging agent doses are then prepared. 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 North America and Latin 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 the significant radiopharmacy groups, including Cardinal, RLS, UPPI, Jubilant Radiopharma and PharmaLogic. 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, 2020, competing primarily with Tc-99m-based generators produced by Curium. Outside of the U.S., we sell generators through supply agreements with radiopharmacy chains, through distributors or to separate customers.

The Mo-99 used in our TechneLite generators can be produced using targets made of either highly-enriched uranium ("HEU") or low-enriched uranium ("LEU"). LEU consists of uranium that contains less than 20% of the uranium-235 isotope. HEU is considered weapons grade material, with 20% or more of uranium-235. The American Medical Isotopes Production Act of 2012 encourages the domestic production of LEU Mo-99 and provides for the eventual prohibition of the export of HEU from the U.S. Although Medicare generally does not provide separate payment to hospitals for the use of diagnostic radiopharmaceuticals administered in an outpatient setting, since 2013, the Centers for Medicare and Medicaid Services ("CMS"), the federal agency responsible for administering the Medicare program, has provided an add-on payment of $10 under the hospital outpatient prospective payment system for every Tc-99m diagnostic dose produced from non-HEU sourced Mo-99, to cover the marginal cost for radioisotopes produced from non-HEU sources. Our LEU TechneLite generator satisfies the reimbursement requirements under the applicable CMS rules.

TechneLite has patent protection in the U.S. and various foreign countries on certain component technology currently 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. We believe that our substantial capital investments in our highly automated 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.

See Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations-Comparison of the Periods Ended December 31, 2020 and 2019-Revenues" for further information on total revenue contributed by TechneLite in each of our last three fiscal years.

Our Portfolio of Clinical Development Candidates

In addition to our commercial products, we now have an extensive portfolio of product candidates in clinical development, including:

- **PyL** (also known as 18F-DCFPyL) is a fluorine 18-based PSMA-targeted PET imaging agent that enables visualization of primary tumors as well as bone and soft tissue metastases, with potential high clinical utility in the detection of recurrent and/or metastatic prostate cancer. Progenics has completed a clinical development program that consisted of two pivotal clinical studies, which were designed to provide robust, prospective, well-controlled, and pathology- or composite truth standard-verified data to establish the safety and diagnostic performance of PyL across the disease continuum of prostate cancer. The

results from these studies provide data in support of the potential of PyL to reliably detect and localize disease, including in patients with low PSA values, and may help enable appropriate disease management, thus supporting the potential use for detection of recurrent or metastatic prostate cancer. We filed the PyL NDA with the FDA in September 2020 and received notice of priority review in December 2020 with a PDUFA date of May 28, 2021.

- **flurpiridaz F 18** is a fluorine 18-based PET MPI agent designed to assess blood flow to the heart in patients suspected of coronary artery disease (CAD). In April 2017, we announced entering into a definitive, exclusive Collaboration and License Agreement with GE Healthcare for the agent's continued Phase 3 development and worldwide commercialization. The second Phase 3 trial is now underway; however, because of the COVID-19 pandemic, enrollment in the global clinical development program had been delayed and has now resumed at a slower recruiting pace. GE Healthcare now expects to complete enrollment in the second half of 2021 and, assuming regulatory approval, begin commercialization in early 2023.
- **1095** (also known as I-131-1095) is a 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. Progenics initiated eleven clinical sites in the U.S. along with the six active sites in Canada to support enrollment in the Company's multicenter, randomized, controlled, ARROW Phase 2 study in mCRPC. Because of the COVID-19 pandemic, Progenics new enrollment in the Phase 2 trial was paused to minimize the risk to subjects and healthcare providers during the pandemic. Subjects who were active and had been randomized for the study continued to receive treatment doses and were monitored for safety and efficacy in a manner that is permissible by each clinical site. New enrollment in the ARROW Phase 2 study restarted in October 2020.
- **LMI 1195** is a fluorine 18-based PET imaging agent for the norepinephrine pathway. We have designed but not yet commenced two Phase 3 clinical trials for the use of LMI 1195 for the diagnosis and management of neuroendocrine tumors in pediatric and adult populations, respectively. The FDA has granted an Orphan Drug designation for the use of LMI 1195 in the management indication. We have also received notice of eligibility for a rare pediatric disease priority review voucher for a subsequent human drug application so long as LMI 1195 is approved by the FDA for its rare pediatric disease indication. Pursuant to federal legislation passed and signed into law in late 2020, the expiration date of the rare pediatric disease priority review voucher program was extended from September 30, 2022 to September 30, 2026.
- **PSMA TTC** is a thorium-227 labeled PSMA-targeted antibody therapeutic. PSMA TTC is designed to deliver a dose of alpha radiation directly to prostate cancer cells with minimal impact on the surrounding healthy tissues. Bayer AG ("Bayer") has exclusive worldwide rights to develop and commercialize products using our PSMA antibody platform in combination with Bayer's alpha-emitting radionuclides. Bayer is conducting a Phase 1 trial of PSMA TTC in subjects with metastatic castration-resistant prostate cancer ("mCRPC").
- **1404** is a Tc-99m labeled small molecule which binds to PSMA and is used as a SPECT/CT imaging agent to diagnose and detect localized prostate cancer as well as soft tissue and bone metastases. ROTOP has exclusive rights to develop, manufacture and commercialize 1404 in Europe.
- **PSMA-AI** is an AI-based imaging analysis technology that assists readers in quantification and standardized reporting of PSMA-targeted PET/CT imaging, providing an objective understanding of disease status. The technology automatically analyzes the CT image to segment anatomical regions – 51 bones and 12 soft tissue organs. This CT segmentation enables automated localization, detection and quantification of potential PSMA-avid lesions in the PET image, which is incorporated into a standardized report for physicians. In a recent study, the technology demonstrated better consistency in quantitative assessment across multiple readers and high sensitivity (>90%) in detecting potential lesions in PSMA PET/CT. The clinical utility of the device is being investigated in multiple outcome-based studies.
- **leronlimab** (PRO 140) is an investigational humanized monoclonal antibody targeting the CCR5 receptor. CCR5 appears to act as an HIV entry inhibitor and may play a broader role in tumor metastasis and immune-mediated illnesses. It is owned by CytoDyn Inc. ("CytoDyn") pursuant to our agreement with CytoDyn, as described below. In May 2020, CytoDyn announced it submitted a Biologics License Application ("BLA") to the FDA for approval of leronlimab in combination therapy for HIV infection. On July 13, 2020, CytoDyn announced that it had received a refusal to file letter from the FDA for the BLA. In August and September 2020, the FDA provided written responses to CytoDyn's questions and met telephonically with CytoDyn key personnel and its clinical research organization concerning its recent BLA for this HIV combination therapy to expedite the resubmission of its BLA filing for this indication. CytoDyn is working diligently to resubmit the BLA, which it expects to file in the first half of calendar year 2021. Leronlimab is also being evaluated by CytoDyn for patients with mild/moderate COVID-19 indications in a Phase 2 randomized clinical trial that was recently completed. Also, CytoDyn has started recruiting for a Phase 2b/3 trial for 390 severe or critical COVID-19 patients.

For the years ended December 31, 2020, 2019 and 2018, we invested $32.8 million, $20.0 million and $17.1 million in research and development ("R&D"), respectively. Our R&D team 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 clinical development programs.

Strategic Partnerships

In connection with our commercial products and product candidates, we now have a number of strategic partnerships, including:

- **Bausch Agreement** -- Under its agreement with Salix Pharmaceuticals, Inc., a wholly-owned subsidiary of Bausch, Progenics received a $40.0 million development milestone upon U.S. marketing approval for subcutaneous RELISTOR in non-cancer pain patients in 2014, a $50.0 million development milestone for the U.S. marketing approval of an oral formulation of RELISTOR in July 2016, and a $10.0 million sales milestone for RELISTOR achieving U.S. net sales in excess of $100.0 million in 2019. We are also eligible to receive additional 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. We are also eligible to receive royalties from Bausch and its affiliates based on the following royalty scale: 15% on worldwide net sales up to $100.0 million, 17% on the next $400.0 million in worldwide net sales, and 19% on worldwide net sales over $500.0 million each calendar year, and 60% of any upfront, milestone, reimbursement or other revenue (net of costs of goods sold, as defined, and territory-specific research and development expense reimbursement) Bausch receives from sublicensees outside the U.S.

- **GE Healthcare Agreement –** Under our April 2017 Collaboration and License Agreement, GE Healthcare will complete the worldwide development of flurpiridaz F 18, pursue worldwide regulatory approvals, and, if successful, lead a worldwide launch and commercialization of the agent, with us collaborating on both development and commercialization through a joint steering committee. We also have 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.
- **Curium Agreement** – Curium has licensed exclusive rights to develop and commercialize PyL in Europe. Under the terms of the collaboration, Curium is responsible for the development, regulatory approvals and commercialization of PyL in Europe, and we are entitled to double-digit royalties on net sales of PyL. Curium is currently in late-stage development in Europe.
- **Bayer Agreements** – Under Progenics’ April 2016 agreement with a subsidiary of Bayer granting Bayer exclusive worldwide rights to develop and commercialize products using our PSMA antibody platform, in combination with Bayer’s alpha-emitting radionuclides, Progenics received an upfront payment of $4.0 million and milestone payments totaling $5.0 million. We could receive up to an additional $44.0 million in potential clinical and development milestones. We are also entitled to single-digit royalties on net sales, and potential net sales milestone payments up to an aggregate of $130.0 million. In addition, in October 2020, we entered into a PyL Clinical Supply Agreement with Bayer to include PyL in their clinical trial for prostate cancer. PyL will be used by Bayer to assess PSMA expression levels at baseline and during treatment.
- **CytoDyn Agreement** -- Progenics sold leronlimab to CytoDyn in 2012, which sale included milestone and royalty payment obligations to Progenics. Under the 2012 agreement, CytoDyn is responsible for all development, manufacturing and commercialization efforts. Pursuant to such agreement, Progenics received $5.0 million in upfront and milestone payments, and we have the right to receive an additional $5.0 million upon the first U.S. or E.U. approval for the sale of the drug, and a 5% royalty on the net sales of approved products.
- **ROTOP Agreement** -- In May 2019, Progenics entered into an exclusive license agreement with ROTOP, a Germany-based developer of radiopharmaceuticals for nuclear medicine diagnostics, to develop, manufacture and commercialize 1404 in Europe. Under the terms of the collaboration, ROTOP is responsible for the development, regulatory approvals and

commercialization of 1404 in Europe while we are entitled to double-digit, tiered royalties on net sales of 1404 in Europe. ROTOP is in discussions with EMA regarding the development path in Europe.

- **FUJIFILM Agreement** -- In June 2019, EXINI entered into a transfer agreement with FUJIFILM for the rights to the bone scan index product in Japan for use under the name BONENAVI. Under the terms of the transfer agreement, FUJIFILM acquired, by a combination of purchase and license, the Japanese software, source code, supporting data and all Japanese patents associated with the bone scan index product from EXINI for use in Japan. In exchange, EXINI received $4.0 million in an upfront payment and FUJIFILM agreed to pay EXINI support and service fees for bone scan index and other AI products over the next three years in Japan. BONENAVI has been licensed to FUJIFILM for use in Japan since 2011. In February 2021, EXINI entered into a new agreement with FUJIFILM for the heart myocardial perfusion analysis software, cREPO, in Japan.
- **Regeneron Agreement** – In June 2020, we entered into a PyL Clinical Supply Agreement with Regeneron Pharmaceuticals, Inc. (“Regeneron”) under which we will supply PyL to Regeneron as an imaging agent to evaluate and follow subjects for a Phase 1/2 clinical study of Regeneron’s PSMA-targeted mCRPC therapeutic candidate.
- **POINT Biopharma –** In December 2020, we entered into a PyL Clinical Supply Agreement with POINT Biopharma US Inc. (“POINT Biopharma”) under which we will supply PyL to POINT Biopharma as an imaging agent to evaluate and follow subjects for a Phase 3 clinical study of POINT Biopharma’s PSMA-targeted mCRPC therapeutic candidate.

Distribution, Marketing and Sales

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

Product	Approved Markets
DEFINITY	Australia, Canada, European Union, European Economic Area, India, Israel, Mexico, New Zealand, Singapore, South Korea, Taiwan, United States
TechneLite	Australia, Brazil, Canada, Colombia, Costa Rica, New Zealand, Panama, South Korea, Taiwan, United States
NEUROLITE	Australia, Austria, Belgium, Canada, Costa Rica, Denmark, France, Germany, Hong Kong, Italy, Japan, Luxembourg, New Zealand, Philippines, Slovenia, South Korea, Spain, Taiwan, Thailand, United States
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
Xenon	Canada, United States
Cardiolite	Australia, Canada, Costa Rica, Hong Kong, Israel, Japan, New Zealand, Panama, Philippines, South Korea, Taiwan, Thailand, United States
Gallium	Australia, Canada, Colombia, Costa Rica, New Zealand, Pakistan, Panama, South Korea, Taiwan, United States
Thallium	Australia, Canada, Colombia, New Zealand, Pakistan, Panama, South Korea, Taiwan, United States
AZEDRA	United States
QUADRAMET	United States

In the U.S. and Canada, our sales team of approximately 80 employees is split into separate sales teams for each of DEFINITY, AZEDRA and our radiopharmaceutical products. We are also beginning to assemble a sales and commercial team for PyL in anticipation of potential FDA approval and a commercial launch later in 2021.

We sell a majority of our radiopharmaceutical products in the U.S. to five radiopharmacy groups—namely Cardinal, RLS, UPPI, Jubilant Radiopharma and PharmaLogic. Our contractual distribution and other arrangements with these radiopharmacy groups are as follows:

- Cardinal maintains approximately 131 radiopharmacies that are typically located in large, densely populated urban areas in the U.S. We estimate that Cardinal's radiopharmacies distributed approximately 44% of the aggregate U.S. SPECT doses sold in the first half of 2020. Our supply agreement with Cardinal relating to TechneLite, Xenon, NEUROLITE and other products has been extended until December 31, 2022. The agreement specifies pricing levels and requirements to purchase minimum percentages of certain products during certain periods. The agreement may be terminated upon the occurrence of specified events, including a material breach by the other party and certain force majeure events.
- RLS maintains approximately 31 radiopharmacies in the U.S. that purchase our TechneLite generators. RLS purchased these radiopharmacies from GE Healthcare in the third quarter of 2020. We estimate that RLS distributed approximately 8% of the aggregate U.S. SPECT doses sold in the first half of 2020. We currently have an agreement with RLS for the distribution of TechneLite, Xenon and Gallium. The agreement provides that RLS will purchase a minimum percentage of TechneLite generators as well as certain other products from us. Our agreement, which has been extended until December 31, 2021, may be terminated by either party upon the occurrence of specified events including a material breach by either party, bankruptcy by either party, certain irresolvable regulatory changes or economic circumstances, or force majeure events.
- UPPI is a cooperative purchasing group (roughly analogous to a group purchasing organization) of approximately 52 independently owned or smaller chain radiopharmacies located in the U.S. UPPI's radiopharmacies are typically broadly dispersed geographically, with some urban presence and a substantial number of radiopharmacies located in suburban and rural areas of the country. We estimate that these independent radiopharmacies, together with approximately 13 unaffiliated, independent radiopharmacies, distributed approximately 19% of the aggregate U.S. SPECT doses sold in the first half of 2020. We currently have an agreement with UPPI for the distribution of TechneLite, Xenon and certain other products to radiopharmacies or families of radiopharmacies within the UPPI cooperative purchasing group. The agreement contains specified pricing levels based upon specified purchase amounts for UPPI. We are entitled to terminate the UPPI agreement upon 60 days written notice. The UPPI agreement has been extended until December 31, 2023.
- Jubilant Radiopharma maintains approximately 48 radiopharmacies in the U.S. that purchase a range of our products. We estimate that Jubilant Radiopharma distributed approximately 13% of the aggregate U.S. SPECT doses sold in the first half of 2020. We currently have an agreement with Jubilant Radiopharma for the distribution of TechneLite, Xenon, NEUROLITE and other products. The agreement specifies pricing levels and volume and percentage purchase requirements. The agreement has been extended until June 30, 2021 and may be terminated upon the occurrence of specified events, including a material breach by the other party.
- PharmaLogic maintains approximately 27 radiopharmacies in the U.S. that purchase a range of our products. We estimate that PharmaLogic distributed approximately 4% of the aggregate U.S. SPECT doses sold in the first half of 2020. Our written supply agreement with PharmaLogic relating to TechneLite, Xenon, Cardiolite and other products has been extended until December 31, 2021. The agreement specifies pricing levels and requirements to purchase minimum percentages of certain products during certain periods. The agreement may be terminated upon the occurrence of specified events, including a material breach by the other party and certain force majeure events.

In addition to the distribution arrangements for our radiopharmaceutical products described above, we also sell certain of our radiopharmaceutical products to independent radiopharmacies and directly to hospitals and clinics that maintain in-house radiopharmaceutical capabilities and operations. In the latter case, this represents a small percentage of overall sales because the majority of hospitals and clinics do not maintain these in-house capabilities.

In Canada, we operate some direct distribution activities and also rely on third party distributors. In Europe, Australia, Asia-Pacific and Latin America, we utilize third party distributor relationships to market, sell and distribute our products, either on a country-by-country basis or on a multi-country regional basis.

In March 2012, we entered into a development and distribution arrangement with Double-Crane for DEFINITY in China, Hong Kong and Macau. With Double-Crane's support, we are currently pursuing Chinese regulatory approval required to commercialize DEFINITY. In July 2013, we submitted a clinical trial application to the NMPA seeking an Import Drug License. After a very extensive waiting period caused by a large number of drugs seeking NMPA regulatory approval, in February 2016, the NMPA approved our clinical trial application. 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 March 2020, we filed an Import Drug License application with the NMPA for the use of DEFINITY for the echocardiography indication. We believe this is an important milestone in our efforts to commercialize DEFINITY in China. Double-Crane is also in the process of analyzing the clinical results relating to the liver and kidney indications and will also work with us to prepare an Import Drug License application for those indications.

Seasonality

For the diagnostic portion of our business, we have some modest seasonality as patients may seek to schedule diagnostic imaging 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 year ended December 31, 2020.

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 DEFINITY, our competitors currently include GE Healthcare and Bracco.
- For a number of our radiopharmaceutical commercial products, our competitors currently include Curium, GE Healthcare, Bracco and Jubilant Life Sciences, an affiliate of JHS and Jubilant Radiopharma, as well as other competitors, including NorthStar Medical Radioisotopes.
- For PyL, if and when it is approved by the FDA, it will compete with Bracco's Axumin (fluciclovine F 18). We also may face competition from Telix Pharmaceuticals Limited, which also has a PSMA-targeted prostate cancer PET diagnostic imaging agent currently under review with the FDA.
- For RELISTOR, our principal competitors include Nektar Therapeutics, in collaboration with AstraZeneca PLC; Cubist Pharmaceuticals, a subsidiary of Merck & Co., Inc.; Mallinckrodt plc, in collaboration with Takeda Pharmaceutical Company Limited; and BioDelivery Sciences International, Inc.; together with other prescription, as well as over-the-counter, laxatives used as first line therapy for OIC.
- For AZEDRA, there are currently no other FDA approved anticancer treatments in the U.S. for malignant, recurrent, and/or unresectable pheochromocytoma and paraganglioma.
- For 1095, our principal competitors in the field of mCRPC for radiopharmaceutical therapeutics may include Novartis AG; Point Biopharma; Telix Pharmaceuticals Limited; and Bayer HealthCare Pharmaceuticals Inc., each of which have product candidates in development.

We cannot anticipate the actions of our current or future competitors in the same or competing diagnostic modalities, such as significant price reductions on products that are comparable to our own, development of new products that are more cost-effective or have superior performance than our current products or the introduction of generic versions after our proprietary products lose their patent protection. In addition, distributors of our products could attempt to shift end-users to competing diagnostic modalities and

products, or bundle the sale of a portfolio of products, 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 either recently sold or for sale. In addition, the supply-demand dynamics of the industry are complex because of large market positions of some participants, legacy businesses, government subsidies (in particular, relating to the manufacture of radioisotopes), and group purchasing arrangements. We cannot predict what impact new owners and new operators may have on the strategic decision-making of our competitors, customers and suppliers.

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, 2020, our largest suppliers of raw materials and supplies were Institute for Radioelements ("IRE"), ANSTO and NTP, which, in the aggregate, accounted for approximately 23% 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 Cardiolite and NEUROLITE, 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 also provides for an increased supply of Mo-99 derived from LEU targets upon IRE's completion of its ongoing conversion program to modify its facilities and processes in accordance with Belgian nuclear security commitments. 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, 2022, and is renewable by LMI on a year-to-year basis thereafter.

Our agreement with NTP (the "NTP Agreement"), with NTP acting for itself and on behalf of its subcontractor ANSTO, specifies LMI's percentage purchase requirements and unit pricing, and provides for the supply of Mo-99 derived from LEU targets from NTP and ANSTO. 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, 2021.

Despite our globally diverse Mo-99 suppliers, we still face challenges in our Mo-99 supply chain. The NTP processing facility had periodic outages in 2017, 2018 and 2019. When NTP was not producing, we relied on Mo-99 supply from both IRE and ANSTO to limit the impact of the NTP outages. In 2019 and 2020, ANSTO experienced multiple facility issues that resulted in ANSTO outages and volume limitations, during which time we relied on IRE and NTP to limit the impact of those outages and limitations. Because of the COVID-19 pandemic, we experienced challenges receiving regularly scheduled orders of Mo-99 from our global suppliers, particularly in the second quarter of 2020. We continue to 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.

We are also pursuing additional sources of Mo-99 from potential new producers to further augment our current supply. In November 2014, we entered into a strategic arrangement with SHINE for the future supply of Mo-99. Under the terms of the supply agreement, SHINE will provide Mo-99 produced using its proprietary LEU-solution technology for use in our TechneLite generators once SHINE's facility becomes operational and receives all necessary regulatory approvals, which SHINE now estimates will occur in 2022. However, we cannot assure you that SHINE or any other possible additional sources of Mo-99 will result in commercial quantities of Mo-99 for our business, or that these new suppliers together with our current suppliers will be able to deliver a sufficient quantity of Mo-99 to meet our needs.

Xenon

Xenon is a by-product of the Mo-99 production process. Under a strategic agreement we entered into in 2015, 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 June 30, 2022, and is subject to further extension. Until we can qualify an additional source of bulk unprocessed Xenon, we will rely on IRE as a sole source provider.

Iodine 131

Iodine 131 is also a by-product of the Mo-99 production process, and it is the active radioisotope ingredient in both AZEDRA and 1095. We receive Iodine 131 from IsoSolutions Marketing & Management Inc., which sources the isotope from IRE in Belgium. We use Iodine 131 at our Somerset facility to manufacture and produce AZEDRA. We also rely on Center for Probe Development and Commercialization (CPDC) for our clinical supply requirements for 1095. CPDC sources Iodine 131 from IRE in Belgium and NTP in South Africa.

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

We maintain manufacturing operations at our North Billerica, Massachusetts facility. We manufacture TechneLite on a highly automated production line, Thallium and Gallium and certain radiochemicals using our cyclotron technology, and we process and finish Xenon and QUADRAMET using our hot cell infrastructure. We also operate a manufacturing facility at Somerset, NJ for AZEDRA that may also provide manufacturing support for 1095 in the future. 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 highly automated generator production line, our cyclotrons and our other manufacturing assets, 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. 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 North Billerica, Massachusetts facility.

PyL and flurpiridaz F 18 will require the creation of a field-based network of specialized PMFs with radioisotope-producing cyclotrons. The radioisotope used in both PyL and flurpiridaz F 18 is fluorine-18, or F 18, which has a 110 minute half-life, requiring that these products 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 either PyL or flurpiridaz F 18. PyL or flurpiridaz F 18 is next transferred to a radiopharmacist who prepares and dispenses patient-specific doses from the final product. Because each of the PMFs manufacturing these products will be deemed by the FDA to be a separate manufacturing site, each will have to be approved by the FDA, and we can give no assurance that the FDA will do this in accordance with the planned roll-out schedule for the products. In our PyL NDA, we included a limited number of PMFs for approval, and we intend to add in a sequenced manner, using FDA site approval processes, additional PMFs to our manufacturing network in the months following FDA product approval with the goal of having broad availability for the U.S. population within six months of product approval.

We are also in the final stages of an extensive, multi-year effort to add specialized manufacturing capabilities at our North Billerica, Massachusetts facility. This project should not only deliver efficiencies and supply chain redundancy for our current portfolio but should also afford us increased flexibility as we consider additional external opportunities. We currently expect to make use of this in-house manufacturing capability in late 2021. However, we can give no assurance that we will be successful in these efforts or that we will be able to successfully manufacture any additional commercial products at our North Billerica, Massachusetts facility.

Manufacturing and Supply Arrangements

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

- *DEFINITY*—In February 2012, we entered into a Manufacturing and Supply Agreement with JHS, for the manufacture of DEFINITY. Under the agreement, JHS manufactured DEFINITY for us for an initial term of five years. In September 2016, we extended the agreement through January 2022. The agreement contains automatic renewals for additional one-year periods thereafter. 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 place orders for a minimum percentage of our requirements for DEFINITY with JHS. Based on our current projections, we believe that we will have sufficient supply of DEFINITY from JHS to meet expected demand.

  On May 3, 2016, we entered into a Manufacturing and Supply Agreement with SBL to perform technology transfer and process development services to manufacture and supply DEFINITY RT. There are no minimum purchase requirements under this agreement, which has an initial term of five years from the date of first commercial sale and is renewable at our option for an additional five years. This agreement allows for termination upon the occurrence of certain events, including material breach or bankruptcy of either party. We believe DEFINITY RT will become commercially available later in 2021, although that timing cannot be assured.

- *Cardiolite*—In May 2012, we entered into a Manufacturing and Supply Agreement with JHS for the manufacture of Cardiolite products. In the third quarter of 2016, we completed the technology transfer process and received FDA approval to manufacture Cardiolite at JHS. Under the agreement, JHS has agreed to manufacture products for an initial term of five years from the effective date. That agreement has now been extended until December 31, 2021, and can be further extended for two additional one-year periods thereafter so long as the parties, using good faith, reasonable efforts, agree to new pricing for the upcoming additional term. The agreement allows for termination upon the occurrence of specified events, including material breach or bankruptcy by either party. The agreement requires us to place orders for 100% of our requirements for Cardiolite products with JHS during such term. Based on our current projections, we believe that we will have sufficient supply of Cardiolite products from JHS to meet expected demand.

- *NEUROLITE*—In May 2012, we entered into a Manufacturing and Supply Agreement with JHS for the manufacture of NEUROLITE, and in January 2015, the FDA granted approval to manufacture NEUROLITE at JHS. Under the agreement, JHS agreed to manufacture NEUROLITE for an initial term of five years from the effective date. That agreement has now been extended until December 31, 2021, and can be further extended for two additional one-year periods thereafter so long as the parties, using good faith, reasonable efforts, agree to new pricing for the upcoming additional term. The agreement allows for termination upon the occurrence of specified events, including material breach or bankruptcy by either party. The agreement also requires us to place orders for 100% of our requirements for NEUROLITE during such term. Based on our current projections, we believe that we will have sufficient supply of NEUROLITE from JHS to meet expected demand.

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

Strategic Activities

In addition to integrating the new assets and programs resulting from the Progenics Acquisition, we continue to seek ways to further expand our portfolio of products and product candidates and how best to optimize the value of our current assets, evaluating a number of different opportunities to collaborate with others or to acquire or in-license additional products, product candidates, businesses and technologies to drive our future growth. As the Progenics Acquisition indicates, we are particularly interested in expanding our presence in oncology, in both radiotherapeutics and diagnostics. In May 2019, we commenced an initiative to build out our Pharma Services capabilities by entering into a strategic collaboration and license agreement with NanoMab Technology Limited (“NanoMab”), a privately-held biopharmaceutical company focusing on the development of next generation radiopharmaceuticals for cancer precision medicine. We believe this collaboration will provide the first broadly-available PD-L1 imaging biomarker research tool to pharmaceutical companies and academic centers conducting clinical trials on immuno-oncology treatments, including combination therapies. We have also expanded our Pharma Services offering to include PyL for pharmaceutical companies developing PSMA-targeted therapies and have entered into PyL clinical supply agreements with each of Regeneron, Bayer and POINT BioPharma for use of PyL in drug development programs. We can give no assurance as to when or if any of these Pharma Services collaborations will be successful or accretive to earnings.

In addition, as described above, we continue to expand our microbubble franchise. In October 2020, we announced a strategic collaboration with Insightec which will use our microbubbles in connection with Insightec's transcranial guided focused ultrasound device for the treatment of glioblastoma as well as other neurodegenerative conditions. Glioblastoma is a lethal and devastating form of brain cancer with median survival of 15 months after diagnosis. Previously, we announced a strategic commercial supply agreement with CarThera for the use of our microbubbles in combination with SonoCloud, a proprietary implantable device in development for the treatment of recurrent glioblastoma. We also previously announced a strategic development and commercial collaboration with 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. Retinal vein occlusion is one of the most common causes of vision loss worldwide.

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

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 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 our intellectual property rights, our competitiveness could be impaired, which would limit our growth and future revenue.

Trademarks, Service Marks and Trade Names

We own various trademarks, service marks and trade names, including, among others, DEFINITY, DEFINITY RT, TechneLite, Cardiolite, NEUROLITE, VIALMIX, VIALMIX RFID, QUADRAMET, Luminity, PyL, AZEDRA, AZEDRA Service Connection, RELISTOR, Lantheus, Lantheus Medical Imaging, Progenics, Progenics Pharmaceuticals, Molecular Insight, EXINI, PyL Research Access Program and Find, Fight and Follow. We have 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. As of December 31, 2020, our patent portfolio included a total of 107 issued U.S. patents, 804 issued foreign patents, 49 pending U.S. patent applications and 239 pending foreign applications, owned or exclusively licensed.

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

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 own a total of four Orange Book-listed method of use patents, one of which expires in 2035 and three of which expire in 2037, as well as additional manufacturing patents that are not Orange Book-listed expiring in 2021, 2023 and 2037. In the U.S. for DEFINITY RT, we own a total of five Orange Book-listed patents, including a composition of matter patent which expires in 2035. Outside of the U.S., while our original DEFINITY patent protection and regulatory exclusivity have generally expired, we are currently prosecuting 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 Abbreviated New Drug Applications ("ANDAs") for generic versions of drugs if the ANDA applicant demonstrates, among other things, that (i) its generic candidate is the same as the innovator product by establishing bioequivalence and providing relevant chemistry, manufacturing and product data, and (ii) the marketing of that generic candidate does not infringe an Orange Book-listed patent or that an Orange Book-listed patent is invalid. With respect to any Orange Book-listed patent covering the innovator product, the ANDA applicant must give a notice to the innovator (a "Notice") that the ANDA applicant certifies that its generic candidate will not infringe the innovator's Orange Book-listed patent or that the Orange Book-listed patent is invalid. The innovator can then challenge the ANDA applicant in court within 45 days of receiving that 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 ANDA applicant is resolved in court. The 30 month stay could potentially expire sooner if the courts determine that no infringement had occurred or that the challenged Orange Book-listed patent is invalid or if the parties otherwise settle their dispute.

As of the date of filing of this Annual Report on Form 10-K, we have not received any Notice from an ANDA applicant. If we were to (i) receive any such Notice in the future, (ii) bring a patent infringement suit against the ANDA applicant within 45 days of receiving that Notice, and (iii) successfully obtain the full 30 month stay, then the ANDA 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 ANDA applicant in March 2021 and the full 30 month stay was obtained, then the ANDA applicant would be precluded from commercialization until at least September 2023. If we received a Notice some number of months in the future and the full 30 month stay was obtained, the commercialization date would roll forward in the future by the same calculation.

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.

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. Xenon, Thallium and Gallium have no patent protection; however, 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.

RELISTOR – Although the composition of matter patent for the active ingredient, methylnaltrexone, has expired, there are additional patents and pending patent applications covering various inventions relating to the product. There are eight Orange Book listed patents that cover the subcutaneous RELISTOR product, which have expiration dates ranging from 2024 to 2030, and there are nine Orange Book listed patents that cover the RELISTOR tablet product, which have expiration dates ranging from 2029 to 2031.

Progenics has entered into three separate settlement agreements that have granted non-exclusive limited licenses with respect to certain RELISTOR subcutaneous injection applications. The non-exclusive limited licenses with two parties are currently effective on January 1, 2028 and the third non-exclusive limited license is currently effective on July 1, 2028, in each case, subject to potential acceleration clauses in those agreements. Four Canadian patents (two expiring in 2024, one in 2027 and one in 2029) have been listed with Health Canada relating to subcutaneous RELISTOR.

AZEDRA - The AZEDRA technology patent family was licensed from the University of Western Ontario ("UWO"). While certain of those patents, and associated license, have already expired, a patent relating to alternative approaches for preparing AZEDRA (not currently implemented) expires worldwide in 2022 and 2024. In addition, we own pending applications worldwide for manufacturing improvements, and the resulting compositions which, if issued, would expire in 2035.

PyL - The PyL patent family was licensed from the Johns Hopkins University ("JHU"). Patent protection for composition of matter patents, radiolabeled forms of the compound, and methods of use in the U.S. expire in 2029 and 2030. Corresponding patents issued or pending worldwide, all expire in 2029. Process improvement patent applications are pending worldwide and, if issued, would expire in 2037.

flurpiridaz F 18 - 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.

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

LMI 1195 - We own patents and patent applications in numerous jurisdictions covering composition, use, and manufacturing, including in the U.S. a composition of matter patent expiring in 2030, a method of use patent expiring in 2027, and manufacturing-related patents expiring in 2031 and 2032, and patent applications which, if granted, will expire in 2027 and in 2031.

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-licensed patents relating to reagents for radiolabeling expire in the U.S. in 2022.

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. Patent applications are pending in the U.S. and worldwide relating to aBSI improvements which, if issued will expire in 2040.

PSMA-AI – U.S. Patents and pending patent applications worldwide relating to automated medical image analysis, have expiration ranges from 2037 to 2040.

PSMA Antibody TTC – We own and in-license composition of matter patents on PSMA antibodies expiring in the U.S. in 2022 and 2023 and outside of the U.S. in 2022.

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. These confidentiality agreements may not prevent unauthorized disclosure of trade secrets and other proprietary information, and we cannot provide assurances that an employee or an outside party will not make an unauthorized disclosure of our trade secrets, other technical know-how or proprietary information. We may not have adequate monitoring abilities to discover, or adequate remedies for, any unauthorized disclosure. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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 of the patent rights on RELISTOR from Wyeth LLC and on the PyL patent family from 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 agents and 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 investigations, manufacturing, marketing, 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 pharmaceutical and medical device 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 studies may begin, including review and approval by any institutional review board ("IRB"), serving any of the institutions participating in the clinical studies;
- Performance of adequate and well-controlled human clinical studies 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 a new drug application ("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 agents in development will be granted on a timely basis, if at all. Once a pharmaceutical agent 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 study may begin. Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The agent 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 agent 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 studies in a limited patient population to identify possible adverse effects and safety risks, to evaluate preliminarily the efficacy of the agent for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.
- *Phase 3.* Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to collect sufficient safety and efficacy data to support the NDA for FDA approval.

Progress reports detailing the results of the clinical studies 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 testing 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 study 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 study at a relevant institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the agent 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 studies, 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 agent 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 agent does not undergo unacceptable deterioration over its shelf life.

The results of product development, preclinical studies and clinical studies, 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 agent. 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 studies 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 studies 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 studies 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. AZEDRA currently has the Orphan Drug designation 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, 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 pharmaceutical or medical device 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 studies, product recalls or seizures, product detention or refusal to permit the import or export of pharmaceuticals or medical device products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions, or civil or criminal penalties.

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 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 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.

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.

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, or 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; 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 MRI, computed tomography ("CT"), PET 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. For example, tax reform legislation was enacted at the end of 2017 that effectively eliminated the "individual mandate" to maintain health insurance coverage by eliminating the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019. In December 2018, a federal district court judge, in a challenge brought by a number of state attorneys general, found the Healthcare Reform Act unconstitutional in its entirety because once Congress repealed the "individual mandate" provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. In December 2019, a federal appeals court agreed that the individual mandate provision was unconstitutional, but remanded the case back to the district court to assess more carefully whether any provisions of the Healthcare Reform Act were severable and could survive. In November 2020, the U.S. Supreme Court heard an appeal of the federal appeals court decision, but has not opined on the constitutionality of the individual mandate or the severability of the remaining aspects of the Healthcare Reform Act. Pending resolution of this case, the Healthcare Reform Act is still operational.

Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. For example, in May 2018, President Trump and the Secretary of the Department of Health and Human Services released a "blueprint" to lower prescription drug prices and out-of-pocket costs. Certain proposals in the blueprint, and related drug pricing measures proposed since the blueprint, could cause significant operational and reimbursement changes for the pharmaceutical industry. As an example, legislation passed in 2019 revised how certain prices reported by manufacturers under the Medicaid Drug Rebate Program are calculated, a revision that the Congressional Budget Office has estimated will save the federal government approximately $3.0 billion in the next ten years. As another example, in November 2020, CMS issued an interim final rule that announced a new "most favored nation" payment model for certain Medicare Part B drugs, which would reduce the Medicare payment amount for such drugs to the lowest price that drug manufacturers receive in other similar countries. (Multiple federal courts have issued temporary injunctions blocking implementation of this final rule). Efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products could limit our flexibility in establishing prices for our products or otherwise adversely affect our business if implemented. Changes could occur at the federal level or state level and may be adopted by statute, rule, or sub-regulatory policies. 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 Coronavirus Aid, Relief, and Economic Security (CARES) Act suspended the 2% payment adjustment for dates of service from May 1 through December 31, 2020, and the Consolidated Appropriations Act 2021 subsequently extended this suspension until March 31, 2021. 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 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 take effect on January 1, 2023, and generally will apply to personal information collected by regulated businesses on or after January 1, 2022. The California Attorney General will have authority to begin enforcing the CPRA's amendments to the CCPA beginning on July 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 regulatory matters.

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.

We are required to maintain a number of environmental permits and nuclear licenses for our North Billerica, Massachusetts facility, which is 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, 2020, we currently estimate the D&D cost of all of our manufacturing sites (including our Puerto Rico radiopharmacy which we sold on January 29, 2021) to be approximately $26.9 million. As of December 31, 2020 and 2019, we have a liability recorded associated with the fair value of the asset retirement obligations of $14.0 million and $12.9 million, respectively. 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 site 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, in 2020, we developed a mechanism to track and monitor our energy use, water use and waste generation. We use an Energy Star Portfolio Manager to track energy and water use that we believe will help us calculate associated greenhouse gas emissions and compare the performance of our North Billerica buildings against a yearly baseline, national medians, and other 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, 2020, we had 595 employees, of which 569 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 will make us an employer of choice, maintain good standing with the regulatory authorities and customers and benefit stockholders in the long run.

We have a female CEO, 50% of our Vice Presidents and above are women, and approximately 44% 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 candidates in the spirit of diversity and inclusion.

We are committed to promoting a culture of ethics and compliance. Our Code of Conduct and Ethics reflects the Company's 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 also have a formal Ethics and Compliance Committee that develops, implements and overseas our ethics and compliance programs.

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 market-competitive pay, cash bonuses and restricted stock and other equity grants to certain levels of employees, health care and retirement benefits, paid time off and family leave, among others. 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 the Company's overall strategy. To this end, we utilize a variety of channels to facilitate open and direct communication, including: (i) quarterly town hall meetings with our executive team; (ii) regular ongoing update communications; (iii) employee engagement surveys; and (iv) 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.

With respect to the COVID-19 pandemic, we operate a "Pandemic Response Team" to implement and oversee appropriate precautions to minimize the spread of COVID-19 in our teams and communities. We continue to have all non-critical employees and contractors work-remotely and avoid non-essential work-related travel. Further, we established a "Return to Office" team to develop plans for employees to safely return to all our facilities.

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 (collectively "Avista") formed Lantheus Holdings and acquired our medical imaging business from BMS. On June 30, 2015, we completed an initial public offering ("IPO") of our common stock. We completed our acquisition of Progenics Pharmaceuticals, Inc. on June 19, 2020. 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 www.investor.lantheus.com. We recognize our website as a key channel of distribution to reach public investors and as a means of disclosing material non-public information to comply with our disclosure obligations under SEC Regulation FD. Information contained on our website shall not be deemed incorporated into, or to be part of this 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. The information on our website is neither part of nor incorporated by reference in this Annual Report on Form 10-K.

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.

Risk Factor Summary

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 the appropriate use of DEFINITY in suboptimal echocardiograms in the face of segment competition from other echocardiography ultrasound enhancing agents and potential generic competition as a result of patent and regulatory exclusivity expirations.
- The instability of the global Mo-99 supply, including periodic supply outages and limitations at the NTP Radioisotopes ("NTP") processing facility in South Africa and the Australian Nuclear Science and Technology Organisation's ("ANSTO") processing facility in Australia, in each case resulting in our inability to fill some or all of the demand for our TechneLite generators on certain manufacturing days during the outage or limitation periods.
- Our dependence upon third parties for the manufacture and supply of a substantial portion of our products, raw materials and components, including DEFINITY at JHS and DEFINITY RT at SBL.
- Risks related to RELISTOR, commercialized by Bausch, and that the revenues generated for us thereby may not meet expectations.
- Risks related to the commercialization of AZEDRA, including in connection with market acceptance and reimbursement, that may cause the product not to meet revenue or operating income expectations.
- Risks associated with our DEFINITY RT formulation, approved by the FDA in November 2020, including our ability gain post-approval market acceptance and adequate reimbursement.

Risks Related to Our Portfolio of Clinical Development Candidates

- Risks associated with our lead agent in development, PyL, for which an New Drug Application ("NDA") was accepted by the FDA and granted priority review with an assigned Prescription Drug User Fee Act ("PDUFA") action date of May 28, 2021, including:
    - Our ability to obtain FDA approval of PyL in 2021;
    - Our ability to successfully gain post-approval market acceptance and adequate reimbursement for PyL;
    - Our dependence upon third parties for the manufacture and supply of PyL and the timing of that manufacturing capacity becoming available; and
    - Our ability to compete successfully with other prostate cancer imaging agents, including those that target prostate specific membrane antigen ("PSMA").
- Risks associated with flurpiridaz F 18, which in 2017 we out-licensed to GE Healthcare, including:
    - GE Healthcare's ability to successfully complete the Phase 3 development program, including delays in enrollment that have resulted from the COVID-19 pandemic;
    - GE Healthcare's ability to obtain FDA approval; and
    - GE Healthcare's ability to gain post-approval market acceptance and adequate reimbursement.
- Risks related to the development and commercialization of our AI product offerings, including relating to assessment of disease burden targeting PSMA;

- Risks associated with 1095, including delays in enrollment that have resulted from the COVID-19 pandemic and our ability to successfully complete the Phase 2 study in mCRPC.

Risks related to the Integration of the Progenics Acquisition

- The continued integration of the Progenics Acquisition may involve unexpected costs, liabilities or delays, including the ability of our combined business to continue to retain and hire key personnel and maintain relationships with customers, suppliers and others with whom we or Progenics do business.
- The anticipated benefits of the Progenics Acquisition may not be fully realized or may take longer to realize than we expect.
- The contractual contingent value rights ("CVRs") we issued as part of the Progenics Acquisition may result in substantial future payments and could divert the attention of our management.

Risks Related to Reimbursement and Regulation

- The dependence of certain of our customers upon third-party healthcare payors and the uncertainty of third-party coverage and reimbursement rates.
- Uncertainties regarding the impact of 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 and generic drug competition.
- 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

- The impact of the on-going global COVID-19 pandemic on our business, financial condition or prospects, including: a decline in the volume of procedures and treatments using our products, in particular Xenon because of institutional concerns and professional society guidelines relating to the possible spread of COVID-19 to technicians and other patients given that Xenon is both inhaled and exhaled by the patient; potential delays and disruptions to global supply chains, manufacturing activities, logistics, operations, clinical development programs, employees and contractors, the business activities of our suppliers, distributors, customers and other business partners; and the effects on worldwide economies, financial markets, social institutions, labor markets and healthcare systems.
- Our ability to introduce new products and adapt to an evolving technology and medical practice landscape.
- Risks associated with our investment in, and construction of, additional specialized manufacturing capabilities at our North Billerica, Massachusetts facility, including our ability to bring the new capabilities online in 2021.

Risks Related to our Capital Structure

- Risks related to our outstanding indebtedness and our ability to satisfy those obligations.
- Risks related to the ownership of our common stock.

Risks Related to Our Portfolio of Commercial Products

The near-term growth of our business is substantially dependent on our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms in the face of increased segment competition from other existing echocardiography agents and potential generic competitors.

The growth of our business is substantially dependent on our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms. There were approximately 31.5 million echocardiograms in 2020 according to a third-party source. Assuming 20% of echocardiograms produce suboptimal images, as stated in the clinical literature, we estimate that approximately 6.3 million echocardiograms in 2020 produced suboptimal images. We estimate that DEFINITY held over 80% of the U.S. market for ultrasound enhancing agents in echocardiography procedures as of December 31, 2020. DEFINITY currently competes with Optison, a GE Healthcare product, Lumason, a Bracco product (known as SonoVue outside the U.S.), 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 now own a total of four Orange Book-listed method of use patents, one of which expired in 2035 and three of which expire in 2037, as well as additional manufacturing patents that are not Orange Book-listed expiring in 2021, 2023 and 2037. In the U.S. for DEFINITY RT, we own a total of five Orange Book-listed patents, including a composition of matter patent which expires in 2035. Outside of the U.S., while our original DEFINITY

patent protection and regulatory exclusivity have generally expired, we are currently prosecuting 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) the marketing of that generic candidate does not infringe an Orange Book-listed patent or that an Orange Book-listed patent is invalid. The ANDA applicant must also give Notice to the innovator, which would then enable the innovator to challenge the ANDA applicant in court within 45 days of receiving such Notice. If the innovator challenges the ANDA 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 ANDA applicant is resolved in court. The 30 month stay can be shortened if the patent infringement suit is resolved in the ANDA 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, or USPTO, proceedings and appeals process.

As of the date of filing of this Annual Report on Form 10-K, we have not received any such Notice from any ANDA applicant but 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 ANDA 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 a generic candidate 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 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 and Insightec, and (iii) we have completed construction of our specialized in-house manufacturing capabilities at our North Billerica facility for DEFINITY and, potentially, other sterile vial products. However, we can give no assurance that our microbubble franchise strategy will be successful or that a modified formulation, new applications or new manufacturing capabilities will grow our microbubble franchise.

We believe DEFINITY RT will become commercially available later in 2021, although that timing cannot be assured.

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.

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.

The NTP processing facility had periodic outages in 2017, 2018 and 2019. When NTP was not producing, we relied on Mo-99 supply from both IRE and ANSTO to limit the impact of the NTP outages. In 2019 and 2020, ANSTO experienced multiple facility issues that resulted in ANSTO outages and volume limitations, during which time we relied on IRE and NTP to limit the impact of those outages and limitations. Because of the COVID-19 pandemic, we experienced challenges receiving regularly scheduled orders of Mo-99 from our global suppliers, particularly in the second quarter of 2020. We continue to 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.

We are also pursuing additional sources of Mo-99 from potential new producers to further augment our current supply. In November 2014, we entered into a strategic arrangement with SHINE for the future supply of Mo-99. Under the terms of the supply agreement, SHINE will provide Mo-99 produced using its proprietary LEU-solution technology for use in our TechneLite generators once SHINE's facility becomes operational and receives all necessary regulatory approvals, which SHINE now estimates will occur in 2022. However, we cannot assure you that SHINE or any other possible additional sources of Mo-99 will result in commercial quantities of Mo-99 for our business, or that these new suppliers together with our current suppliers will be able to deliver a sufficient quantity of Mo-99 to meet our needs.

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 further 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.

The instability of the global supply of Mo-99, including supply shortages, has resulted in increases in the cost of Mo-99, which has negatively affected our margins, and more restrictive agreements with suppliers, which could further increase our costs.

With the general instability in the global supply of Mo-99, we have faced substantial increases in the cost of Mo-99 in comparison to historical costs. We expect these cost increases to continue in the future as the Mo-99 suppliers move closer to a full cost recovery business model. The Organization of Economic Cooperation and Development ("OECD") defines full cost recovery as the identification of all of the costs of production and recovering these costs from the market. While we are generally able to pass Mo-99 cost increases on to our customers in our customer contracts, if we are not able to do so in the future, our margins may decline further with respect to our TechneLite generators, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

We obtain a substantial portion of our products from third party manufacturers and suppliers. We rely on JHS as our sole source manufacturer of DEFINITY, NEUROLITE, Cardiolite and evacuation vials. We rely on SBL as our sole source manufacturer of DEFINITY RT.

Based on our current estimates, we believe that we will have sufficient supply of DEFINITY, NEUROLITE, Cardiolite and evacuation vials from JHS, and sufficient supply of saline from our sole manufacturer, to meet expected demand. However, we can give no assurances that JHS or our other manufacturing partner will be able to manufacture and distribute our products in a high quality and timely manner and in sufficient quantities to allow us to avoid product stock-outs and shortfalls. Currently, regulatory authorities in certain countries have not yet approved JHS as a manufacturer of certain of our products. Accordingly, until those regulatory approvals have been obtained, our business, results of operations, financial condition and cash flows will continue to be adversely affected.

Xenon is captured as a by-product of the Mo-99 production process. We receive bulk unprocessed Xenon from IRE resulting from HEU Mo-99 production, which we process and finish for our customers. We do not yet receive Xenon resulting from LEU Mo-99 production at IRE and can give no assurances as to the timing of the availability of LEU Xenon. We believe we will have a sufficient supply of Xenon to meet our customers' needs. However, until IRE converts to LEU Xenon production or we can qualify an additional source of bulk unprocessed Xenon, we will rely on IRE as a sole source provider of HEU Xenon.

1095 is currently manufactured only at the CPDC. Until December 2019, the CPDC was subject to an Import Alert by the FDA, which restricted the CPDC's ability to ship products to the U.S. Although the CPDC has since been cleared by the FDA to ship products to the U.S., there can be no guarantee that the CPDC, or any other third-party manufacturer that we may partner with in the future, will not be subject to similar restrictions in the future.

In addition to the products described above, for reasons of quality assurance or cost-effectiveness, we purchase certain components and raw materials from sole suppliers (including, for example, the lead casing for our TechneLite generators and the lipid blend material used in the processing of DEFINITY). 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. At our North Billerica, Massachusetts facility, we manufacture TechneLite on a highly automated production line, as well as Thallium and Gallium using our older cyclotron technology and Xenon and QUADRAMET using our hot cell infrastructure. As with all manufacturing facilities, equipment and infrastructure age and become subject to increasing maintenance and repair. If we or one of our manufacturing partners experiences 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 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 have also completed construction of our specialized in-house manufacturing capabilities at our North Billerica, Massachusetts facility. This project should not only deliver efficiencies and supply chain redundancy for our current portfolio but also should afford us increased flexibility as we consider external opportunities. 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.

We rely on Bausch to develop and commercialize RELISTOR, exposing us to significant risks.

We rely on Bausch to pursue and complete further development and obtain regulatory approvals for RELISTOR worldwide and to effectively commercialize the product and manage pricing, sales and marketing practices and inventory levels in the distribution channel. The revenue derived from royalty and milestone payments from our RELISTOR collaboration with Bausch can fluctuate significantly from period to period, and our past revenue is therefore not necessarily indicative of our future revenue. We are and will be dependent upon Bausch and any other business partners with which we may collaborate in the future to perform and fund development, including clinical testing of RELISTOR, making related regulatory filings and manufacturing and marketing products, including for new indications and in new formulations, in their respective territories. Revenue from the sale of RELISTOR depends entirely upon the efforts of Bausch and its sublicensees, which have significant discretion in determining the efforts and resources they apply to sales of RELISTOR. Bausch may not be effective in obtaining approvals for new indications or formulations, marketing existing or future products or arranging for necessary sublicense or distribution relationships. Our business relationships with Bausch and other partners may not be scientifically, clinically or commercially successful. For example, Bausch has a variety of marketed products and its own corporate objectives, which may not be consistent with our best interests, and may change its strategic focus or pursue alternative technologies in a manner that results in reduced or delayed revenue to us. Bausch may also have commercial and financial interests that are not fully aligned with ours in a given territory or territories, which may make it more difficult for us to fully realize the value of RELISTOR. We may have future disagreements with Bausch, which has significantly greater financial and managerial resources which it could draw upon in the event of a dispute. Such disagreements could lead to lengthy and expensive litigation or other dispute-resolution proceedings as well as extensive financial and operational consequences to us and have an adverse effect on our business, results of operations and financial condition. In addition, independent actions may be taken by Bausch concerning product development, marketing strategies, manufacturing and supply issues, and rights relating to intellectual property.

We are also dependent on Bausch for compliance with regulatory requirements as they apply to RELISTOR.

The RELISTOR commercialization program continues to be subject to risk.

Future developments in the commercialization of RELISTOR may result in Bausch taking independent actions concerning product development, marketing strategies or other matters, including termination of its efforts to develop and commercialize the drug.

Under our license agreement with Bausch, Bausch is responsible for obtaining supplies of RELISTOR, including contracting with contract manufacturing organizations (“CMOs”) for supply of RELISTOR active pharmaceutical ingredient and subcutaneous and oral finished drug product. These arrangements may not be on terms that are advantageous and will subject us to risks that the counterparties may not perform optimally in terms of quality or reliability.

Bausch’s ability to optimally commercialize either oral or subcutaneous RELISTOR in a given jurisdiction may be impacted by applicable labeling and other regulatory requirements. If clinical trials indicate, or regulatory bodies are concerned about, actual or

possible serious problems with the safety or efficacy of RELISTOR, Bausch may stop or significantly slow further development or commercialization of RELISTOR. In such an event, we could be faced with either further developing and commercializing the drug on our own or with one or more substitute collaborators, either of which paths would subject us to the development, commercialization, collaboration and/or financing risks.

There has been growing public concern regarding the use of opioid drugs. Any efforts by the FDA or other governmental authorities to restrict or limit the use of opioids may negatively impact the market for RELISTOR. In addition, there is a substantial risk that the revenue targets for receiving additional RELISTOR milestone payments will not be met. As a result, there is no assurance that we will realize the potential revenue represented by future RELISTOR milestone payments.

Any such significant action adverse to the further development and commercialization of RELISTOR could have an adverse impact on our business.

Our AZEDRA commercialization program is subject to significant risk.

Progenics received FDA approval for AZEDRA in July 2018. Since then, the AZEDRA commercial program has faced numerous challenges, including, among other things:

- limited success in manufacturing patient-ready doses of AZEDRA;
- a small Orphan Drug patient population;
- reluctance by some potential hospital customers to invest in the necessary facility build-out to accommodate the administration of a highly radioactive therapeutic agent (including, among other things, the construction of lead-lined rooms to accommodate inpatients following AZEDRA's administration); and
- the high cost of the drug and reimbursement.

Because of these issues, we can give no assurance that AZEDRA will become a commercial success. After increased experience administering AZEDRA, clinicians may conclude that the complexity of administration and/or safety concerns with using a highly radioactive therapeutic agent may not justify AZEDRA's perceived clinical benefits. AZEDRA became eligible for new technology add-on payments (NTAP) under the Medicare Hospital Inpatient Prospective Payment System (IPPS) effective October 1, 2019. As required by statute, NTAP eligibility under the IPPS can continue for a period of at least two years, but not more than three years. Under the fiscal year 2021 IPPS Final Rule, published in September 2020, CMS finalized continuation of AZEDRA's NTAP for fiscal year 2021—i.e., from October 1, 2020 through September 30, 2021. Although there is potential for AZEDRA to receive an additional year of NTAP coverage, CMS may not decide to renew NTAP coverage for the period of October 1, 2021 through September 30, 2022. If post-pass-through payment levels impact market acceptance for AZEDRA, the drug may not generate enough revenue to make it economically viable. In addition, the market may react negatively to the high cost of AZEDRA, which could result in negative publicity and potentially reputational harm to us. Further, to the extent new Federal restrictions relating to drug pricing are implemented and apply to AZEDRA, the additional pricing pressure could further limit AZEDRA's economic viability.

If AZEDRA is determined to be challenging to administer, not economically viable or we are unable to successfully commercialize it, our business, results of operations, financial condition and cash flows could be adversely affected.

We may not be able to maintain Orphan Drug exclusivity for AZEDRA and, even if we do, that exclusivity may not prevent the FDA, from approving competing products.

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. AZEDRA currently has the Orphan Drug designation 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.

We may not be able to maintain Orphan Drug exclusivity for AZEDRA. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Even after an Orphan Drug is approved, the FDA can

subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. A loss of the Orphan Drug exclusivity for AZEDRA may have an adverse impact on our ability to adequately commercialize AZEDRA.

Our just-in-time manufacturing of radiopharmaceutical products relies on 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.

Because a number of our radiopharmaceutical products, including our TechneLite generators and AZEDRA, rely on radioisotopes with limited half-lives, we must manufacture, finish and distribute these products on a just-in-time basis, because the underlying radioisotope is in a constant state of radio decay. For example, 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 nuclear medical imaging products. 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, Jubilant Radiopharma and PharmaLogic, to distribute our current largest volume nuclear imaging products. 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. We generally have distribution arrangements with our major radiopharmacy customers pursuant to multi-year contracts, each of which is subject to renewal. If these contracts are terminated prior to 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 all of our medical imaging products, we 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. and Canada, 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 Canada, we maintain our own direct sales force to sell DEFINITY. 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 DEFINITY, our competitors currently include GE Healthcare and Bracco.
- For a number of our radiopharmaceutical commercial products, our competitors currently include Curium, GE Healthcare, Bracco and Jubilant Life Sciences, an affiliate of JHS and Jubilant Radiopharma, as well as other competitors, including NorthStar Medical Radioisotopes.
- For PyL, if and when approved by the FDA, we will compete with Bracco’s Axumin (fluciclovine F 18). We also may face competition from Telix Pharmaceuticals Limited, which also has a PSMA-targeted prostate cancer PET diagnostic imaging agent currently under review with the FDA.
- For RELISTOR, our principal competitors include Nektar Therapeutics, in collaboration with AstraZeneca PLC; Cubist Pharmaceuticals, a subsidiary of Merck & Co., Inc.; Mallinckrodt plc, in collaboration with Takeda Pharmaceutical Company Limited; and BioDelivery Sciences International, Inc.; together with other prescription, as well as over-the-counter, laxatives used as first line therapy for OIC.
- For AZEDRA, there are currently no approved anticancer treatments in the U.S. for malignant, recurrent, and/or unresectable pheochromocytoma and paraganglioma.

- For 1095, our principal competitors in the field of radiopharmaceutical therapeutics for mCRPC may include Novartis AG; Point Biopharma; Telix Pharmaceuticals Limited; and Bayer HealthCare Pharmaceuticals Inc., each of which have product candidates in development.

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

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

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 micro-bubble 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 micro-bubble contrast 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. 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 our Portfolio of Clinical Development Candidates

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 two active clinical development programs in the U.S. – PyL and 1095. 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 agents 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 agent 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.

Our agents in development are also subject to the risks of failure inherent in drug development and testing. 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, agents that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. Agents 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 agents 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. 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 agents 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 agents 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 agents in development. The NDA must include extensive nonclinical and clinical data and supporting information to establish the agent'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 studies and surveillance or other risk management measures to monitor the safety or efficacy of the agent. Markets outside of the U.S. also have requirements for approval of agents with which we must comply prior to marketing. Obtaining regulatory approval for marketing of an agent 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 or agents in development, once obtained, may be withdrawn. Approvals might not be granted on a timely basis, if at all.

Our lead agent in development, PyL, faces risks relating to regulatory approval.

Our lead agent in development is PyL™ (18F-DCFPyL), our PSMA-targeted PET imaging agent for prostate cancer. We filed an NDA for PyL in September 2020. The NDA was accepted by the FDA in December 2020, granted priority review, and assigned a PDUFA action date of May 28, 2021. The PyL NDA is supported by data from two pivotal studies (OSPREY and CONDOR), designed to establish the safety and diagnostic performance of PyL imaging across the disease continuum of prostate cancer. Results from OSPREY Cohort A demonstrated improvement in specificity and positive predictive value of PyL PET imaging over conventional imaging in men with high risk prostate cancer but did not meet one of the study's primary endpoints for sensitivity. OSPREY Cohort B and CONDOR studied men with prostate cancer in various disease states, including biochemical recurrent prostate cancer, hormone sensitive prostate cancer, non-metastatic castrate resistant prostate cancer, and metastatic castrate resistant prostate cancer. OSPREY Cohort B demonstrated sensitivity in detecting metastatic lesions, while CONDOR, in patients with biochemical recurrent prostate cancer and non-informative baseline findings, demonstrated a high correct localization rate and high detection rate, including patients with low PSA values. In the CONDOR study, 63.9% of patients had a change in intended disease management plans due to the PyL imaging results. While we believe the results from these two studies, taken as a whole, demonstrate the ability of PyL to reliably detect and localize disease and could enable more appropriate patient management, if the FDA determines that these study results are not sufficient or convincing, we may not be able to obtain FDA approval to commercialize PyL in the U.S. in 2021 and may have to perform additional clinical studies with PyL. If that were to result, our business, results of operations, financial condition and cash flows could be adversely affected.

We can give no assurance that GE Healthcare will be successful with the further clinical development of flurpiridaz F 18.

In May 2015, we announced complete results from the first of two planned Phase 3 clinical trials for flurpiridaz F 18. 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 F 18 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 F 18. Under the License Agreement, GE Healthcare will, among other things, complete the worldwide development of flurpiridaz F 18 by conducting a second Phase 3 trial and pursue worldwide regulatory approvals. We cannot assure any particular outcome from GE Healthcare's continued Phase 3 development of the agent or from regulatory review of either our or their Phase 3 study of the agent, that any of the data generated in either our or their sponsored Phase 3 study will be sufficient to support an NDA approval, that GE Healthcare will only have to conduct the one additional Phase 3 clinical study prior to filing an NDA, or that flurpiridaz F 18 will ever be approved as a PET MPI imaging agent by the FDA. Any failure or significant delay in completing clinical

trials for our product candidates or in receiving regulatory approval for the sale of our product candidates may harm our business and delay or prevent us from being able to generate additional future 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. The manufacturing, marketing and distribution of radiopharmaceuticals is complex. Rather than being manufactured at our own facilities, both PyL and flurpiridaz F 18 will require the creation of a field-based network of specialized PET manufacturing facilities, or PMFs, with radioisotope-producing cyclotrons. The radioisotope used in both PyL and flurpiridaz F 18 is fluorine-18, or F 18, which has a 110 minute half-life, requiring that these products 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 either PyL or flurpiridaz F 18. PyL or flurpiridaz F 18 is next transferred to a radiopharmacist who prepares and dispenses patient-specific doses from the final product. Because each of the PMFs manufacturing these products will be deemed by the FDA to be a separate manufacturing site, each will have to be approved by the FDA, and we can give no assurance that the FDA will do this in accordance with the planned roll-out schedule for the products. In our PyL NDA, we included a limited number of PMFs for approval, and we intend to add in a sequenced manner, using FDA site approval processes, additional PMFs to our manufacturing network in the months following FDA product approval with the goal of having broad availability for the U.S. population within six months of product approval. If we are delayed in our PyL commercial launch by FDA approval of our manufacturing sites or other challenges, our business, results of operations, financial condition and cash flows could be adversely affected.

In addition, in the case of both PyL and flurpiridaz F 18, obtaining adequate reimbursement will be critical, including not only coverage from Medicare, Medicaid, other government payors as well as private payors but also appropriate payment levels which adequately cover the substantially higher manufacturing and distribution costs associated with an F 18-based agent in comparison to a Tc-99m-based agent. We can give no assurance, even if PyL and flurpiridaz F 18 obtain regulatory approval, that adequate reimbursement can be secured to allow the approved agents 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 on-going development activities, we currently depend, and expect to continue to depend, on numerous collaborators. For example, in addition to our collaboration with GE Healthcare on flurpiridaz F 18, we have collaborations with Bayer to develop and commercialize products using our PSMA antibody technology, with Curium for the development and commercialization of PyL in Europe, and with ROTOP for the development and commercialization of 1404 in Europe. 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 RELISTOR from Wyeth LLC and on PyL from JHU. 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, 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.

Risks Related to the Integration of the Progenics Acquisition

We may not be able to successfully integrate the Progenics business into our business and realize the anticipated benefits of the Progenics Acquisition.

The ultimate success of the Progenics Acquisition will depend on our ability to successfully combine the business of Progenics with our own and realize the anticipated benefits, including synergies, cost savings, innovation and operational efficiencies and revenue growth from the combination. If we are unable to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits may not be realized fully or at all, or may take longer to realize than expected, and the value of our common stock may suffer.

The Progenics Acquisition involves the continued integration of Progenics' business into our existing business, which has been a complex, costly and time-consuming process. The on-going integration may result in material challenges, including, without limitation:

- The diversion of management's attention from ongoing business concerns and performance shortfalls at one or both of the companies;
- Managing a larger combined company;
- Maintaining employee morale and attracting, motivating and retaining management personnel and other key employees;
- Unanticipated risks to our integration plan including in connection with timing, talent, and the potential need for additional resources;
- New or previously unidentified manufacturing, regulatory, or research and development issues in the Progenics business;
- Retaining existing business and operational relationships and attracting new business and operational relationships;
- Unanticipated changes in federal or state laws or regulations; and
- Unforeseen expenses or delays associated with the Progenics Acquisition.

Many of these factors are outside of our control and any one of them could result in delays, increased costs, decreases in the amount of expected revenues and diversion of management's time and energy, which could materially affect our financial position, results of operations and cash flows.

Our future results may be adversely impacted if we do not effectively manage our expanded operations following the completion of the Progenics Acquisition.

Our combined business is now significantly larger and more complex than our business was immediately prior to the consummation of the Progenics Acquisition. Our ability to successfully manage this combined business will depend upon our ability to continue to integrate the two separate businesses and manage the combined business with its increased scale and scope, and increased costs and complexity. We may not be successful or may not realize the expected operating efficiencies, cost savings and other benefits previously disclosed.

The CVRs we issued as part of the Progenics Acquisition may result in substantial future payments and could divert the attention of our management.

As part of the consideration for the Progenics Acquisition, we issued CVRs to the stockholders of Progenics and holders of in-the-money Progenics equity awards entitling them to future cash payments of 40% of PyL net sales over $100.0 million in 2022 and over $150.0 million in 2023. These payments could be substantial and could adversely impact our liquidity. In addition, we are obligated to exercise a level of effort, expertise and resources consistent with those normally used in a medical diagnostics business similar to our size and resources with respect to developing, seeking regulatory approval for and commercializing a product of similar market potential at a similar stage in its development or product life to PyL. We are also required to produce net sales statements for PyL that may be reviewed and challenged by CVR holders, with any disagreement to be resolved by an independent accountant. These requirements could divert management time and resources and result in additional costs.

The financial analyses and forecasts considered by us and Progenics and their respective financial advisors in connection with the Progenics Acquisition may not be realized, which may adversely affect the market price of our common stock in the future.

In performing their financial analyses and rendering their opinions related to the Progenics Acquisition, each of the respective financial advisors to us and Progenics relied on, among other things, internal stand-alone financial analyses and forecasts as separately provided by us and Progenics. These analyses and forecasts were prepared by, or as directed by, our management or the management of Progenics, as applicable. None of these analyses or forecasts were prepared with a view towards public disclosure or compliance with the published guidelines of the SEC or U.S. Generally Accepted Accounting Principles. These projections are inherently based on various estimates and assumptions that are subject to the judgment of those preparing them. These projections are also subject to significant economic, competitive, industry and other uncertainties and contingencies, all of which are difficult or impossible to predict and many of which are beyond our control and the control of Progenics. We can give no assurance that our current or future financial condition or results of operations will be consistent with what was set forth in such analyses and forecasts, which could have an adverse impact on the market price of our common stock or our current or future financial position.

We expect to continue to incur substantial expenses related to the integration of the Progenics business with our business.

We have incurred, and expect to continue to incur, substantial expenses in connection with the integration of the Progenics business with our own. There are a large number of processes, policies, procedures, operations, technologies and systems that have been, or must be, integrated, including purchasing, accounting and finance, sales, payroll, pricing, revenue management, marketing and benefits. The substantial majority of these costs have been, and will continue to be, non-recurring expenses related to the Progenics Acquisition, facilities and systems consolidation costs. We may also incur additional costs to maintain employee morale and to attract, motivate or retain management personnel or key employees.

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 potential 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. For example, certain radiopharmaceuticals, when used for non-invasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease, are currently subject to a Medicare National Coverage Determination ("NCD"). The NCD permits the coverage of such radiopharmaceuticals only when certain criteria are met. Our partnered PET pipeline product flurpiridaz F 18, if approved, may become subject to this NCD, and may not be covered at all. 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 coverage, coding 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 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.

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:

- Limiting payments for imaging services in physician offices and free-standing imaging facility settings based upon rates paid to hospital outpatient departments;
- 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. For example, 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. Medicare physician schedule payment rates may also be impacted by other Congressional policy priorities (e.g., annual updates ranging from 0% to 0.75% under the Medicare Access and CHIP Reauthorization Act of 2015, and a 3.75% increase in CY 2021 (intended to offset a portion of the widespread reductions in the Relative Value Units (RVUs) underlying rate calculations)

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. Since 2013, although Medicare generally does not provide separate payment to hospitals for the use of diagnostic radiopharmaceuticals administered in an outpatient setting, CMS has had a policy to make a nominal additional payment ($10) to hospitals that utilize products with non-HEU, meaning the product is 95% derived from non-HEU sources. This payment policy continues in 2021. Although some of our TechneLite generators are manufactured using non-HEU, not all of our TechneLite generators currently meet CMS’s definition of non-HEU, and therefore this payment is not available for doses produced by the latter category of TechneLite generators used by our customers. 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 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.

We also expect increased regulation and oversight of advanced diagnostic testing in which our products are used. 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”). Reimbursement penalties will apply in 2022 if this requirement is not met (and documented on the claim). 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.

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. And more recently, Congress enacted legislation in 2017 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 CARES Act temporarily suspended the 2% payment adjustment for dates of service from May 1 through December 31, 2020, and the Consolidated Appropriations Act 2021 subsequently extended this suspension until March 31, 2021. 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 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 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 and agents in development, we, our products, development agents, 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, including, among other things, anti-trust and competition laws and regulations and the recently enacted General Data Protection Regulation (GDPR) in the European Union (the "EU"). 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.

Under U.S. law, for example, we are required to report certain adverse events and production problems, if any, to the FDA. 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 that 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 a third party manufacturer, the FDA could take regulatory action which could limit or suspend the ability of that third party 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 "federal ceiling price" drug pricing 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. As a specific example, in 2010, we entered into a Medicaid Drug Rebate Agreement with the federal government for some but not all of our products, and in 2016 entered into a separate Medicaid Drug Rebate Agreement for the balance of our products. These 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.

Regulations are subject to change as a result of legislative, administrative or judicial action, which may also increase our costs or reduce sales. 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.

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.

Starting as of the end of fiscal 2019, we are required to maintain additional procedures and practices related to internal control over financial reporting, and we may identify deficiencies that we may not be able to remediate in time to meet the necessary deadline.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting. Since we are no longer an “emerging growth company” and are now a “large accelerated filer”, our independent registered public accounting firm is required to attest to the effectiveness of our internal controls on an annual basis, starting with our Annual Report on Form 10-K for the year ended December 31, 2019. The rules governing the standards that must be met for our management and independent registered public accounting firm to assess our internal controls are complex and require significant documentation, testing and possible remediation of our existing controls and the incurrence of significant additional expenditures.

Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us or our independent registered public accounting firm conducted in connection with Section 404 of the Sarbanes-Oxley Act may reveal deficiencies in our internal controls that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Internal control deficiencies could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. Internal control deficiencies could also result in a restatement of our financial results in the future. We could become subject to stockholder or other third party litigation, as well as investigations by the SEC or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions, payment of damages or other remedies. Further, any delay in compliance with the auditor attestation provisions of Section 404 could subject us to a variety of administrative sanctions, including ineligibility for short-form resale registration, action by the SEC and the suspension or delisting of our common stock, which could reduce the trading price of our common stock and could harm our business.

Risks Related to Our Business Operations and Financial Results

The COVID-19 pandemic has had, and could continue to have, a material impact on our business, results of operation and financial condition, operating results, cash flows and prospects.

In December 2019, a novel strain of coronavirus (COVID-19) emerged in Wuhan China. Less than four months later, in March 2020, the World Health Organization declared COVID-19 a pandemic. While the outbreak initially was largely concentrated in China and caused significant disruptions in its economy, the virus has now spread throughout much of the world, including in Massachusetts, New York, New Jersey, Canada and Sweden, where our offices and manufacturing facilities are located.

Towards the end of the first quarter of 2020 we began to experience, and through the date of this filing we are continuing to experience, impacts to our business and operations related to the COVID-19 pandemic, including the impact of stay-at-home mandates and advisories, and a decline in the volume of procedures using our products. In response to the pandemic, healthcare providers have, and may need to further, reallocate resources, such as physicians, staff and facilities, as they prioritize limited resources and personnel

capacity to focus on the treatment of patients with COVID-19 and implement limitations on access to hospitals and other medical institutions due to concerns about the potential spread of COVID-19 in such settings.

In particular, there has been a reduction in the number of echocardiograms performed in 2020 (approximately 31.5 million) as compared to the number performed in 2019 (approximately 35.1 million), in each case, according to a third party source. There has also been a reduction in pulmonary ventilation studies in which our Xenon is used because of institutional concerns and professional society guidelines relating to the possible spread of COVID-19 to technicians and other patients, given that Xenon is both inhaled and exhaled by the patient. As a result, Xenon sales have decreased. We expect Xenon sales to continue to be at reduced levels so long as COVID-19 precautions remain in place.

These actions have significantly delayed the provision of other medical care including procedures involving our products, having an adverse effect on our revenue. These measures and challenges may continue for the duration of the COVID-19 pandemic, and such duration is uncertain and may significantly reduce our revenue and cash flows while the pandemic continues and thereafter until we and our customers are able to resume normal business operations. We cannot predict the magnitude or duration of the pandemic's impact on our business.

In connection with the COVID-19 pandemic, the following risks could have a material effect on our business, financial condition, results of operations and prospects:

- The delay or cancellation by hospitals and clinics of the procedures in which our products are used as a result of their COVID-19 response efforts and the duration of such effects, thereby reducing sales of our products for an unknown period of time;
- The inability or unwillingness of some patients to visit hospitals or clinics in order to undergo procedures in which our products are used, thereby reducing sales of our products for an unknown period of time;
- The inability of some patients to pay for procedures and/or the co-pay associated with those procedures in which our products are used due to job loss or lack of insurance, thereby reducing sales of our products for an unknown period of time;
- The inability of our distributors, radiopharmacy customers, PET manufacturing partners, hospitals, clinics and other customers to conduct their normal operations, including supplying or conducting procedures in which our products are used, because of their COVID-19 response efforts, or the reduced capacity or productivity of their employees and contractors as a result of possible illness, quarantine or other inability to work, thereby reducing sales of our products for an unknown period of time;
- The financial challenges experienced by certain of our customers due to the COVID-19 pandemic resulting in increased pressure from those customers on the pricing of our commercial products;
- The inability of global suppliers of raw materials or components used in the manufacture of our products, or contract manufacturers of our products, to supply and/or transport those raw materials, components and products to us in a timely and cost effective manner due to shutdowns, interruptions or delays, limiting and potentially precluding the production of our finished products, impacting our ability to supply customers, reducing our sales, increasing our costs of goods sold, and reducing our absorption of overhead;
- The partial or complete delay or cancellation of international or domestic flights by our airfreight carriers, resulting in our inability to receive raw materials, components and products from our global suppliers or to ship and deliver our finished products to our domestic and international customers in a timely or cost effective manner, thereby potentially increasing our freight costs as we seek alternate, potentially more expensive, methods to ship raw materials, components or products, and negatively impacting our sales;
- The reduced capacity or productivity of our complex, on-campus operations as a result of possible illness, quarantine or other inability of our employees and contractors to work, despite all of the preventative measures we continue to undertake to protect the health and safety of our workforce;
- The illiquidity or insolvency of our suppliers, contract manufacturers (including our PET manufacturing partners) or freight carriers whose business activities could be shut down, interrupted or delayed;
- The illiquidity or insolvency of our distributors or customers, or their inability to pay our invoices in full or in a timely manner, due to the reduction in their revenues caused by the cancellation or delay of procedures and other factors, which could potentially reduce our cash flow, reduce our liquidity and increase our bad debt reserves;
- A portion of our raw materials or finished product inventory may expire due to reduced demand for our drugs;
- Delays in our ability, and the ability of our contract research organizations and development partners to conduct, enroll and complete clinical development programs such as our ARROW Phase 2 study in mCRPC, the flurpiridaz F 18 Phase 3 clinical

development program currently being conducted by GE Healthcare, or the Phase 1 trial of PSMA TTC being conducted by Bayer AG;

- Delays of regulatory reviews and approvals, including with respect to our product candidates and manufacturing facilities, by the FDA or other health or regulatory authorities;
- Decreased sales of those of our products that are promotionally sensitive, like DEFINITY, due to the reduction of in-person sales and marketing activities and training caused by travel restrictions, quarantines, other similar social distancing measures and more restrictive hospital access policies;
- Our ability to maintain employee morale and motivate and retain management personnel and other key employees as a result of our previous work week and salary reductions;
- A disruption or delay in regulatory approval for, and operation of, our new, on-campus manufacturing facility, which would delay implementation of our supply diversification strategy for certain of our key products and impact our ability to benefit from a lower cost of goods for those products;
- A reduction in revenue with continued incurrence of high fixed costs relating to our already-existing, complex and expensive radiopharmaceutical manufacturing facility could adversely affect our cash flows, liquidity and ability to comply with the financial covenants in our 2019 Facility, and there can be no assurance that any required waiver or consent related to any such failure to comply would be granted by our current lenders similar to the waiver of total net leverage ratio in exchange for a consolidated liquidity covenant agreed to in June 2020;
- The increased reliance on our personnel working from home, which may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business;
- A delay in achieving, or inability to achieve, successful integration of Lantheus and Progenics, or the synergies, cost savings, innovation and other anticipated benefits of the acquisition due to impact of the COVID-19 pandemic on the operations, financial condition and prospects of our Company;
- The instability to worldwide economies, financial markets, social institutions, labor markets and the healthcare systems as a result of the COVID-19 pandemic, which could result in an economic downturn that could adversely impact our business, results of operations and financial condition, as well as that of our suppliers, distributors, customers or other business partners; and
- A recurrence of the COVID-19 pandemic after social distancing and other similar measures have been relaxed.

The extent to which the COVID-19 pandemic impacts our business and our results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge in connection with the severity of the virus, the ability to treat and ultimately prevent it with vaccines, its potential recurrence or transformation into new or more contagious or virulent strains, and further actions that federal, state, local, or foreign governments may take to contain its impact.

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 agents or new indications for existing agents, anticipate and satisfy customer needs, obtain regulatory approval on a timely basis based on performance of our agents in development versus their clinical study 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 reimbursement. 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 market and distribute our products effectively;
- Market acceptance of our products; and
- Our ability to obtain adequate reimbursement.

The field of diagnostic medical imaging is dynamic, with new products, including hardware, software and agents, 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 agents in a given diagnostic modality may be developed that provide benefits superior to the then-dominant hardware, software and agents in that modality, resulting in commercial displacement of the agents. Similarly, changing perceptions about comparative efficacy and safety including, among other things, comparative radiation exposure, as well as changing availability of supply may favor one agent 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.

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.

Even after giving effect to the Progenics Acquisition, we are continuing to 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 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. 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. Prior to disposal, we store any low level radioactive waste at our facilities to decay until the 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 currently lease a small portion of our North Billerica, Massachusetts facility 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. 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 agents 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;
- Our patent applications or patents may be subject to 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; or
- The patents of others may have an adverse effect on our business.

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.

For DEFINITY, our highest revenue and highest margin commercial product in 2020, we continue to actively pursue patents in both the U.S. and internationally. In the U.S. for DEFINITY we now own a total of four Orange Book-listed method of use patents, one of which expires in 2035 and three of which expire in 2037, as well as additional manufacturing patents that are not Orange Book-listed expiring in 2021, 2023 and 2037. In the U.S. for DEFINITY RT, we own a total of five Orange Book-listed patents, including a composition of matter patent which expires in 2035. Outside of the U.S., while our original DEFINITY patent protection and regulatory exclusivity have generally expired, we are currently prosecuting 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.

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, including, among others, DEFINITY®, TechneLite®, Cardiolite®, NEUROLITE®, VIALMIX®, QUADRAMET®, Luminity®, PyL™, AZEDRA®, AZEDRA Service Connection®, RELISTOR®, Progenics®, Progenics Pharmaceuticals®, EXINI®, Molecular Insight®, Find, Fight and Follow®, PyL Research Access Program®, and Lantheus Medical Imaging®. 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. For example, Progenics (along with Bausch and Wyeth LLC) received notifications of a Paragraph IV certification for RELISTOR subcutaneous injection and for RELISTOR Tablets, for certain patents that are listed in the FDA Orange Book. The certifications resulted from filings by entities such as Mylan Pharmaceuticals Inc., Actavis LLC and Par Sterile Products, LLC of ANDAs with the FDA, challenging such patents for RELISTOR subcutaneous injection and seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection and filings by Actavis Laboratories FL, Inc. seeking to obtain approval to market a generic version of RELISTOR Tablets before some or all of these patents expire. 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. For example, we received notices of opposition to three European patents relating to RELISTOR.

Pursuant to the RELISTOR license agreement between us and Bausch, Bausch has the first right to enforce the intellectual property rights at issue and is responsible for the costs of such enforcement. At the same time, we may incur substantial further costs

in supporting the effort to uphold the validity of patents or to prevent infringement. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. Progenics has previously been and is currently involved in patent litigation, and we expect to be subject to patent litigation in the future.

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. 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 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. 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.

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, 2020, we derived approximately 13.1% of our revenues from outside the fifty United States. Accordingly, our business is subject to risks associated with doing business internationally, including:

- Less stable political and economic environments 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 due to COVID-19, 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;
- 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 fifty United States could have a material adverse effect on our business, results of operations, financial condition and cash flows. As our international exposure increases and as we execute our strategy of international expansion, these risks may intensify.

We face currency and other risks associated with international sales.

We generate revenue from export sales, as well as from operations conducted outside the fifty 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 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 and personally identifiable data relating to employees), 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 of 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 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, 2020, we had U.S. federal income tax loss carryforwards of $492.5 million, $354.5 million of which will begin to expire in 2021 and will completely expire in 2037, $138.0 million of which can be carried forward indefinitely, and state income tax loss carryforwards of $18.0, 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 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. Although 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 because of 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 President, and other members of our executive leadership and senior management team play a significant role in generating new business and retaining existing customers. We have an employment agreement with Ms. Heino 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 both voluntary and involuntary turnover on our executive leadership team, to date we have been able to attract new, qualified individuals to lead our company and key functional areas. 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.

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. These proceedings are complex and extended and occupy the resources of our management and employees. These 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 such claims 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 payers 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 Capital Structure

We have a substantial amount of 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, 2020, we had approximately $185.0 million of total principal indebtedness remaining under our five-year secured term loan facility, which matures on June 30, 2024 (the “2019 Term Facility” and the loans thereunder, the “2019 Term Loans”) and availability of $200.0 million under our five-year revolving credit facility (the “2019 Revolving Facility” and, together with the 2019 Term Facility, the “2019 Facility”). As of December 31, 2020, we had approximately $32.6 million of total principal indebtedness remaining on our royalty-backed loan, which matures on June 30, 2025. Our substantial 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;
- 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 substantial 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 not within 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 or agents 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 substantial 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 2019 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, 2019 Facility will not prevent us from incurring obligations that do not constitute indebtedness under the agreements.

Our 2019 Facility contains restrictions that will limit our flexibility in operating our business.

Our 2019 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 2019 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.

If LIBOR is phased out, as anticipated, starting at the beginning of 2022, we will need to agree to a replacement index rate to be used under our 2019 Facility, which may have an adverse effect on our financial condition.

At present LIBOR is expected to be published only on a limited basis after 2021. The 2019 Facility does not specify a particular "hard-wired" replacement index rate (or related margin) when LIBOR becomes unavailable, but relies on the administrative agent and the Company reaching agreement on such a replacement rate (and related margin) that gives due consideration to the then prevailing market convention for determining rates of interest for syndicated loans denominated in U.S. dollars in the United States. We expect to amend our credit facilities to provide a market-based replacement index rate and margin prior to the time when LIBOR is no longer available. Any replacement rate will be based on a negotiation between us and the administrative agent and could result in an increase in our interest expense.

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 our 2019 Facility could be higher than under our current 2019 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 2019 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 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 medical technology and pharmaceutical 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; 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 cease coverage of our company or fail 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 downgrade 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.

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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

The following table summarizes information regarding our significant leased and owned properties, as of December 31, 2020:

Location	Purpose	Segment	Square Footage	Ownership	Lease Term End
U.S.					
North Billerica, Massachusetts	Corporate Headquarters, Manufacturing, Laboratory, Mixed Use and Other Office Space	U.S. Segment	431,000	Owned	N/A
New York, New York	Progenics Headquarters, Office Space	U.S. Segment	26,000	Leased	September 2030
Somerset, New Jersey	Manufacturing, Mixed Use and Office Space	U.S. Segment	11,400	Leased	November 2028
Canada					
Quebec	Mixed Use and Office Space	International Segment	1,106	Leased	April 2021
Quebec	Distribution Center and Office Space	International Segment	1,433	Leased	May 2022
Puerto Rico					
San Juan	Manufacturing, Laboratory, Mixed Use and Office Space	International Segment	9,550	Leased	October 2024
Sweden					
Lund	Office Space	International Segment	4,000	Leased	December 2021

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

On November 30, 2020, we entered into an agreement to sell our Puerto Rico radiopharmacy and PET manufacturing facility (“PMF”) to PharmaLogic, one of our existing radiopharmacy customers. The transaction closed on January 29, 2021.

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

The Company's common stock began trading on the NASDAQ Global Market under the symbol "LNTH" on June 25, 2015. Prior to that time, there was no established public trading market for our common stock.

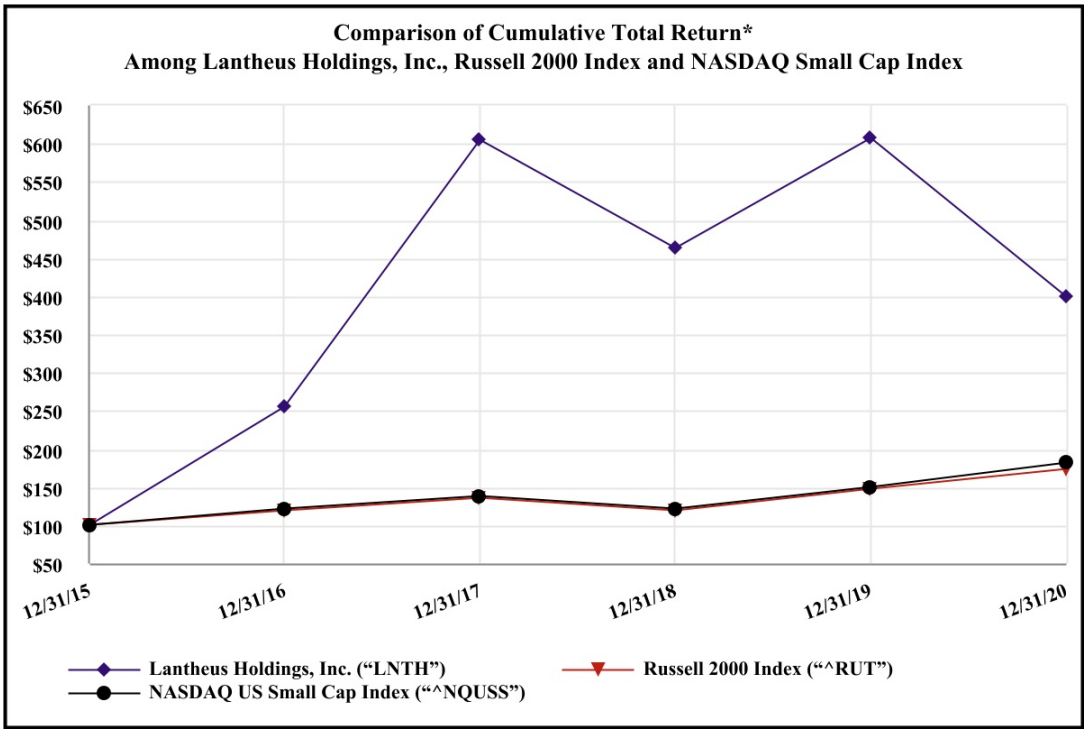
Holders of Record

On February 19, 2021, there were approximately 43 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 the Company explicitly incorporates 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 and (ii) the NASDAQ US Small Cap Index, commencing on December 31, 2015 and ending December 31, 2020. The graph assumes a hypothetical $100 investment in our common stock and in each of the comparative indices on December 31, 2015. 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, 2015, including reinvestment of dividends.*

Performance Graph Data

The following table sets forth the cumulative total shareholder return on the hypothetical $100 investment in the Company's common stock and each of the comparative indices on December 31, 2015:

Date	Lantheus Holdings, Inc. ("LNTH")	Russell 2000 Index ("^RUT")	NASDAQ US Small Cap Index ("^NQUSS")
12/31/15	$ 100.00	$ 100.00	$ 100.00
12/31/16	$ 254.44	$ 119.48	$ 122.02
12/31/17	$ 605.03	$ 135.18	$ 138.58
12/31/18	$ 463.02	$ 118.72	$ 121.97
12/31/19	$ 606.80	$ 146.89	$ 149.25
12/31/20	$ 399.11	$ 173.86	$ 181.29

Issuer Purchase of Equity Securities

None.

Dividend Policy

We did not declare or pay any dividends, and we do not currently intend to pay dividends in the foreseeable future. We currently expect to retain future earnings, if any, for the foreseeable future, to finance the growth and development of our business and to repay indebtedness. Our ability to pay dividends is restricted by our financing arrangements. See Part 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.

Repurchases

The following table presents information with respect to purchases of common stock we made during the quarter ended December 31, 2020. The Company does not currently have a share repurchase program in effect. The 2015 Equity Incentive Plan, adopted by the Company on June 24, 2015, as amended on April 26, 2016 and as further amended on April 27, 2017 and April 24, 2019 (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. These shares are then sold in compliance with Rule 10b5-1 into the market to allow the Company to satisfy the tax withholding requirements in cash.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program
October 2020 **	1,957	$ 13.23	*	*
November 2020 **	1,465	$ 12.46	*	*
December 2020 **	243	$ 14.26	*	*
Total	3,665		*	

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

** Reflects shares withheld to satisfy minimum statutory tax withholding amounts due from employees related to the receipt of stock which resulted from the exercise 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 2021 Annual Meeting of Stockholders to be filed with the SEC no later than 120 days after the close of our year ended December 31, 2020.

Item 6. Selected Financial Data

Basis of Financial Information

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

Selected Financial Data

In the table below, we provide you with our selected consolidated financial data for the periods presented. We have prepared this information using our audited consolidated financial statements for the years ended December 31, 2020, 2019, 2018, 2017 and 2016.

The following selected consolidated financial information should be read in conjunction with our consolidated financial statements, the related notes and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K. The results indicated below and elsewhere in this Annual Report on Form 10-K are not necessarily indicative of results to be expected for any future period.

	Year Ended December 31,				
	2020[b]	2019	2018	2017	2016
Statement of Operations	(in thousands, except per share data)				
Revenues	$ 339,410	$ 347,337	$ 343,374	$ 331,378	$ 301,853
Cost of goods sold	200,649	172,526	168,489	169,243	164,073
Sales and marketing	40,901	41,888	43,159	42,315	36,542
General and administrative	69,270	61,244	50,167	49,842	38,832
Research and development	32,788	20,018	17,071	18,125	12,203
Gain on sales of assets	—	—	—	—	6,385
Operating (loss) income	(4,198)	51,661	64,488	51,853	56,588
Interest expense	9,479	13,617	17,405	18,410	26,618
Debt retirement costs	—	—	—	—	1,896
Loss on extinguishment of debt	—	3,196	—	2,442	—
Other (income) loss	(2,198)	6,221	(2,465)	(8,638)	(220)
(Loss) income before income taxes	(11,479)	28,627	49,548	39,639	28,294
Income tax expense (benefit)[a]	1,994	(3,040)	9,030	(83,746)	1,532
Net (loss) income	$ (13,473)	$ 31,667	$ 40,518	$ 123,385	$ 26,762
Net (loss) income per common share:					
Basic	$ (0.25)	$ 0.81	$ 1.06	$ 3.31	$ 0.84
Diluted	$ (0.25)	$ 0.79	$ 1.03	$ 3.17	$ 0.82
Weighted-average common shares:					
Basic	54,134	38,988	38,233	37,276	32,044
Diluted	54,134	40,113	39,501	38,892	32,656

	December 31,				
	2020[b]	2019	2018	2017	2016
Balance Sheet Data	(in thousands)				
Cash and cash equivalents	$ 79,612	$ 92,919	$ 113,401	$ 76,290	$ 51,178
Total assets	$ 869,821	$ 405,919	$ 439,831	$ 383,858	$ 255,898
Long-term debt, net	$ 197,699	$ 183,927	$ 263,709	$ 265,393	$ 274,460
Total liabilities	$ 355,616	$ 291,318	$ 368,829	$ 360,567	$ 362,414
Total stockholders' equity (deficit)	$ 514,205	$ 114,601	$ 71,002	$ 23,291	$ (106,516)

(a) The 2017 amount reflects the release of our valuation allowance of $141.1 million against its deferred tax assets offset by a provision of $45.1 million for remeasuring the Company's deferred tax assets for the change in tax rates enacted under the Tax Cuts and Jobs Act of 2017.

(b) Includes the impact of the Progenics Acquisition on June 19, 2020. See Note 8, "Business Combinations", in our accompanying financial statements for further information.

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 Item 6, "Selected Financial Data" and 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.

Overview

Our Business

We are an established leader and fully integrated provider of innovative imaging diagnostics, targeted therapeutics, and artificial intelligence solutions to Find, Fight and Follow serious medical conditions. Clinicians use our imaging agents and products across a range of imaging modalities, including echocardiography and nuclear imaging. We believe that the resulting improved diagnostic information enables healthcare providers to better detect and characterize, or rule out, disease, potentially achieving improved patient outcomes, reducing patient risk and limiting overall costs for payers and the entire healthcare system.

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

We sell our products globally and operate our business in two reportable segments, which are further described below:

- *U.S. Segment* produces and markets our medical imaging agents and products throughout the U.S. In the U.S., we primarily sell our products to radiopharmacies, PMFs, integrated delivery networks, hospitals, clinics and group practices.
- *International Segment* operations consist of direct distribution in Canada and Puerto Rico, as well as third-party distribution relationships in Europe, Canada, Australia, Asia-Pacific and Latin America and our EXINI business in Sweden.

We are in the process of evaluating our operating and reporting structure. We anticipate this evaluation, which we expect to complete during 2021, may result in a change to our existing operating segment reporting structure.

Progenics Acquisition

On June 19, 2020, we completed the Progenics Acquisition. Progenics is an oncology company focused on developing and commercializing innovative targeted medicines and artificial intelligence to Find, Fight and Follow cancer. Progenics' portfolio of products and product candidates includes, among other things, therapeutic agents designed to target cancer (AZEDRA, 1095 and PSMA TTC), diagnostic imaging agents designed to target PSMA for prostate cancer (PyL and 1404), RELISTOR for OIC, AI imaging technologies and leronlimab being developed for HIV infection and COVID-19 applications. Progenics' current revenue is generated from two principal sources: first, royalties, development and commercial milestones from strategic partnerships, including royalties from Bausch from sales of RELISTOR; and second, AZEDRA sales.

Holdings issued 26,844,877 shares of Holdings common stock and 86,630,633 CVRs to former Progenics stockholders in connection with the Progenics Acquisition. Holdings also assumed 34,000 in-the-money Progenics stock options and 6,507,342 out-of-the-money Progenics stock options, each converted into Replacement Stock Options at an exchange ratio of 0.31.

Key Factors Affecting Our Results

Our 2021 financial performance will reflect full year results of the Progenics business, whereas current year only incorporated results since the June 19, 2020 acquisition date. We also expect that the anticipated approval and launch of PyL during fiscal year 2021 may result in increased revenues.

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

COVID-19 Pandemic

The global COVID-19 pandemic has had, and will continue to have, a material impact on our business. Towards the end of the first quarter of 2020 we began to experience, and through the date of this filing we are continuing to experience, impacts to our business and operations related to the COVID-19 pandemic, including the impact of stay-at-home mandates and advisories, and a decline in the volume of procedures and treatments using our products. For example, there has been a reduction in the number of

echocardiograms performed in 2020 (approximately 31.5 million) as compared to the number performed in 2019 (approximately 35.1 million), in each case, according to a third party source. In addition, there has been a substantial reduction in pulmonary ventilation studies in which our Xenon is used because of institutional concerns and professional society guidelines relating to the possible spread of COVID-19 to technicians and other patients, given that Xenon is both inhaled and exhaled by the patient. As a result, Xenon sales have decreased. We expect Xenon sales to continue to be at reduced levels so long as COVID-19 precautions remain in place. We cannot predict the magnitude or duration of the pandemic's impact on our business.

As a result of the COVID-19 pandemic, we undertook a thorough analysis of all of our discretionary expenses. In the first quarter of 2020 we implemented certain cost reduction initiatives. For most of the second quarter of 2020, we reduced our work week from five days to four days and reduced the pay for our personnel by varying amounts, depending on level of seniority.

We can give no assurances that we will not have to take additional cost reduction measures if the pandemic continues to adversely affect the volume of procedures and treatments using our products.

During the second quarter of 2020, Progenics also implemented certain cost reduction initiatives, and new enrollment in the Phase 2 trial of 1095 in mCRPC patients was paused to minimize the risk to subjects and healthcare providers during the pandemic. New enrollment in that study restarted in October 2020.

GE Healthcare, our development and commercialization partner for flurpiridaz F 18, also delayed enrollment in the second Phase 3 clinical trial because of the pandemic and resumed enrollment in the third quarter of 2020.

While we are currently unable to estimate the impact of COVID-19 on our overall 2020 operations and financial results, we ended the fourth quarter of 2020 with $79.6 million of cash and cash equivalents. With our available liquidity and prudent expense management, we believe we will be able to maintain a state of preparedness to resume full business activities to support our customers as external conditions allow, although we can give no assurances that we will have sufficient liquidity if the pandemic continues to adversely affect the volume of procedures and treatments using our products for an extended period of time.

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

We believe the market opportunity for our ultrasound microbubble enhancing agent, DEFINITY, continues to be significant. DEFINITY has been our fastest growing and highest margin commercial product. We anticipate DEFINITY sales will continue to grow in the future. As we continue to educate the physician and healthcare provider community about the benefits and risks of DEFINITY, we believe we will be able to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms. In a U.S. market with three echocardiography ultrasound enhancing agents approved by the FDA, we estimate that DEFINITY had over 80% of the market as of December 31, 2020.

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

- Patents - We continue to actively pursue additional patents in connection with DEFINITY and DEFINITY RT, both in the U.S. and internationally. In the U.S. for DEFINITY we now own a total of four Orange Book-listed method of use patents, one of which expires in 2035 and three of which expire in 2037, as well as additional manufacturing patents that are not Orange Book-listed expiring in 2021, 2023 and 2037. In the U.S. for DEFINITY RT, we now own a total of five Orange Book-listed patents, including a composition of matter patent which expires in 2035. Outside of the U.S., while our original DEFINITY patent protection and regulatory exclusivity have generally expired, we are currently prosecuting 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.

  Hatch-Waxman Act - Even though our longest duration Orange Book-listed DEFINITY patent extends until March 2037, because our Orange Book-listed composition of matter patent expired in June 2019, we may face generic DEFINITY challengers in the near to intermediate term. Under the Hatch-Waxman Act, the FDA can approve Abbreviated New Drug Applications ("ANDAs") for generic versions of drugs if the ANDA applicant demonstrates, among other things, that (i) its generic candidate is the same as the innovator product by establishing bioequivalence and providing relevant chemistry, manufacturing and product data, and (ii) the marketing of that generic candidate does not infringe an Orange Book-listed patent or that an Orange Book-listed patent is invalid. With respect to any Orange Book-listed patent covering the innovator product, the ANDA applicant must give a notice to the innovator (a "Notice") that the ANDA applicant certifies that its generic candidate will not infringe the innovator's Orange Book-listed patent or that the Orange Book-listed patent is invalid. The innovator can then challenge the ANDA applicant in court within 45 days of receiving that 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 ANDA applicant is resolved in court. The 30

month stay could potentially expire sooner if the courts determine that no infringement had occurred or that the challenged Orange Book-listed patent is invalid or if the parties otherwise settle their dispute.

As of the date of filing of this Annual Report on Form 10-K, we have not received any Notice from an ANDA applicant. If we were to (i) receive any such Notice in the future, (ii) bring a patent infringement suit against the ANDA applicant within 45 days of receiving that Notice, and (iii) successfully obtain the full 30 month stay, then the ANDA 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 ANDA applicant in March 2021 and the full 30 month stay was obtained, then the ANDA applicant would be precluded from commercialization until at least September 2023. If we received a Notice some number of months in the future and the full 30 month stay was obtained, the commercialization date would roll forward in the future by the same calculation.

- *DEFINITY RT* - In November 2020, the FDA approved our supplemental new drug application (sNDA) for DEFINITY RT. DEFINITY RT is a modified formulation of DEFINITY that allows both storage and shipment at room temperature (DEFINITY's previously approved formulation requires refrigerated storage). The modified formulation provides clinicians an additional choice and allows for greater utility of this formulation in broader clinical settings. We believe DEFINITY RT will become commercially available later in 2021, although that timing cannot be assured. Given its physical characteristics, we believe DEFINITY RT is also well-suited for inclusion in kits requiring microbubbles for other indications and applications (including in kits developed by third parties of the type described in the paragraph entitled *New Clinical Applications* below).
- *VIALMIX RFID* – In August 2020, we announced the FDA approved our sNDA for our next-generation activation device designed specifically for both DEFINITY and DEFINITY RT. The activation rate and time are controlled by VIALMIX RFID through the use of radio-frequency identification technology ("RFID") to ensure reproducible activation of DEFINITY and DEFINITY RT. The RFID tag, which is affixed to the vial label, enables the DEFINITY or DEFINITY RT vial to be appropriately activated when utilized with the VIALMIX RFID activation device.
- *New Clinical Applications* - As we continue to look for other opportunities to expand our microbubble franchise, we are evaluating new indications and clinical applications beyond echocardiography and ultrasound enhancing agent imaging generally.
    - In April 2019, we announced a strategic development and commercial collaboration with Cerevast Medical, Inc. ("Cerevast") in which our microbubble will be used in connection with Cerevast's ocular ultrasound device to improve blood flow in occluded retinal veins in the eye. Retinal vein occlusion is one of the most common causes of vision loss worldwide.
    - In December 2019, we announced a strategic commercial supply agreement with CarThera for the use of our microbubbles in combination with SonoCloud, a proprietary implantable device in development for the treatment of recurrent glioblastoma. Glioblastoma is a lethal and devastating form of brain cancer with median survival of 15 months after diagnosis.
    - In October 2020, we announced a strategic collaboration with Insightec Ltd. ("Insightec") which will use our microbubbles in connection with Insightec's transcranial guided focused ultrasound device for the treatment of glioblastoma as well as other neurodegenerative conditions.
- *In-House Manufacturing* - We have completed construction of specialized, in-house manufacturing capabilities at our North Billerica, Massachusetts facility for DEFINITY and, potentially, other sterile vial products. We believe the investment in these efforts will allow us to better control DEFINITY manufacturing and inventory, reduce our costs in a potentially more price competitive environment, and provide us with supply chain redundancy. We currently expect to make use of this in-house manufacturing capability in late 2021, although that timing cannot be assured.
- *DEFINITY in China* - In March 2020 in connection with our Chinese development and distribution arrangement with Double-Crane Pharmaceutical Company ("Double-Crane"), we filed an Import Drug License application with the National Medical Products Administration, or the NMPA, for the use of DEFINITY for the echocardiography indication. We believe this is an important milestone in our efforts to commercialize DEFINITY in China. Double-Crane is also in the process of analyzing the clinical results relating to the liver and kidney indications and will also work with us to prepare an Import Drug License application for those indications.

Integration of the Progenics Acquisition

The ultimate success of the Progenics Acquisition will depend on our ability to successfully combine the business of Progenics with our own and realize the anticipated benefits, including synergies, cost savings, innovation and operational efficiencies and revenue growth from the combination. If we are unable to achieve these objectives within the anticipated time frame, or at all, the

anticipated benefits may not be realized fully or at all, or may take longer to realize than expected, and the value of our common stock may suffer.

Our combined business is now significantly larger and more complex than our business was immediately prior to the consummation of the Progenics Acquisition. Our ability to successfully manage this combined business will depend upon our ability to continue to integrate the two separate businesses and manage the combined business with its increased scale and scope, and increased costs and complexity.

We have incurred, and expect to continue to incur, substantial expenses in connection with the integration of the Progenics business with our own. There are a large number of processes, policies, procedures, operations, technologies and systems that have been, or must be, integrated, including purchasing, accounting and finance, sales, payroll, pricing, revenue management, marketing and benefits. The substantial majority of these costs have been, and will continue to be, non-recurring expenses related to the Progenics Acquisition, facilities and systems consolidation costs. We may also incur additional costs to maintain employee morale and to attract, motivate or retain management personnel or key employees.

Global Mo-99 Supply

We currently have Mo-99 supply agreements with Institute for Radioelements ("IRE"), running through December 31, 2022, and renewable by us on a year-to-year basis thereafter, and with NTP and ANSTO, running through December 31, 2021. We also have a Xenon supply agreement with IRE which runs through June 30, 2022, and which is subject to further extension.

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. The NTP processing facility had periodic outages in 2017, 2018 and 2019. When NTP was not producing, we relied on Mo-99 supply from both IRE and ANSTO to limit the impact of the NTP outages. In 2019 and 2020, ANSTO experienced multiple facility issues that resulted in ANSTO outages and volume limitations, during which time we relied on IRE and NTP to limit the impact of those outages and limitations. Because of the COVID-19 pandemic, we experienced challenges receiving regularly scheduled orders of Mo-99 from our global suppliers, particularly in the second quarter of 2020. We continue to 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.

We are also pursuing additional sources of Mo-99 from potential new producers to further augment our current supply. In November 2014, we entered into a strategic arrangement with SHINE for the future supply of Mo-99. Under the terms of the supply agreement, SHINE will provide Mo-99 produced using its proprietary LEU-solution technology for use in our TechneLite generators once SHINE's facility becomes operational and receives all necessary regulatory approvals, which SHINE now estimates will occur in 2022. However, we cannot assure you that SHINE or any other possible additional sources of Mo-99 will result in commercial quantities of Mo-99 for our business, or that these new suppliers together with our current suppliers will be able to deliver a sufficient quantity of Mo-99 to meet our needs.

Inventory Supply

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

In addition to JHS, we rely on SBL as our sole source manufacturer of DEFINITY RT. We have also completed construction of specialized, in-house manufacturing capabilities at our North Billerica, Massachusetts facility, which will also allow us to optimize our costs and reduce our supply chain risk. We can give no assurance as to when or if we will be successful in these efforts or that we will be able to successfully manufacture any additional commercial products at our North Billerica, Massachusetts facility.

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

Research and Development Expenses

To remain a leader in the marketplace, we have historically made substantial investments in new product development, including, among other things, our flurpiridaz F 18 clinical development program, the expenses of which are now being borne by GE Healthcare. The Progenics Acquisition brings additional and substantial clinical development expense. The PyL NDA filed with the

FDA on September 29, 2020, was accepted and granted priority review with PDUFA action date of May 28, 2021. For 1095, the ARROW Phase 2 study in mCRPC patients had been paused to minimize risk to subjects and healthcare providers during the pandemic, and new enrollment in that study restarted in October 2020. In addition, the Company's development activities for PSMA AI are on-going. Our investments in these additional clinical activities 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 will be approved.

New Initiatives

In addition to integrating the new assets and programs resulting from the Progenics Acquisition, we continue to seek ways to further expand our portfolio of products and product candidates and how best to optimize the value of our current assets, evaluating a number of different opportunities to collaborate with others or to acquire or in-license additional products, product candidates, businesses and technologies to drive our future growth. As the Progenics Acquisition indicates, we are particularly interested in expanding our presence in oncology, in both radiotherapeutics and diagnostics. In May 2019, we commenced an initiative to build out our Pharma Services capabilities by entering into a strategic collaboration and license agreement with NanoMab, a privately-held biopharmaceutical company focusing on the development of next generation radiopharmaceuticals for cancer precision medicine. We believe this collaboration will provide the first broadly-available PD-L1 imaging biomarker research tool to pharmaceutical companies and academic centers conducting clinical trials on immuno-oncology treatments, including combination therapies. We have also expanded our Pharma Services offering to include PyL for pharmaceutical companies developing PSMA-targeted therapies and have entered into PyL clinical supply agreements with each of Regeneron, Bayer and POINT BioPharma for use of PyL in prostate cancer drug development programs. We can give no assurance as to when or if any of these Pharma Services collaborations will be successful or accretive to earnings.

In addition, as described above, we continue to expand our microbubble franchise. In October 2020, we announced a strategic collaboration with Insightec which will use our microbubbles in connection with Insightec's transcranial guided focused ultrasound device for the treatment of glioblastoma as well as other neurodegenerative conditions. Glioblastoma is a lethal and devastating form of brain cancer with median survival of 15 months after diagnosis. Previously, we announced a strategic commercial supply agreement with CarThera for the use of our microbubbles in combination with SonoCloud, a proprietary implantable device in development for the treatment of recurrent glioblastoma. We also previously announced a strategic development and commercial collaboration with 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. Retinal vein occlusion is one of the most common causes of vision loss worldwide.

Results of Operations

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

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Revenues	$ 339,410	$ 347,337	$ 343,374
Cost of goods sold	200,649	172,526	168,489
Gross profit	138,761	174,811	174,885
Operating expenses			
Sales and marketing	40,901	41,888	43,159
General and administrative	69,270	61,244	50,167
Research and development	32,788	20,018	17,071
Total operating expenses	142,959	123,150	110,397
Operating (loss) income	(4,198)	51,661	64,488
Interest expense	9,479	13,617	17,405
Loss on extinguishment of debt	—	3,196	—
Other (income) loss	(2,198)	6,221	(2,465)
(Loss) income before income taxes	(11,479)	28,627	49,548
Income tax expense (benefit)	1,994	(3,040)	9,030
Net (loss) income	$ (13,473)	$ 31,667	$ 40,518

Comparison of the Periods Ended December 31, 2020 and 2019

Revenues

Segment revenues are summarized by product as follows:

(in thousands)	Year Ended December 31, 2020	2019	2018	2020 vs. 2019 Change $	2020 vs. 2019 Change %	2019 vs. 2018 Change $	2019 vs. 2018 Change %
U.S.							
DEFINITY	$ 207,270	$ 211,777	$ 178,440	$ (4,507)	(2.1)%	$ 33,337	18.7 %
TechneLite	69,729	72,534	74,042	(2,805)	(3.9)%	(1,508)	(2.0)%
Other nuclear	36,864	36,231	48,935	633	1.7 %	(12,704)	(26.0)%
Rebates and allowances	(19,067)	(16,553)	(12,837)	(2,514)	15.2 %	(3,716)	28.9 %
Total U.S. Revenues	294,796	303,989	288,580	(9,193)	(3.0)%	15,409	5.3 %
International							
DEFINITY	6,046	5,731	4,633	315	5.5 %	1,098	23.7 %
TechneLite	16,512	14,058	24,816	2,454	17.5 %	(10,758)	(43.4)%
Other nuclear	22,060	23,574	25,349	(1,514)	(6.4)%	(1,775)	(7.0)%
Rebates and allowances	(4)	(15)	(4)	11	(73.3)%	(11)	275.0 %
Total International Revenues	44,614	43,348	54,794	1,266	2.9 %	(11,446)	(20.9)%
Worldwide							
DEFINITY	213,316	217,508	183,073	(4,192)	(1.9)%	34,435	18.8 %
TechneLite	86,241	86,592	98,858	(351)	(0.4)%	(12,266)	(12.4)%
Other nuclear	58,924	59,805	74,284	(881)	(1.5)%	(14,479)	(19.5)%
Rebates and allowances	(19,071)	(16,568)	(12,841)	(2,503)	15.1 %	(3,727)	29.0 %
Total Revenues	$ 339,410	$ 347,337	$ 343,374	$ (7,927)	(2.3)%	$ 3,963	1.2 %

2020 vs. 2019

The decrease in U.S. segment revenues during the year ended December 31, 2020, as compared to the prior year is primarily due to COVID-19 related business losses which include a $4.5 million decrease in DEFINITY revenue and a $2.8 million decrease in TechneLite revenue. Additionally, rebates and allowances increased $2.5 million. Other nuclear revenue increased $0.6 million driven by the addition of Progenics revenue portfolio, which was nearly offset by a reduction in Xenon volume.

The increase in International segment revenues during the year ended December 31, 2020, as compared to the prior year is primarily due to a $2.5 million higher TechneLite revenue as a result of resolution of supplier disruptions and opportunistic incremental demand, partially offset by a decrease in revenue in other nuclear products driven by COVID-19 demand losses.

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 buying patterns and the resulting applicable contractual rebate to be earned over a contractual period.

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

(in thousands)	Rebates and Allowances
Balance, January 1, 2020	$ 6,985
Provision related to current period revenues	19,675
Adjustments relating to prior period revenues	(604)
Payments or credits made during the period	(16,706)
Balance, December 31, 2020	$ 9,350

Gross Profit

Gross profit is summarized by segment as follows:

(in thousands)	Year Ended December 31, 2020	2019	2018	2020 vs. 2019 Change $	Change %	2019 vs. 2018 Change $	Change %
U.S.	$ 127,778	$ 164,051	$ 161,760	$ (36,273)	(22.1)%	$ 2,291	1.4 %
International	10,983	10,760	13,125	223	2.1 %	(2,365)	(18.0)%
Total Gross profit	$ 138,761	$ 174,811	$ 174,885	$ (36,050)	(20.6)%	$ (74)	— %

2020 vs. 2019

The decrease in the U.S. segment gross profit for the year ended December 31, 2020, as compared to the prior year is primarily due to lower DEFINITY, TechneLite, and Xenon unit volumes due to COVID-19, amortization expense of assets acquired in the Progenics acquisition, a contract termination including a loss on disposal of assets and an asset impairment loss of $7.3 million on other nuclear products.

Sales and Marketing

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

Sales and marketing expense is summarized by segment as follows:

(in thousands)	Year Ended December 31, 2020	2019	2018	2020 vs. 2019 Change $	Change %	2019 vs. 2018 Change $	Change %
U.S.	$ 38,992	$ 39,672	$ 40,579	$ (680)	(1.7)%	$ (907)	(2.2)%
International	1,909	2,216	2,580	(307)	(13.9)%	(364)	(14.1)%
Total Sales and marketing	$ 40,901	$ 41,888	$ 43,159	$ (987)	(2.4)%	$ (1,271)	(2.9)%

2020 vs. 2019

The decrease in the U.S. segment sales and marketing expenses for the year ended December 31, 2020, as compared to the prior year period is primarily due to reduced marketing promotional programs, reduced travel due to COVID-19 impact and reduced hiring and lower employee related costs offset by market research and the addition of the Progenics business. The Progenics business contributed approximately $6.4 million of expense to the U.S. segment for the year ended December 31, 2020.

The decrease in the International segment sales and marketing expenses for the for the year ended December 31, 2020, as compared to the prior year period is primarily due to lower marketing promotional activities.

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 expense is summarized by segment as follows:

(in thousands)	Year Ended December 31, 2020	2019	2018	2020 vs. 2019 Change $	Change %	2019 vs. 2018 Change $	Change %
U.S.	$ 68,283	$ 60,752	$ 49,149	$ 7,531	12.4 %	$ 11,603	23.6 %
International	987	492	1,018	495	100.6 %	(526)	(51.7)%
Total General and administrative	$ 69,270	$ 61,244	$ 50,167	$ 8,026	13.1 %	$ 11,077	22.1 %

2020 vs. 2019

The increase in U.S. segment general and administrative expenses for the year ended December 31, 2020, as compared to the prior year is driven primarily by an increase in acquisition-related costs associated with the Progenics Acquisition and the addition of the Progenics business offset by lower medical insurance costs, travel with COVID-19 limitations and a gain on changes in fair value of contingent assets and liabilities. The Progenics business contributed approximately $5.5 million of expense to the U.S. segment for the year ended December 31, 2020.

The International segment general and administrative expenses increased for the year ended December 31, 2020, as compared to the prior year, driven primarily by the addition of the Progenics business and an insurance benefit received in 2019 which was partially offset by lower employee related costs in 2020. The Progenics business contributed approximately $0.4 million of expense to the International segment for the year ended December 31, 2020.

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. We do not allocate research and development expenses incurred in the U.S. to our International segment.

Research and development expense is summarized by segment as follows:

	Year Ended December 31,			2020 vs. 2019		2019 vs. 2018	
(in thousands)	**2020**	**2019**	**2018**	**Change $**	**Change %**	**Change $**	**Change %**
U.S.	$ 30,866	$ 19,352	$ 15,705	$ 11,514	59.5 %	$ 3,647	23.2 %
International	1,922	666	1,366	1,256	188.6 %	(700)	(51.2)%
Total Research and development	$ 32,788	$ 20,018	$ 17,071	$ 12,770	63.8 %	$ 2,947	17.3 %

2020 vs. 2019

The increase in U.S. segment research and development expenses for the year ended December 31, 2020, as compared to the prior year is primarily driven by the addition of the Progenics business, including the PyL NDA filing fee, an in-process research and development (“IPR&D”) asset impairment loss of $2.7 million partially offset by clinical research expenses related to DEFINITY studies completing and lower employee related expenses. The Progenics business contributed approximately $17.2 million of expense to the U.S. segment for the year ended December 31, 2020.

The increase in the International segment research and development expenses for the year ended December 31, 2020, as compared to the prior year period is primarily driven by the addition of the Progenics business partially offset by regulatory costs related to Brexit matters. The Progenics business contributed approximately $1.3 million of expense to the International segment for the year ended December 31, 2020.

Interest Expense

Interest expense for the year ended December 31, 2020 decreased $4.1 million as compared to the prior year period due to the refinancing of our existing indebtedness in the second quarter of 2019 which reduced our underlying principal amount and decreased interest rates on our long-term debt offset by debt we assumed as part of the Progenics acquisition.

Loss on Extinguishment of Debt

During the year ended December 31, 2019, we incurred a $3.2 million loss on extinguishment of debt in connection with the refinancing of our existing indebtedness.

Other (Income) Loss

Other (income) loss changed by $8.4 million for the year ended December 31, 2020 as compared to the prior year, due to an increase in tax indemnification income primarily due to the reduction of indemnified receivables related to the release of our uncertain tax positions in the prior year offset by an arbitration award that occurred in the prior year.

Income Tax Expense (Benefit)

Income tax expense (benefit) is summarized as follows:

(in thousands)	Year Ended December 31, 2020	2019	2018	2020 vs. 2019 Change $	Change %	2019 vs. 2018 Change $	Change %
Income tax expense (benefit)	$ 1,994	$ (3,040)	$ 9,030	$ 5,034	(165.6)%	$ (12,070)	(133.7)%

The income tax expense for the year ended December 31, 2020 was primarily due to the accrual of interest associated with uncertain tax positions and the impact of non-deductible acquisition costs, offset by the tax benefits on losses generated in the period, the recognition of the deferred tax asset on held for sale assets, and tax credits. In accordance with the Company's accounting policy, the change in the tax liability, penalties and interest associated with these uncertain tax positions (net of any offsetting federal or state benefit) is recognized within income tax (benefit) expense. Contemporaneously, changes in the tax indemnification receivable are recognized within other loss (income) in the consolidated statement of operations. Accordingly, as these reserves change, adjustments are included in income tax (benefit) expense with an offsetting adjustment included in other loss (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. Refer to Note 5, Income Taxes.

The income tax benefit for the year ended December 31, 2019 was primarily due to the release of tax contingency reserves as well as the release of the valuation allowance against our Canada deferred tax assets and tax benefits arising from stock compensation deductions, offset by tax expense on income generated in the period and the accrual of interest associated with uncertain tax positions.

We regularly assess our ability to realize our deferred tax assets. Assessing the realizability of deferred tax assets requires significant management judgment. In determining whether our deferred tax assets are more-likely-than-not realizable, we evaluate all available positive and negative evidence, and weigh the objective evidence and expected impact. We released the full valuation allowance recorded against our Canada deferred tax assets during the year ended December 31, 2018. We continue to record a valuation allowance against certain of our foreign net deferred tax assets and a small component of our domestic deferred tax assets.

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

	Year Ended December 31, 2020	2019	2018
Effective tax rate	(17.4)%	(10.6)%	18.2%

Our effective tax rate in fiscal 2020 differs from the U.S. statutory rate of 21% principally due to non-deductible acquisition costs and the accrual of interest on uncertain tax positions, offset by the benefit created by the recognition of the deferred tax asset on held for sale assets and tax credits.

The decrease in the effective income tax rate for the year ended December 31, 2020 as compared to the prior year period is primarily due to the large non-recurring benefit recorded in 2019 associated with the release of tax contingency reserves, non-deductible acquisition costs offset by the benefit created by the recognition of the deferred tax asset on held for sale assets. The 2020 effective tax rate is a tax expense recorded against a pre-tax loss, whereas the 2019 effective tax rate is a tax benefit recorded against pre-tax income.

Comparison of the Periods Ended December 31, 2019 and 2018

For a comparison of our results of operations for the fiscal years ended December 31, 2019 and December 31, 2018, 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, 2019, filed with the SEC on February 25, 2020.

Liquidity and Capital Resources

Cash Flows

The following table provides information regarding our cash flows:

(in thousands)	Year Ended December 31, 2020	2019	2018
Net cash provided by operating activities	$ 16,396	$ 80,384	$ 61,193
Net cash used in investing activities	$ (4,912)	$ (22,061)	$ (19,132)
Net cash used in financing activities	$ (21,861)	$ (78,881)	$ (4,668)

For a discussion of our liquidity and capital resources related to our cash flow activities for the fiscal year ended December 31, 2018, 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, 2019, filed with the SEC on February 25, 2020.

Net Cash Provided by Operating Activities

Net cash provided by operating activities of $16.4 million in the year ended December 31, 2020 was driven primarily by a net loss of $13.5 million, a net decrease of $22.4 million related to movements in our working capital accounts during the period and a net decrease of $2.0 million in the fair value of contingent assets and liabilities offset by $24.7 million of depreciation, amortization and accretion expense, stock-based compensation expense of $14.1 million, impairment of long-lived assets of $9.9 million and a loss on disposal of assets of $2.3 million. The overall decreases in cash from our working capital accounts were primarily driven by the increase in accounts receivable due to the Progenics Acquisition and increase in collection period as well as change in inventory related to the COVID-19 impact on products and the timing of payments and payments of accruals related to G&A expenses in connection with the Progenics Acquisition.

Net cash provided by operating activities of $80.4 million in the year ended December 31, 2019 was driven primarily by net income of $31.7 million plus $13.4 million of depreciation, amortization and accretion expense, changes in long-term income tax payable and other long-term liabilities of $13.2 million, stock-based compensation expense of $12.5 million, changes in long-term income tax receivable of $10.6 million, changes in deferred taxes of $9.7 million and debt extinguishment expense of $3.2 million. These net sources of cash were further increased by a net increase of $9.0 million related to movements in our working capital accounts during the period. The overall increases in cash from our working capital accounts were primarily driven by accrued expenses and the timing of purchases.

Net Cash Used in Investing Activities

Net cash used in investing activities during the year ended December 31, 2020 reflected $10.0 million in lending on a note receivable to Progenics prior to the acquisition and $12.5 million in capital expenditures offset by $17.6 million of acquired cash related to the Progenics Acquisition.

Net cash used in investing activities during the year ended December 31, 2019 reflected $22.1 million in capital expenditures.

Net Cash Used in Financing Activities

Net cash used in financing activities during the year ended December 31, 2020 is primarily attributable to the payments on long-term debt and other borrowings of $15.5 million related to the 2019 Term Facility and Royalty-Backed Loan (defined below), equity issuance costs related to the Progenics Acquisition of $3.8 million, and payments for minimum statutory tax withholding related to net share settlement of equity awards of $2.1 million.

Net cash used in financing activities during the year ended December 31, 2019 is primarily attributable to the net cash outflow of approximately $73.0 million in connection with the refinancing of our previous 2017 Facility, payments on long-term debt of $5.0 million related to the 2019 Term Facility and payments for minimum statutory tax withholding related to net share settlement of equity awards of $2.5 million. Starting in 2019, we require certain senior executives to cover tax liabilities resulting from the vesting of their equity awards pursuant to sell-to-cover transactions under 10b5-1 plans.

External Sources of Liquidity

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

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

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

Please refer to Note 13, “Long-Term Debt, Net, and Other Borrowings” for further details on the 2019 Facility.

On June 19, 2020, we amended our 2019 Credit Agreement (“the Amendment”) as a result of the impact of the COVID-19 pandemic on our business and operations and the near-term higher level of indebtedness resulting from our decision not to immediately repay the Progenics debt secured by the RELISTOR royalties following our Progenics Acquisition.

The Amendment provides for, among other things, modifications to our financial maintenance covenants. The covenant related to Total Net Leverage Ratio (as defined in the Amended Credit Agreement) has been waived from the date of the Amendment through December 31, 2020. The maximum total net leverage ratio and interest coverage ratio permitted by the financial covenant is displayed in the table below:

2020 Amended Credit Agreement

Period	Total Net Leverage Ratio
Q1 2021	5.50 to 1.00
Q2 2021	3.75 to 1.00
Thereafter	3.50 to 1.00

Period	Interest Coverage Ratio
Q4 2020 to Q1 2021	2.00 to 1.00
Thereafter	3.00 to 1.00

The Amendment also introduces a new financial covenant requiring Consolidated Liquidity (as defined in the Amended Credit Agreement) to be no less than $150.0 million. The Consolidated Liquidity covenant is tested on a continuing basis beginning on the date of the Amendment and ending on the date on which we deliver a compliance certificate for the fiscal quarter ending March 31, 2021. As of December 31, 2020, we were in compliance with all financial and other covenants under the Amendment.

For the period beginning on the date of the Amendment and ending on the Adjustment Date (as defined in the Amended Credit Agreement) for the fiscal quarter ending March 31, 2021, loans under the Amended Credit Agreement bear interest at LIBOR plus 3.25% or the Base Rate plus 2.25%. On and after the Adjustment Date for the fiscal quarter ending on March 31, 2021, loans bear interest at LIBOR plus a spread that ranges from 1.50% to 3.00% or the Base Rate plus a spread that ranges from 0.50% to 2.00%, in each case based on our Total Net Leverage Ratio.

The commitment fee applicable to the Revolving Facility is 0.50% until the Adjustment Date for the fiscal quarter ending March 31, 2021. On and after the Adjustment Date for the fiscal quarter ending on March 31, 2021, the commitment fee ranges from 0.15% to 0.40% based on our Total Net Leverage Ratio.

On June 19, 2020, as a result of the Progenics Acquisition, we assumed Progenics outstanding debt as of such date in the amount of $40.2 million. Progenics, through a wholly-owned subsidiary MNTX Royalties Sub LLC (“MNTX Royalties”), entered into a $50.0 million loan agreement (the “Royalty-Backed Loan”) with a fund managed by HealthCare Royalty Partners III, L.P. (“HCRP”) on November 4, 2016. Under the terms of the Royalty-Backed Loan, the lenders have no recourse to Progenics or any of its assets other than the right to receive royalty payments from the commercial sales of RELISTOR products owed under Progenics’ license agreement with Salix Pharmaceuticals, Inc., a wholly-owned subsidiary of Bausch. The RELISTOR royalty payments will be used to repay the principal and interest on the loan. The Royalty-Backed Loan bears interest at a per annum rate of 9.5% and matures on June 30, 2025. On June 22, 2020, HCRP waived the automatic acceleration of the Royalty-Backed Loan that otherwise would have been

triggered by the consummation of the Progenics Acquisition and MNTX Royalties agreed not to prepay the loan until after December 31, 2020.

Under the terms of the loan agreement, payments of interest and principal, if any, are made on the last day of each calendar quarter out of RELISTOR royalty payments received since the immediately-preceding payment date. On each payment date, 50% of RELISTOR royalty payments received since the immediately-preceding payment date in excess of accrued interest on the loan are used to repay the principal of the loan, with the balance retained by us. Starting on September 30, 2021, all of the RELISTOR royalties received since the immediately-preceding payment date will be used to repay the interest and outstanding principal balance until the balance is fully repaid.

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

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

Funding Requirements

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

- The level of product sales and the pricing environment of our currently marketed products, particularly DEFINITY and any additional products that we may market in the future, including decreased product sales resulting from the COVID-19 pandemic;
- Revenue mix shifts and associated volume and selling price changes that could result from contractual status changes with key customers and additional competition;
- The costs of acquiring or in-licensing, developing, obtaining regulatory approval for, and commercializing, new products, businesses or technologies, together with the costs of pursuing opportunities that are not eventually consummated;
- Our investment in the further clinical development and commercialization of products and development candidates, including the newly acquired Progenics assets AZEDRA, PyL, 1095, aBSI and PSMA AI;
- The costs of investing in our facilities, equipment and technology infrastructure;
- The costs and timing of establishing manufacturing and supply arrangements for commercial supplies of our products and raw materials and components;
- Our ability to have product manufactured and released from JHS and other manufacturing sites in a timely manner in the future;
- 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 extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products;
- The legal costs relating to maintaining, expanding and enforcing our intellectual property portfolio, pursuing insurance or other claims and defending against product liability, regulatory compliance or other claims; and
- The cost of interest on any additional borrowings which we may incur under our financing arrangements.

Until we successfully become dual sourced for our principal products, we are vulnerable to future supply shortages. Disruption in our financial performance could also occur if we experience significant adverse changes in product or customer mix, broad economic downturns, 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 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 Credit Agreement, which could result in additional expenses associated with obtaining the amendment or waiver, we will seek to obtain such a waiver to remain in compliance with those covenants. However, we cannot be assured that such an amendment or waiver would be granted, or that additional capital will be available on acceptable terms, if at all.

At December 31, 2020, our only current committed external source of funds is our borrowing availability under our 2019 Revolving Facility. We had $79.6 million of cash and cash equivalents at December 31, 2020. Our 2019 Facility, as amended, contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. Incremental borrowings under the 2019 Revolving Facility, as amended, may affect our ability to comply with the covenants in the 2019 Facility, as amended, including the financial covenants restricting consolidated net leverage and interest coverage. Accordingly, we may be limited in utilizing the full amount of our 2019 Revolving Facility, as amended, as a source of liquidity.

In addition, in connection with the Progenics Acquisition, which we closed in June 2020, we incurred legal, accounting, financial advisory, consulting and printing fees, and transition, integration and other costs which we funded from our available cash and the available cash of Progenics. The CVRs we issued in the Progenics Acquisition entitle holders thereof to future cash payments of 40% of PyL net sales over (i) $100.0 million in 2022 and (ii) $150.0 million in 2023, which, if payable, we currently intend to fund from our then-available cash. In no event will our aggregate payments under the CVRs, together with any other non-stock consideration treated as paid in connection with the Progenics Acquisition, exceed 19.9% (which we estimate could be approximately $100.0 million) of the total consideration we pay in the Progenics Acquisition. Refer to Note 4, “Fair Value of Financial Instruments”, for further details on contingent consideration liabilities.

Based on our current operating plans, including our prudent expense management in response to the COVID-19 pandemic, we believe that our existing cash and cash equivalents, results of operations and availability under our 2019 Revolving Facility, as amended, will be sufficient to continue to fund our liquidity requirements for the foreseeable future.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, certain suppliers, contingent royalty payments and/or scientific, regulatory, or commercial milestone payments under development agreements. The following table summarizes our contractual obligations as of December 31, 2020:

	Payments Due by Period				
(in thousands)	**Total**	**Less than 1 Year**	**1 - 3 Years**	**3 -5 Years**	**More than 5 Years**
Debt obligations (principal)	$ 217,553	$ 20,452	$ 48,351	$ 148,750	$ —
Interest on debt obligations[(a)]	26,537	9,697	14,454	2,386	—
Operating lease obligations[(b)]	23,239	1,964	4,468	4,637	12,170
Purchase obligations[(c)]	6,198	4,132	2,066	—	—
Finance lease obligations	525	231	294	—	—
Fixed payments under license agreements [(d)]	733	164	328	203	38
Other long-term liabilities[(e)(f)]	—	—	—	—	—
Asset retirement obligations[(g)]	—	—	—	—	—
Total contractual obligations	$ 274,785	$ 36,640	$ 69,961	$ 155,976	$ 12,208

(a) Amounts relate to the estimated interest under our 2019 Term Facility and interest rate swaps based on interest rates in effect as of December 31, 2020 as well as future principal and interest, based upon estimated sales projections, under our Royalty-Backed Loan.

(b) Operating leases include minimum payments under leases for our facilities. Amounts exclude lease payments of $0.9 million associated with the Puerto Rico subsidiary that is classified as held for sale.

(c) Excludes purchase orders for inventory in the normal course of business.

(d) Does 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 $90.6 million in contingent payments under our license agreements.

(e) Our other long-term liabilities in the consolidated balance sheet include unrecognized tax benefits and related interest and penalties. As of December 31, 2020, we had unrecognized tax benefits of $29.9 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; therefore, such amounts are not included in the above contractual obligation table.

(f) Our other long-term liabilities in the consolidated balance sheet also include the fair values of contingent consideration liabilities including CVRs and contingent consideration liabilities related to a previous acquisition completed by Progenics in 2013. We may be required to pay up to approximately $100.0 million related to the CVRs and approximately $85.0 million related to the contingent consideration. These contingent payments have been excluded from the above table due to uncertainty around the timing of the future cash outflows.

(g) We have excluded asset retirement obligations from the table above due to the uncertainty of the timing of the future cash outflows related to the decommissioning of our radioactive operations. As of December 31, 2020, the liability, which was approximately $14.3 million, including amounts recorded in liabilities held for sale was measured at the present value of the obligation expected to be incurred of approximately $26.9 million.

Off-Balance Sheet Arrangements

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

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

Effects of Inflation

We do not believe that inflation has had a significant impact on our revenues or results of operations since inception. 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 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 and Estimates

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 policies and 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 principally to hospitals and clinics, radiopharmacies, and distributors 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 on-going 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 the Company’s 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 the Company’s 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.

Our IPR&D represents 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 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 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

Under our 2019 Facility, as amended, we have substantial variable rate debt. Fluctuations in interest rates may affect our business, financial condition, results of operations and cash flows. As of December 31, 2020, we had $185.0 million outstanding principal under our 2019 Term Facility with variable interest rates.

Furthermore, we are subject to interest rate risk in connection with our 2019 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, 2020, there was availability of $200.0 million on the 2019 Revolving Facility. Any increase in the

interest rate under the 2019 Revolving Facility may have a negative impact on our future earnings to the extent we have outstanding borrowings under the 2019 Revolving Facility.

The Company uses interest rate swaps to reduce the variability in cash flows associated with a portion of the Company's forecasted interest payments on its variable rate debt. As of December 31, 2020, the Company had 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 as of December 31, 2020 was approximately 0.82%. This agreement involves the receipt of floating rate amounts in exchange for fixed rate interest payments over the life of the agreement without an exchange of the underlying principal amount. Please refer to Note 14, "Derivative Instruments", for further details on the interest rate swaps.

The effect of a 100 basis points adverse change in market interest rates on our 2019 Term Facility, in excess of applicable minimum floors, on our interest expense would be approximately $1.9 million excluding the impact of our interest rate swaps.

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 ours, 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, 2020, 2019 and 2018, the net impact of foreign currency changes on transactions was a loss of $0.3 million, a gain of less than $0.1 million and a loss of $0.6 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, 2020, 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, 2020 and 2019, the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 25, 2021, 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.

Valuation of Certain Intangible Assets in the Progenics Pharmaceuticals, Inc. Acquisition — Refer to Note 8 to the financial statements.

Critical Audit Matter Description

The Company completed the acquisition of Progenics Pharmaceuticals, Inc. ("Progenics") common stock for a purchase price of $419.0 million on June 19, 2020 by means of an all-stock transaction. Management accounted for the acquisition under the acquisition method of accounting for business combinations. Accordingly, the purchase price was allocated to the assets acquired and liabilities assumed based on their respective fair values at the date of acquisition, including to the currently marketed product intangible asset ("currently marketed product") and in-process research and development intangible assets ("IPR&D assets"). Management estimated the fair value of the currently marketed product and IPR&D assets for the Progenics acquisition using the multi-period excess earnings method of the income approach. The fair value determination of the currently marketed product and IPR&D assets required management to make significant estimates and assumptions related to forecasted future cash flows, and the selection of the discount rates.

We identified the valuation of the Company's currently marketed product and IPR&D assets for the Progenics acquisition as a critical audit matter because of the significant estimates and assumptions used by management to determine the fair value of these assets. This required a high degree of auditor judgment and an increased extent of effort, including the involvement of our valuation

specialists, when performing audit procedures to evaluate the reasonableness of management's forecasted future cash flows and the selection of the discount rates.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the valuation of the currently marketed product and IPR&D assets for the Progenics acquisition, including forecasted future cash flows and the selection of the discount rates included the following, among others:

- We tested the effectiveness of controls over the valuation of the currently marketed product and IPR&D assets, including management's controls over forecasted future cash flows, and the selection of discount rates.
- We evaluated the appropriateness and consistency of the methods and assumptions used by management to forecast future cash flows and select the discount rates.
- We assessed the reasonableness of management's forecasted future cash flows by comparing the projections to historical results, and comparing the projections to certain peer companies, and internal and external market data and studies.
- With the assistance of our fair value specialists, we evaluated the reasonableness of the (1) valuation methodology and (2) discount rates by:
    - Testing the source information underlying determination of the discount rates and testing the mathematical accuracy of the calculation.
    - Developing a range of independent estimates and comparing those to the discount rates selected by management.
- We evaluated whether the estimated future cash flows were consistent with evidence obtained in other areas of the audit.

/s/ Deloitte & Touche LLP
Boston, Massachusetts
February 25, 2021

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

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

	December 31,	
	2020	**2019**
Assets		
Current assets		
Cash and cash equivalents	$ 79,612	$ 92,919
Accounts receivable, net	54,002	43,529
Inventory	35,744	29,180
Other current assets	9,625	7,283
Assets held for sale	5,242	—
Total current assets	184,225	172,911
Property, plant and equipment, net	120,171	116,497
Intangibles, net	376,012	7,336
Goodwill	58,632	15,714
Deferred tax assets, net	70,147	71,834
Other long-term assets	60,634	21,627
Total assets	$ 869,821	$ 405,919
Liabilities and stockholders' equity		
Current liabilities		
Current portion of long-term debt and other borrowings	$ 20,701	$ 10,143
Accounts payable	16,284	18,608
Accrued expenses and other liabilities	41,726	37,360
Liabilities held for sale	1,793	—
Total current liabilities	80,504	66,111
Asset retirement obligations	14,020	12,883
Long-term debt, net and other borrowings	197,699	183,927
Other long-term liabilities	63,393	28,397
Total liabilities	355,616	291,318
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; 66,875 and 39,251 shares issued and outstanding, respectively)	669	393
Additional paid-in capital	665,530	251,641
Accumulated deficit	(149,946)	(136,473)
Accumulated other comprehensive loss	(2,048)	(960)
Total stockholders' equity	514,205	114,601
Total liabilities and stockholders' equity	$ 869,821	$ 405,919

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,		
	2020	**2019**	**2018**
Revenues	$ 339,410	$ 347,337	$ 343,374
Cost of goods sold	200,649	172,526	168,489
Gross profit	138,761	174,811	174,885
Operating expenses			
Sales and marketing	40,901	41,888	43,159
General and administrative	69,270	61,244	50,167
Research and development	32,788	20,018	17,071
Total operating expenses	142,959	123,150	110,397
Operating (loss) income	(4,198)	51,661	64,488
Interest expense	9,479	13,617	17,405
Loss on extinguishment of debt	—	3,196	—
Other (income) loss	(2,198)	6,221	(2,465)
(Loss) income before income taxes	(11,479)	28,627	49,548
Income tax expense (benefit)	1,994	(3,040)	9,030
Net (loss) income	$ (13,473)	$ 31,667	$ 40,518
Net (loss) income per common share:			
Basic	$ (0.25)	$ 0.81	$ 1.06
Diluted	$ (0.25)	$ 0.79	$ 1.03
Weighted-average common shares outstanding:			
Basic	54,134	38,988	38,233
Diluted	54,134	40,113	39,501

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

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

	Year Ended December 31,		
	2020	**2019**	**2018**
Net (loss) income	$ (13,473)	$ 31,667	$ 40,518
Other comprehensive (loss) income:			
Foreign currency translation	330	148	(74)
Unrealized loss on cash flow hedges, net of tax	(1,418)	—	—
Total other comprehensive (loss) income	(1,088)	148	(74)
Comprehensive (loss) income	$ (14,561)	$ 31,815	$ 40,444

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		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2018	37,765	$ 378	$ 232,960	$ (209,013)	$ (1,034)	$ 23,291
Net income	—	—	—	40,518	—	40,518
Forfeiture of dividend equivalent right	—	—	—	355	—	355
Other comprehensive loss	—	—	—	—	(74)	(74)
Stock option exercises and employee stock plan purchases	223	2	1,578	—	—	1,580
Vesting of restricted stock awards	672	7	(7)	—	—	—
Shares withheld to cover taxes	(194)	(2)	(3,384)	—	—	(3,386)
Stock-based compensation	—	—	8,718	—	—	8,718
Balance, December 31, 2018	38,466	385	239,865	(168,140)	(1,108)	71,002
Net income	—	—	—	31,667	—	31,667
Other comprehensive income	—	—	—	—	148	148
Stock option exercises and employee stock plan purchases	95	1	1,745	—	—	1,746
Vesting of restricted stock awards	796	8	(8)	—	—	—
Shares withheld to cover taxes	(106)	(1)	(2,453)	—	—	(2,454)
Stock-based compensation	—	—	12,492	—	—	12,492
Balance, December 31, 2019	39,251	393	251,641	(136,473)	(960)	114,601
Net loss	—	—	—	(13,473)	—	(13,473)
Other comprehensive loss	—	—	—	—	(1,088)	(1,088)
Stock option exercises and employee stock plan purchases	73	1	759	—	—	760
Vesting of restricted stock awards and units	847	8	(8)	—	—	—
Shares withheld to cover taxes	(141)	(2)	(2,127)	—	—	(2,129)
Issuance of common stock, net of $3,776 issuance costs	26,845	269	394,065	—	—	394,334
Fair value of replacement stock options related to precombination services	—	—	7,125	—	—	7,125
Stock-based compensation	—	—	14,075	—	—	14,075
Balance, December 31, 2020	66,875	$ 669	$ 665,530	$ (149,946)	$ (2,048)	$ 514,205

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,		
	2020	**2019**	**2018**
Operating activities			
Net (loss) income	$ (13,473)	$ 31,667	$ 40,518
Adjustments to reconcile net (loss) income to net cash flows from operating activities:			
Depreciation, amortization and accretion	24,689	13,379	13,929
Impairment of long-lived assets	9,935	—	—
Amortization of debt related costs	119	978	1,279
Changes in fair value of contingent assets and liabilities	(2,000)	—	—
Loss on extinguishment of debt	—	3,196	—
Provision for excess and obsolete inventory	2,365	1,851	2,875
Stock-based compensation	14,075	12,492	8,718
Loss on disposal of assets	2,250	286	842
Deferred taxes	(1,334)	9,725	5,762
Long-term income tax receivable	(2,218)	10,635	(2,855)
Long-term income tax payable and other long-term liabilities	2,828	(13,156)	3,219
Other	1,525	282	878
Increases (decreases) in cash from operating assets and liabilities:			
Accounts receivable	(7,462)	156	(3,985)
Inventory	(8,459)	1,994	(8,690)
Other current assets	1,941	(2,411)	(661)
Accounts payable	(4,224)	3,233	(2,886)
Accrued expenses and other liabilities	(4,161)	6,077	2,250
Net cash provided by operating activities	16,396	80,384	61,193
Investing activities			
Capital expenditures	(12,474)	(22,061)	(20,132)
Proceeds from sale of assets	—	—	1,000
Lending on bridge loan	(10,000)	—	—
Cash acquired in acquisition of business	17,562	—	—
Net cash used in investing activities	(4,912)	(22,061)	(19,132)
Financing activities			
Proceeds from issuance of common stock	683	573	428
Equity issuance costs	(3,777)	—	—
Proceeds from issuance of long-term debt	—	199,461	—
Payments on long-term debt and other borrowings	(15,491)	(275,376)	(2,862)
Deferred financing costs	(1,224)	(2,258)	—
Proceeds from stock option exercises	77	1,173	1,152
Payments for minimum statutory tax withholding related to net share settlement of equity awards	(2,129)	(2,454)	(3,386)
Net cash used in financing activities	(21,861)	(78,881)	(4,668)
Effect of foreign exchange rates on cash and cash equivalents	152	76	(282)
Net (decrease) increase in cash and cash equivalents and restricted cash	(10,225)	(20,482)	37,111
Cash and cash equivalents and restricted cash, beginning of year	92,919	113,401	76,290
Cash and cash equivalents and restricted cash, end of year	$ 82,694	$ 92,919	$ 113,401

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

	Year Ended December 31,		
	2020	**2019**	**2018**
Reconciliation to amounts within the consolidated balance sheets			
Cash and cash equivalents	$ 79,612	$ 92,919	$ 113,401
Cash and cash equivalents included in assets held for sale	941	—	—
Restricted cash included in other long-term assets	2,141	—	—
Cash, cash equivalents and restricted cash at end of period	$ 82,694	$ 92,919	$ 113,401

	Year Ended December 31,		
	2020	**2019**	**2018**
Supplemental disclosure of cash flow information			
Cash paid during the period for:			
Interest	$ 9,368	$ 12,253	$ 15,869
Income taxes, net of refunds of $331, $2 and $35, respectively	$ 340	$ 274	$ 90
Schedule of non-cash investing and financing activities			
Additions of property, plant and equipment included in liabilities	$ 2,227	$ 4,175	$ 7,395
Consideration transferred in acquisition	$ 419,009	$ —	$ —

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 for the period from June 19 through December 31, 2020, Progenics Pharmaceuticals, Inc., a Delaware corporation ("Progenics"). See "Progenics Acquisition".

The Company develops, manufactures and commercializes innovative diagnostic and therapeutic agents and products that assist clinicians in the diagnosis and treatment of heart disease, cancer and other diseases. For the Company's diagnostic agents, they believe that the resulting improved diagnostic information enables healthcare providers to better detect and characterize, or rule out, disease, potentially achieving improved patient outcomes, reducing patient risk and limiting overall costs for payers and the entire healthcare system.

The Company's commercial products are used by cardiologists, nuclear physicians, radiologists, internal medicine physicians, technologists and sonographers working in a variety of clinical settings. The Company sells its products to radiopharmacies, PMFs, integrated delivery networks, hospitals, clinics and group practices.

The Company sells its products globally and has operations in the U.S. and Canada and third-party distribution relationships in Europe, Canada, Australia, Asia-Pacific and Latin America.

Sales of the Company's microbubble ultrasound enhancing agent, DEFINITY, are made in the U.S. and Canada through a DEFINITY direct sales team. In the U.S., the Company's nuclear imaging products, including TechneLite, Xenon, NEUROLITE and Cardiolite, are primarily distributed through commercial radiopharmacies, the majority of which are controlled by or associated with GE Healthcare, Cardinal, UPPI, Jubilant Radiopharma and PharmaLogic. A small portion of the Company's nuclear imaging product sales in the U.S. are made through the Company's direct sales force to hospitals and clinics that maintain their own in-house radiopharmaceutical preparation capabilities. AZEDRA is also sold in the U.S. through an AZEDRA direct sales team. RELISTOR was licensed to Bausch, and the Company collects quarterly royalties based on those sales.

The Company also maintains its own direct sales force in Canada for certain of its products. In Europe, Australia, Asia-Pacific and Latin 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 headquarters are located in North Billerica, MA with offices in New York, NY, 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 previously announced 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 accordance with the Merger Agreement, at the effective time of the Progenics Acquisition (the "Effective Time"), each share of Progenics common stock, par value $0.0013 per share, issued and outstanding immediately prior to the Effective Time (other than shares of Progenics common stock owned by Holdings, Progenics or any of their wholly-owned subsidiaries) was automatically cancelled and converted into the right to receive (i) 0.31 (the "Exchange Ratio") of a share of Holdings common stock, par value $0.01 per share, and (ii) one contingent value right (a "CVR") tied to the financial performance of PyL (18F-DCFPyL), Progenics' prostate-specific membrane antigen ("PSMA") targeted imaging agent designed to visualize prostate cancer, currently a late stage clinical candidate ("PyL"). Each CVR will entitle its holder to receive a pro rata share of aggregate cash payments equal to 40% of U.S. net sales generated by PyL in 2022 and 2023 in excess of $100.0 million and $150.0 million, respectively. In no event will the Company's aggregate payments in respect of the CVRs, together with any other non-stock consideration treated as paid in connection with the Progenics Acquisition, exceed 19.9% (which the Company estimates could be approximately $100.0 million) of the total consideration the Company pays in the Progenics Acquisition. No fractional shares of Holdings common stock were issued in the Progenics Acquisition, and Progenics' former stockholders have received cash in lieu of any fractional shares of Holdings common stock.

In addition, in accordance with the Merger Agreement, at the Effective Time, each Progenics stock option with a per share exercise price less than or equal to $4.42 (an "in-the-money Progenics stock option") received in exchange for each such in-the money Progenics stock option: (i) an option to purchase Holdings common stock (each, a "Replacement Stock Option") converted based on the Exchange Ratio, and (ii) a vested or unvested CVR depending on whether the underlying in-the-money Progenics stock option was vested at the Effective Time. Each Progenics stock option with a per share exercise price greater than $4.42 (an "out-of-the-money

Progenics stock option") received in exchange for such out-of-the-money Progenics stock options a Replacement Stock Option converted at an exchange ratio determined based on the average of the volume weighted average price per share of common stock of Progenics and Lantheus Holdings prior to the Effective Time, which exchange ratio was 0.31, the same as the Exchange Ratio.

As a result of the acquisition, Holdings issued 26,844,877 shares of Holdings common stock and 86,630,633 CVRs to former Progenics stockholders. Holdings also assumed 34,000 in-the-money Progenics stock options and 6,507,342 out-of-the-money Progenics stock options, each converted into Replacement Stock Options as noted above. In addition, Lantheus assumed Progenics equity plans, which, on an as-converted basis, increased the number of Lantheus shares available for issuance by an aggregate of 4,211,290 shares prior to converting the stock options noted above, subject to certain limitations as to eligibility for issuance.

Please refer to Note 8, "Business Combinations", for further details on the acquisition.

COVID-19

The Company experienced operational and financial impacts from the COVID-19 pandemic beginning late in the first quarter of 2020 and through the date of this filing, including the impact of stay-at-home mandates and advisories, and a decline in the volume of procedures and treatments using the Company's products. As a result of the COVID-19 pandemic, the Company undertook a thorough analysis of all of its discretionary expenses. In the first quarter of 2020, the Company implemented certain cost reduction initiatives. For most of the second quarter, the Company reduced the Company's work week from five days to four days and reduced the pay for employees by varying amounts depending on level of seniority.

During the second quarter of 2020, Progenics also implemented certain cost reduction initiatives and paused new enrollment in the Phase 2 trial of 1095 in metastatic castrate-resistant prostate cancer ("mCRPC") patients to minimize the risk to subjects and healthcare providers during the pandemic. New enrollment in that study restarted in October 2020. GE Healthcare Limited ("GE Healthcare"), the Company's development and commercialization partner for flurpiridaz F 18, also delayed enrollment in the second Phase 3 clinical trial of flurpiridaz F 18 because of the pandemic and resumed enrollment in the third quarter of 2020.

The severity of the on-going impact of the COVID-19 pandemic on the Company's business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic, and the extent and severity of the impact on the Company's customers and suppliers, all of which are uncertain and cannot be predicted. While the impact of COVID-19 on the Company's results of operations and cash flows has been, and is expected to continue to be, material, given the continually evolving nature of the pandemic, the Company is currently unable to accurately predict the impact of COVID-19 on its overall 2021 operations and financial results or cash flows for the foreseeable future and whether the impact of COVID-19 could lead to potential future impairments.

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.

Reclassifications

Certain immaterial reclassifications in the prior period consolidated statement of cash flows have been reclassified to conform to the current year period financial statement presentation. Reclassifications include $0.1 million and $0.3 million from provision for bad debt to other at December 31, 2019 and 2018, respectively, as well as $0.3 million and $0.8 million from other to loss on disposal of assets at December 31, 2019 and 2018, respectively.

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 more significant 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.

Income Taxes

The Company accounts for income taxes using an asset and liability approach. Income tax expense (benefit) 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

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 if those securities were converted or exercised. 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 at December 31, 2020, represents primarily collateral for a letter of credit securing a lease obligation and a security deposit. The Company believes the carrying value of this asset 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 large national distributors, which in turn, resell the Company’s products.

As of December 31, 2020 and 2019, 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, 2020, 2019 and 2018.

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 has Mo-99 supply agreements with IRE of Belgium, running through December 31, 2022, and renewable by the Company on a year-to-year basis thereafter, and with ANSTO and NTP, running through December 31, 2021. The Company also has a Xenon supply agreement with IRE which runs through June 30, 2022, and which is subject to further extension. The Company currently relies on IRE as the sole supplier of bulk-unprocessed Xenon which the Company processes and finishes for its customers. The Company currently relies on JHS as its sole source manufacturer of DEFINITY, NEUROLITE, Cardiolite and evacuation vials for TechneLite.

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

	Year Ended December 31,		
	2020	**2019**	**2018**
DEFINITY	62.8%	62.6%	53.3%
TechneLite	25.4%	24.9%	28.8%

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. As of December 31, 2020 and 2019, the Company had no capitalized inventories associated with product that did not have regulatory approval, respectively.

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 is computed on a straight-line basis over the estimated useful lives of the related assets. 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, equipment and fixtures 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.

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 they 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 did not recognize any goodwill impairment charges during the years ended December 31, 2020, 2019 or 2018.

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.

The Company's in-process research and development ("IPR&D") represents 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 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 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 11, "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.

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 estimated fair value of the Company's long term debt approximates its carrying values as the applicable interest rates are subject to change with market interest rates. The estimated fair value of the Company's royalty-backed long-term debt approximates its carrying value as the interest rate is in line with the market interest rates for this type of debt with the respective underlining collateral value. See note 4, "Fair Value of Financial Instruments".

Contingent Consideration Liabilities

The estimated fair value of contingent consideration liabilities, 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.

Derivative Instruments

The Company uses interest rate swaps to reduce the variability in cash flows associated with a portion of the Company's forecasted interest payments on its variable rate debt. 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, 2020, 2019 and 2018, the Company incurred $5.2 million, $3.8 million and $4.0 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 (income) loss 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 (Income) Loss

Other (income) loss consisted of the following:

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Foreign currency losses (gains)	$ 260	$ (33)	$ 557
Tax indemnification (income) expense, net	(2,218)	10,635	(2,855)
Interest income	(238)	(686)	(167)
Arbitration award	—	(3,453)	—
Other	(2)	(242)	—
Total other (income) loss	$ (2,198)	$ 6,221	$ (2,465)

Comprehensive (Loss) Income

Comprehensive (loss) income consists of net (loss) income and other gains and losses affecting stockholders' equity that, under U.S. GAAP, are excluded from net income. For the Company, other comprehensive (loss) income consists of foreign currency translation gains and losses as well as unrealized gains and losses on cash flow hedges related to the Company's interest rate swaps. The accumulated other comprehensive loss balance consists entirely of foreign currency translation gains and losses and unrealized gains and losses on 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 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, 2020 and 2019, 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, 2020 and 2019.

Self-Insurance Reserves

The Company's consolidated balance sheets at December 31, 2020 and 2019 include $0.6 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

Standard	Description	Effective Date for Company	Effect on the Consolidated Financial Statements
Accounting Standards Adopted During the Year Ended December 31, 2020			
ASU 2020-04 and 2021-01, "Reference Rate Reform (Topic 848)"	ASU 2020-04 provides optional guidance for a limited period of time to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting. ASU 2021-01 amends the previous standard to clarify certain expedient options are applicable to derivative instruments that use an interest rate for margining, discounting, or contract price alignment.	January 1, 2020	The adoption of this standard did not have a material impact on the Company's consolidated financial statements.
ASU 2016-13, "Financial Instruments-Credit Losses (Topic 326)"	This ASU requires financial instruments measured at amortized cost and accounts receivable to be presented at the net amount expected to be collected. The new model requires an entity to estimate credit losses based on historical information, current information and reasonable and supportable forecasts that affect the collectability of the reported amount.	January 1, 2020	The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

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 and reportable segment as follows:

	Year Ended December 31,		
Major Products/Service Lines by Segment (in thousands)	**2020**	**2019**	**2018**
U.S.			
Product revenue, net[1]	$ 284,885	$ 303,989	$ 288,580
License and royalty revenues	9,911	—	—
Total U.S. revenues	294,796	303,989	288,580
International			
Product revenue, net[1]	42,810	41,287	52,556
License and royalty revenues	1,804	2,061	2,238
Total International revenues	44,614	43,348	54,794
Total revenues	$ 339,410	$ 347,337	$ 343,374

(1) The Company's principal products include DEFINITY and TechneLite and are categorized within product revenue, net. The Company applies the same revenue recognition policies and judgments for all of its principal products.

Product Revenue, Net

The Company sells its products principally to hospitals and clinics, radiopharmacies and distributors. 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.

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 not within 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, 2020, the Company is constraining variable consideration related to development milestone payments requiring regulatory approvals and sales milestone payments related to achievement of certain sales targets.

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)	**2020**	**2019**
Amounts included in the contract liability at the beginning of the period	$ 33	$ 33

The Company did not record any revenue related to performance obligations satisfied (or partially satisfied) in previous periods during the years ended December 31, 2020 and 2019.

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 are 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 14, "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. Please refer to Note 8, "Business Combinations", for further details on the acquisition.

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

	December 31, 2020			
(in thousands)	**Total Fair Value**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Money market	$ 35,457	$ 35,457	$ —	$ —
Contingent receivable	11,300	—	—	11,300
Total assets	$ 46,757	$ 35,457	$ —	$ 11,300
Liabilities:				
Interest rate swaps	$ 1,908	$ —	$ 1,908	$ —
Contingent consideration liabilities	15,800	—	—	15,800
Total liabilities	$ 17,708	$ —	$ 1,908	$ 15,800

	December 31, 2019			
(in thousands)	**Total Fair Value**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Money market	$ 39,530	$ 39,530	$ —	$ —
Total assets	$ 39,530	$ 39,530	$ —	$ —

During the years ended December 31, 2020 and 2019, there were no transfers into or out of Level 3.

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

regulatory events and sales targets. The most significant unobservable inputs are the probabilities of achieving regulatory approval of the development projects and subsequent commercial success.

As part of the Progenics Acquisition, the Company issued CVRs and recorded the fair value as part of consideration transferred. Refer to Note 1, "Description of Business" for further details on the CVRs. Additionally, the Company assumed contingent consideration liabilities related to a previous acquisition completed by Progenics in 2013 ("2013 Acquisition"). These contingent consideration liabilities include potential payments of up to $70.0 million if the Company attains certain net sales targets primarily for AZEDRA and 1095 and a $5.0 million 1095 commercialization milestone. Additionally, there is a potential payment of up to $10.0 million related to a 1404 commercialization milestone. The Company's total potential payments related to the 2013 Acquisition are approximately $85.0 million. The Company considers the contingent consideration liabilities 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 and Monte Carlo simulation models that included 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 or the probabilities as to the periods in which milestones will be achieved 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 following tables summarize quantitative information and assumptions pertaining to the fair value measurement of assets and liabilities using Level 3 inputs at June 19, 2020.

(in thousands)	Fair Value at June 19, 2020	Valuation Technique	Unobservable Input	Assumption
Contingent receivable:				
Regulatory milestone	$ 3,100	Probability adjusted discounted cash flow model	Period of expected milestone achievement	2021
			Probability of success	90 %
			Discount rate	23 %
Royalties	7,000	Probability adjusted discounted cash flow model		
			Probability of success	13% - 77%
			Discount rate	23 %
Total	$ 10,100			

(in thousands)	Fair Value at June 19, 2020	Valuation Technique	Unobservable Input	Assumption
Contingent consideration liability:				
Net sales targets - PyL (CVRs)	$ 3,700	Monte-Carlo simulation	Period of expected milestone achievement	2022 - 2023
			Discount rate	23 %
1095 commercialization milestone	2,200	Probability adjusted discounted cash flow model	Period of expected milestone achievement	2026
			Probability of success	45 %
			Discount rate	0.48 %
Net sales targets - AZEDRA and 1095	10,700	Monte-Carlo simulation	Probability of success	40% - 100%
			Discount rate	22% - 23%
Total	$ 16,600			

The following tables summarize quantitative information and assumptions pertaining to the fair value measurement of assets and liabilities using Level 3 inputs at December 31, 2020.

(in thousands)	Fair Value at December 31, 2020	Valuation Technique	Unobservable Input	Assumption
Contingent receivable:				
Regulatory milestone	$ 3,200	Probability adjusted discounted cash flow model	Period of expected milestone achievement	2021
			Probability of success	90 %
			Discount rate	24 %
Royalties	8,100	Probability adjusted discounted cash flow model		
			Probability of success	13% - 77%
			Discount rate	24 %
Total	$ 11,300			

(in thousands)	Fair Value at December 31, 2020	Valuation Technique	Unobservable Input	Assumption
Contingent consideration liability:				
Net sales targets - PyL (CVRs)	$ 4,200	Monte-Carlo simulation	Period of expected milestone achievement	2022 - 2023
			Discount rate	24 %
1095 commercialization milestone	2,200	Probability adjusted discounted cash flow model	Period of expected milestone achievement	2026
			Probability of success	45 %
			Discount rate	0.51 %
Net sales targets - AZEDRA and 1095	9,400	Monte-Carlo simulation	Probability of success	40% - 100%
			Discount rate	23% - 24%
Total	$ 15,800			

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

	Financial Assets	Financial Liabilities
(in thousands)	Year Ended December 31, 2020	Year Ended December 31, 2020
Fair value, beginning of period	$ —	$ —
Progenics acquisition	10,100	16,600
Changes in fair value included in net loss	1,200	(800)
Fair value, end of period	$ 11,300	$ 15,800

The change in fair value of the contingent financial asset and contingent financial liabilities resulted in a gain of $2.0 million for the year ended December 31, 2020 was primarily due to a change in the forecast for AZEDRA, changes in market conditions and the passage of time.

5. Income Taxes

The components of income before income taxes is summarized as follows:

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
U.S.	$ (5,495)	$ 25,432	46,945
International	(5,984)	3,195	2,603
(Loss) income before income taxes	$ (11,479)	$ 28,627	$ 49,548

The income tax expense (benefit) is summarized as follows:

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Current			
Federal	$ —	$ 287	$ (21)
State	3,158	(13,166)	3,424
International	170	114	(135)
	3,328	(12,765)	3,268
Deferred			
Federal	(1,506)	8,712	7,821
State	(178)	790	1,411
International	350	223	(3,470)
	(1,334)	9,725	5,762
Income tax expense (benefit)	$ 1,994	$ (3,040)	$ 9,030

The reconciliation of income taxes at the U.S. federal statutory rate to the actual income taxes is as follows:

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
U.S. statutory rate	$ (2,411)	$ 6,012	$ 10,405
Permanent items	1,406	3,210	152
Acquisition costs - Progenics	2,723	—	—
Recognition of deferred tax asset - assets held for sale	(3,000)	—	—
Section 162(m)	717	527	353
Uncertain tax positions	2,818	(13,156)	3,227
Other tax credits	(1,065)	(1,685)	(742)
State and local taxes	1,457	1,914	2,125
Foreign tax rate differential	(254)	(238)	30
Valuation allowance	(318)	(22)	(4,073)
Benefit of windfall related to stock compensation	(128)	(2,768)	(1,760)
Change in indemnification deferred tax asset	(590)	2,531	(731)
Other	639	635	44
Income tax expense (benefit)	$ 1,994	$ (3,040)	$ 9,030

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

	December 31,	
(in thousands)	**2020**	**2019**
Deferred Tax Assets		
Federal benefit of state tax liabilities	$ 5,867	$ 5,278
Reserves, accruals and other	32,030	15,026
Inventory obsolescence	404	550
Capitalized research and development	2,553	5,086
Amortization of intangibles other than goodwill	1,325	1,569
Net operating loss carryforwards	127,369	47,095
Depreciation	1,014	56
Deferred tax assets	170,562	74,660
Deferred Tax Liabilities		
Reserves, accruals and other	(5,676)	(881)
Intangible assets	(91,283)	(707)
Deferred tax liability	(96,959)	(1,588)
Less: valuation allowance	(3,456)	(1,238)
	$ 70,147	$ 71,834
Recorded in the accompanying consolidated balance sheets as:		
Noncurrent deferred tax assets, net	$ 70,147	$ 71,834

On June 19, 2020, the Company completed the Progenics Acquisition in a transaction that is expected to qualify as a tax-deferred reorganization under Section 368 of the Internal Revenue Code. The transaction resulted in an ownership change of Progenics under Section 382 of the Internal Revenue Code, and a limitation on the utilization of Progenics' precombination tax attributes. All of Progenics' precombination research credits and Orphan drug credits have been removed from the balance sheet, and the gross carrying value of the tax loss carryforwards reduced to their realizable value on the opening balance sheet, in accordance with the Section 382 limitation. Deferred tax liabilities of $92.3 million on acquired identified intangibles were recorded at acquisition resulting in a small net overall deferred tax liability for Progenics after the application of acquisition accounting. The Company also acquired estimated utilizable U.S. federal loss carryforwards of $338.7 million, tax-effected state loss carryforwards of $12.5 million and state tax credits of $2.5 million as a result of the Progenics acquisition. The utilization of these losses and credits is subject to annual limitations based on Sections 382 and 383 of the Internal Revenue Code.

The Company regularly assesses its ability to realize its deferred tax assets. Assessing the realizability of deferred tax assets requires significant management judgment. In determining whether its deferred tax assets are more-likely-than-not realizable, the Company evaluated all available positive and negative evidence, and weighed the objective evidence and expected impact. During the fourth quarter of fiscal year 2018, the Company's Canada subsidiary entered an accumulated three year period of profitability, removing a strong item of negative evidence previously supporting the recording of a full valuation allowance. Management determined that the weight of the relevant positive evidence outweigh the negative evidence, and released the valuation allowance against its Canada subsidiary's net deferred tax assets, resulting in an income tax benefit of $4.0 million in fiscal 2018. The Company continues to record valuation allowances of $1.2 million against the net deferred tax assets of its U.K. subsidiary, $2.1 million against the net deferred tax assets of its Sweden subsidiary, and $0.1 million against certain domestic state tax credits and state loss carryforwards.

The Company will continue to assess the level of the valuation allowance required. If the weight of negative evidence exists in future periods to again support the recording of a partial or full valuation allowance against the Company's deferred tax assets, there would likely be a material negative impact on the Company's results of operations in that future period.

A summary of the changes in the Company's valuation allowance is summarized below:

(in thousands)	Amount
Balance, January 1, 2019	$ 1,240
Charged to income tax (benefit) expense	(22)
Foreign currency	20
Release valuation allowance	—
Balance, December 31, 2019	1,238
Charged to income tax (benefit) expense	311
Foreign currency	31
Increase due to Progenics acquisition	2,479
Release valuation allowance	(603)
Balance, December 31, 2020	$ 3,456

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 jurisdictions' statutes of limitation, and in the case of Sweden, up to six years after the end of the financial year.

At December 31, 2020, the Company has U.S. federal net operating loss carryovers of approximately $492.5 million,$354.5 million of which will expire between 2021 and 2037, and $138.0 million of which can be carried forward indefinitely. The Company's state net operating losses are $18.0 million on a tax-effected basis, which will expire between 2021 and 2040. The Company also has U.S. federal research credits carryforwards of $2.4 million which will begin to expire in 2037. The Company has state research credit carryforwards of $4.2 million, which will expire between 2021 and 2035. The Company has state investment tax credit carryforwards of $2.6 million net of federal impact, $0.7 million of which have no expiration date, $1.8 million of which will expire between 2021 and 2023, and the remainder of which will fully expire by 2034.

A reconciliation of the Company's changes in uncertain tax positions for 2020 and 2019 is as follows:

(in thousands)	Amount
Balance of uncertain tax positions as of January 1, 2019	$ 9,788
Additions related to current year tax positions	—
Reductions related to prior year tax positions	(4,496)
Settlements	—
Lapse of statute of limitations	—
Balance of uncertain tax positions as of December 31, 2019	5,292
Additions related to current year tax positions	—
Reductions related to prior year tax positions	—
Settlements	—
Lapse of statute of limitations	—
Balance of uncertain tax positions as of December 31, 2020	$ 5,292

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

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.

As of December 31, 2020 and 2019, total liabilities for uncertain tax positions including interest and penalties were $29.9 million and $27.0 million, respectively, consisting of uncertain tax positions of $5.3 million, interest accruals of $23.5 million and $20.7 million, respectively, and penalty accruals of $1.0 million. As of December 31, 2020 and 2019, these liabilities were included in other long-term liabilities. Included in the 2020, 2019 and 2018 tax provisions are an expense of $2.8 million, a benefit of $13.2 million and an expense of $3.2 million, respectively, relating to accrual of interest, net of benefits for reversals of uncertain tax positions recognized upon settlements, effective settlements, or lapses of relevant statutes of limitation.

The total long-term asset related to the indemnification was $20.8 million and $18.9 million at December 31, 2020 and 2019, respectively. Included in other (income) loss for the years ended December 31, 2020, 2019 and 2018, is tax indemnification expense (income), net of $(2.2) million, $10.6 million and $(2.9) million, respectively.

The Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, was passed by the Congress and signed into law on March 27, 2020. The Company has reviewed the relevant measures of the Act. No material impacts of the Cares Act have been identified nor are any anticipated. On December 27, 2020, the Taxpayer Certainty and Disaster Tax Relief Act of 2020 was signed into law, modifying certain aspects of the CARES Act. This Act contains numerous provisions some of which may be beneficial to the Company. The Company is analyzing those impacts but has not yet concluded its analysis.

6. Inventory

Inventory consisted of the following:

	December 31,	
(in thousands)	**2020**	**2019**
Raw materials	$ 16,000	$ 11,417
Work in process	11,212	9,450
Finished goods	8,532	8,313
Total inventory	$ 35,744	$ 29,180

7. Property, Plant and Equipment, Net

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

	December 31,	
(in thousands)	**2020**	**2019**
Land	$ 13,450	$ 13,450
Buildings	70,381	75,654
Machinery, equipment and fixtures	77,854	87,763
Computer software	23,644	20,739
Construction in progress	11,254	10,546
	196,583	208,152
Less: accumulated depreciation and amortization	(76,412)	(91,655)
Total property, plant and equipment, net	$ 120,171	$ 116,497

Depreciation and amortization expense related to property, plant & equipment, net, was $12.5 million, $10.3 million and $10.1 million for the years ended December 31, 2020, 2019 and 2018, 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 three months ended March 31, 2020, as a result of a decline in expected future cash flows and the effect of COVID-19 related to certain other nuclear legacy manufacturing assets in the U.S. segment, the Company determined certain impairment triggers had occurred. Accordingly, the Company performed an undiscounted cash flow analysis as of March 31, 2020. Based on the undiscounted cash flow analysis, the Company determined that the manufacturing assets had net carrying values that exceeded their estimated undiscounted future cash flows. The Company then estimated the fair values 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 non-cash impairment of $7.3 million for the year ended December 31, 2020 in cost of goods sold in the consolidated statement of operations.

In connection with a contract termination in the fourth quarter of 2020, the Company transferred ownership of certain manufacturing assets and recorded a non-cash loss on disposal of assets of $1.8 million as well as paid $0.5 million, all of which is recorded in cost of goods sold in the consolidated statement of operations.

8. Business Combinations

On June 19, 2020, the Company completed the Progenics Acquisition. Progenics is an oncology company developing innovative medicines and artificial intelligence to Find, Fight and Follow cancer. The acquisition combines the commercialization, supply chain and manufacturing expertise of the Company with the currently commercialized products and R&D pipeline of Progenics. Progenics brings several commercial products and a pipeline of product candidates that will further diversify the Company's commercial and clinical development portfolios.

Under the terms of the Merger Agreement, the Company acquired all of the issued and outstanding shares of Progenics common stock for a purchase price of $419.0 million by means of an all-stock transaction, which includes Replacement Stock Options for precombination services as well as CVRs.

The CVRs were accounted for as contingent consideration, the fair value of which was determined using a Monte-Carlo simulation. Additionally, the fair value of Replacement Stock Options related to precombination services was recorded as a component of consideration transferred. Finally, as a result of the acquisition, Lantheus effectively settled an existing bridge loan with Progenics at the recorded amount (principal and accrued interest) of $10.1 million, representing the effective settlement of a preexisting relationship. This effective settlement of the bridge loan was treated as a component of consideration transferred. The Company determined that the bridge loan was at market terms and no gain or loss was recorded upon settlement.

The acquisition date fair value of the consideration transferred in the acquisition consisted of the following:

(in thousands)		Amount
Issuance of common stock	$	398,110
Fair value of replacement stock options		7,125
Fair value of bridge loan settled at close		10,074
Fair value of contingent considerations (CVRs)		3,700
Total consideration transferred	$	419,009

The transaction was accounted for as a business combination which requires that assets acquired and liabilities assumed be recognized at their fair value as of the acquisition date. While the Company uses its best estimates and assumptions as part of the purchase price allocation process to value the assets acquired and liabilities assumed on the acquisition date, its estimates and assumptions are subject to refinement. Fair value estimates are based on a complex series of judgments about future events and uncertainties and rely heavily on estimates and assumptions. The judgments used to determine the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact the Company's results of operations. As of December 31, 2020, the Company finalized all measurement period adjustments related to the Progenics acquisition other than tax related balances.

The following table summarizes the provisional amounts recognized for assets acquired and liabilities assumed as of the acquisition date, as well as measurement period adjustments made to the amounts initially recorded in June 2020. The measurement period adjustments primarily resulted from finalizing the fair values of certain intangible assets and liabilities and other changes to certain tangible assets and liability accounts. The related impact to net loss that would have been recognized in previous periods if the adjustments were recognized as of the acquisition date is immaterial to the consolidated financial statements.

(in thousands)	Amounts Recognized as of Acquisition Date (as previously reported)	Measurement Period Adjustments	Amounts Recognized as of Acquisition Date (as adjusted)
Cash and cash equivalents	$ 15,421	$ —	$ 15,421
Accounts receivable	5,787	—	5,787
Inventory	915	160	1,075
Other current assets	3,250	434	3,684
Property, plant and equipment	14,972	—	14,972
Identifiable intangible assets (weighted-average useful life):		—	—
Currently marketed product (15 years)	142,100	800	142,900
Licenses (11.5 years)	87,500	(1,700)	85,800
Developed technology (9 years)	3,000	(600)	2,400
IPR&D	150,900	200	151,100
Other long-term assets	37,631	—	37,631
Accounts payable	(1,616)	—	(1,616)
Accrued expenses and other liabilities	(8,207)	(80)	(8,287)
Other long-term liabilities	(30,778)	(380)	(31,158)
Long-term debt and other borrowings	(40,200)	—	(40,200)
Deferred tax liabilities	(3,717)	299	(3,418)
Goodwill	42,051	867	42,918
Total consideration transferred	$ 419,009	$ —	$ 419,009

Intangible assets acquired consist of currently marketed products, licenses, developed technology and IPR&D. The fair value of the acquired intangible assets was determined based on estimated future revenues, royalty rates and discount rates, among other variables and estimates. The acquired intangible assets subject to amortization were assigned useful lives based on the expected use of the assets and the regulatory and economic environment within which they are being used and are being amortized on a straight-line basis over the respective estimated useful lives. The estimated fair values of the IPR&D assets were determined based on the present values of the expected cash flows to be generated by the respective underlying assets. The Company used a discount rate of 23.0% and cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions.

As part of the acquisition, the Company acquired the right to receive certain future milestone and royalty payments due to Progenics, related to a prior sale of certain intellectual property. The estimated fair value of the acquired contingent receivable of $10.1 million was determined by applying a probability adjusted discounted cash flow model based on estimated future expected payments and recorded in other long-term assets.

The goodwill recognized is attributable to future technologies that are not separately identifiable that could potentially add to the currently developed and pipeline products and Progenics' assembled workforce. Future technologies did not meet the criteria for recognition separately from goodwill because they are part of the future development and growth of the business. Goodwill of $42.9 million recognized in connection with the acquisition is not deductible for tax purposes and has been assigned to a reporting unit within the U.S. reportable segment.

The Company recognized $11.9 million of acquisition-related costs, including legal, accounting, compensation arrangements and other related fees that were expensed when incurred in the year ended December 31, 2020, respectively. These costs are recorded in general and administrative expenses in the consolidated statements of operations.

Progenics Pro Forma Financial Information

Progenics has been included in the Company's consolidated financial statements since the acquisition date. Progenics contributed revenues of $12.4 million, as well as a net loss of $27.1 million to the Company's consolidated statement of operations for the year ended December 31, 2020.

The following unaudited pro forma financial information presents the Company's results as if the Progenics acquisition had occurred on January 1, 2019:

(in thousands)	Year Ended December 31, 2020 Amount	Year Ended December 31, 2019 Amount
Pro forma revenue	$ 350,315	$ 382,323
Pro forma net loss	$ 29,190	$ 42,032

The unaudited pro forma financial information for all periods presented adjusts for the effects of material business combination items, including amortization of acquired intangible assets, transaction-related costs, adjustments to interest expense related to the assumption of long-term debt, retention and severance bonuses and the corresponding income tax effects of each. These pro forma results have been prepared for comparative purposes only and do not purport to be indicative of the operating results of the Company that would have been achieved had the acquisition actually taken place on January 1, 2019. In addition, these results are not intended to be a projection of future results and do not reflect events that may occur after the acquisition, including, but not limited to, revenue enhancements, cost savings or operating synergies that the combined company may achieve as a result of the acquisition.

9. Assets Held for Sale

During the fourth quarter of 2020, the Company entered into a stock purchase agreement (“SPA”) with one of its existing radiopharmacy customers to sell all of the stock of its Puerto Rican radiopharmacy servicing subsidiary. This event qualified for held for sale accounting 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 finalized on January 29, 2021.

The purchase price for the stock sale was $18.0 million in cash and will also include a working capital adjustment once settled. The SPA contains customary representations, warranties and covenants by each of the parties. Subject to certain limitations, the buyer will be indemnified for damages resulting from breaches or inaccuracies of the Company’s representations, warranties and covenants in the SPA.

As part of the transaction, the Company and the buyer also entered into a customary transition services agreement and a long-term supply contract under which the Company will supply the buyer with certain of the Company’s products on commercial terms and under which the buyer has agreed to certain product minimum purchase commitments.

The Company does not believe this sale of certain net assets in the international segment constituted a strategic shift that would have a major effect on its operations or financial results. As a result, this transaction is not classified as discontinued operations in the Company’s accompanying consolidated financial statements.

The following table summarizes the major classes of assets and liabilities held for sale as of December 31, 2020:

(in thousands)	Amount
Current Assets:	
Cash and cash equivalents	$ 941
Accounts receivable, net	2,191
Inventory	420
Other current assets	43
Total current assets	3,595
Non-Current Assets:	
Property, plant & equipment, net	761
Intangibles, net	96
Other long-term assets	790
Total assets held for sale	$ 5,242
Current Liabilities:	
Accounts payable	$ 224
Accrued expense and other liabilities	661
Total current liabilities	885
Non-Current Liabilities:	
Asset retirement obligations	302
Other long-term liabilities	606
Total liabilities held for sale	$ 1,793

10. Asset Retirement Obligations

The Company considers its legal obligation to remediate its facilities upon a decommissioning of its radioactive-related operations as an asset retirement obligation. The Company has production facilities which manufacture and process radioactive materials at its North Billerica, Massachusetts, and prior to its subsequent sale as discussed in Note 23, “Subsequent Events”, San Juan, Puerto Rico sites. As of December 31, 2020, the liability for the San Juan, Puerto Rico site is recorded in liabilities held for sale. As of December 31, 2020, the liability is measured at the present value of the obligation expected to be incurred, of approximately $26.9 million.

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

(in thousands)	Amount
Balance, January 1, 2020	$ 12,883
Transfer to liabilities held for sale	(302)
Accretion expense	1,439
Balance, December 31, 2020	$ 14,020

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

11. Intangibles, Net and Goodwill

Intangibles, net, consisted of the following:

	December 31, 2020			
(in thousands)	**Amortization Method**	**Cost**	**Accumulated Amortization**	**Net**
Trademarks	Straight-Line	$ 13,540	$ (10,958)	$ 2,582
Customer relationships	Accelerated	96,865	(93,770)	3,095
Currently marketed product	Straight-Line	142,900	(5,053)	137,847
Licenses	Straight-Line	85,800	(4,008)	81,792
Developed technology	Straight-Line	2,400	(144)	2,256
IPR&D	N/A	148,440	—	148,440
Total		$ 489,945	$ (113,933)	$ 376,012

	December 31, 2019			
(in thousands)	**Amortization Method**	**Cost**	**Accumulated Amortization**	**Net**
Trademarks	Straight-Line	$ 13,540	$ (10,407)	$ 3,133
Customer relationships	Accelerated	99,019	(94,816)	4,203
Total		$ 112,559	$ (105,223)	$ 7,336

The Company recorded amortization expense for its intangible assets of $10.8 million, $1.8 million and $2.6 million for the years ended December 31, 2020, 2019 and 2018, respectively.

The Company performed its annual impairment test of its IPR&D assets as of October 31, 2020. As a result of a timing delay in the development of an AZEDRA IPR&D asset due to the impact of COVID-19, the Company determined that the carrying value of $18.3 million exceeded the fair value of the asset. Accordingly, the Company recorded a non-cash impairment charge of $2.7 million for the year ended December 31, 2020 in research and development expenses in the consolidated statements of operations. The estimated fair value of the AZEDRA IPR&D asset was determined based on the present values of the expected cash flows. The Company used a discount rate of 23.0% and cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions.

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

(in thousands)	**Amount**
2021	$ 18,628
2022	18,504
2023	17,898
2024	17,824
2025	17,766
2026 and thereafter	136,952
Total	$ 227,572

Goodwill by reportable segment consisted of the following:

(in thousands)	**U.S.**	**Total**
Balance, January 1, 2020	$ 15,714	$ 15,714
Acquisition[1]	42,918	42,918
Balance, December 31, 2020	$ 58,632	$ 58,632

(1) Refer to Note 8, “Business Combinations” for additional details related to the Progenics acquisition

12. Accrued Expenses and Other Liabilities

Accrued expenses are comprised of the following:

	December 31,	
(in thousands)	**2020**	**2019**
Compensation and benefits	$ 17,669	$ 15,100
Freight, distribution and operations	5,653	6,260
Accrued rebates, discounts and chargebacks	9,350	6,985
Accrued professional fees	2,925	6,917
Other	6,129	2,098
Total accrued expenses and other liabilities	$ 41,726	$ 37,360

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

As of December 31, 2020, the Company's maturities of principal obligations under its long-term debt and other borrowings are as follows:

(in thousands)	**Amount**
2021	$ 20,452
2022	26,296
2023	22,055
2024	148,750
Total principal outstanding	217,553
Unamortized debt premium, net	954
Unamortized debt issuance costs	(602)
Finance lease liabilities	495
Total	218,400
Less: current portion	(20,701)
Total long-term debt, net, and other borrowings	$ 197,699

In June 2019, the Company refinanced its previous $275.0 million five-year term loan agreement (the "2017 Term Facility") with a new five-year $200.0 million term loan facility (the "2019 Term Facility" and the loans thereunder, the "2019 Term Loans"). In addition, the Company replaced its previous $75.0 million five-year revolving credit facility (the "2017 Revolving Facility") with a new $200.0 million five-year revolving credit facility (the "2019 Revolving Facility" and, together with the 2019 Term Facility, the "2019 Facility"). The terms of the 2019 Facility are set forth in the Credit Agreement, dated as of June 27, 2019 (the "2019 Credit Agreement"), by and among Holdings, the Company, the lenders from time to time party thereto and Wells Fargo Bank, N.A., as administrative agent and collateral agent. The Company has the right to request an increase to the 2019 Term Facility or request the establishment of one or more new incremental term loan facilities, in an aggregate principal amount of up to $100.0 million, plus additional amounts, in certain circumstances.

The net proceeds of the 2019 Term Facility, together with approximately $73.0 million of cash on hand, were used to refinance in full the aggregate remaining principal amount of the loans outstanding under the 2017 Term Facility and pay related interest, transaction fees and expenses. No amounts were outstanding under the 2017 Revolving Facility at that time. The Company accounted for the refinancing of the 2017 Term Facility as a debt extinguishment and the 2017 Revolving Facility as a debt modification by evaluating the refinancing on a creditor by creditor basis. The Company recorded a loss on extinguishment of debt of $3.2 million related to the write-off of unamortized debt issuance costs and debt discounts. In addition, the Company incurred and capitalized $2.8 million of new debt issuance costs and debt discounts related to the refinancing.

2019 Term Facility

The 2019 Term Loans under the 2019 Term Facility bear interest, with pricing based from time to time at the Company's election at (i) LIBOR plus a spread ranging from 1.25% to 2.25% as determined by the Company's total net leverage ratio (as defined in the 2019 Credit Agreement) or (ii) the Base Rate (as defined in the 2019 Credit Agreement) plus a spread ranging from 0.25% to 1.25% as determined by the Company's total net leverage ratio. The use of the LIBOR is expected to be phased out by the end of 2021. The 2019 Credit Agreement allows for a replacement interest rate in the event the LIBOR is phased out.

The Company is permitted to voluntarily prepay the 2019 Term Loans, in whole or in part, without premium or penalty. The 2019 Term Facility requires the Company to make mandatory prepayments of the outstanding 2019 Term Loans in certain circumstances. The 2019 Term Loans mature in June 2024. At December 31, 2020, the Company's interest rate under the 2019 Term Facility was 3.4%.

2019 Revolving Facility

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

The Revolving Loans under the 2019 Revolving Facility bear interest, with pricing based from time to time at the Company's election at (i) LIBOR plus a spread ranging from 1.25% to 2.25% as determined by the Company's total net leverage ratio or (ii) the Base Rate plus a spread ranging from 0.25% to 1.25% as determined by the Company's total net leverage ratio. The 2019 Revolving Facility also includes a commitment fee, which ranges from 0.15% to 0.30% as determined by 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 and Letters of Credit exceeds the total Revolving Commitment, the Company must prepay the Revolving Loans in an amount equal to such excess. As of December 31, 2020, there were no outstanding borrowings under the 2019 Revolving Facility.

2019 Facility Covenants

The 2019 Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. The 2019 Facility requires the Company 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 ending September 30, 2019, must be at least 3.00 to 1.00.

The Company may elect to increase the maximum total net leverage ratio by 0.50 to 1.00 (subject to a maximum of 4.25 to 1.00) up to two separate times during the term of the 2019 Facility in connection with any Material Acquisition (as defined in the Credit Agreement).

The 2019 Facility contains usual and customary restrictions on the ability of the Company and its subsidiaries to: (i) incur additional indebtedness (ii) create liens; (iii) consolidate, merge, sell or otherwise dispose of all or substantially all of its assets; (iv) sell certain assets; (v) pay dividends on, repurchase or make distributions in respect of capital stock or make other restricted payments; (vi) make certain investments; (vii) repay subordinated indebtedness prior to stated maturity; and (viii) enter into certain transactions with its affiliates.

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

The 2019 Facility is guaranteed by Holdings and Lantheus MI Real Estate, LLC, and obligations under the 2019 Facility are generally secured by first priority liens over substantially all of the assets of each of LMI, Holdings and Lantheus MI Real Estate, LLC (subject to customary exclusions set forth in the transaction documents) owned as of June 27, 2019 or thereafter acquired.

2020 Amendment

On June 19, 2020, the Company amended its 2019 Credit Agreement ("the Amendment") as a result of the impact of the COVID-19 pandemic on the business and operations of the Company and the near-term higher level of indebtedness resulting from the Company's decision not to immediately repay the Progenics debt secured by the RELISTOR royalties following the Progenics Acquisition. The Company accounted for the Amendment as a debt modification and capitalized $1.2 million of associated costs.

The Amendment provides for, among other things, modifications to LMI's financial maintenance covenants. The covenant related to Total Net Leverage Ratio (as defined in the Amended Credit Agreement) has been waived from the date of the Amendment through December 31, 2020. The maximum total net leverage ratio and interest coverage ratio permitted by the financial covenant is displayed in the table below:

2020 Amended Credit Agreement

Period	Total Net Leverage Ratio
Q1 2021	5.50 to 1.00
Q2 2021	3.75 to 1.00
Thereafter	3.50 to 1.00

Period	Interest Coverage Ratio
Q4 2020 to Q1 2021	2.00 to 1.00
Thereafter	3.00 to 1.00

The Amendment also introduces a new financial covenant requiring Consolidated Liquidity (as defined in the Amended Credit Agreement) to be no less than $150.0 million. The Consolidated Liquidity covenant is tested on a continuing basis beginning on the date of the Amendment and ending on the date on which LMI delivers a compliance certificate for the fiscal quarter ending March 31, 2021.

For the period beginning on the date of the Amendment and ending on the Adjustment Date (as defined in the Amended Credit Agreement) for the fiscal quarter ending March 31, 2021, loans under the Amended Credit Agreement bear interest at LIBOR plus 3.25% or the Base Rate plus 2.25%. On and after the Adjustment Date for the fiscal quarter ending on March 31, 2021, loans bear interest at LIBOR plus a spread that ranges from 1.50% to 3.00% or the Base Rate plus a spread that ranges from 0.50% to 2.00%, in each case based on LMI's Total Net Leverage Ratio.

The commitment fee applicable to the Revolving Facility is 0.50% until the Adjustment Date for the fiscal quarter ending March 31, 2021. On and after the Adjustment Date for the fiscal quarter ending on March 31, 2021, the commitment fee ranges from 0.15% to 0.40% based on LMI's Total Net Leverage Ratio.

Royalty-Backed Loan

On June 19, 2020, as a result of the acquisition, the Company assumed Progenics outstanding debt as of such date in the amount of $40.2 million. Progenics, through a wholly-owned subsidiary MNTX Royalties Sub LLC ("MNTX Royalties"), entered into a $50.0 million loan agreement (the "Royalty-Backed Loan") with a fund managed by HealthCare Royalty Partners III, L.P. ("HCRP") on November 4, 2016. Under the terms of the Royalty-Backed Loan, the lenders have no recourse to Progenics or any of its assets other than the right to receive royalty payments from the commercial sales of RELISTOR products owed under Progenics' license agreement with Salix Pharmaceuticals, Inc., a wholly-owned subsidiary of Bausch Health Companies Inc. ("Bausch"). The RELISTOR royalty payments will be used to repay the principal and interest on the loan. The Royalty-Backed Loan bears interest at a per annum rate of 9.5% and matures on June 30, 2025. On June 22, 2020, HCRP waived the automatic acceleration of the Royalty-Backed Loan that otherwise would have been triggered by the consummation of the Progenics Acquisition and MNTX Royalties agreed not to prepay the loan until after December 31, 2020.

Under the terms of the loan agreement, payments of interest and principal, if any, are made on the last day of each calendar quarter out of RELISTOR royalty payments received since the immediately-preceding payment date. On each payment date, 50% of RELISTOR royalty payments received since the immediately-preceding payment date in excess of accrued interest on the loan are used to repay the principal of the loan, with the balance retained by the Company. Starting on September 30, 2021, all of the RELISTOR royalties received since the immediately-preceding payment date will be used to repay the interest and outstanding principal balance until the balance is fully repaid.

14. Derivative Instruments

The Company uses interest rate swaps to reduce the variability in cash flows associated with a portion of the Company's forecasted interest payments on its variable rate debt. In March 2020, the Company entered into interest rate swap contracts to fix the LIBOR rate on a notional amount of $100.0 million through May 31, 2024. The average fixed LIBOR rate on the interest rate swaps is approximately 0.82%. This agreement involves the receipt of floating rate amounts in exchange for fixed rate interest payments over the life of the agreement without an exchange of the underlying principal amount. The interest rate swaps were designated as cash flow hedges. In accordance with hedge accounting, the interest rate swaps are recorded on the Company's consolidated balance sheets at fair value, and changes in the fair value of the swap agreements are recorded to other comprehensive loss and reclassified to interest expense in the period during which the hedged transaction affected earnings or it will become probable that the forecasted transaction would not occur. At December 31, 2020, accumulated other comprehensive loss included $0.7 million of pre-tax deferred losses that are expected to be reclassified to earnings during the next 12 months.

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

(in thousands)		December 31, 2020	December 31, 2019
Derivatives type	**Classification**		
Liabilities:			
Interest rate swap	Accrued expenses and other liabilities	$ 1,908	$ —

15. Accumulated Other Comprehensive Loss

The components of Accumulated Other Comprehensive Loss, net of tax of $0.5 million and $0.0 million for the year ended December 31, 2020 and 2019, respectively, consisted of the following:

(in thousands)	Foreign currency translation	Unrealized loss on cash flow hedges	Accumulated other comprehensive loss
Balance at January 1, 2020	$ (960)	$ —	$ (960)
Other comprehensive income (loss) before reclassifications	330	(1,833)	(1,503)
Amounts reclassified to earnings	—	415	415
Balance at December 31, 2020	$ (630)	$ (1,418)	$ (2,048)
Balance at January 1, 2019	$ (1,108)	$ —	$ (1,108)
Other comprehensive income before reclassifications	148	—	148
Amounts reclassified to earnings	—	—	—
Balance at December 31, 2019	$ (960)	$ —	$ (960)

16. Stock-Based Compensation

Equity Incentive Plans

As of December 31, 2020, 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 ("DERs") 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 and 2019 which increased the common stock reserved for issuance under the plan to an aggregate 6,580,277 shares. The Company assumed Progenics equity plans due to the acquisition as discussed in Note 1, "Description of Business".

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

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Cost of goods sold	$ 2,820	$ 2,091	$ 1,140
Sales and marketing	1,821	1,953	1,244
General and administrative	7,333	6,990	4,990
Research and development	2,101	1,458	1,344
Total stock-based compensation expense	$ 14,075	$ 12,492	$ 8,718

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 2020 is presented below:

	Total Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at January 1, 2020	272,224	$ 17.44		
Options granted	2,027,744	$ 19.44		
Options exercised	(8,868)	$ 8.72		
Options cancelled and forfeited	(715,881)	$ 19.47		
Outstanding at December 31, 2020	1,575,219	$ 19.03	4.8	229,390
Exercisable at December 31, 2020	1,271,041	$ 19.72	3.8	228,958

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

	Year Ended December 31, 2020
Expected volatility	71.1 %
Risk-free interest rate	0.3 %
Expected life (in years)	3.5
Expected dividend yield	—

All options granted during the year ended December 31, 2020 represent Replacement Stock Options issued in connection with the Progenics Acquisition, of which $7.1 million related to precombination services for awards that had vested prior to the acquisition and was recorded as a component of consideration transferred in the Progenics Acquisition. The unvested Replacement Stock Options have remaining vesting terms ranging from 0.1 years to 3.7 years and will be recognized as expense over the requisite service period. There were no options granted during the years ended December 31, 2019 and 2018.

The weighted average grant-date fair value for stock option awards granted during the fiscal year ended December 31, 2020 was $5.67 per option.

During the years ended December 31, 2020, 2019 and 2018, 8,868, 67,558 and 192,550 options were exercised having aggregate intrinsic values of $0.1 million, $0.6 million and $2.4 million, respectively.

As of December 31, 2020, there was $1.9 million of unrecognized compensation expense related to outstanding stock options, which is expected to be recognized over a weighted-average period of 2.3 years.

Restricted Stock

A summary of restricted stock awards and restricted stock units activity for 2020 is presented below:

	Shares	Weighted-Average Grant Date Fair Value Per Share
Nonvested balance at January 1, 2020	1,031,772	$ 15.20
Granted	786,006	$ 15.00
Vested	(610,804)	$ 12.45
Forfeited	(99,108)	$ 15.53
Nonvested balance at December 31, 2020	1,107,866	$ 16.58

Restricted stock generally vest over 3 years. As of December 31, 2020, there was $11.8 million of unrecognized compensation expense related to outstanding restricted stock, which is expected to be recognized over a weighted-average period of 1.9 years.

The weighted average grant-date fair value for restricted stock granted during the fiscal years ended December 31, 2020, 2019 and 2018 was $15.00, $23.33 and $15.46 per share, respectively. The total fair value of restricted stock vested in fiscal years 2020, 2019 and 2018 was $7.6 million, $6.8 million and $4.3 million, respectively.

Performance Restricted Stock Awards

Performance awards vest based on the requisite service period subject to the achievement of specific financial performance targets. The Company monitors the probability of achieving the performance targets on a quarterly basis and may adjust periodic stock compensation expense accordingly. The performance targets include the achievement of internal performance targets only.

A summary of performance restricted stock award activity for 2020 is presented below:

	Shares	Weighted-Average Grant Date Fair Value Per Share
Nonvested balance at January 1, 2020	226,010	$ 16.62
Granted	9,767	$ 16.40
Vested	(235,777)	$ 16.40
Forfeited	—	$ —
Nonvested balance at December 31, 2020	—	$ —

The total fair value of the performance restricted stock vested in fiscal year 2020 was $3.9 million. Performance restricted stock awards granted in 2020 relate to the Company's overachievement of performance targets. There were no performance restricted stock awards granted during the years ended December 31, 2019 and 2018.

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

During the years ended December 31, 2020, 2019 and 2018, 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,		
	2020	**2019**	**2018**
Expected volatility	53.3 %	71.7 %	84.3 %
Risk-free interest rate	0.7 %	2.4 %	2.4 %
Expected life (in years)	2.8	2.9	2.8
Expected dividend yield	—	—	—

A summary of TSR Award activity for 2020 is presented below:

	Shares	**Weighted-Average Grant Date Fair Value Per Share**
Nonvested balance at January 1, 2020	306,230	$ 30.56
Granted	220,971	$ 23.43
Vested	—	$ —
Forfeited	(35,430)	$ 27.47
Nonvested balance at December 31, 2020	491,771	$ 27.58

As of December 31, 2020, there was $6.2 million of unrecognized compensation expense related to outstanding performance restricted stock which is expected to be recognized over a weighted-average period of 1.8 years.

The weighted average grant-date fair value for TSR Awards granted during the fiscal years ended December 31, 2020, 2019 and 2018 was $23.43, $39.92 and $22.76 per share, respectively.

17. Leases

Adoption of ASC Topic 842, "Leases"

The Company adopted ASC 842 on January 1, 2019, using the prospective approach which provides a method for recording existing leases at adoption using the effective date of the standard as its initial application date. ASC 842 generally requires all leases to be recognized on the balance sheet. In addition, the Company elected the relief package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allowed the Company not to reassess whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for any existing leases. The reported results for 2020 and 2019 reflect the application of ASC 842 guidance. The adoption of ASC 842 resulted in the recording of an additional lease asset and lease liability of approximately $1.1 million as of January 1, 2019. ASC 842 did not materially impact the Company's consolidated results of operations, equity or cash flows as of the adoption date or for the periods presented.

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 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 excluded the Puerto Rico operating lease amounts classified as held for sale as of December 31, 2020.

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, 2020	December 31, 2019
Assets			
Operating	Other long-term assets	$ 18,441	$ 935
Finance	Property, plant and equipment, net	525	348
Total leased assets		$ 18,966	$ 1,283
Liabilities			
Current			
Operating	Accrued expenses and other liabilities	$ 1,164	$ 193
Finance	Current portion of long-term debt and other borrowings	249	143
Noncurrent			
Operating	Other long-term liabilities	17,501	812
Finance	Long-term debt, net and other borrowings	246	186
Total leased liabilities		$ 19,160	$ 1,334

The components of lease expense were as follows:

(in thousands)	Year Ended December 31, 2020	Year Ended December 31, 2019
Operating lease expense	$ 1,471	$ 223
Finance lease expense		
Amortization of ROU assets	196	167
Interest on lease liabilities	21	11
Short-term lease expense	70	91
Total lease expense	$ 1,758	$ 492

Other information related to leases were as follows:

	December 31, 2020	December 31, 2019
Weighted-average remaining lease term (Years):		
Operating leases	9.7	4.8
Finance leases	2.4	2.5
Weighted-average discount rate:		
Operating leases	4.4%	5.1%
Finance leases	5.3%	5.4%

(in thousands)	Year Ended December 31, 2020	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	1,202	230
Operating cash flows from finance leases	21	11
Financing cash flows from finance leases	207	190
ROU assets obtained in exchange for lease obligations:		
Operating leases	19,210	—
Finance leases	373	379

Future minimum lease payments under non-cancellable leases as of December 31, 2020 were as follows:

(in thousands)	Operating Leases [1]	Finance Leases
2021	$ 1,964	$ 231
2022	2,213	216
2023	2,255	78
2024	2,297	—
2025	2,340	—
Thereafter	12,170	—
Total future minimum lease payments	23,239	525
Less: interest	4,574	30
Total	$ 18,665	$ 495

(1) Amounts exclude lease payments of $0.9 million associated with its Puerto Rico subsidiary that is classified as held for sale

18. Net (Loss) Income Per Common Share

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

(in thousands, except per share amounts)	Year Ended December 31, 2020	2019	2018
Net (loss) income	$ (13,473)	$ 31,667	$ 40,518
Basic weighted-average common shares outstanding	54,134	38,988	38,233
Effect of dilutive stock options	—	75	61
Effect of dilutive restricted stock	—	1,050	1,207
Diluted weighted-average common shares outstanding	54,134	40,113	39,501
Basic (loss) income per common share	$ (0.25)	$ 0.81	$ 1.06
Diluted (loss) income per common share	$ (0.25)	$ 0.79	$ 1.03
Antidilutive securities excluded from diluted net (loss) income per common share	3,175	50	424

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, 2020, future payments required under purchase commitments are as follows:

(in thousands)	Amount
2021	$ 4,132
2022	2,066
Total	$ 6,198

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, 2020, future fixed payments required under license agreements are $0.7 million. The Company may be required to pay additional amounts up to approximately $90.6 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, 2020, the Company had the following material ongoing litigation in which the Company was a party:

RELISTOR Subcutaneous Injection

Between November 19, 2015 and September 18, 2017, Progenics, Salix, Valeant (now Bausch) and Wyeth filed multiple lawsuits against Mylan Pharmaceuticals and certain of its affiliates (collectively, "Mylan") in the United States District Court for the District of New Jersey (the "NJ Court") for infringement of certain U.S. patents based upon Mylan's filing of multiple ANDAs seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection before some or all of those patents expire. These actions were later consolidated into two separate actions in the District of New Jersey.

On May 1, 2018, in the lead action, the NJ Court granted Plaintiffs' motion for partial summary judgment as to the validity of a particular claim that Mylan had admitted it infringed. On May 23, 2018, the NJ Court entered an order for final judgment in favor of Plaintiffs and against Mylan on that particular claim. As a result, trial on the merits in the lead action was adjourned, allowing trial, if necessary, to be consolidated with the lagging, second action. On August 20, 2020, the parties agreed to dismiss all claims, affirmative defenses, and counterclaims in the lagging action and proceed to a full trial on the merits for the patents asserted in the lead action.

On May 25, 2018, Mylan filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit ("CAFC"). On April 8, 2020, the CAFC issued its decision reversing the NJ Court's grant of summary judgment and remanding for further proceedings. On June 22, 2020, Plaintiffs filed a petition for rehearing/rehearing en banc, and on July 24, 2020, that petition was denied.

On December 23, 2020, Plaintiffs and Mylan entered into a Settlement and License Agreement (the "Mylan Settlement Agreement") relating to the actions in the NJ Court. The Mylan Settlement Agreement provides for a full settlement and release by both Plaintiffs and Mylan for all claims that were or could have been asserted in the district court cases and all resulting damages or other remedies. Plaintiffs and Mylan filed a Stipulated Order of Dismissal after the execution of the Mylan Settlement Agreement, and the matter has been dismissed.

RELISTOR Tablets - Actavis

Between December 6, 2016 and December 8, 2017, Progenics, Salix, Bausch, and Wyeth filed suit against Actavis, Actavis LLC, Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries Ltd. (collectively, "Actavis") in the NJ Court for infringement of certain U.S. patents based upon Actavis's filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR tablets before some or all of those patents expire. The actions were later consolidated into a single action in the NJ Court.

On May 6-9, 2019, a bench trial was held, and on July 17, 2019, the NJ Court issued an Order finding the asserted claims of a certain U.S. patent valid and infringed. The NJ Court additionally ordered that the effective date of any approval of Actavis's ANDA may not be earlier than the expiration date of that patent. Actavis filed an appeal of the NJ Court's decision with the CAFC on August 13, 2019. The matter is currently pending on appeal at the CAFC and merits briefing has concluded. Actavis's opening brief was filed February 6, 2020. The Plaintiffs filed their responsive brief on September 15, 2020. Actavis's reply brief was filed on December 7, 2020.

On June 13, 2019, Progenics, Salix, Bausch, and Wyeth filed another suit against Actavis in the NJ Court for infringement of a separate, and at that time, recently granted U.S. patent based upon Actavis's filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR tablets before this patent expires.

On February 12, 2021, Plaintiffs and Actavis entered into a Settlement and License Agreement (the "Actavis Settlement Agreement") relating to the actions in the NJ Court and the related Federal Circuit appeal. The Actavis Settlement Agreement provides for a full settlement and release by both Plaintiffs and Actavis of all claims that were or could have been asserted in the NJ Court cases and all resulting damages or other remedies. Plaintiffs and Actavis have further agreed to file a Stipulation and Order to dismiss the pending district court action and a Motion for Voluntary Dismissal of the appeal.

RELISTOR European Opposition Proceedings

In addition to the above described ANDA notifications, in October 2015, Progenics received notices of opposition to three European patents relating to methylnaltrexone. Notices of opposition were filed separately by each of Actavis Group PTC ehf and Fresenius Kabi Deutschland GmbH. Between May 11, 2017 and July 4, 2017, the opposition division provided notice that the three European patents would be revoked. Each of these matters were appealed to the European Patent Office. Oral proceedings for EP1615646 were held on September 22, 2020. The decision under appeal was set aside and the case was remitted to the opposition division for further prosecution. The deadline for written submissions prior to an oral hearing is July 27, 2021. The oral hearing is set for September 27, 2021. On November 13, 2020, Progenics withdrew the appeal for EP2368553 and EP2368554. Notices of

termination of the proceedings with revocation of the patent were issued on November 23, 2020 for EP2368553 and EP2368554. Because the outcome of litigation is uncertain, the Company cannot predict how or when this matter will ultimately be resolved.

German PSMA-617 Litigation

On November 8, 2018, Molecular Insight Pharmaceuticals, Inc., a subsidiary of Progenics ("MIP"), filed a complaint against the University of Heidelberg (the "University") in the District Court in Mannheim, Germany (the "German District Court"). In this Complaint, MIP claimed that the discovery and development of PSMA-617 was related to work performed under a research collaboration sponsored by MIP. MIP alleged that the University breached certain contracts with MIP and that MIP is the co-owner of inventions embodied in certain worldwide patent filings related to PSMA-617 that were filed by the University. On February 27, 2019, Endocyte, Inc., a wholly owned subsidiary of Novartis AG, filed a motion to intervene in the German litigation. Endocyte is the exclusive licensee of the patent rights that are the subject of the German proceedings.

On November 27, 2018, MIP requested that the European Patent Office ("EPO") stay the examination of a certain European Patent (EP) and related Divisional Applications, pending a decision from the German District Court on MIP's Complaint. On December 10, 2018, the EPO granted MIP's request and stayed the examination of the patent and patent applications effective November 27, 2018. MIP filed a Confirmation of Ownership with the United States Patent and Trademark Office ("USPTO") in corresponding U.S. patent applications (U.S. Serial Nos. 15/131,118; 15/805,900; 16/038,729, 16/114,988, 16/510,495, 16/551,198). MIP's filing with the USPTO takes the position that, in light of the collaboration and contracts between MIP and the University, MIP is the co-owner of these pending U.S. patent applications (U.S. Serial Nos. 16/510,495, 16/551,198). On March 6, 2020, MIP filed with the USPTO a notice stating that the Power of Attorney in certain pending U.S. patent applications was signed by less than all applicants or owners of the applications.

On February 27, 2019, the German District Court set €0.4 million as the amount MIP must deposit with the German District Court as security in the event of an unfavorable final decision on the merits of the dispute. The German District Court held the first oral hearing in the case on August 6, 2019. The German District Court considered procedural matters and granted the parties the right to make further submissions. A further oral hearing occurred July 23, 2020, during which the German District Court heard live testimony from several witnesses, testifying on behalf of the defendants. On August 24, 2020, the German District Court issued its decision dismissing MIP's claims, stating that MIP failed to discharge its burden of proof in the matter.

MIP filed a Notice of Appeal of the German District Court's decision on September 24, 2020 and filed its appeal brief on November 26, 2020. Responsive briefs are due on March 12, 2021. MIP is also considering its legal and procedural alternatives against the defendants in other jurisdictions and proceedings. If MIP is not successful in its appeal, it will be responsible for the German court fees and fees and disbursements of defendant's and intervenor's counsel, both at first instance and on appeal. Most of such fees and disbursements at first instance are covered by the aforementioned cash security deposited with the German District Court. Because the outcome of litigation is uncertain, the Company cannot predict how or when this matter will ultimately be resolved.

Whistleblower Complaint

In July 2019, Progenics received notification of a complaint submitted by Dr. Syed Mahmood, the former Vice President of Medical Affairs for Progenics, to the Occupational Safety and Health Administration of the United States Department of Labor ("DOL"), alleging that the termination of his employment by Progenics was in violation of Section 806 of the Sarbanes-Oxley Act of 2002 ("SOX"). Dr. Mahmood sought reinstatement to his former position of Vice President of Medical Affairs, back pay, front pay in lieu of reinstatement, interest, attorneys' fees and costs incurred, and special damages. In March 2020, Dr. Mahmood filed a complaint in the U.S. District Court for the Southern District of New York (as permitted by SOX because the DOL had not issued a decision within 180 days). Dr. Mahmood's federal complaint asserted claims of violation of Section 806 of SOX. The DOL action has been dismissed. Progenics filed an answer to Dr. Mahmood's complaint on August 26, 2020 and the initial pre-trial conference was held on September 16, 2020. The parties entered into mediation in connection with Dr. Mahmood's complaint on December 8, 2020, and the matter was settled pursuant to a Confidential Negotiated Settlement Agreement dated December 30, 2020. A Stipulation of Dismissal with Prejudice was then filed with the court, and the matter was dismissed with prejudice.

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 $0.8 million, $2.1 million and $1.8 million for the years ended December 31, 2020, 2019 and 2018, respectively.

21. Segment Information

The Company reports two operating segments, U.S. and International, based on geographic customer base. The results of these operating segments are regularly reviewed by the Company's chief operating decision maker, the President and Chief Executive Officer. The Company's segments derive revenues through the manufacture, marketing, selling and distribution of medical imaging products, focused primarily on cardiovascular diagnostic imaging. The Company does not identify or allocate assets to its segments other than goodwill. Management is in the process of evaluating the Company's operating and reporting structure. The Company anticipates this evaluation, which it expects to complete during 2021, may result in a change to the Company's existing operating segment reporting structure.

Selected information regarding the Company's segments are provided as follows:

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Revenue by product and geography from external customers			
U.S.			
DEFINITY	$ 207,270	$ 211,777	$ 178,440
TechneLite	69,729	72,534	74,042
Other nuclear	36,864	36,231	48,935
Rebates and allowances	(19,067)	(16,553)	(12,837)
Total U.S. Revenues	294,796	303,989	288,580
International			
DEFINITY	6,046	5,731	4,633
TechneLite	16,512	14,058	24,816
Other nuclear	22,060	23,574	25,349
Rebates and allowances	(4)	(15)	(4)
Total International Revenues	44,614	43,348	54,794
Worldwide			
DEFINITY	213,316	217,508	183,073
TechneLite	86,241	86,592	98,858
Other nuclear	58,924	59,805	74,284
Rebates and allowances	(19,071)	(16,568)	(12,841)
Total Revenues	$ 339,410	$ 347,337	$ 343,374

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Operating income			
U.S.	$ (10,363)	$ 44,275	$ 56,327
International	6,165	7,386	8,161
Total operating (loss) income	(4,198)	51,661	64,488
Interest expense	9,479	13,617	17,405
Loss on extinguishment of debt	—	3,196	—
Other (income) loss	(2,198)	6,221	(2,465)
(Loss) income before income taxes	$ (11,479)	$ 28,627	$ 49,548
Depreciation and amortization			
U.S.	$ 23,007	$ 11,673	$ 12,278
International	244	414	491
Total depreciation and amortization	$ 23,251	$ 12,087	$ 12,769

(in thousands)	December 31, 2020	2019
Long-lived assets		
U.S.	$ 120,147	$ 115,560
International[(1)]	24	937
Total long-lived assets	$ 120,171	$ 116,497

(1) 2020 Amount excludes Puerto Rico as the Company has identified its Puerto Rico entity as held for sale.

22. Valuation and Qualifying Accounts

(in thousands)	Balance at Beginning of Year	Charged to Income	Deductions from Reserves[(1)]	Other Adjustments	Balance at End of Year
Allowance for doubtful accounts					
Year ended December 31, 2020	$ 942	$ 313	$ (160)	$ (7)	$ 1,088
Year ended December 31, 2019	$ 1,119	$ 146	$ (323)	$ —	$ 942
Year ended December 31, 2018	$ 977	$ 321	$ (179)	$ —	$ 1,119
Rebates and allowances					
Year ended December 31, 2020	$ 6,985	$ 19,675	$ (16,706)	$ (604)	$ 9,350
Year ended December 31, 2019	$ 4,654	$ 16,729	$ (14,237)	$ (161)	$ 6,985
Year ended December 31, 2018	$ 2,860	$ 13,202	$ (11,047)	$ (361)	$ 4,654

(1) Amounts charged to deductions from allowance for doubtful accounts represent the write-off of uncollectible balances and represent payments for rebates and allowances.

23. Subsequent Events

On January 29, 2021, the Company sold all of the stock of its Puerto Rican radiopharmacy servicing subsidiary to PharmaLogic Holdings Corp. ("PharmaLogic") pursuant to its previously announced Securities Purchase Agreement. The Company and PharmaLogic also entered into a long-term supply agreement under which the Company will continue to supply the Puerto Rico operations with certain products to meet a percentage of PharmaLogics' commercial requirements.

As previously disclosed, the purchase price paid for the transaction is $18.0 million in cash, subject to working capital and other customary adjustments. The Company expects to record a gain on the sale. Proceeds from this transaction will be used in the Company's core businesses and product pipeline.

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, 2020. 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, 2020, 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, 2020, 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, 2020, 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, 2020, 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, 2020, of the Company and our report dated February 25, 2021, 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 25, 2021

Changes in Internal Controls Over Financial Reporting

Management has completed the evaluation and integration of the internal controls of the acquired Progenics business into the Company's existing operations for the year ended December 31, 2020. After such evaluation and integration, there were no material changes in the Company's internal control over financial reporting during the quarter ended December 31, 2020, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

As a result of the COVID-19 pandemic, certain employees began working remotely in March 2020. Notwithstanding these changes to the working environment, we have not identified any material changes in our internal control over financial reporting from the commencement of such changes. We are continually monitoring and assessing the pandemic status to determine any potential impact on the design and operating effectiveness of our internal controls over financial reporting.

Item 9B. Other Information

None.

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 of Directors. 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 2021 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, 2020.

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 2021 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, 2020.

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 2021 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, 2020.

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 2021 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, 2020.

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 2021 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, 2020.

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
2.1	Agreement and Plan of Merger, dated as of October 1, 2019, among Lantheus Holdings, Inc., Plato Merger Sub, Inc. and Progenics Pharmaceuticals, Inc.	8-K	001-36569	10.1	October 2, 2019
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	April 27, 2018
4.1	Common Stock Certificate.	8-K	001-36569	4.1	June 30, 2015
4.2*	Description of Registrant's Securities				
10.4+	Lantheus Holdings, Inc. 2008 Equity Incentive Plan.	S-4	333-169785	10.18	October 6, 2010
10.5+	Amendment No. 1 to Lantheus Holdings, Inc. 2008 Equity Incentive Plan.	S-4	333-169785	10.19	October 6, 2010
10.6+	Amendment No. 2 to Lantheus Holdings, Inc. 2008 Equity Incentive Plan.	S-4	333-169785	10.20	October 6, 2010
10.7+	Form of Option Grant Award Agreement.	S-4	333-169785	10.21	October 6, 2010
10.9†	Manufacturing and Supply Agreement, dated as of February 1, 2012, for the manufacture of DEFINITY® by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterStier LLC.	10-Q	333-169785	10.2	May 15, 2012
10.10†	First Amendment to Manufacturing and Supply Agreement, dated as of May 3, 2012, for the manufacture of DEFINITY® by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterStier LLC.	10-Q	333-169785	10.1	August 14, 2012
10.12+	Lantheus Holdings, Inc. 2013 Equity Incentive Plan.	8-K	333-169785	10.1	May 6, 2013
10.13+	Form of Employee Option Grant Award Agreement.	8-K	333-169785	10.2	May 6, 2013
10.14+	Form of Non-Employee Director Option Grant Award Agreement.	8-K	333-169785	10.3	May 6, 2013
10.15+	2015 Equity Incentive Plan of Lantheus Holdings, Inc.	S-1	333-196998	10.37	June 24, 2015
10.16+	Form of 2015 Restricted Stock Agreement of Lantheus Holdings, Inc.	S-1	333-196998	10.38	June 24, 2015
10.17+	Form of 2015 Option Award Agreement of Lantheus Holdings, Inc.	S-1	333-196998	10.39	June 24, 2015
10.18+	Form of Amendment to the Lantheus Holdings, Inc. 2013 Equity Incentive Plan.	S-1	333-196998	10.40	June 24, 2015
10.19+	Form of Amendment to the Lantheus Holdings, Inc. 2008 Equity Incentive Plan.	S-1	333-196998	10.41	June 24, 2015
10.20+	Amendment to Lantheus Holdings, Inc. 2015 Equity Incentive Plan.	8-K	001-36569	10.1	April 28, 2016
10.21†	Second Amendment, effective September 2, 2016, to the Manufacturing and Supply Agreement, dated as of February 1, 2012 and amended on May 3, 2012, by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterStier LLC.	10-Q	001-36569	10.2	November 1, 2016

Exhibit Number	Description of Exhibits	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
10.22+	Second Amendment to Lantheus Holdings, Inc. 2015 Equity Incentive Plan	8-K	001-36569	10.1	April 28, 2017
10.23+	Lantheus Holdings, Inc. 2017 Employee Stock Purchase Plan	8-K	001-36569	10.2	April 28, 2017
10.24†	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
10.25+	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
10.26+	Employment Agreement dated as of November 22, 2013, by and between Lantheus Medical Imaging, Inc. and Michael Duffy.	10-K	001-36569	10.69	February 20, 2019
10.27+	Form of Severance Agreement (executives with existing employment agreements).	10-K	001-36569	10.70	February 20, 2019
10.28+	Form of Severance Agreement (executives without existing employment agreements).	10-K	001-36569	10.71	February 20, 2019
10.29+	Third Amendment to Lantheus Holdings, Inc. 2015 Equity Incentive Plan	10-Q	001-36569	10.1	April 30, 2019
10.30+	Fourth Amendment to Lantheus Holdings, Inc. 2015 Equity Incentive Plan	10-Q	001-36569	10.2	July 25, 2019
10.31	Credit Agreement dated as of June 27, 2019 by and among Wells Fargo 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.	10-Q	001-36569	10.3	July 25, 2019
10.32	Amendment No. 1 to Credit Agreement, dated as of June 19, 2020, among Lantheus Medical Imaging, Inc., as borrower, Lantheus Holdings, Inc. and Wells Fargo Bank, N.A., as administrative agent and collateral agent*	10-Q	001-36539	10.2	July 31, 2020
10.33	Contingent Value Rights Agreement dated as of June 19, 2020, by and between Lantheus Holdings, Inc. and Computershare Trust Company, N.A., as rights agent.	8-K	001-36569	10.1	June 22, 2020
10.34	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
10.35	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
10.36	License Agreement, dated February 3, 2011, by and between Salix Pharmaceuticals, Inc., the Registrant, Progenics Pharmaceuticals Nevada, Inc. and Excelsior Life Sciences Ireland Limited.	10-Q	000-23143	10.37(16)	May 10, 2011
10.37	Lease, dated December 31, 2015, between the Registrant and WTC TOWER 1 LLC.	8-K	000-23143	10.46 (21)	January 5, 2016
10.38	Loan Agreement, dated November 4, 2016, between the Registrant through its wholly-owned subsidiary MNTX Royalties Sub LLC and Healthcare Royalty Partners III, L.P.	8-K	000-23143	10.53(24)	November 7, 2016
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.				
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:	President and Chief Executive Officer
Date:	February 25, 2021

We, the undersigned directors and officers of Lantheus Holdings, Inc., hereby severally constitute and appoint Mary Anne Heino, Robert J. Marshall, Jr. and Michael P. Duffy, 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, President and Director (Principal Executive Officer)	February 25, 2021
/S/ ROBERT J. MARSHALL, JR. Robert J. Marshall, Jr.	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 25, 2021
/S/ BRIAN MARKISON Brian Markison	Chairman of the Board of Directors	February 25, 2021
/S/ SAMUEL R. LENO Samuel R. Leno	Director	February 25, 2021
/S/ JULIE H. MCHUGH Julie H. McHugh	Director	February 25, 2021
/S/ GARY J. PRUDEN Gary J. Pruden	Director	February 25, 2021
/S/ GERARD BER Gerard Ber	Director	February 25, 2021
/S/ DR. FREDERICK A. ROBERTSON Dr. Frederick A. Robertson	Director	February 25, 2021
/S/ HEINZ MAUSLI Heinz Mausli	Director	February 25, 2021
/S/ DR. JAMES H. THRALL Dr. James H. Thrall	Director	February 25, 2021

Exhibit 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

The following description sets forth certain material terms and provisions of Lantheus Holdings, Inc.'s (the "Company", "us", "we", or "our") securities that are registered under Section 12 of the Securities Exchange Act of 1934, as amended.

DESCRIPTION OF CAPITAL STOCK

The following summary description sets forth some of the general terms and provisions of the capital stock. Because this is a summary description, it does not contain all of the information that may be important to you. For a more detailed description of the preferred and common stock, you should refer to the provisions of our amended and restated certificate of incorporation and our bylaws, as amended and restated, each of which is an exhibit to the Annual Report on Form 10-K to which this description is an exhibit.

General

Our authorized capital stock consists of 250,000,000 shares of common stock, par value $0.01 per share, and 25,000,000 shares of preferred stock, par value $0.01 per share. The shares of common stock currently outstanding are fully paid and nonassessable. No shares of preferred stock are currently outstanding.

Common Stock

Holders of our common stock are entitled to the following rights:

Voting Rights

Each share of common stock entitles the holder to one vote with respect to each matter presented to our stockholders on which the holders of common stock are entitled to vote; provided, however, that the Board of Directors may issue or grant shares of common stock that are subject to vesting or forfeiture and that restrict or eliminate voting rights with respect to such shares until any such vesting criteria is satisfied or such forfeiture provisions lapse. Our common stock votes as a single class on all matters relating to the election and removal of directors on our Board of Directors and as provided by law. Holders of our common stock do not have cumulative voting rights. Except as otherwise provided in our amended and restated certificate of incorporation or our bylaws or required by law, all matters to be voted on by our stockholders must be approved by a majority of the shares present in person or by proxy at the meeting and entitled to vote on the subject matter.

Dividend Rights

Holders of common stock share equally on a per share basis in any dividend declared by our Board of Directors, subject to any preferential rights of the holders of any outstanding preferred stock.

Liquidation Rights

In the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs, holders of our common stock would be entitled to share ratably in our assets that are legally available for distribution to stockholders after payment of liabilities. If we have any preferred stock outstanding at that time, holders of the preferred stock may be entitled to distribution and/or liquidation preferences. In either case, we must pay the applicable distribution to the holders of our preferred stock before we may pay distributions to the holders of our common stock.

Other Rights

Our stockholders have no subscription privileges. Our common stock does not entitle its holders to preemptive rights for additional shares. All of the outstanding shares of our common stock are fully paid and nonassessable. The rights, preferences and privileges of the holders of our common stock are subject to the rights of the holders of shares of any series of preferred stock which we may issue.

Preferred Stock

Our Board of Directors is authorized to provide for the issuance of preferred stock in one or more series and to fix the preferences, powers and relative, participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including the dividend rate, conversion rights, voting rights, redemption rights and liquidation preference and to fix the number of shares to be included in any such series without any further vote or action by our stockholders. Any preferred stock so issued may rank senior to our common stock with respect to the payment of dividends or amounts upon liquidation, dissolution or winding up, or both. In addition, any such shares of preferred stock may have class or series voting rights. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of our Company without further action by the stockholders and may adversely affect the voting and other rights of the holders of our common stock.

Anti-takeover Provisions

Our amended and restated certificate of incorporation and bylaws contain provisions that delay, defer or discourage transactions involving an actual or potential change in control of us or change in our management. We expect that these provisions, which are summarized below, will discourage coercive takeover practices or inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board of Directors, which we believe may result in an improvement of the terms of any such acquisition in favor of our stockholders. However, they also give our board the power to discourage transactions that some stockholders may favor, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Accordingly, these provisions could adversely affect the price of our common stock.

Classified Board

Our amended and restated certificate of incorporation provides that our board is comprised of such number of directors as may be fixed from time to time by resolution of at least a majority of our Board of Directors then in office and that our board is divided into three classes, with one class being elected at each annual meeting of stockholders. Each director serves a three-year term, with expiration staggered according to class.

The classification of our board could make it more difficult for a third-party to acquire, or discourage a third party from seeking to acquire, control of our Company.

Requirements for Advance Notification of Stockholder Meetings, Nominations and Proposals

Our bylaws provide that special meetings of the stockholders may be called only upon the request of a majority of our board or upon the request of the chairman of our Board of Directors or our Chief Executive Officer.

Our bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board or a committee of our board. In order for any matter to be “properly brought” before a meeting, a stockholder will have to comply with the advance notice requirements of directors. Our bylaws allow our Board of Directors to adopt such rules and regulations for the conduct of the meetings as they may deem proper, which may be delegated to a chairperson of the meeting and which may have the effect of precluding the conduct of certain business at a meeting if the rules and regulations are not followed. These provisions may also defer, delay or discourage a potential acquirer from conducting a solicitation of proxies to elect the acquirer’s own slate of directors or otherwise attempting to obtain control of our Company.

No Stockholder Action by Written Consent

Our amended and restated certificate of incorporation provides that, subject to the rights of any holders of preferred stock to act by written consent instead of a meeting, stockholder action may be taken only at an annual meeting or special meeting of stockholders and may not be taken by written consent instead of a meeting, unless the action to be taken by written consent of stockholders and the taking of this action by written consent has been unanimously approved in advance by our board. Failure to satisfy any of the requirements for a stockholder meeting could delay, prevent or invalidate stockholder action.

Section 203 of the Delaware General Corporation Law, as amended (“DGCL”)

Our amended and restated certificate of incorporation provides that the provisions of Section 203 of the DGCL, which relate to business combinations with interested stockholders, do not apply to us. Section 203 of the DGCL prohibits a publicly held

Delaware corporation from engaging in a business combination transaction with an interested stockholder (a stockholder who owns more than 15% of our common stock) for a period of three years after the interested stockholder became such unless the transaction fits within an applicable exemption, such as board approval of the business combination or the transaction that resulted in such stockholder becoming an interested stockholder. These provisions would apply even if the business combination could be considered beneficial by some stockholders. Although we have elected to opt out of the statute's provisions, we could elect to be subject to Section 203 in the future.

Exclusive Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing in advance to the selection of an alternative forum, the Delaware Court of Chancery shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by, or any wrongdoing by, any of our directors, officers or employees to our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation (including as it may be amended from time to time) or our bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our bylaws, or (v) any action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits with respect to such claims. However, it is possible that a court could rule that this provision is unenforceable or inapplicable.

Listing

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

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Exhibit 21.1

LANTHEUS HOLDINGS, INC.
SUBSIDIARIES

Subsidiary	State or Other Jurisdiction of Organization
Lantheus Medical Imaging, Inc.	Delaware
Lantheus MI Canada, Inc.	Ontario, Canada
Lantheus MI Real Estate, LLC	Delaware
Lantheus MI Radiopharmaceuticals, Inc.	Commonwealth of Puerto Rico
Lantheus MI UK Limited	England and Wales
Lantheus EU Limited	Ireland
Progenics Pharmaceuticals, Inc.	Delaware
Molecular Insight Pharmaceuticals, Inc.	Delaware
Molecular Insight Limited	England and Wales
MNTX Royalties Sub LLC	Delaware
EXINI Diagnostics AB	Sweden
Excelsior Life Sciences Ireland Limited	Ireland
Progenics Life Sciences Limited	England and Wales
Progenics Pharmaceuticals Nevada, Inc.	Nevada
PSMA Development Company LLC	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-239491, 333-214343, 333-205211, 333-220049, 333-220050 and 333-232919 on Form S-8 of our reports dated February 25, 2021, relating to the financial statements of Lantheus Holdings, Inc. and the effectiveness of Lantheus Holdings, Inc.'s internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 25, 2021

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a)

I, Mary Anne Heino, certify that:

1. I have reviewed this Annual Report on Form 10-K of Lantheus Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2021

/s/ MARY ANNE HEINO

Name: Mary Anne Heino

Title: *President and Chief Executive Officer*

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a)

I, Robert J. Marshall, certify that:

1. I have reviewed this Annual Report on Form 10-K of Lantheus Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2021

/s/ ROBERT J. MARSHALL, JR.

Name: Robert J. Marshall, Jr.

Title: *Chief Financial Officer and Treasurer*

(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350

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

1. The Annual Report on Form 10-K for the fiscal year ended December 31, 2020 (the "Report") of the Company fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2021

/s/ MARY ANNE HEINO

Name: Mary Anne Heino

Title: *President and Chief Executive Officer*

(Principal Executive Officer)

Date: February 25, 2021

/s/ ROBERT J. MARSHALL, JR.

Name: Robert J. Marshall, Jr.

Title: *Chief Financial Officer and Treasurer*

(Principal Financial Officer and Principal Accounting Officer)

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