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: September 25, 2021

or

☐ **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: 1-36214

HOLOGIC, INC.
(Exact name of registrant as specified in its charter)

Delaware	**04-2902449**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

250 Campus Drive, Marlborough, Massachusetts 01752
(Address of Principal Executive Offices) (Zip Code)

Registrant's Telephone Number, Including Area Code (508) 263-2900

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	HOLX	The NASDAQ Global Select 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 electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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 in Rule 12b-2 of the Exchange Act.) Yes ☐ No ☒

The aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant as of March 27, 2021 was $18,639,078,720 based on the price of the last reported sale on NASDAQ Global Select Market on that date.

As of November 11, 2021, 251,420,529 shares of the registrant's Common Stock, $0.01 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the registrant's annual meeting of stockholders to be filed within 120 days of the end of its fiscal year ended September 25, 2021 are incorporated into Part III (Items 10, 11, 12, 13 and 14) of this Annual Report on Form 10-K where indicated.

HOLOGIC, INC.

ANNUAL REPORT ON FORM 10-K
For the Fiscal Year Ended September 25, 2021

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this report and documents incorporated by reference herein 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 statements involve known and unknown risks, uncertainties and other factors which may cause our or our industry's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements may include, but are not limited to, statements regarding:

- the ongoing and possible future effects of the global COVID-19 pandemic and associated economic disruptions, including supply chain constraints and inflation, on our business, financial condition, results of operations and cash flows and our ability to further draw down our revolver;
- the ongoing and possible future effects of the global COVID-19 pandemic on our customers and suppliers;
- continued demand for our COVID-19 assays;
- the timing, scope and effect of further U.S. and international governmental, regulatory, fiscal, monetary and public health responses, including emerging vaccine mandates, to the COVID-19 pandemic;
- our ability to manufacture, on a scale necessary to meet demand, our COVID-19 assays as well as the systems on which the assays run;
- our ability to predict accurately the demand for our products, and products under development and to develop strategies to address markets successfully;
- the effect of the continuing worldwide macroeconomic uncertainty, including the UK's decision to leave the European Union (known as Brexit), on our business and results of operations;
- the effect of the worldwide political and social uncertainty and divisions throughout the world, including the impact on trade regulation and tariffs, that may adversely impact the cost and sale of our products in certain countries, or increase the costs we may incur to purchase materials, parts and equipment from our suppliers;
- the development of new competitive technologies and products;
- the impact and anticipated benefits of completed acquisitions and acquisitions we may complete in the future;
- the ability to consolidate certain of our manufacturing and other operations on a timely basis and within budget, without disrupting our business and to achieve anticipated cost synergies related to such actions;
- the ability to successfully manage ongoing organizational and strategic changes, including our ability to attract, motivate and retain key employees and maintain engagement and efficiency in remote work environments;
- our ability to obtain regulatory approvals and clearances for our products, including the implementation of the new European Union Medical Device Regulations, and maintain compliance with complex and evolving regulations;
- potential cybersecurity threats and targeted computer crime;
- the coverage and reimbursement decisions of third-party payors;
- the uncertainty of the impact of cost containment efforts and federal healthcare reform legislation on our business and results of operations;
- the guidelines, recommendations, and studies published by various organizations relating to the use of our products;
- the effect of consolidation in the healthcare industry;
- the possibility of interruptions or delays at our manufacturing facilities, or the failure to secure alternative suppliers if any of our sole source third-party manufacturers fail to supply us;
- our ability to meet production and delivery schedules for our products;
- our ability to protect our intellectual property rights;
- the possibility that products may contain undetected errors or defects or otherwise not perform as anticipated;
- the anticipated development of markets we sell our products into and the success of our products in these markets;
- the anticipated performance and benefits of our products;
- business strategies;
- estimated asset and liability values;
- the impact of future tax legislation;
- conducting business internationally;
- the impact and costs and expenses of any litigation we may be subject to now or in the future;
- our compliance with covenants contained in our debt agreements;

- anticipated trends relating to our financial condition or results of operations, including the impact of interest rate and foreign currency exchange fluctuations, including the potential impact of the phase out of LIBOR by June 30, 2023; and
- our liquidity, capital resources and the adequacy thereof.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” "intends," “anticipates,” “believes,” “estimates,” “projects,” “predicts,” "likely," "future," "strategy," “potential,” "seeks," "goal" and similar expressions intended to identify forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this report. Except as otherwise required by law, we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statement contained in this report to reflect any change in our expectations or any change in events, conditions or circumstances on which any of our forward-looking statements are based. Factors that could cause or contribute to differences in our future financial results include the cautionary statements set forth herein and in our other filings with the Securities and Exchange Commission, including those set forth under “Risk Factors” set forth in Part I, Item 1A of this Annual Report on Form 10-K (this "Annual Report"). We qualify all of our forward-looking statements by these cautionary statements.

TRADEMARK NOTICE

Hologic is a trademark of Hologic, Inc. Other trademarks, logos, and slogans registered or used by Hologic and its divisions and subsidiaries in the United States and other countries include, but are not limited to, the following: 3Dimensions, 3D Mammography, 3D Performance, 3DQuorum, Acessa, Acessa Health, Acessa ProVu, AccuProbe, Aixplorer, Affirm, Affirm Prone, Alpha Imaging, Amplidiag, Aptima, ATEC, Biotheranostics, BioZorb, Brevera, Celero, Clarity HD, C-View, Definity, DirectRay, Emsor, Eviva, Faxitron, Faxitron Bioptics, Fluent, Fluoroscan, Focal, Focal Therapeutics, Genius 3D, Genius 3D Mammography, Genius AI, Health Beacons, Hitec-Imaging, Hologic, Horizon DXA, Insight, Intelligent 2D, ImageChecker CAD, LOCalizer, Medicor, Mobidiag, MyoSure, NovaSure, Novodiag, NXC Imaging, Panther, Panther Fusion, Progensa, Quantra, Rapid Ffn, SecurViewDX, Selenia, Selenia Dimensions, Sertera, SmartCurve, Smart-Depth, SmartSlices, SuperSonic Imagine, ThinPrep, Tigris, Tomcat, UltraFast, and Unify Workspace.

All other brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective owners. Hologic’s use or display of other parties’ trademarks, trade dress or products in this Annual Report does not imply that Hologic has a relationship with, or endorsement or sponsorship of, the trademark or trade dress owners.

PART I

Item 1. Business

Overview

We are a developer, manufacturer and supplier of premium diagnostics products, medical imaging systems, and surgical products focused on women's health and well-being through early detection and treatment. We sell and service our products through a combination of direct sales and service personnel and a network of independent distributors and sales representatives. We operate in four segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health. Until December 30, 2019, our product portfolio included aesthetic and medical treatment systems sold by our former Medical Aesthetic business. We completed the sale of our Medical Aesthetics segment on December 30, 2019 (the first day of the second quarter of fiscal 2020).

Through our Diagnostics segment, we offer a wide range of diagnostic products, which are used primarily to aid in the screening and diagnosis of human diseases. Our primary Diagnostics products include our molecular diagnostic assays, which run on our advanced instrumentation systems (Panther, Panther Fusion and Tigris), our ThinPrep cytology system, and the Rapid Fetal Fibronectin Test. Our Aptima family of molecular diagnostic assays is used to detect, among other things, the infectious microorganisms that cause common sexually transmitted diseases, or STDs, such as chlamydia and gonorrhea, or CTGC, certain high-risk strains of human papillomavirus, or HPV; and *Trichomonas vaginalis*, the parasite that causes trichomoniasis; Mycoplasma genitalium; and Herpes Simplex viruses 1 and 2. We also offer viral load tests for HIV, Hepatitis C and Hepatitis B for use on our Panther instrument system. Our assay portfolio also includes diagnostic tests for a range of acute respiratory infections, including SARS-CoV-2, as well as a test for the detection of Group B Streptococcus, or GBS, that are run on the Panther Fusion system, a field upgradeable instrument addition to the base Panther system. In response to the COVID-19 pandemic, we developed and launched the Aptima SARS-CoV-2 assay (which runs on our standard Panther system) and the Panther Fusion SARS-CoV-2 assay (which runs on our Panther Fusion system). The Panther Fusion SARS-CoV-2 assay and the Aptima SARS-CoV-2 assay were launched at the end of our second quarter and in the third quarter of fiscal 2020, respectively. The ThinPrep System is primarily used in cytology applications, such as cervical cancer screening, and the Rapid Fetal Fibronectin Test assists physicians in assessing the risk of pre-term birth.

Our Breast Health segment offers a broad portfolio of solutions for breast cancer care primarily in the areas of radiology, breast surgery, pathology and treatment. These solutions include 3D digital mammography systems, image analytics software utilizing artificial intelligence, reading workstations, ultrasound imaging, minimally invasive breast biopsy guidance systems, breast biopsy site markers, localization, specimen radiology, connectivity solutions and breast conserving surgery products. Our most advanced breast imaging platforms, Selenia Dimensions and 3Dimensions, utilize tomosynthesis to produce 3D images that show multiple contiguous slice images of the breast, which we refer to as the Genius 3D Mammography exam.

Our GYN Surgical products include our NovaSure endometrial ablation system, or NovaSure, our MyoSure hysteroscopic tissue removal system, or MyoSure, our Fluent fluid management system, or Fluent, as well as our Acessa ProVu laparoscopic radiofrequency ablation system, or Acessa. The NovaSure portfolio is comprised of the NovaSure CLASSIC and NovaSure ADVANCED devices and, most recently, the NovaSure V5 device for the treatment of abnormal uterine bleeding. The MyoSure suite of devices offers four options to provide incision-less removal of fibroids, polyps, and other pathology within the uterus. The Fluent system is a fluid management system that provides liquid distention during diagnostic and operative hysteroscopic procedures. The Acessa system is a fully integrated system that uses laparoscopic ultrasound, guidance mapping and radiofrequency ablation to treat nearly all types of fibroids.

Our Skeletal Health segment's products include the Horizon DXA, a dual energy x-ray system, which evaluates bone density and performs body composition assessments, and the Fluoroscan Insight FD mini C-arm, which assists in performing minimally invasive orthopedic surgical procedures on a patient's extremities, such as the hand, wrist, knee, foot, and ankle.

Unless the context otherwise requires, references to we, us, Hologic or our company refer to Hologic, Inc. and its consolidated subsidiaries.

Available Information

Our internet website address is *www.hologic.com*. Through our website, we make available, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as well as proxy statements, and, from time to time, other documents as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC). These SEC reports can be accessed through the investor relations section of our website. The information found on our website is not part of this or any other report we file with or furnish to the SEC.

Investors and others should note that we announce material financial information to our investors using our investor relations website (*investors.hologic.com*), SEC filings, press releases, public conference calls and webcasts. We use these channels as well as social media to communicate with our members and the public about our Company, our services and other issues. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our Company to review the information we post on the social media channels listed on our investor relations website. We have used, and intend to continue to use, our investor relations website, as well as our Twitter account (@Hologic), as means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Additional corporate governance information, including our certificate of incorporation, bylaws, governance guidelines, board committee charters, and code of business conduct and ethics, is also available on our investor relations website under the heading "Corporate Governance." The contents of our websites are not intended to be incorporated by reference into this Annual Report or in any other report or document we file with the SEC, and any references to our websites are intended to be inactive textual references only.

The SEC maintains an internet website that contains reports, proxy and information statements, and other information regarding Hologic and other issuers that file electronically with the SEC. The SEC's internet website address is *www.sec.gov*.

Products

We view our operations and manage our current business in four principal reporting segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health. Financial information concerning these segments is provided in Note 16 to our audited consolidated financial statements contained in Item 15 of this Annual Report. The following describes our principal products in each of our segments.

Diagnostics Product Offerings

Molecular Diagnostic Assay Portfolio

Aptima Family of Molecular Diagnostic Assays. Our Aptima molecular diagnostic assays are used to detect, among other things, the infectious microorganisms that cause common sexually transmitted diseases, or STDs, such as chlamydia and gonorrhea, or GTGC; certain high-risk strains of human papillomavirus, or HPV; *Trichomonas vaginalis*, the parasite that causes trichomoniasis; Mycoplasma genitalium; and Herpes simplex viruses 1 and 2. In addition, we also offer viral load assays for the quantitation of Hepatitis B virus, or HBV, Hepatitis C virus, or HCV, and human immunodeficiency virus, or HIV-1, for use on our Panther instrument system. All three of these viral load assays are both CE-marked and FDA approved. Our fourth viral load assay for the quantitation of human cytomegalovirus, or CMV, was CE-marked in June 2021, and we have submitted an application to the FDA for approval of our Aptima CMV Quant assay in the U.S. We also offer our Aptima BV and Aptima CV/TV assays for the diagnosis of vaginitis, a common and complex ailment affecting millions of women a year. In response to the COVID-19 pandemic, we developed and launched our Aptima SARS-CoV-2 assay for the detection of SARS-CoV-2, the virus that causes COVID-19 disease, which runs on our standard Panther and Panther Fusion systems. The Aptima SARS-CoV-2 assay for our standard Panther system was granted Emergency Use Authorization by the FDA in May 2020 and is also CE-marked. Our Aptima products integrate a number of proprietary core technologies, including our target capture technology, our Transcription Mediated Amplification, or TMA, technology, and our hybridization protection assay, or HPA, and dual kinetic assay, or DKA, technologies, to produce highly sensitive amplification assays. Each of these technologies is described in greater detail below.

Target Capture/Nucleic Acid Extraction Technology. The detection of target organisms that are present in small numbers in a large-volume clinical sample requires that target organisms be concentrated to a detectable level. One way to accomplish this is to isolate the particular nucleic acid of interest by binding it to a solid support. This support, with the target bound to it, can then be separated from the original sample. We refer to such techniques as "target capture." We have developed target capture techniques to immobilize nucleic acids on magnetic beads by using a "capture probe" that binds to the bead and to the target nucleic acid. We use magnetic separation to concentrate the target by drawing the magnetic beads to the sides of a sample tube, while the remainder of the sample is removed from the tube. When used in conjunction with our amplification procedures, target capture techniques concentrate the nucleic acid target(s) and also remove materials in the sample that might otherwise

interfere with amplification.

Transcription-Mediated Amplification (TMA) Technology. The goal of amplification technologies is to increase the copy number of a target nucleic acid sequences that may be present in samples in small numbers. These copies can then be detected using nucleic acid probes. Amplification technologies can yield results in only a few hours versus the several days or weeks required for traditional culture methods. TMA is a transcription-based amplification system that uses two different enzymes to drive the process. The first enzyme is a reverse transcriptase that creates a double-stranded DNA copy from an RNA or DNA template. The second enzyme, an RNA polymerase, makes thousands of copies of the complementary RNA sequence, known as the "RNA amplicon," from the double-stranded DNA template. Each RNA amplicon serves as a new target for the reverse transcriptase and the process repeats automatically, resulting in an exponential amplification of the original target that can produce over a billion copies of the RNA amplicon in less than thirty minutes.

Hybridization Protection Assay (HPA) and Dual Kinetic Assay (DKA) Technologies. With our HPA technology, we have simplified testing, further increased test sensitivity and specificity, and increased convenience. In the HPA process, the acridinium ester, or AE, molecule is protected within the double-stranded helix that is formed when the probe binds to its specific target. Prior to activating the AE molecule, known as "lighting off," a chemical is added that destroys the AE molecule on any unhybridized probes, leaving the label on the hybridized probes largely unaffected. When the "lighting off" or detection reagent is added to the specimen, only the label attached to the hybridized probe is left to produce a signal indicating that the target organism's DNA or RNA is present. All of these steps occur in a single tube and without any wash steps, which were required as part of conventional probe tests. Our DKA technology uses two types of AE molecules that can be differentiated from each other — one that "flashes" and another one that "glows." By using DKA technology, we have created nucleic acid test, or NAT, assays that can detect two separate targets simultaneously.

Panther Fusion Family of Molecular Diagnostic Assays. The Panther Fusion molecular diagnostic assays are performed on the Panther Fusion system and utilize polymerase chain reaction, or PCR, technology to amplify target nucleic acid sequences for easier detection. Our Panther Fusion assay portfolio includes diagnostic tests for a range of acute respiratory infections (influenza A virus, influenza B virus, respiratory syncytial virus, adenovirus, human metapneumovirus, rhinovirus and parainfluenza), as well as a test for the detection of Group B Streptococcus, or GBS. In addition, in response to the COVID-19 pandemic, in fiscal 2020 we developed and launched the Panther Fusion SARS-CoV-2 assay for the detection of SARS-CoV-2. The Panther Fusion SARS-CoV-2 assay was granted Emergency Use Authorization by the FDA in March 2020.

Molecular Diagnostic Instrumentation

We have developed and continue to develop instrumentation and software designed specifically for use with certain of our molecular diagnostic assays. We also provide technical support and service to maintain these instrument systems in the field. By placing our proprietary instrumentation in laboratories and hospitals, we can establish a platform for future sales of our assays.

Our instrumentation includes the Tigris system, an integrated, fully-automated testing instrument for high-volume laboratories which is approved for use with a number of our Aptima assays; the Panther instrument system, an integrated, fully-automated testing instrument capable of serving high-, medium- and low-volume laboratories; and our semi-automated direct tube sampling, or DTS, instruments which are used to run a number of infectious disease assays. Our instrumentation also includes the Tomcat instrument, a fully automated general-purpose instrument designed to improve pre-analytical sample processing by eliminating the inefficient and error-prone activities associated with manually transferring samples from one tube to another. In addition, our Panther Fusion system, including the related Fusion assays for flu and respiratory testing, extends the capabilities of our Panther system by adding the flexibility of PCR, functionality to our existing TMA-based technology. The Panther Fusion systems is available as a modular in-lab upgrade to our base Panther system. We received CE-mark approval for the Panther Fusion system in the third quarter of fiscal 2017 and FDA clearance in October 2017.

ThinPrep System

The ThinPrep System is the most widely used method for cervical cancer screening in the U.S. The ThinPrep System has multiple configurations, including one or more of the following: the ThinPrep 2000 Processor, ThinPrep 5000 Processor, ThinPrep5000 Processor with Autoloader, ThinPrep Genesis Processor, ThinPrep Imaging System, ThinPrep Integrated Imager, and related reagents, filters and other supplies, such as the ThinPrep Pap Test and our ThinPrep PreservCyt Solution.

The ThinPrep Process. The ThinPrep process begins with the patient's cervical sample being obtained by the physician using a cervical sampling device that, rather than being smeared on a microscope slide as in a conventional Pap smear, is inserted into a vial filled with our proprietary ThinPrep PreservCyt Solution. This enables most of the patient's cell samples to be preserved before the cells can be damaged by air drying. The ThinPrep specimen vial is then labeled and sent to a laboratory equipped with a ThinPrep Processor for slide preparation. At the laboratory, the ThinPrep specimen vial is inserted into a ThinPrep Processor, a proprietary sample preparation device, which automates the process of preparing cervical slides for staining and microscopic examination. Additionally, an aliquot used for subsequent molecular testing can be produced using the ThinPrep Genesis Processor.

In the case of manual screening, the cytotechnologist screens each Pap test slide with a microscope to first determine the adequacy of the slide and then to examine the entire slide to differentiate diseased or abnormal cells from normal cells. With the ThinPrep Imaging Systems, the screening process has been automated to combine the power of computer imaging technology with human interpretive skills. Prior to human review, the ThinPrep Imaging Systems rapidly scan, locate and highlight areas of interest for review. By directing the cytotechnologist to areas of interest on a slide, these systems may increase a cytology laboratory's screening productivity and diagnostic accuracy.

Additional Applications. In addition to serving as a replacement for the conventional Pap smear, the ThinPrep System can also be used for non-gynecological cytology screening applications including fine-needle aspiration specimens (e.g., breast, thyroid, lung or liver), body fluids (e.g., urine, pleural fluid, ascitic fluid or pericardial fluid), respiratory specimens (e.g., sputum or brushing of respiratory tracts) and ancillary testing (e.g., cell blocks, immunocytochemistry or special stains).

Rapid Fetal Fibronectin Test

The Rapid Fetal Fibronectin Test is a single-use disposable test used to determine a woman's risk of pre-term birth by detecting the presence of a specific protein, fetal fibronectin, in vaginal secretions during pregnancy. The test utilizes a single-use, disposable cassette and is analyzed on our instrument, the TLI IQ System.

Oncology Product Offerings

In February 2021, we completed the acquisition of Biotheranostics, Inc., or Biotheranostics, and now offer two proprietary laboratory developed tests, or LDTs, that support physicians in the treatment of cancer: the Breast Cancer Index test and the CancerTYPE ID test. The Breast Cancer Index, or BCI, test is a PCR-based gene expression test used for determining which patients with early-stage, hormone-receptor positive, or HR+, breast cancer is likely to benefit from extended endocrine therapy. In January 2021, the National Comprehensive Cancer Network revised its clinical practice guidelines to include BCI as the only gene expression assay to predict benefit from extended endocrine therapy for patients with early-stage HR+ breast cancer. The CancerTYPE ID test is a PCR-based gene expression test that is designed to identify the source of metastatic cancer in order to improve diagnostic accuracy and inform treatment decisions. Both of these LDTs are offered as a service solely out of our Biotheranostics' licensed, CLIA-certified, CAP-accredited laboratory in San Diego, California.

Mobidiag Product Offerings

In June 2021, we completed the acquisition of Mobidiag Oy, or Mobidiag, a developer of innovative molecular diagnostic tests and instrumentation, headquartered in Espoo, Finland. Mobidiag develops and markets PCR-based tests for acute care conditions such as gastrointestinal and respiratory infections (including SARS-CoV-2), antimicrobial resistance management, and healthcare associated infections. The Amplidiag and Novodiag platforms are automated instruments that deliver rapid turnaround times ranging from 50 minutes to two hours. The Novodiag instrument combines real-time PCR and microarray capabilities to provide high level multiplexing, assisting clinicians in efficiently identifying which organism is responsible for an infection. Although Mobidiag currently does not offer any of its products in the U.S., we intend to invest in assay development to drive growth of the Novodiag instrument, including seeking clearance for the Novodiag instrument and related assays in the U.S.

Breast Health Products

Mammography Solutions

Our Dimensions platform includes the Selenia Dimensions and 3Dimensions systems capable of performing both 2D and 3D tomosynthesis image acquisition and display. When operating in tomosynthesis mode, each system acquires a series of low dose x-ray images taken in a scanning motion at various angles. The images are mathematically processed into a series of small slices, allowing for visualization of the breast in multiple contiguous slices. Our clinical results for FDA approval demonstrated that conventional 2D digital mammography with the addition of our Genius 3D Mammography is superior to 2D digital mammography alone for both screening and diagnostics. Hologic Clarity HD technology provides our highest resolution

imaging, and our C-View and Intelligent 2D software products provide 2D images that are mathematically synthesized from the data within a tomosynthesis exam. Elimination of the 2D exposure reduces the breast compression time and patient dose compared to the current "combo" exam, which includes a tomosynthesis exam and a conventional digital 2D exam.

Our 3DQuorum technology, powered by Genius AI, is an artificial intelligence, or AI, powered algorithm that expedites mammography exam reading time without compromising image quality, sensitivity or accuracy. The 3DQuorum technology uses Genius AI-powered analytics to uniquely reconstruct high-resolution 3D data to produce 6 mm “SmartSlices.” By utilizing 3DQuorum technology the number of 3D images to review is reduced by two-thirds, saving an estimated average of one hour per eight hours of daily image interpretation time. The 3DQuorum technology also reduces the typical Hologic Clarity HD and Intelligent 2D study size by approximately 50%, bringing the storage space and network impact back down to that of standard resolution 3D imaging.

The images captured by digital mammography systems are typically transmitted electronically for review by a radiologist at a reading workstation. To address this process, we offer the SecurViewDX workstation approved for interpretation of mammograms from most vendors as well as images from other diagnostic breast modalities. We also offer image analytic products such as Genius AI Detection (Hologic's first artificial intelligence cancer detection algorithm utilizing deep-learning technology) and ImageChecker CAD to provide markings of suspicious areas of the breast that may be cancerous, as well as Quantra software to automate breast density measurement tools for our mammography systems. These technologies provide reviewers with the potential to focus on key patients that might otherwise be overlooked during the review process, thus potentially increasing cancer detection.

Stereotactic Breast Biopsy Systems

We provide clinicians with the flexibility of choosing prone or upright systems for breast biopsy by offering two minimally invasive stereotactic breast biopsy guidance systems: the Affirm Prone breast biopsy table and the Affirm upright system. The Affirm upright attachment is used with our Dimensions systems. These breast biopsy systems provide an alternative to open surgical biopsy and can be performed as an outpatient procedure under local anesthesia, allowing shorter recovery times. The Affirm tomosynthesis option provides faster lesion targeting and reduced patient procedure time compared to traditional stereotactic biopsy procedures. The Affirm system is pre-programmed for use with our Brevera, Eviva and ATEC vacuum-assisted breast biopsy devices.

Ultrasound Solutions

Ultrasound is used extensively by clinicians across the breast health continuum including screening, diagnosis, interventions, and surgical treatments. Ultrasound is commonly used as a complement to 3D mammography screening for women with dense breast tissue, as a diagnostic tool to further characterize lesions prior to biopsy, and for interventional and surgical guidance. Our UltraFast technology enables innovative imaging modes and frame rates of up to 20,000 images per second resulting in high performance and image quality. Our portfolio consists of premium ultrasound carts including the Aixplorer, Mach 20, Mach 30, and Mach 40 ultrasound system. The Supersonic Mach 40 ultrasound systems offers integration benefits with our existing breast health portfolio.

Breast Biopsy and Surgery Products

We offer a wide range of minimally invasive products for breast biopsy and breast surgery. Our breast biopsy portfolio includes three types of tethered vacuum-assisted breast biopsy products; the Brevera, ATEC, and Eviva devices. Each tethered device is powered by a console and utilizes our fluid management system. The ATEC device can be used under all standard imaging guidance modalities (stereotactic x-ray, ultrasound, MRI and molecular breast imaging) whereas our Brevera and Eviva devices are used exclusively under stereotactic x-ray guidance. We also offer the Celero and Sertera biopsy devices, both of which are non-tethered (no separate console), spring-loaded, disposable core biopsy devices, which are used exclusively under ultrasound-guidance. We also have products for marking, localizing and filling the void after surgery in addition to specimen imaging products for radiology, surgery and pathology.

GYN Surgical Products

NovaSure

The NovaSure CLASSIC endometrial ablation system allows physicians to treat women suffering from abnormal uterine bleeding. The system features Smart-Depth technology that continuously monitors and measures tissue impedance to provide a more customized, reliable and reproducible depth of ablation for every patient. The NovaSure system consists of a disposable device and a controller that delivers RF energy to ablate the endometrial lining of the uterus in order to eliminate or reduce the

patient's abnormal bleeding. The NovaSure disposable device is a hand-held, single-use device that incorporates a flexible gold-plated mesh electrode used to deliver the RF energy to the endometrial tissue. The NovaSure RF Controller generates and delivers RF energy customized for each patient, monitors several critical treatment and safety parameters, and automatically controls the endpoint of the procedure. We also offer the NovaSure ADVANCED and NovaSure V5 device which have a slimmer diameter. These devices are designed to improve patient comfort and physician ease-of-use while maintaining the clinical efficacy of the NovaSure system.

MyoSure

The MyoSure system is designed to provide efficient and effective hysteroscopic removal of tissue within the uterus, including fibroids and polyps. Removal of fibroids can provide effective relief from heavy menstrual bleeding commonly attributed to such pathology. Unlike other methods of tissue removal, the excavated tissue samples remain intact, which allows them to be tested for abnormalities. The MyoSure system consists of a tissue removal device, control unit, and hysteroscope. The MyoSure tissue removal device is single-use and features simultaneous tissue cutting and removal. The device incorporates a rapidly rotating and reciprocating cutting blade. During the procedure, the tissue removal device is inserted through the MyoSure hysteroscope. This tissue removal device is powered by a control unit, which features a simple user interface and is foot pedal activated. We offer multiple handpiece devices that differ in size and are focused on addressing different pathology types.

Fluent Fluid Management System

Our Fluent Fluid Management System is utilized for diagnostic and operative hysteroscopic procedures. Fluent is designed for simplified setup and operation, and streamlined workflow for the operating room team.

Acessa ProVu System

The Acessa ProVu System is used by laparoscopic surgeons to treat fibroids using controlled radiofrequency energy (heat) to cause coagulative necrosis. The treated tissue softens and shrinks over time, allowing fibroid symptoms to resolve without more invasive treatment. The Acessa System includes an ultrasound probe to locate the fibroids, guidance mapping that provides visual cues, and a percutaneous handpiece that deploys radiofrequency energy.

Skeletal Health Products

Horizon DXA Systems

Bone densitometry is the measurement of bone density to assist in the diagnosis and monitoring of osteoporosis and other metabolic bone diseases that can lead to frailty and debilitating bone fractures. Osteoporosis is a disease that is most prevalent in post-menopausal women. Our Horizon line of x-ray bone densitometers incorporates advanced features designed for bone health screening and body composition assessment. Body composition assessment is the precise measurement of bone, lean mass, and fat mass within the body. These measurements are valued within the health and wellness and human performance categories, informing nutrition and exercise programming decisions.

Fluoroscan Insight FD

Our Fluoroscan Insight FD is a mini C-arm imaging system that provides low intensity, real-time x-ray imaging, with high-resolution images at radiation levels and at a cost below those of conventional x-ray and standard sized fluoroscopic equipment. Mini C-arm systems are used primarily by orthopedic surgeons to assist in performing minimally invasive surgical procedures on a patient's extremities, such as the hand, wrist, knee, foot and ankle.

Marketing, Sales and Service

We sell and service our products through a combination of direct sales and service forces and a network of independent distributors and sales representatives. In fiscal 2021, 2020, and 2019, no customer accounted for more than 10% of our consolidated revenues. In fiscal 2020 revenues from two customers accounted for 12.5% and 10.9%, respectively, of our Diagnostics segment revenue, and in fiscal 2019 revenues from one customer accounted for 14.5% of our Diagnostics segment revenue. These customers were all large clinical laboratories reflecting the consolidation in that industry. No other customer accounted for more than 10% of our revenues in any other business segment in fiscal 2021, 2020, or 2019.

Our U.S. sales force is structured to specifically target the customers in each of our business segments. We maintain distinct teams focused on the Diagnostics, Breast Health, GYN Surgical, and Skeletal Health markets. Our end customers include clinical laboratories, hospitals, healthcare providers and surgeons in both hospital and office settings, and we target various specialists at healthcare entities who use our products, such as ob-gyns, radiologists and breast surgeons.

A critical element of our strategy in the U.S. for our Diagnostics, Breast and Skeletal Health, and GYN Surgical divisions has been to utilize the results of our clinical trials and expanded FDA labeling to demonstrate safety, efficacy and productivity improvements to our target customers. Our U.S. sales efforts for these divisions also includes the use of national account managers focused on obtaining purchasing contracts from large purchasing entities, such as managed care organizations, integrated delivery networks and government healthcare facilities. In addition, in certain regions of the U.S., we use a limited number of independent dealers or distributors to sell and service certain of our products. Internationally, our products in all divisions are marketed and sold through a combination of a direct sales force and a network of distributors.

Our service organization is responsible for installing our products and providing warranty and repair services, applications training and biomedical training. Products sold by our direct sales force typically carry limited warranties covering parts and labor for twelve months. Products sold through dealers also carry limited warranties that are typically for twelve months and cover only parts and components. We also offer service contracts that generally cover one to three years after the original warranty period. We provide both repair services and routine maintenance services under these arrangements, and also offer repair and maintenance services on a time and materials basis to customers that do not have service contracts. Our Breast Health business generates a majority of our service revenue, primarily relating to service contracts for our digital mammography and related products. Internationally, we primarily use distributors, sales representatives and third parties to provide maintenance service for our products, however we do provide direct service in countries where we have a subsidiary (Germany, UK, France, Spain, Japan, China, and Australia).

Competition

The healthcare industry is highly competitive and characterized by continual change and improvements in technology. This is particularly the case in the market segments in which we operate. A number of companies have developed or are expected to develop products that compete or will compete with our products. Many of these competitors offer a broader product portfolio and have greater brand recognition than we do, which may make these competitors more attractive to hospitals, radiology clients, group purchasing organizations, laboratories, physicians and other potential customers. Competitors may develop superior products or products of similar quality for sale at the same or lower prices. Moreover, our products could be rendered obsolete by changes to industry standards or guidelines or advances in technology. We can give no assurance that we will be able to compete successfully with existing or new competitors.

In the current environment of managed care, economically motivated buyers, consolidation among healthcare providers, increased competition and declining reimbursement rates, we have been increasingly required to compete on the basis of price, value, reliability and efficiency. We believe the current global economic conditions and healthcare reform measures are putting additional competitive pressure on us, including on our average selling prices, overall procedure rates and market sizes.

We believe that the success of our products depends on our ability to differentiate ourselves and to demonstrate that our products deliver the clinical and operational attributes that are most important and cost-effective to customers. These attributes include, but are not limited to, superiority in efficacy, ease of use, reliability, accuracy, quality and cost. We believe our continued success depends in large part upon our ability to invest in product enhancements and technologies that will help us distinguish ourselves from our competitors.

Diagnostics. Our ThinPrep liquid-based cytology product faces direct competition in the U.S. primarily from Becton, Dickinson and Company, or BD, which manufactures a competitive offering. We also compete with the conventional Pap smear and other alternative methods for detecting cervical cancer and/or its precursors. Internationally, our ThinPrep product competes with a variety of companies and other non-FDA approved tests, since fewer regulatory barriers exist in most international markets as compared to the U.S. Additionally, testing volume in this category is also under pressure due to clinical guideline changes, which lengthen the interval between screenings and increasingly afford the option of HPV testing as the primary means of detection.

We believe that our Rapid Fetal Fibronectin Test is currently the only available in vitro diagnostic test for predicting the risk of pre-term birth in the U.S. Internationally, our Rapid Fetal Fibronectin Test competes with Actim Partus manufactured by Medix Biochemical and PartoSure manufactured by Qiagen GmbH, or Qiagen. However, our Rapid Fetal Fibronectin Test could also experience competition from companies that manufacture and market pregnancy-related diagnostic products and services. In addition, healthcare providers use diagnostic techniques such as clinical examination and transvaginal ultrasound to help diagnose the likelihood of pre-term birth and may use these techniques together with the Rapid Fetal Fibronectin Test or instead of using the Rapid Fetal Fibronectin Test.

In the molecular diagnostics market, our products compete with many companies in the U.S. and abroad engaged in the development, commercialization and distribution of similar products intended for clinical molecular diagnostic applications. Clinical laboratories also may offer testing services that are competitive with our products and may use reagents purchased

from us or others to develop their own lab developed tests. The market for our COVID-19 assays is new and rapidly evolving both in the United States and in the rest of the world. For example, in the United States over 400 assays have received Emergency Use Authorization from the FDA, and we compete with the providers of all of these tests, including manufacturers of molecular diagnostic tests (including so-called high throughput nucleic acid tests, rapid antigen tests and at-home testing solutions), and antibody tests, as well clinical laboratories making their own lab developed tests for the detection of SARS-CoV-2.

In the global clinical diagnostics market, we compete with several companies offering alternative technologies to our diagnostic products. For example, in the U.S., our Aptima Combo 2 test competes against BD and Roche Diagnostics Corporation, or Roche, and our Aptima HPV test competes with tests marketed by BD, Qiagen and Roche.

Breast Health. Our mammography and related products and subsystems compete on a worldwide basis with products offered by a number of competitors, including General Electric Company, or GE, Siemens AG, or Siemens, Koninklijke Philips NV, or Philips, Planmed Oy, or Planmed, Carestream Health, Inc., or Carestream, FUJIFILM Holdings Corporation, or Fuji, Internazionale Medico Scientifica Srl, or I.M.S., and Toshiba Corporation. In the U.S., our digital mammography systems compete with digital mammography systems from GE, Siemens, Fuji, I.M.S., Philips and Planmed. Our digital mammography systems also compete with Fuji's and Carestream's Computed Radiography, or CR mammography systems, and other lower-priced alternatives to 2D digital mammography and analog mammography systems. In the U.S., GE, Siemens and Fuji have received FDA approval for their breast tomosynthesis systems, and we believe that other competitors are developing tomosynthesis systems for commercial use in the U.S. Our Dimensions tomosynthesis systems also compete in certain countries outside of the U.S. with tomosynthesis systems developed by GE, Siemens, Fuji, and I.M.S.

The primary competitor for our breast biopsy product line is Devicor Medical Products, Inc., part of Danaher Corporation's Leica Biosystems division. In addition, other competitors include CareFusion, a BD company, Sanarus Technologies, LLC and Intact Medical Corporation.

GYN Surgical. Our NovaSure system currently faces direct competition from The Cooper Companies, Inc., or CooperSurgical, and Minerva Surgical, Inc., or Minerva, each of which currently markets an FDA-approved endometrial ablation device for the treatment of abnormal uterine bleeding. In addition to these devices, we also compete with alternative treatments to our NovaSure system, such as drug therapy, intrauterine devices, hysterectomy, dilation and curettage and rollerball ablation. Because drug therapy is an alternative to our NovaSure procedure, NovaSure's competitors also include many major pharmaceutical companies that manufacture hormonal drugs for women.

Our MyoSure product competes directly with hysteroscopic loop resection, as well as hysteroscopic tissue removal systems such as Medtronic plc's TruClear device and Minerva's (formerly Boston Scientific Corporations') Symphion device. The MyoSure product also competes with alternative therapeutic techniques such as hysteroscopic resection with a monopolar or bipolar loop, which is currently the most common technique for removing intrauterine fibroids and polyps.

Our Acessa ProVu System competes directly with Gynesonics, Inc., which currently markets a radiofrequency ablation device for treating uterine fibroids. The Acessa ProVu System also competes with alternative fibroid treatment options such as hysterectomy, laparoscopic myomectomy, and uterine artery embolization.

Skeletal *Health.* GE is our primary competitor in the bone densitometry market, and we also compete with Orthoscan Inc. in the mini-C arm market.

Manufacturing

We purchase many of the components, subassemblies, and raw materials used in our products from numerous suppliers worldwide. For reasons of quality assurance, scarcity and/or cost effectiveness, certain components, subassemblies, and raw materials used in our products are available only from one or a limited number of suppliers. We work closely with our suppliers to develop contingency plans to ensure continuity of quality and reliable supply. We established long-term supply contracts with many of our suppliers, and in other instances, we developed in-house capability to offset potential shortages caused by sole source suppliers. Due to the high standards and FDA requirements applicable to manufacturing our products, such as the FDA's Quality System Regulation and Good Manufacturing Practices, we may not be able to quickly establish additional or replacement sources for certain components or materials. In addition, the COVID-19 pandemic and associated economic disruptions have had an adverse impact on our supply chains. Moreover, we use certain components in our products, including semiconductor chips, that have been the subject of recent global supply chain shortages and disruptions. In the event that we are unable to obtain sufficient quantities of raw materials or components or subassemblies on commercially reasonable terms or in a timely manner, our ability to manufacture our products on a timely and cost-competitive basis may be compromised, which may have a material adverse effect on our business, financial condition and results of operations.

Our current supplier of certain key raw materials for certain of our amplified NAT diagnostic assays is Roche, a direct competitor of our Diagnostics business. Our Diagnostic business has two supply agreements with GE Healthcare Bio-Sciences Corp., an affiliate of GE, for membranes used in connection with our ThinPrep product line and for primers used in the manufacture of Aptima, Fusion, Progensa and AccuProbe product lines. GE is a direct competitor with our Breast Health and Skeletal Health businesses.

We have sole source third-party contract manufacturers for each of our molecular diagnostics instrument product lines and for our Skeletal Health products. KMC Systems, Inc., or KMC Systems, is the only manufacturer of the Tigris instrument spare parts; Stratec Biomedical AG, or Stratec, is the only manufacturer of the Panther instrument, and Flextronics Medical Sales and Marketing, LTD, or Flextronics, is the only manufacturer of our Skeletal Health finished goods products. We are dependent on these sole source third-party manufacturers, and this dependence exposes us to increased risks associated with production delays, delivery schedules, manufacturing capability, quality control, quality assurance and costs. We have no firm long-term volume commitments with either KMC Systems, Stratec or Flextronics. If KMC Systems, Stratec, Flextronics or any of our other third-party manufacturers experiences delays, disruptions, capacity constraints or quality control problems in its development or manufacturing operations, curtails operations or otherwise fails to supply us with products in sufficient quantities, instrument and equipment shipments to our customers could be delayed or cancelled, which would decrease our revenues and may harm our competitive position and reputation. Further, because we place orders with our manufacturers based on forecasts of expected demand for our instruments and Skeletal Health products, if we inaccurately forecast demand, we may be unable to obtain adequate manufacturing capacity or adequate quantities of components to meet our customers' delivery requirements.

We, and our contract manufacturers, manufacture our products at a limited number of different facilities located in the U.S. and throughout the world. In most cases, the manufacturing of each of our products is concentrated in one or a few locations. An interruption in manufacturing capabilities at any of these facilities, as a result of equipment failure or other reasons, could reduce, delay or prevent the production of our products. Some of our manufacturing operations are located outside of the U.S., including in Costa Rica and the United Kingdom. Those manufacturing operations are also subject to additional challenges and risks associated with international operations described under the caption “Risk Factors” set forth in Part I, Item 1A of this Annual Report.

From time-to-time new regulations are enacted that can affect the content and manufacturing of our products. We evaluate the necessary steps for compliance with regulations as they are enacted. In August 2012, the SEC adopted a rule requiring disclosures of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured by public companies. The conflict minerals rule requires companies annually to disclose and report whether or not such minerals originate from the Democratic Republic of Congo or an adjoining country. The conflict minerals rule could affect sourcing at competitive prices and availability in sufficient quantities of certain minerals used in the manufacture of our products, including tantalum, tin, gold and tungsten. The number of suppliers who provide conflict-free minerals may be limited. In addition, there may be material costs associated with complying with the disclosure requirements, such as costs related to determining the source of certain minerals used in our products, as well as costs of possible changes to products, processes, or sources of supply as a consequence of such verification activities. Since our supply chain is complex, we may not be able to sufficiently verify the origins of the relevant minerals used in our products through the due diligence procedures that we implement, which may harm our reputation. In addition, we may encounter challenges to satisfy those customers who require that all of the components of our products be certified as conflict-free, which could place us at a competitive disadvantage if we are unable to do so.

Other regulations which affect the content and manufacturing of our products include, for example, the Registration, Evaluation, Authorization and Restriction of Chemical substances, or REACH, the Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Directive, or RoHS, and the Waste Electrical and Electronic Equipment Directive, or WEEE, enacted in the European Union which require the registration of and regulate the use of certain hazardous substances and chemicals in, and require the collection, reuse and recycling of waste from, certain products we manufacture. Similar legislation that has been or is in the process of being enacted in Japan and China and various states of the U.S. may require us to re-design our products to ensure compliance with the applicable standards, for example by requiring the use of different types of materials. These redesigns or alternative materials may detrimentally impact the performance of our products, add greater testing lead-times for product introductions, result in additional costs or have other similar negative effects.

Research and Development

The markets in which we participate are characterized by rapid technological change, frequent product introductions and evolving customer requirements. Investment in research and development is critical to driving our future growth. Our research and development efforts are focused on the further development and improvement of our existing products, the design and

development of new innovative medical technologies and regulatory compliance across all our business segments. In fiscal 2020, in response to the COVID-19 pandemic, we developed and launched the Aptima SARS-CoV-2 assay (which runs on our Panther system) and the Panther Fusion SARS-CoV-2 assay (which runs on our Panther Fusion system).

In addition to product development, our research and development personnel play an active role in the review of product specifications, clinical protocols and FDA submissions, as well as ensuring that certain of our products conform to European health, safety and environmental requirements, or CE-marking.

Patents and Proprietary Rights

We rely primarily on a combination of trade secrets, patents, copyrights, trademarks and confidentiality procedures to protect our products and technology. Due to the rapid technological changes that characterize the markets we operate in, we believe that trade secrets and other unpatented know-how relied upon in connection with the development of new products and the enhancement of existing products are generally as important as patent protection in establishing and maintaining a competitive advantage. Nevertheless, we have obtained patents and will continue to make efforts to obtain patents, when available, in connection with our product development programs. We do not consider our business to be materially dependent upon any individual patent.

We own numerous U.S. patents and have applied for numerous additional U.S. patents relating to our technologies. We also own or have applied for corresponding patents in selected foreign countries. These patents relate to various aspects of most of our products. We do not know if current or future patent applications will be issued with the full scope of the claims sought, if at all, or whether any patents issued will be challenged or invalidated. There is a risk that our patent applications will not result in granted patents or that granted patents will not provide significant protection for our products and technology. Third parties may infringe, misappropriate or otherwise violate our intellectual property rights, or copy or reverse engineer portions of our technology. Our competitors may independently develop similar or superior technology that our patents do not cover. In addition, because patent applications in the U.S. are not generally publicly disclosed until eighteen months after the application is filed, unpublished applications may have been filed by third parties that relate to our technology. Moreover, there is a risk that foreign intellectual property laws will not protect our intellectual property rights to the same extent as intellectual property laws in the U.S. The rights provided by a patent are finite in time. Over the coming years, certain patents relating to current products will expire in the U.S. and abroad which may allow third parties to exploit those technologies. In the absence of significant patent protection, we may be vulnerable to competitors who attempt to copy our products, processes or technology.

In addition to the patents we have been issued or we have acquired, we license patents from others on a variety of terms and conditions.

We are engaged in intellectual property litigation as described in Note 14 to our consolidated financial statements entitled "Litigation and Related Matters," and as may also be described herein, and we may be notified in the future of claims that we may be infringing, misappropriating or otherwise violating the intellectual property rights of third parties. In connection with any such claims, we may seek to enter into settlement and/or licensing arrangements. There is a risk in these situations that no license will be available or that a license will not be available on reasonable terms. Alternatively, we may decide or be required to litigate such claims. A successful claim against us may require us to remove the alleged infringing product from the market or to design around the third party's patent, potentially resulting in less market demand for the product.

Regulatory

The manufacture, sale, lease and service of medical diagnostic and surgical devices intended for commercial use are subject to extensive governmental regulation by the FDA in the U.S. and by a variety of regulatory agencies in other countries. Under the Federal Food, Drug and Cosmetic Act, known as the FD&C Act, manufacturers of medical products and devices must comply with certain regulations governing the design, testing, manufacturing, packaging, servicing and marketing of medical products. Some of our products are also subject to the Radiation Control for Health and Safety Act, administered by the FDA, which imposes performance standards and record keeping, reporting, product testing and product labeling requirements for devices that emit radiation, such as x-rays. FDA product approvals may be withdrawn or suspended if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

The FDA classifies medical devices into three classes based on risk. Regulatory control increases from Class I (lowest risk) to Class III (highest risk). The FDA generally must clear or approve the commercial sale of new medical devices in Classes II and III. Commercial sales of our Class II (except for Class II exempt devices) and Class III medical devices within the U.S. must be preceded by either a pre-market notification filing pursuant to Section 510(k) of the FD&C Act (Class II) or the granting of a pre-market approval, or PMA (Class III). Our Class I and Class II exempt medical devices must follow Hologic’s internal Quality System processes prior to commercialization and throughout their product lifecycle. All classes of devices must meet FDA's quality system (QS), establishment registration, medical device listing, labeling and medical device

reporting (MDR) regulations. The FDA can authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product, referred to as Emergency Use Authorization, or EUA, for certain emergency circumstances after the Health and Human Services Secretary has made a declaration of emergency justifying authorization of emergency use. An EUA allows use in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by emerging infectious disease threats when there are no adequate, approved, and available alternatives. The FDA may also waive otherwise-applicable current good manufacturing practice (CGMP) requirements to accommodate emergency response needs. In March 2020, the FDA granted EUA for our Panther Fusion SARS-CoV-2 assay for testing for the COVID-19 virus. In May 2020, the FDA granted EUA for our Aptima SARS-CoV-2 assay for use on our standard Panther instrument.

A 510(k) pre-market notification filing must contain information establishing that the device to be sold is substantially equivalent to a device commercially distributed prior to May 28, 1976 or to a device that has been determined by the FDA to be substantially equivalent. The PMA procedure involves a complex and lengthy testing process that is subject to review by the FDA and may require several years to obtain. We may need to first obtain an investigational device exemption (for significant risk devices), known as an IDE, in order to conduct extensive clinical testing of the device to obtain the necessary clinical data for submission to the FDA. The FDA will approve a PMA only if after evaluating the supporting technical data it finds that the PMA contains sufficient, valid scientific evidence to assure that the device is safe and effective for its intended use(s). This approval may be granted with post-approval requirements including inspection of manufacturing facilities and/or additional patient follow-up for an indefinite period of time.

Our Biotheranostics laboratory in San Diego, California and the laboratories that purchase certain of our products, including the Aptima SARS-CoV-2 EUA, Aptima Flu Multiplex EUA, Fusion SARS-CoV-2 EUA, ThinPrep System, ThinPrep Imaging System, Rapid Fetal Fibronectin Test, Aptima Combo 2, Aptima HPV tests and Aptima HIV-1 Quant, HCV Quant Dx, HBV Quant, Aptima Trichomonas Vaginalis (Trich), Aptima Mycoplasma Genitalium (MGen), Aptima HSV 1 & 2, Aptima BV, Aptima CV/TV, and Panther Fusion Assays are subject to extensive regulation under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, which requires laboratories to meet specified standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Adverse interpretations of current CLIA regulations or future changes in CLIA regulations could have an adverse effect on sales of any affected products or services. These laboratories are also licensed by the appropriate state agencies in the states in which they operate, where such licensure is required. In addition, our laboratories hold state licenses or permits, as applicable, from various states to the extent that they accept specimens from one or more of these states, each of which requires out-of-state laboratories to obtain licensure. If a laboratory is out of compliance with CLIA or with state laws or regulations governing licensed laboratories, penalties may include suspension, limitation or revocation of the license or CLIA certificate, assessment of financial penalties or fines, or imprisonment. Loss of a laboratory's CLIA certificate or state license may also result in the inability to receive payments from state and federal health care programs as well as private third party payors.

Certain analyte specific reagents, referred to as ASR products, as with other Class I products, may be sold without 510(k) clearance or PMA approval. However, ASR products are subject to significant restrictions. The manufacturer may not make clinical or analytical performance claims for the ASR product, may not promote their use with specific laboratory equipment and may only sell the ASR product to clinical laboratories that are qualified to run high complexity tests under CLIA. Each laboratory must validate the ASR product for use in diagnostic procedures as a laboratory developed test.

We are also subject to a variety of federal, state and foreign laws which broadly relate to our interactions with healthcare practitioners and other participants in the healthcare system, including, among others, the following:

- anti-kickback and anti-bribery laws, such as the Foreign Corrupt Practices Act, or the FCPA, the UK's Bribery Act 2010, or the UK Anti-Bribery Act;
- laws regulating the confidentiality of sensitive personal information and the circumstances under which such information may be released and/or collected, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and the European Union General Data Protection Regulation, or GDPR; and
- healthcare reform laws, such as the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, which we refer to together as PPACA, which include new regulatory mandates and other measures designed to constrain medical costs, as well as stringent new reporting requirements of financial relationships between device manufacturers and physicians and teaching hospitals.

In addition, we are subject to numerous federal, state, foreign and local laws relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous

substances, data privacy and protection among others. We may be required to incur significant costs to comply with these laws and regulations in the future and complying with these laws may result in a material adverse effect upon our business, financial condition and results of operations.

Sales of medical devices outside of the U.S. are subject to foreign requirements that vary widely from country to country. For example, our ability to market our products outside of the U.S. is contingent upon maintaining our International Standards Organization, or ISO, Quality System certification, complying with European directives and in some cases receiving specific marketing authorization from the appropriate foreign regulatory authorities. Foreign registration is an ongoing process as we register additional products and/or product modifications.

The time required to obtain approval from a foreign country to market and sell our products may be longer or shorter than that required for FDA approval and the requirements may differ. In addition, we may be required to meet the FDA's export requirements or receive FDA export approval for the export of our products to foreign countries.

Our products are also subject to approval and regulation by foreign regulatory and safety agencies. For example, the EU has adopted the EU Medical Device Regulation (the "EU MDR") and the In Vitro Diagnostic Regulation (the "EU IVDR"), each of which impose stricter requirements for the marketing and sale of medical devices, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. Manufacturers of currently approved medical devices had until May 2021 to meet the requirements of the EU MDR and will have until May 2022 to meet the EU IVDR. Complying with the requirements of these regulations may require us to incur significant expenditures. Failure to meet these requirements could adversely impact our business in the EU and other regions that tie their product registrations to the EU requirements. The recently rebranded National Medical Products Administration (formerly CFDA), or the NMPA, has historically been conservative leading to extended review times. However, more recently, the NMPA has been more interactive, which we attribute to its response to the long delays in getting lifesaving medical devices into China. If this continues, this could favorably affect our ability to introduce new products in the Chinese market.

The regulatory environment in China continues to evolve, and officials in the Chinese government exercise broad discretion in deciding how to interpret and apply regulations. It is possible that the Chinese government's current or future interpretation and application of existing or new regulations will negatively impact our China operations, result in regulatory investigations or lead to fines or penalties.

We anticipate that governmental authorities will continue to scrutinize the healthcare industry closely and that changes in laws, regulations or policies by governmental authorities may cause increases in uncertainties and compliance costs, exposure to litigation and other adverse effects to our business and operations. Delays in receipt of, or failure to obtain, clearances or approvals for future products could delay or preclude realization of product revenues from new products or result in substantial additional costs which could decrease our profitability.

For additional information about the regulations to which our business is subject and the impact such regulations may have on our business, see the disclosures under the captions "Manufacturing" and "Reimbursement" in this Item 1, and "Risk Factors" in Item 1A below.

Reimbursement

Market acceptance of our medical products in the U.S. and other countries is dependent upon the purchasing and procurement practices of our customers and patient need for our products and procedures and, the coverage and reimbursement of patients' medical expenses by government healthcare programs, private insurers or other healthcare payors. In the U.S., the Centers for Medicare & Medicaid Services, known as CMS, establishes coverage policies and payment rates for Medicare beneficiaries. CMS publishes payment rates for physician, hospital, laboratory and ambulatory surgical center services on an annual basis. Under current CMS policies and regulations, varying payment levels have been established for tests and procedures performed using our products. Coverage policies for Medicare patients may vary by regional Medicare contractor in the absence of a national coverage determination and payment rates for procedures will vary based on the geographic price index. Coverage policies and reimbursement rates for Medicaid patients are dependent on each state Medicaid plan and will vary. Coverage policies and reimbursement rates for patients with private insurance is dependent on the individual private payor's decisions. Moreover, private insurance carriers may choose not to follow the CMS coverage policies or payment rates. The use of our products outside of the U.S. is similarly affected by reimbursement policies adopted by foreign regulatory authorities and insurance carriers.

Healthcare policy and payment reform proposals and medical cost containment measures are being adopted in the U.S. and in many foreign countries. The ability of our customers to obtain adequate reimbursement for our products and services

from private and governmental third-party payors is critical to the success of medical technology companies because it may affect which products customers purchase and the prices they are willing to pay. Reimbursement and coverage vary by country and can significantly impact acceptance of new products and technologies. Even if we develop a promising new product, we may find limited demand for the product unless reimbursement approval and coverage is obtained from private and governmental third-party payors. Further, ongoing legislative or administrative reform to the reimbursement system in the U.S. and other countries may impact reimbursement for procedures using our medical products and/or limit coverage for those procedures facilitated by our products. This includes price regulation, competitive bidding and tendering, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements. These trends could have a material adverse effect on our business, financial condition or results of operations.

Human Capital

We view human capital management and the strength of our employees as integral to the long-term success of our business and the strengthening of our communities. We understand that we rely on our employees worldwide to propel our organization forward with great ideas, innovations and leadership.

As of September 25, 2021, we had 6,705 full-time employees, including 1,965 in manufacturing operations, 1,666 in sales and marketing, 1,424 in support services, 913 in research and development, and 737 in general administration. Approximately 3,920 of these employees are in the U.S. and approximately 2,785 were outside the U.S. In various countries outside the U.S., certain of our employees are unionized and, where local law requires, participate in works councils.

Employee Engagement

Our goal is to develop and maintain a talented, engaged and diverse workforce that has a positive impact on our performance, and on our customers and their patients. We have been conducting an annual engagement survey since 2015 in which most of employees regularly participate. We believe our foundation of employee engagement, our commitment to our employees, and their commitment to each other fortifies our leaders and teams and improves their business performance. We also offer a range of programs to develop our managers and enhance our leadership across the Company. Our professional development efforts are aimed at increasing organizational talent and capabilities and identifying and developing potential successors for key leadership positions.

Compensation and Benefits

We invest in the physical, emotional and financial well-being of our employees through our robust compensation and benefit programs. These programs (which vary by country/region) include a variety of health plan options, tax-favorable savings accounts and other wellness offerings.

COVID-19 Pandemic Response

Starting at the beginning of the COVID-19 pandemic, we took precautions to protect the health and safety of our employees by instituting robust hygiene practices, implementing temperature scanning stations, installing temporary safety structures, and increasing our cleaning protocols. For the front-line employees who came to work throughout the COVID-19 pandemic to develop and manufacture our COVID-19 tests, or who installed Panther instruments in locked-down hospitals during the most uncertain times of the COVID-19 pandemic, we were able to provide extraordinary financial awards.

We continue to actively monitor the COVID-19 pandemic, and respond based on guidance from U.S. and global health organizations, relevant governmental guidance and evolving practices. In addition, in response to the continuing challenges stemming from the COVID-19 pandemic, we developed several employee-focused initiatives to support the physical, mental, and financial well-being of our employees. These initiatives include providing enhanced accident and critical illness insurance, increasing access to telehealth services, developing an employee assistance program that provides mental health therapy, wellness coaching, and medication management, and offering subscriptions to self-care mobile apps.

Diversity Drives Performance

We are committed to creating an inclusive and diverse work environment that promotes equal opportunity, dignity and respect, starting with our Board and our Leadership team. Of our eight directors, three are women, three were born outside of the U.S., and two were predominantly educated outside of the U.S. We believe that our focus on the lives of women has helped us to attract a diverse workforce and build an inclusive ethos where different perspectives are valued and respected. Building a diverse workforce begins with our hiring practices and extends to our access to opportunities, strategic development and promotion of internal talent. We seek to identify and develop high-potential women and other diverse individuals within the Company. In addition to women holding several key roles within the Company (Chief Financial Officer; Chief Human Resources Officer; Division President, Breast and Skeletal Health; Vice President of Tax; Treasurer; and Chief of Staff), African American leaders have assumed important leadership roles as Division President, GYN Surgical, Vice President of Sales, Breast and Skeletal Health, Corporate Secretary, and Chief Information Security Officer. Additionally, given that our commercial teams are an important pipeline for senior management, we are pleased that a significant number of our commercial

team members below the level of vice president are women and/or people of color.

We strive to hire the most qualified person for the job and believe that, over time, this will lead to an increasingly diverse workforce. As a part of finding the most qualified people, we are committed to ensuring that diverse slates of candidates are identified and considered for all roles, from the boardroom and c-suite to all levels of the workforce. We believe our focus on talent identification, development, engagement and succession planning has been particularly successful in developing a deep and diverse talent pipeline.

Health and Safety

We seek to comply in letter and in spirit with applicable health and safety laws and regulations and implement programs, policies and procedures to achieve compliance throughout the Company. We also establish our own environmental health and safety standards in addition to those that are legally required. We employ management systems and procedures designed to protect human safety, health, and the environment. We seek to reduce risk and protect our employees and communities by employing safe technologies and operating procedures, and by maintaining a business continuity program to stay prepared for emergencies. We have also developed safety rules and procedures to address behaviors and work practices that can lead to accidents and injuries. Safety performance is assessed throughout the year by management and during annual performance reviews.

Community Engagement and Volunteerism

We take the role we play as leaders in the communities where we live and work seriously. Our philanthropic and charitable efforts are an important part of our culture. We center our giving efforts in three specific areas to maximize our impact in ways that align with the values of our employees and customers: (i) women's health, and other healthcare fields in which Hologic operates; (ii) science, technology, engineering, and math education (STEM), especially for underprivileged groups; and (iii) social and racial equality, especially in healthcare. We also support employees in giving back to community organizations through volunteering and matching donations.

Seasonality

Worldwide sales, including U.S. sales, do not reflect any significant degree of seasonality; however, customer purchases of our GYN Surgical products have been historically lower in our second fiscal quarter compared to our other fiscal quarters. Our respiratory infectious disease product line within our Diagnostics segment is also subject to significant seasonal and year-over-year fluctuations. In addition, the summer months, which occur during our fourth fiscal quarter, typically have had lower order rates internationally for most of our products.

Item 1A. Risk Factors

In evaluating our business, the risks described below, as well as other information contained in this Annual Report and in our other filings with the SEC should be considered carefully. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business. The occurrence of any of these events or circumstances could individually or in the aggregate have a material adverse effect on our business, financial condition, cash flow or results of operations. This report contains forward-looking statements; please refer to the cautionary statements made under the heading "Special Note Regarding Forward-Looking Statements" for more information on the qualifications and limitations on forward-looking statements.

THE COVID-19 GLOBAL PANDEMIC

The extent to which the COVID-19 pandemic and associated economic disruptions could have a material adverse impact on our business and the demand for many of our products will depend on future developments that are highly uncertain and difficult to predict.

The COVID-19 pandemic has created significant volatility, uncertainty and economic disruption in the markets we sell our products into and operate in, primarily the U.S., Europe, and Asia-Pacific and negatively impacted business and healthcare activity globally. We believe that the COVID-19 pandemic's impact on our operating results, cash flows and financial condition remains uncertain and will be primarily driven by the severity and duration of the COVID-19 pandemic (including the extent of future surges, variants and the efficacy of vaccination); the COVID-19 pandemic's impact on the U.S. and international healthcare systems, the U.S. economy and worldwide economy; the timing, scope and effectiveness of U.S. and international governmental responses to the COVID-19 pandemic and associated economic disruptions; and the impact of the COVID-19 pandemic on the health, well-being and productivity of our employees. As healthcare systems continue to respond to the demands of managing COVID-19 and the resulting economic uncertainties, governments around the world have imposed measures designed to reduce the transmission of COVID-19 and individuals continue to respond to the fear of contracting COVID-19. In particular, elective procedures and exams were delayed or cancelled, there has been a significant reduction in physician office visits, and hospitals postponed or canceled capital purchases as well as limited or eliminated services. While

elective procedures and exams and capital purchases have increased from initially depressed levels, the reduction in elective procedures, exams and capital purchases has had, and we believe may continue to have, a negative impact on the sales of most of our products (other than our COVID-19 assays and related systems and ancillaries) which has adversely affected our operating results, cash flows and financial condition. Additionally, governments and other third-party payors around the world facing tightening budgets could move to further reduce the reimbursement rates or the scope of coverage offered, which could further adversely affect sales of our products.

We may not realize anticipated revenue from our COVID-19 diagnostic assays.

We have developed assays to detect COVID-19. While we have seen significant demand for our COVID-19 assays, other companies are working to produce or have produced tests for COVID-19 which may lead to the diversion of customers away from us and toward other companies. Moreover, considerable uncertainty remains as to the demand for ongoing COVID-19 testing, and thus, for our COVID-19 assays. There is no guarantee that current or anticipated demand will continue, or if demand does continue or increases, that we will be able to produce in quantities to meet the demand. A significant decline in demand for our COVID-19 assays without a corresponding increase in our other businesses could have a material, adverse effect on our results of operations, cash flow and financial position.

The COVID-19 pandemic and associated economic disruptions have had and may continue to have a material adverse effect on manufacturing, distribution and supply chain.

The COVID-19 pandemic and associated economic disruptions have had an adverse impact on our manufacturing capacity, supply chains and distribution systems, including as a result of impacts associated with preventive and precautionary measures that we, other businesses and governments are taking. A number of our suppliers and manufacturers have been adversely affected by the COVID-19 pandemic. Delays or disruptions experienced by our suppliers and manufacturers caused by the COVID-19 pandemic and associated economic disruptions may prevent us from obtaining raw materials, components and subassemblies for our products in a timely manner. In addition, government and customer vaccine mandates may lead to employee attrition for us and our suppliers. Any resulting reduction or interruption in our manufacturing and distribution processes could result in a reduction in our revenues and harm our competitive position and reputation.

GLOBAL CHALLENGES

Continuing worldwide political and social uncertainty, as well as tariffs and social tensions, may adversely affect our business and prospects, both domestically and internationally.

Political and social uncertainty and divisions are rife in the U.S. and throughout the world, impairing political, trade and economic relations worldwide. This impacts how we are able to do business and expand our global footprint. Changes in policy in the U.S. and other countries regarding international trade, including import and export regulation and international trade agreements, could negatively impact our business. In recent years, the U.S. has imposed tariffs on goods imported from China and certain other countries, which has resulted in retaliatory tariffs by China and other countries. Changes or uncertainty in tariffs or further retaliatory trade measures taken by China or other countries in response, could affect the demand for our products and services, impact the competitive position of our products, prevent us from being able to sell products in certain countries or otherwise adversely impact our results of operations. The implementation of more restrictive trade policies, such as more detailed inspections, higher tariffs or new barriers to entry, could negatively impact our business, results of operations and financial condition.

Our international operations and foreign acquisitions expose us to additional operational challenges that we might not otherwise face.

International expansion is a key component of our growth strategy. In fiscal 2021, 30.7% of our revenue came from outside of the U.S. As we grow internationally, our future and existing international operations may subject us to a number of additional risks and expenses, any of which could harm our operating results. These risks and expenses include:

- political and economic changes and disruptions, export/import controls and tariff regulations;
- difficulties in developing staffing and simultaneously managing operations in multiple locations as a result of, among other things, distance, language and cultural differences;
- governmental currency controls;
- multiple, conflicting and changing government laws and regulations (including, among other things, antitrust and tax requirements);
- protectionist laws and business practices that favor local companies;
- difficulties in the collection of trade accounts receivable;
- difficulties and expenses related to implementing internal controls over financial reporting and disclosure controls and procedures;

- expenses associated with customizing products for clients in foreign countries;
- possible adverse tax consequences;
- the inability to obtain and maintain required regulatory approvals or favorable third-party reimbursement;
- operation in parts of the world where strict compliance with anti-bribery laws may conflict with local customs and practices;
- the inability to effectively obtain, maintain, protect or enforce intellectual property rights, reduced protection for intellectual property rights in some countries, and the inability to otherwise protect against clone or "knock off" products;
- the lack of ability to enforce non-compete agreements with former owners of acquired businesses competing with us in China and other foreign countries; and
- lower margins on a number of our products sold outside of the U.S.

BUSINESS DEVELOPMENT AND COMPETITION

Our long-term success will depend upon our ability to integrate acquired businesses and execute on business development activities.

During fiscal 2021, we made a number of tactical acquisitions which complemented our existing businesses. Any inability to successfully integrate new businesses, decreases in customer loyalty or product orders, failure to retain or develop the acquired workforce, failure to realize anticipated economic, operational and other benefits and synergies in a timely manner, failure to establish and maintain appropriate controls or unknown or contingent liabilities could adversely affect our ability to realize the anticipated benefits of any new product or acquisition. The integration of an acquired business, whether or not successful, requires significant efforts which may result in additional expenses and divert the attention of our management and technical personnel from other projects. Acquisitions, in particular, are inherently risky, and we cannot guarantee that any past or future transaction will be successful. As part of our long-term strategy, we are also engaged in business development activities including evaluating future acquisitions, joint development opportunities, technology licensing arrangements and other opportunities to further expand our presence in or diversify into priority growth areas by accessing new products and technologies. We may not be able to identify appropriate business development activities or acquisition candidates, consummate transactions or obtain agreements with favorable terms, if at all. We may also be subject to increasing regulatory scrutiny from competition and antitrust authorities in connection with acquisitions. If we are successful in pursuing future acquisitions, we may be required to expend significant funds, incur additional debt or other obligations, or issue additional securities, which may negatively affect our operating results and financial condition. If we spend significant funds or incur additional debt or obligations, our ability to obtain financing for working capital or other purposes could be adversely affected, and we may be more vulnerable to economic downturns and competitive pressures. If we fail to identify, acquire and integrate complementary businesses and products, our business, results of operations and/or financial condition could be adversely affected.

We face intense competition from other companies and may not be able to compete successfully.

The markets in which we sell our products are intensely competitive, subject to rapid technological change and may be significantly affected by new product introductions and other market activities of industry participants, and these competitive pressures may reduce the demand and prices for our products. Other companies may develop products that are superior to and/or less expensive than our products. Improvements in existing competitive products or the introduction of new competitive products may reduce our ability to compete for sales, particularly if those competitive products demonstrate better safety or effectiveness, clinical results, ease of use or lower costs.

Some companies may have significant competitive advantages over us, which may make them more attractive to hospitals, clinics, radiology clients, group purchasing organizations, laboratories, and physicians, including:

- greater brand recognition;
- larger or more established distribution networks and customer bases;
- a broader product portfolio, resulting in the ability to offer rebates or bundle products to offer discounts or incentives to gain a competitive advantage;
- higher levels of automation and greater installed bases of such equipment;
- more extensive research, development, sales, marketing, and manufacturing capabilities and greater financial resources; and
- greater technical resources positioning them to continue to improve their technology in order to compete in an evolving industry.

Challenges in the development of our products could materially impact our long-term success.

Our growth depends in large part on our ability to identify and develop new products or new indications for or enhancements of existing products. The development of new products and enhancement of existing products requires significant investment in research and development, clinical trials and regulatory approvals. The results of our product development efforts may be affected by a number of factors, including our ability to anticipate customer needs, innovate and develop new products, complete clinical trials, obtain regulatory clearances and approvals and reimbursement in the U.S. and abroad, manufacture products in a cost-effective manner, obtain, maintain, protect and enforce appropriate intellectual property protection for our products, gain and maintain market approval of our products and access capital. If we are not able to successfully enhance existing products or develop new products, our products may be rendered obsolete or uncompetitive by changing technology or new industry standards. We cannot assure that any products now in development or that we may seek to develop in the future will achieve technological feasibility, obtain regulatory approval or gain market acceptance, and we may be unable to recover all or a meaningful part of our investment in such products and technologies.

The markets for our newly developed products and newly introduced enhancements to our existing products may not develop as expected.

The successful commercialization of our newly developed products and newly introduced enhancements to our existing products are subject to numerous risks, both known and unknown, including:

- uncertainty of the development of a market for such product;
- trends relating to, or the introduction or existence of, competing products or technologies that may be more effective, safer or easier to use than our products or technologies;
- the perception of our products as compared to other products;
- recommendation and support for the use of our products by influential customers, such as highly regarded hospitals, physicians and treatment centers;
- the availability and extent of data demonstrating the clinical efficacy of our products or treatments;
- competition, including the presence of competing products sold by companies with longer operating histories, more recognizable names and more established distribution networks; and
- other technological developments.

Often, the development of a significant market for a product will depend upon the establishment of a reimbursement code or an advantageous reimbursement level for use of the product. Moreover, even if addressed, such reimbursement codes or levels frequently are not established until after a product is developed and commercially introduced, which can delay the successful commercialization of a product. If we are unable to successfully commercialize and create a significant market for our newly developed products and newly introduced enhancements to our existing products our business and prospects could be harmed.

If we cannot maintain our current corporate collaborations and enter into new corporate collaborations, our product development could be delayed and our revenue could be adversely impacted.

We have relied and/or expect to rely on corporate collaborators for funding development, marketing, distribution, and the commercialization of certain products. If any of our corporate collaborators were to breach, terminate, fail to renew our agreements or otherwise fail to properly conduct its obligations in a timely manner, the development or commercialization and subsequent marketing of the products contemplated by the collaboration could be delayed or terminated. Further, we would be required to devote additional resources to product development or marketing, to terminate some development programs or to seek alternative corporate collaborations with certain partners or companies that could make it more difficult for us to enter into advantageous business transactions or relationships with others. Any of the foregoing risks could harm our business and prospects.

BUSINESS CONTINUITY AND RELIANCE ON THIRD PARTIES

Supply Chain and Manufacturing

Our reliance on one third-party manufacturer for certain of our product lines and a limited number of suppliers for some key raw materials, components and subassemblies for our products exposes us to increased risks associated with production delays, delivery schedules, manufacturing capability, quality control, quality assurance and costs.

We have sole source third-party manufacturers for each of our Panther and Tigris molecular diagnostics instruments and for our Skeletal Health products. Similarly, we rely on one or a limited number of suppliers for some key components or subassemblies for our products due to cost, quality, expertise or other considerations. We have no firm long-term volume commitments with certain of our sole source suppliers, including the manufacturers of our Panther or Tigris instruments.

Similarly, we rely on one or a limited number of suppliers for some key raw materials for our products due to cost, quality, expertise or other considerations, and some of these suppliers are competitors. For example, F. Hoffmann-LaRoche Ltd, a direct competitor of our Diagnostics business, is the parent company of Roche, our current supplier of certain key raw materials for certain of our amplified NAT diagnostic assays. GE Healthcare Bio-Sciences Corp., an affiliate of GE, supplies us with the membranes used in connection with our ThinPrep product line. GE is a direct competitor with our Breast Health and Skeletal Health businesses. Moreover, we use certain components in our products, including semiconductor chips, that have been the subject of recent global supply chain shortages and disruptions. If any of our sole source manufacturers or suppliers, or other third-party manufacturers or suppliers, experiences delays, disruptions, capacity constraints or quality control problems in its development or manufacturing operations or becomes insolvent or otherwise fails to supply us with goods in sufficient quantities, including as a result of disruptions caused by the COVID-19 pandemic (as described above) or otherwise, then shipments to our customers could be delayed, which would decrease our revenues and harm our competitive position and reputation. Moreover, the failure of a supplier to provide sufficient quantities, acceptable quality and timely delivery of goods at an acceptable price, or an interruption in the delivery of goods from such a supplier could adversely affect our business and results of operations. Obtaining alternative sources of supply of products, components, subassemblies or raw materials could involve significant delays and other costs and regulatory challenges and may not be available to us on reasonable terms, if at all.

We may in the future need to find new contract manufacturers or suppliers to replace existing manufacturers or suppliers, increase our volumes or reduce our costs. We may not be able to find contract manufacturers or suppliers that meet our needs, including regulatory requirements, and even if we do, the process of qualifying such alternative manufacturers and suppliers is often expensive and time consuming. As a result, we may lose revenues and our customer relationships may suffer.

Interruptions, delays, shutdowns or damage at our manufacturing or laboratory facilities could harm our business.

In most cases, the manufacturing of each of our products is concentrated in one or a few locations. In addition, we rely on a single laboratory facility to process each of our Biotheranostics gene expression tests for breast cancer. An interruption in manufacturing or testing capabilities at any of these facilities, as a result of equipment failure, transportation interruptions, disruptions caused by the COVID-19 pandemic, other pandemics or other reasons, could reduce, delay or prevent the production of our products. Our facilities and those of our contract manufacturers or suppliers are subject to the risk of catastrophic loss due to unanticipated events, such as fires, earthquakes, explosions, floods or weather conditions. Our facilities may experience plant shutdowns, strikes or other labor disruptions, or periods of reduced production as a result of equipment failures, loss of power, gray outs, delays in deliveries or extensive damage, which could harm our business and prospects. Some of our manufacturing operations are located outside the U.S., including in Costa Rica and the United Kingdom. Those manufacturing operations are also subject to additional challenges and risks associated with international operations described herein.

Customer Concentration and Distributors

Our Diagnostics segment depends on a small number of customers for a significant portion of its product sales, and the loss of any of these customers or any cancellation or delay of a large purchase by any of these customers could significantly reduce revenues in our Diagnostics segment.

Although we do not currently have any customers that represent more than 10% of our consolidated revenues, or more than 10% of a business segment's revenue in fiscal 2021, historically a material portion of product sales in our Diagnostics segment came from (and we anticipate will continue to come from) a limited number of customers, two of which accounted for 12.5% and 10.9%, respectively, of our Diagnostics segment revenue in fiscal 2020. The loss of any of these key customers, or a significant reduction in sales volume or pricing to these customers, could significantly reduce our Diagnostics segment revenues or profitability.

We utilize distributors for a portion of our sales, the loss of which could harm our revenues in the territory serviced by these distributors.

We rely on strategic relationships with a number of key distributors for sales and service of our products. If any of our strategic relationships terminate without replacement or if our strategic partners fail to perform their contractual obligations, our revenues and/or ability to service our products in the territories serviced by these distributors could be adversely affected. We do not control our distributors, and these parties may not be successful in marketing our products. These parties may fail to commit the necessary resources to market and sell our products to the level of our expectations.

If we elect to distribute new products directly, we will have to invest in additional sales and marketing resources, including additional field sales personnel, which would significantly increase future selling, general and administrative expenses. If we fail to successfully market our products, our product sales will decrease. We may also be exposed to risks as a result of transitioning a territory from a distributor sales model to a direct sales model, such as difficulties maintaining relationships with specific customers, hiring appropriately trained personnel or ensuring compliance with local product

registration requirements, any of which could result in lower revenues than previously received from the distributor in that territory.

TALENT AND EMPLOYEE RETENTION

Our success depends on our ability to attract, motivate and retain key personnel and plan for future executive transitions.

The loss of any of our key personnel, particularly executive management or key research and development personnel, could harm our business and prospects and could impede the achievement of our research and development, operational or strategic objectives. We also continue to face the challenges of maintaining employee well-being, recognizing that the additional financial, family and health burdens that many employees may be experiencing due to the COVID-19 pandemic and related economic uncertainties may adversely impact job performance and employee retention. Government and customer vaccine mandates that apply to us may also lead to employee attrition, challenges securing future labor needs, inefficiencies connected to employee turnover and costs associated with implementation and on-going compliance, which could have a material adverse effect on our business, financial condition, and results of operations. Additionally, in our industry, there is substantial competition for key personnel in the regions in which we operate. We face intense competition for employees, particularly as employees are increasingly able to work remotely. Also, facilitating seamless leadership transitions for key positions is a critical factor in sustaining the success of our organization. If our succession planning efforts are not effective, it could adversely impact our business. We continue to assess the key personnel that we believe are essential to our long-term success. Future organizational changes could also cause our employee attrition rate to increase. If we fail to effectively manage any organizational and/or strategic changes, our financial condition, results of operations, and reputation, as well as our ability to successfully attract, motivate and retain key employees, could be harmed.

CYBERSECURITY AND DATA PRIVACY

Increased cybersecurity requirements, vulnerabilities, threats and more sophisticated and targeted computer crime could pose a risk to our systems, networks, products, solutions, services and data.

Increased global cybersecurity vulnerabilities, threats, computer viruses, ransomware and phishing attacks and more sophisticated and targeted cyber-related attacks, as well as cybersecurity failures resulting from human error and technological errors, pose a risk to the security of Hologic and its customers, business partners' and suppliers' products, systems and networks and the confidentiality, availability and integrity of data on these products, systems and networks. As the perpetrators of such attacks become more capable, as cybercrime becomes commoditized, and as critical infrastructure is increasingly becoming digitized, the risks in this area continue to grow. While we attempt to mitigate these risks by employing a number of measures, including employee training, monitoring and testing, and maintenance of protective systems and contingency plans, we remain potentially vulnerable to additional known or unknown threats, and we cannot assure that the impact from such threats will not be material. In addition to existing risks, the adoption of new technologies and acquisitions of new businesses may also increase our exposure to cybersecurity breaches and failures. We also have access to sensitive, confidential or personal data or information that is subject to privacy and security laws, regulations or customer-imposed controls. Despite our implementation of controls to protect our systems and sensitive, confidential or personal data or information, we may be vulnerable to material security breaches, theft, misplaced, lost or corrupted data, employee errors and/or malfeasance (including misappropriation by departing employees) that could potentially lead to the compromising of sensitive, confidential or personal data or information, improper use of our systems, software solutions or networks, unauthorized access, use, disclosure, modification or destruction of information, defective products, production downtimes and operational disruptions. In addition, a cyber-related attack could result in other negative consequences, including damage to our reputation or competitiveness, remediation or increased protection costs, litigation or regulatory action. Although we have experienced occasional actual or attempted breaches of our computer systems, to date we do not believe any of these breaches has had a material effect on our business, operations or reputation.

Failure to comply with laws relating to the confidentiality of sensitive personal information or standards related to the transmission of electronic health data, may require us to make significant changes to our products, or incur penalties or other liabilities.

State, federal and foreign laws, such as the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, regulate the confidentiality of sensitive personal information and the circumstances under which such information may be released. These measures may govern the disclosure and use of personal and patient medical record information and may require users of such information to implement specified security measures, and to notify individuals in the event of privacy and security breaches. Evolving laws and regulations in this area could restrict the ability of our customers to obtain, use or disseminate patient information, or could require us to incur significant additional costs to re-design our products in a timely manner, either of which could have an adverse impact on our results of operations. Other health information standards, such as regulations under HIPAA, establish standards regarding electronic health data transmissions and transaction code set rules for

specified electronic transactions, for example transactions involving submission of claims to third-party payors. These standards also continue to evolve and are often unclear and difficult to apply. Outside the U.S., we are impacted by privacy and data security requirements at the international, national and regional level, and on an industry specific basis. More privacy and security laws and regulations are being adopted, and more are being enforced, with potential for significant financial penalties. In the EU, increasingly stringent data protection and privacy rules have been enacted. The EU General Data Protection Regulation (GDPR) applies uniformly across the EU and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances. The GDPR also requires companies processing personal data of individuals residing in the EU to comply with EU privacy and data protection rules. Failure to maintain the confidentiality of sensitive personal information in accordance with the applicable regulatory requirements, or to abide by electronic health data transmission standards, could expose us to breach of contract claims, fines and penalties, costs for remediation and harm to our reputation.

THIRD-PARTY REIMBURSEMENT AND GUIDELINES

Healthcare cost containment legislation and the failure of third-party payors to provide appropriate levels of coverage and reimbursement for the use of products and treatments facilitated by our products could harm our business and prospects.

Sales and market acceptance of our diagnostics, breast and skeletal health and surgical products and the treatments facilitated by these products are dependent upon the coverage decisions and reimbursement policies established by government healthcare programs and private health insurers. These policies affect which products customers purchase and the prices they are willing to pay. Reimbursement varies by country and can significantly impact the acceptance of new products and technologies. Even if we develop a promising new product, we may find limited demand for the product unless appropriate reimbursement approval is obtained from private and governmental third-party payors. Further legislative or administrative reforms to the reimbursement systems in the U.S. and other countries in a manner that significantly reduces reimbursement for procedures using our diagnostics, breast and skeletal health and surgical products or denies coverage for those procedures facilitated by our products, including price regulation, competitive bidding and tendering, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements, could have a material adverse effect on our business, financial condition or results of operations.

Guidelines, recommendations and studies published by various organizations may reduce the use of our products.

Professional societies, government agencies, practice management groups, private health/science foundations, and organizations involved in healthcare issues may publish guidelines, recommendations or studies to the healthcare and patient communities. Organizations like these have in the past made recommendations about our products and those of our competitors. If followed by healthcare providers and insurers, such publications could result in decreased use of our products. For example, in November 2012, the American Congress of Obstetrics and Gynecologists, known as the ACOG, released updates in which it recommended less frequent cervical cancer screening similar to guidelines released in March 2012 by the U.S. Preventative Services Task Force, or the USPSTF, and the American Cancer Society. We believe that these recommendations and guidelines may have contributed to increased screening intervals for cervical cancer, which we believe has and may continue to adversely affect our ThinPrep revenues. Our ThinPrep revenues may also be adversely affected by the July 2020 American Cancer Society cervical cancer screening recommendation for a primary human papillomavirus (HPV) test rather than a Pap test. In addition, on October 20, 2015, the American Cancer Society issued guidelines recommending that women start annual mammograms at age 45 instead of 40 and have a mammogram every two years instead of annually. This recommendation could result in a decrease in purchases of our mammography systems.

REGULATORY AND LEGAL

Changes in tax laws or exposures to additional tax liabilities could negatively impact the Company's operating results.

We are subject to income taxes, as well as taxes that are not income-based, in both the U.S. and jurisdictions outside of the U.S. Our future effective tax rate could be unfavorably affected by numerous factors including a change in, or the interpretation of, tax rules and regulations in the jurisdictions in which we operate (including changes in legislation currently being considered), a change in our geographic earnings mix, and/or to the jurisdictions in which we operate, or a change in the measurement of our deferred taxes. We are also subject to ongoing tax audits in various jurisdictions, and tax authorities may disagree with certain positions we have taken and assess additional taxes.

We operate in a highly regulated industry, and changes in healthcare laws and regulations or our inability to obtain in a timely manner or at all U.S. or foreign regulatory clearances or approvals for our current and newly developed products and services or product or service enhancements, could adversely affect our business and prospects.

We operate in a highly regulated industry. As a result, governmental actions may adversely affect our business, operations or financial condition, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, method of delivery and payment for healthcare products and services;
- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;
- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products; and
- new laws, regulations and judicial decisions affecting pricing or marketing practices.

Given the high level of regulatory oversight to which our products are subject, the process of obtaining clearances and approvals can be costly and time consuming. In addition, there is a risk that any approvals or clearances, once obtained, may be withdrawn. Most medical devices cannot be marketed in the U.S. without 510(k) clearance or pre-market approval by the FDA. Any modifications to a device that has received a pre-market approval that affect the safety or effectiveness of the device require a pre-market approval supplement or possibly a separate pre-market approval, either of which is likely to be time consuming, expensive and uncertain to obtain. If the FDA requires us to seek one or more pre-market approval supplements or new pre-market approvals for any modification to a previously approved device, we may be required to cease marketing or to recall the modified device until we obtain approval, and we may be subject to significant criminal and/or civil sanctions, including, but not limited to, regulatory fines or penalties. States may also regulate the manufacture, sale and use of medical devices, particularly those that employ x-ray technology.

Our products are also subject to approval and regulation by foreign regulatory and safety agencies. For example, the EU has adopted the EU Medical Device Regulation (the "EU MDR") and the In Vitro Diagnostic Regulation (the "EU IVDR"), each of which impose stricter requirements for the marketing and sale of medical devices, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. Manufacturers of currently approved medical devices will have until May 2022 to meet the EU IVDR. Complying with the requirements of these regulations may require us to incur significant expenditures. Failure to meet these requirements could adversely impact our business in the EU and other regions that tie their product registrations to the EU requirements.

We anticipate that governmental authorities will continue to scrutinize the healthcare industry closely and that changes in laws, regulations or policies by governmental authorities may cause increased uncertainties and compliance costs, exposure to litigation and other adverse effects to our business and operations. Delays in receipt of, or failure to obtain or maintain, clearances or approvals for future products could delay or preclude realization of product revenues from new or existing products or result in substantial additional costs which could decrease our profitability.

In addition, maintaining compliance with multiple regulators, and multiple centers within the FDA, adds complexity and cost to our manufacturing processes. Our manufacturing facilities and those of our contract manufacturers are subject to periodic regulatory inspections by the FDA and other regulatory agencies, and these facilities are subject to the FDA's Quality System Regulation and Good Manufacturing Practices. We or our contractors may fail to satisfy these regulatory requirements in the future, and any failure to do so may prevent us from selling our products.

Some of our activities may subject us to risks under federal and state laws prohibiting "kickbacks" and false or fraudulent claims.

We are subject to the provisions of a federal law commonly known as the anti-kickback statute, and several similar state laws, which prohibit payments intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. While the federal law applies only to products or services for which payment may be made by a federal healthcare program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements, including sales programs that may be used with hospitals, physicians, laboratories and other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Similarly, the Patient Protection and Affordable Care Act also includes stringent reporting requirements of financial relationships between device manufacturers and physicians and teaching hospitals. Specifically, under one provision of the law, which is commonly referred to as the Physician Payment Sunshine Act, we are required to collect data on and annually report to CMS certain payments or other transfers of value to physicians and teaching hospitals and annually report certain ownership and investment interests held by physicians or

their immediate family members. Anti-kickback and false claims laws and the Physician Payment Sunshine Act prescribe civil and criminal penalties (including fines) for noncompliance that can be substantial.

Similarly, our international operations are subject to the provisions of the U.S. Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), which prohibits U.S. companies and their representatives from offering or making improper payments to foreign officials for the purpose of obtaining or retaining business. In many countries, the healthcare professionals we regularly interact with may meet the definition of a foreign official for purposes of the FCPA. Our international operations are also subject to various other international anti-bribery laws such as the UK Anti-Bribery Act. Despite meaningful measures that we undertake to facilitate lawful conduct, which include training and compliance programs and internal policies and procedures, we may not always prevent unauthorized, reckless or criminal acts by our employees or agents, or employees or agents of businesses or operations we may acquire. Violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction and have a material adverse effect on our business, financial condition and results of operations. We also could be subject to adverse publicity, severe penalties, including criminal and civil penalties, disgorgement, further changes or enhancements to our procedures, policies and controls, personnel changes and other remedial actions. Moreover, our failure to comply with domestic or foreign laws could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, and withdrawal of an approved product from the market.

We are subject to the risk of product liability claims relating to our products for which we may not have adequate insurance.

Our business involves the risk of product liability and other claims inherent to the medical device business. If even one of our products is found to have caused or contributed to injuries or deaths, we could be held liable for substantial damages. We maintain product liability insurance subject to deductibles and exclusions. There is a risk that the insurance coverage will not be sufficient to protect us from product and other liability claims, or that product liability insurance will not be available to us at a reasonable cost, if at all. An under-insured or uninsured claim could harm our business and prospects. In addition, claims could adversely affect the reputation of the related product, which could damage that product's competitive position in the market.

The sale and use of our diagnostic products could also lead to product liability claims if someone were to allege that one of our products contained a design or manufacturing defect that resulted in inaccurate test results or the failure to detect a disorder for which it was being used to screen, or caused injuries to a patient. Any product liability claim brought against us, with or without merit, could result in an increase in our product liability insurance rates or the inability to secure additional coverage in the future. Also, even a meritless or unsuccessful product liability claim could be time consuming and expensive to defend. This could result in a diversion of management's attention from our business and adversely affect the perceived safety and efficacy of our products, which could harm our business and prospects.

We are subject to environmental, health and safety laws and regulations, including related to our use and recycling of hazardous materials and the composition of our products.

Our research and development and manufacturing processes involve the controlled use of hazardous materials, such as toxic and carcinogenic chemicals and various radioactive compounds, and the risk of contamination or injury from these materials cannot be eliminated. In such event, we could be held liable for any resulting damages, and any such liability could be extensive. From time to time new regulations are enacted, and it is difficult to anticipate how such regulations will be implemented and enforced. We continue to evaluate the necessary steps for compliance with regulations as they are enacted. These regulations include, for example, regulations enacted in the EU such as the Registration, Evaluation, Authorization and Restriction of Chemical Substances, or REACH, which requires the registration of and regulates use of certain chemicals, the Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Directive, or RoHS, which regulates the use of certain hazardous substances in certain products we manufacture, and the Waste Electrical and Electronic Equipment Directive, or WEEE, which requires the collection, reuse and recycling of waste from certain products we manufacture. These and similar legislation that has been or is in the process of being enacted in Japan, China and various states of the U.S. may require us to re-design our products to ensure compliance with the applicable standards, for example by requiring the use of different types of materials. These redesigns or the use of alternative materials may detrimentally impact the performance of our products, add greater testing lead times for product introductions, result in additional costs or have other similar effects. We are also subject to other substantial regulation relating to environmental, health and safety matters, including occupational health and safety, environmental protection, hazardous substance control, and waste management and disposal. The failure to comply with such regulations could subject us to, among other things, fines and criminal liability. We may also be required to incur significant costs to comply with these and future regulations, which may result in a material adverse effect upon our business, financial condition and results of operation.

INTELLECTUAL PROPERTY

Our business is dependent on technologies we license, and if we fail to maintain these licenses or license new technologies and rights to particular nucleic acid sequences for targeted diseases in the future, we may be limited in our ability to develop new products.

Our business is dependent on licenses from third parties for some of our key technologies. For example, our patented TMA technology is based on technology we licensed from Stanford University. We anticipate that we will enter into new licensing arrangements in the ordinary course of business to expand our product portfolio and access new technologies to enhance our products and develop new products. Many of these licenses will provide us with exclusive rights to the subject technology or disease marker. If our license with respect to any of these technologies or markers is terminated for any reason, we may not be able to sell products that incorporate that technology. Similarly, we may lose competitive advantages if we fail to maintain exclusivity under an exclusive license.

Our ability to develop additional diagnostic tests for diseases may depend on the ability of third parties to discover particular sequences or markers and correlate them with disease, as well as the rate at which such discoveries are made. Our ability to design products that target these diseases may depend on our ability to obtain the necessary rights from the third parties that make any of these discoveries. In addition, there are a finite number of diseases and conditions for which our NAT diagnostic assays may be economically viable. If we are unable to access new technologies or the rights to particular sequences or markers necessary for additional diagnostic products on commercially reasonable terms, we may be limited in our ability to develop new diagnostic products.

Our products and manufacturing processes may require access to technologies and materials that may be subject to patents or other intellectual property rights held by third parties. Our business could be adversely affected if we are unable to obtain the additional intellectual property rights necessary to commercialize our products.

Our business could be harmed if we are unable to protect our proprietary technology.

We have relied primarily on a combination of trade secrets, patents, copyrights, trademarks and confidentiality procedures to protect our products and technology. Despite these precautions, unauthorized third parties may infringe, misappropriate or otherwise violate our intellectual property, or copy or reverse engineer portions of our technology. The pursuit and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology, involve complex determinations and, therefore, are characterized by substantial uncertainty. We do not know if current or future patent applications will be issued with the full scope of the claims sought, if at all, or whether any patents that are issued will be challenged or invalidated. The patents that we own or license could also be subjected to invalidation proceedings or similar disputes, and an unfavorable outcome could require us to cease using the related technology or to attempt to license rights to the technology from the prevailing party. There is also a risk that intellectual property laws outside of the U.S. will not protect our intellectual property rights to the same extent as intellectual property laws in the U.S. Even if our proprietary information is protected by patents or otherwise, the initiation of actions to protect our proprietary information could be costly and divert the efforts and attention of our management and technical personnel, and the outcome of such litigation is often uncertain. As a result of these uncertainties, we could also elect to forego such litigation or settle such litigation without fully enforcing our proprietary rights. In the absence of significant patent protection, we may be vulnerable to competitors who attempt to copy our products, processes or technology. Additionally, rights provided by a patent are finite in time. Over the coming years, certain patents relating to current products will expire in the U.S. and abroad thus allowing third parties to utilize certain of our technologies.

Our business could be harmed if we infringe upon the intellectual property rights of others.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device, diagnostic products and related industries. We are and have been involved in patent litigation and may in the future be subject to further claims of infringement of intellectual property rights possessed by third parties. In connection with claims of patent infringement, we may seek to enter into settlement and/or licensing arrangements. There is a risk in these situations that no license will be available or that a license will not be available on reasonable terms. Alternatively, we may decide to litigate such claims or to design around the technology. These actions could be costly and would divert the efforts and attention of our management and technical personnel. As a result, any infringement claims by third parties or claims for indemnification by customers resulting from infringement claims, whether or not proven to be true, may harm our business and prospects.

INDEBTEDNESS

We have a significant amount of indebtedness outstanding, which limits our operating flexibility, and could adversely affect our operations and financial results and prevent us from fulfilling our obligations.

As of September 25, 2021, we had approximately $3.05 billion aggregate principal of indebtedness outstanding (exclusive of additional funds that would be available to draw under our revolver and any funds that we may draw under our accounts

receivable securitization program). We also have other contractual obligations and deferred tax liabilities, which as of September 25, 2021, are described under "Notes to Consolidated Financial Statements — Income Taxes, and Non-cancelable Purchase Commitments." This significant level of indebtedness and our other obligations may:

- make it more difficult for us to satisfy our obligations with respect to our outstanding indebtedness;
- increase our vulnerability to general adverse economic and industry conditions, including increases in interest rates;
- require us to dedicate a substantial portion of our cash flow from operations to interest and principal payments on our indebtedness, which would reduce the availability of our cash flow to fund working capital, capital expenditures, expansion efforts, strategic transactions and other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and the markets in which we participate;
- place us at a competitive disadvantage compared to our competitors that have less debt; and
- limit our ability to borrow additional funds for working capital, capital expenditures, expansion efforts, strategic transactions or other general corporate purposes.

In addition, the terms of our financing obligations contain certain covenants that restrict our ability, and that of our subsidiaries, to engage in certain transactions and may impair our ability to respond to changing business and economic conditions, including, among other things, limitations on our ability to:

- incur indebtedness or issue certain preferred equity;
- pay dividends, repurchase our common stock, or make other distributions or restricted payments;
- make certain investments;
- agree to payment restrictions affecting the restricted subsidiaries;
- sell or otherwise transfer or dispose of assets, including equity interests of our subsidiaries;
- enter into transactions with our affiliates;
- create liens;
- designate our subsidiaries as unrestricted subsidiaries;
- consolidate, merge or sell substantially all of our assets; and
- use the proceeds of permitted sales of our assets.

Our amended and restated credit facilities also require us to satisfy certain financial covenants. Our ability to comply with these provisions may be affected by general economic conditions, political decisions, industry conditions and other events beyond our control. Our failure to comply with the covenants contained in our amended and restated credit facilities, including financial covenants, could result in an event of default, which could materially and adversely affect our results of operations and financial condition.

If there were an event of default under one of our debt instruments or a change of control, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately and may be cross-defaulted to other debt, including our outstanding notes. Our assets or cash flow may not be sufficient to fully repay borrowings under our outstanding debt instruments if accelerated upon an event of default or a change of control, and there is no guarantee that we would be able to repay, refinance or restructure the payments on such debt. See "Management's Discussion and Analysis of Financial Condition and Results of Operations-Liquidity and Capital Resources."

We may not be able to generate sufficient cash flow to service all of our indebtedness and other obligations.

Our ability to make payments on and to refinance our indebtedness and to fund planned capital expenditures, strategic transactions and expansion efforts will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. Our business may not be able to generate sufficient cash flow from operations, and we cannot assure that future borrowings will be available to us in amounts sufficient to enable us to pay our indebtedness as such indebtedness matures and to fund our other liquidity needs. If this occurs, we will need to refinance all or a portion of our indebtedness on or before maturity, and there can be no assurance that we will be able to refinance any of our indebtedness on commercially reasonable terms, or at all. We may need to adopt one or more alternatives, such as reducing or delaying planned expenses and capital expenditures, selling assets, restructuring debt, or obtaining additional equity or debt financing. These alternative strategies may not be affected on satisfactory terms, if at all. Our ability to refinance our indebtedness or obtain additional financing, or to do so on commercially reasonable terms, will depend on, among other things, our financial condition at the time, restrictions in agreements governing our indebtedness, and other factors, including the condition of the financial markets and the markets in which we compete. If we do not generate sufficient cash flow from operations, and additional borrowings, refinancings or proceeds from asset sales are not available to us, we may not have sufficient cash to enable us to meet all of our obligations.

A significant portion of our indebtedness is subject to floating interest rates, which may expose us to higher interest payments.

A significant portion of our indebtedness is subject to floating interest rates, which makes us more vulnerable in the event of adverse economic conditions, increases in prevailing interest rates, or a downturn in our business. As of September 25, 2021, approximately $1.6 billion aggregate principal of our indebtedness, which represented the outstanding principal under our amended and restated credit facilities and asset securitization agreement, was subject to floating interest rates. We currently have limited hedging arrangements in place to mitigate the impact of higher interest rates, including an interest rate swap agreement, which expires on December 17, 2023. We cannot assure that we would be able to extend this hedge at an attractive price and terms.

The proposed discontinuation or replacement of LIBOR would require us to amend certain agreements and may otherwise adversely affect our business.

The UK Financial Conduct Authority announced in 2017 that it intends to phase out LIBOR. It is currently anticipated that LIBOR will be completely phased out by June 30, 2023. Changes in the method of calculating LIBOR, or the replacement of LIBOR with an alternative rate or benchmark, may adversely affect interest rates and result in higher borrowing costs. This could materially and adversely affect our results of operations, cash flows and liquidity. If changes are made to the method of calculating LIBOR or LIBOR ceases to exist, we may need to amend certain contracts, and we cannot predict what alternative rate or benchmark would be negotiated. This may result in an increase to our interest expense.

GENERAL RISK FACTORS

Provisions in our charter, bylaws, and indebtedness may have the effect of discouraging advantageous offers for our business or common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

Our charter, bylaws, and the provisions of the Delaware General Corporation Law include provisions that may have the effect of discouraging or preventing a change of control. Our indebtedness also contains provisions which either accelerate or require us to offer to repurchase the indebtedness at a premium upon a change of control. These provisions could limit the price that our stockholders might receive in the future for shares of our common stock.

Our stock price is volatile.

The market price of our common stock has been, and may continue to be, highly volatile. We believe that a variety of factors could cause the price of our common stock to fluctuate, perhaps substantially, including:

- new, or changes in, recommendations, guidelines or studies that could affect the use of our products;
- announcements and rumors of developments related to our business, including changes in reimbursement rates or regulatory requirements, proposed and completed acquisitions, or the industry in which we compete;
- published studies and reports relating to the comparative efficacy of products and markets in which we participate;
- quarterly fluctuations in our actual or anticipated operating results and order levels;
- general conditions in the U.S. or worldwide economy;
- our stock repurchase program;
- announcements of technological innovations;
- new products or product enhancements by us or our competitors;
- developments in patents or other intellectual property rights and litigation;
- developments in relationships with our customers and suppliers;
- the implementation of healthcare reform legislation and the adoption of additional reform legislation in the future; and
- the success or lack of success of integrating our acquisitions.

In addition, the stock market in general and the markets for shares of “high-tech” and life sciences companies, have historically experienced extreme price fluctuations which have often been unrelated to the operating performance of affected companies. Any such fluctuations in the future could adversely affect the market price of our common stock, and the market price of our common stock may decline.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We own and lease real property to support our business, including manufacturing, marketing, research and development, logistical support and administration. The following lists those properties that we own or lease that we believe are material to our business. We believe that we have adequate space for our anticipated needs and that suitable additional space will be available at commercially reasonable prices as needed.

Material Properties Owned:	Primary Use
Newark, DE	DirectRay digital detector research and development and plate manufacturing operations
Manchester, UK	Administrative and supply chain operations
Londonderry, NH	Manufacturing operations
San Diego, CA	Diagnostics headquarters, including administrative and manufacturing operations
San Diego, CA	Diagnostics research and development, administrative and manufacturing operations
Warstein, Germany	Manufacturing operations, research and development and administrative functions

Material Properties Leased:	Primary Use	Lease Expiration (fiscal year)	Renewals
Danbury, CT	Manufacturing facility	2024	None
Danbury, CT	Manufacturing operations and research and development	2024	None
Marlborough, MA	Headquarters, including research and development, manufacturing and distribution operations	2025	2, five-yr. periods
Marlborough, MA	Manufacturing operations	2024	1, five-yr. period
Alajuela, Costa Rica	Manufacturing facility	2028	2, five-yr. periods
Manchester, England	Manufacturing operations and research and development	2035	None
Ougrée, Belgium	Manufacturing operations and research and development	2032	None

We also lease various administrative and customer support centers throughout the world including in Brussels, Belgium, Kerpen, Germany, Madrid, Spain, Beijing, China, Wiesbaden, Germany, Aix-en-Provence, France, and Espoo, Finland, and also maintain specialized research and development and manufacturing operations at various additional locations.

Item 3. Legal Proceedings

For a discussion of legal matters as of September 25, 2021, please see Note 14 to our consolidated financial statements entitled “Litigation and Related Matters,” which is incorporated by reference into this item.

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

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

Market Information. Our common stock is traded on the Nasdaq Global Select Market under the symbol “HOLX.”

Number of Holders. As of November 11, 2021, there were approximately 881 holders of record of our common stock, including multiple beneficial holders at depositories, banks and brokers listed as a single holder in the street name of each respective depository, bank or broker.

Dividend Policy. We have never declared or paid cash dividends on our capital stock, and we currently have no plans to do so. Our current policy is to retain all of our earnings to finance future growth (including acquisitions), pay down our existing indebtedness and repurchase our common stock. The existing covenants under certain of our credit facilities also place limits on our ability to issue dividends and repurchase stock.

Recent Sales of Unregistered Securities. We did not sell unregistered securities during the fourth quarter of fiscal 2021.

Issuer's Purchases of Equity Securities

Period of Repurchase	Total Number of Shares Purchased (#) (1)	Average Price Paid Per Share ($) (1)	Total Number of Shares Purchased As Part of Publicly Announced Plans or Programs (#) (2)	Average Price Paid Per Share As Part of Publicly Announced Plans or Programs ($) (2)	Maximum Number (or Approximate Dollar Value) of Shares That May Yet Be Purchased Under Our Programs (in millions) ($) (2)
June 27, 2021 – July 24, 2021	9,916	$ 67.99	—	$ —	$ 691.6
July 25, 2021 – August 21, 2021	295	75.04	—	—	691.6
August 22, 2021 – September 25, 2021	314	79.51	—	—	691.6
Total	10,525	$ 68.53	—	$ —	$ 691.6

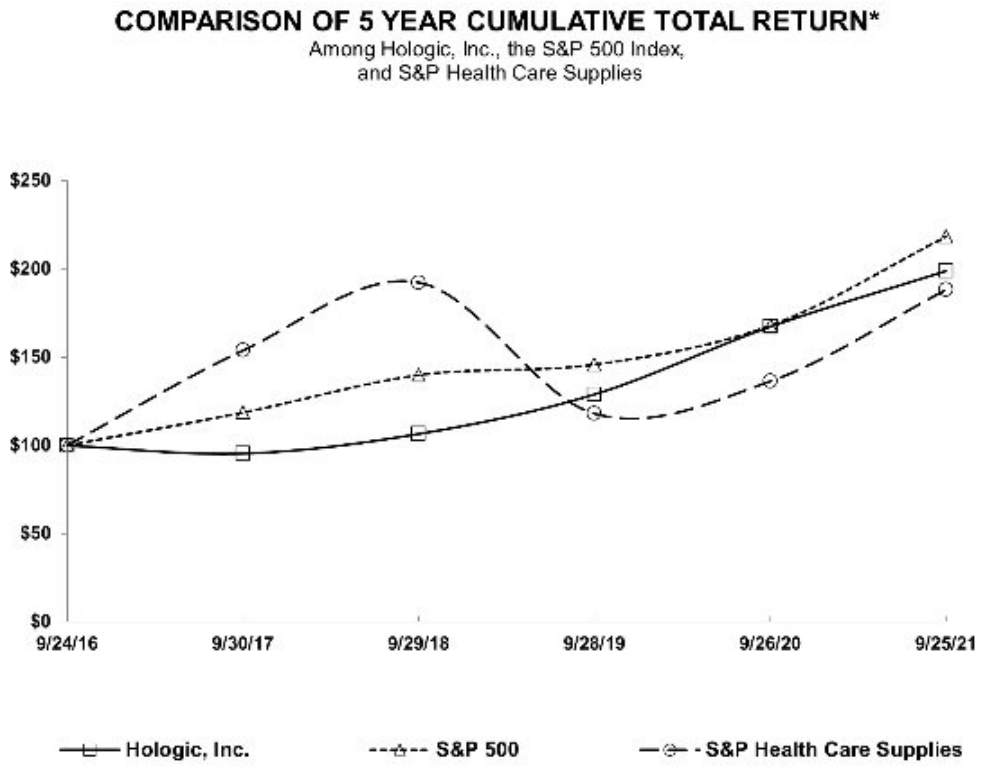
(1) For the majority of restricted stock units granted, the number of shares issued on the date that the restricted stock units vest is net of the minimum statutory tax withholding requirements that we pay in cash to the appropriate tax authorities on behalf of our employees. These repurchases of our common stock were to cover employee income tax withholding obligations in connection with the vesting of restricted stock units under our equity incentive plans.

(2) On December 9, 2020, the Board of Directors authorized a new share repurchase plan to repurchase up to $1.0 billion of the Company's outstanding common stock, effective December 11, 2020. In connection with this authorization, the prior plan was terminated.

Stock Performance Graph

The following information shall not be deemed to be "filed" with the SEC nor shall the information be incorporated by reference into any future filings under the Securities Act, except to the extent that we specifically incorporate it by reference into a document filed under the Securities Act or the Exchange Act.

The following graph compares cumulative total shareholder return on our common stock since September 24, 2016 with the cumulative total return of the Standard & Poor's Health Care Supplies Index. This graph assumes the investment of $100 on September 24, 2016 in our common stock, and the S&P Health Care Supplies Index. Measurement points are the last trading day of each respective fiscal year.



*$100 invested on 9/24/16 in stock or 9/30/16 index, including reinvestment of dividends.
Indexes calculated on month-end basis.

Item 6. Reserved

Not applicable.

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

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements, the information described under the caption "Risk Factors" in Part I, Item 1A of this Annual Report and our Special Note Regarding Forward-Looking Statements at the outset of this Annual Report.

OVERVIEW

We are a developer, manufacturer and supplier of premium diagnostics products, medical imaging systems and surgical products focused on women's health and well-being through early detection and treatment. We sell and service our products through a combination of direct sales and service personnel and a network of independent distributors and sales representatives. We operate in four segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health. Until December 30, 2019, our product portfolio included aesthetic and medical treatments systems sold by our former Medical Aesthetic business. We completed the sale of our Medical Aesthetics segment on December 30, 2019 (the first day of the second quarter of fiscal 2020).

Through our Diagnostics segment, we offer a wide range of diagnostic products, which are used primarily to aid in the screening and diagnosis of human diseases. Our primary Diagnostics products include our molecular diagnostic assays, which run on our advanced instrumentation systems (Panther, Panther Fusion and Tigris), our ThinPrep cytology system, and the Rapid Fetal Fibronectin Test. Our Aptima family of molecular diagnostic assays is used to detect, among other things, the infectious microorganisms that cause common sexually transmitted diseases, or STDs, such as: chlamydia and gonorrhea, or GTGC; certain high-risk strains of human papillomavirus, or HPV; and *Trichomonas vaginalis*, the parasite that causes trichomoniasis; Mycoplasma genitalium; and Herpes simplex viruses 1 and 2. We also offer viral load tests for HIV, Hepatitis C and Hepatitis B for use on our Panther instrument system. Our assay portfolio also includes diagnostic tests for a range of acute respiratory infections, including SARS-CoV-2, as well as a test for the detection of Group B Streptococcus, or GBS, that are run on the Panther Fusion system, a field upgradeable instrument addition to the base Panther system. In response to the COVID-19 pandemic, we developed and launched the Aptima SARS-CoV-2 assay (which runs on our standard Panther system) and the Panther Fusion SARS-CoV-2 assay (which runs on our Panther Fusion system). The Panther Fusion SARS-CoV-2 assay and the Aptima SARS-CoV-2 assay were launched at the end of our second quarter and in the third quarter of fiscal 2020, respectively. The ThinPrep System is primarily used in cytology applications, such as cervical cancer screening, and the Rapid Fetal Fibronectin Test assists physicians in assessing the risk of pre-term birth.

Our Breast Health segment offers a broad portfolio of solutions for breast cancer care primarily in the areas of radiology, breast surgery, pathology and treatment. These solutions include 3D digital mammography systems, image analytics software utilizing artificial intelligence, reading workstations, ultrasound imaging, minimally invasive breast biopsy guidance systems, breast biopsy site markers, localization, specimen radiology, connectivity solutions and breast conserving surgery products. Our most advanced breast imaging platforms, Selenia Dimensions and 3Dimensions, utilize tomosynthesis to produce 3D images that show multiple contiguous slice images of the breast, which we refer to as the Genius 3D Mammography exam.

Our GYN Surgical products include our NovaSure Endometrial Ablation System, or NovaSure, and our MyoSure Hysteroscopic Tissue Removal System, or MyoSure, as well as our Fluent Fluid Management system, or Fluent. The NovaSure portfolio is comprised of the NovaSure CLASSIC and NovaSure ADVANCED devices and involves a trans-cervical procedure for the treatment of abnormal uterine bleeding. The MyoSure suite of devices offers four options to provide incision-less removal of fibroids, polyps, and other pathology within the uterus. The Fluent system is a fluid management system that provides liquid distention during diagnostic and operative hysteroscopic procedures.

Our Skeletal Health segment's products includes the Horizon DXA, a dual energy x-ray system, which evaluates bone density and performs body composition assessments, and the Fluoroscan Insight FD mini C-arm, which assists in performing minimally invasive orthopedic surgical procedures on a patient's extremities, such as the hand, wrist, knee, foot, and ankle.

Our Medical Aesthetics segment consisted of a portfolio of aesthetic treatment systems. We completed the sale of our Medical Aesthetics business on December 30, 2019.

Unless the context otherwise requires, references to we, us, Hologic or our company refer to Hologic, Inc. and its consolidated subsidiaries.

COVID-19 Considerations

The global COVID-19 pandemic has created significant volatility, uncertainty, and economic disruption in the markets we sell our products into, primarily the U.S., Europe and Asia-Pacific. Starting in the second quarter of fiscal 2020, the spread of COVID-19 negatively impacted business and healthcare activity globally. In particular, due to government measures, elective

procedures and exams were delayed or cancelled, there were significant reductions in physician office visits, and hospitals postponed or canceled capital purchases as well as limited or eliminated services; however, in the second half of the third quarter of fiscal 2020, we started to see a recovery of elective procedures and exams as economies were opened back up and restrictions eased, which has continued through the fourth quarter of fiscal 2021. The reductions in testing and procedures had a negative impact on our operating results and cash flows in fiscal 2020, however, the impact of the commercial release of our COVID-19 assays more than offset those negative impacts as we generated significant revenue from the sales of these assays starting in the third quarter of fiscal 2020 through the fourth quarter of fiscal 2021.

While our results of operations and cash flows since the third quarter of fiscal 2020 have been positively impacted by the sale of our COVID-19 assays as well the continued recovery of our other primary product lines and businesses to pre-COVID levels, the COVID-19 pandemic could have an adverse impact on our operating results, cash flows and financial condition in the future. The factors that could create such adverse impact include: reduced demand for COVID-19 testing; competition from existing and new COVID-19 testing technologies and products as well as the timing and effectiveness of distributing vaccines; the severity and duration of the COVID-19 pandemic; the resurgence of COVID-19 infections; the emergence of new COVID strain variants; the COVID-19 pandemic's impact on the U.S. and international healthcare systems, the U.S. economy and worldwide economy; and the timing, scope and effectiveness of U.S. and international governmental, regulatory, fiscal, monetary and public health responses to the COVID-19 pandemic and associated economic disruptions. We expect that as the current COVID-19 pandemic subsides, there may be a significantly reduced demand for ongoing testing, and thus, for our COVID-19 assays. As expected in the third quarter of fiscal 2021, revenues generated from the sale of its COVID-19 assays decreased significantly in the U.S. compared to the prior year period and the first and second quarters of fiscal 2021 as the population of vaccinated people continues to grow in the U.S. In the fourth quarter of fiscal 2021, COVID-19 assay revenues increased compared to the preceding quarter primarily due to the impact of the delta strain of COVID-19 resulting in higher demand for testing. However, COVID-19 assay revenues decreased compared to the corresponding prior year period.

In response to the negative impact of COVID-19 on our business, in April 2020, we initiated cost-cutting measures, which included not only reducing discretionary and variable spend, such as travel, marketing programs and the use of contractors, consultants and temporary help, but we also implemented employee furloughs, salary cuts primarily in the U.S., reduced hours and in certain instances, effected employee terminations. Further in April 2020, we shut down certain manufacturing facilities temporarily and implemented reduced work-week schedules in response to lower near-term demand for many of our products. As of the end of the third quarter of fiscal 2020, substantially all of the Company's employee cost-cutting measures ceased During fiscal 2021 the majority of the impacted manufacturing facilities were back to pre-COVID levels.

We have also taken and continue to take measures to ensure the safety of our employees and to comply with governmental orders. These measures could require that our employees continue to work remotely or otherwise refrain from reporting to their normal workplace for extended periods of time, which in turn could result in a decrease in our commercial and marketing activities. In addition, complying with government and customer vaccine mandates that apply to us may lead to employee attrition, disrupt our workforce and result in additional costs associated with implementation and on-going compliance, which could have an adverse impact on our operating results, cash flows and financial condition.

Acquisitions and Disposition

The following sets forth a description of certain of our acquisitions and dispositions in our last two fiscal years:

Mobidiag

On June 17, 2021, we completed the acquisition of Mobidiag Oy, or Mobidiag, for a purchase price of $729.6 million. Mobidiag, located in Finland, manufactures molecular diagnostic solutions for gastrointestinal infections, antimicrobial resistance management and other infections. This acquisition expanded our molecular diagnostics portfolio into the near-patient testing market. Based on our preliminary valuation, we allocated $399.9 million of the purchase price to the value of intangible assets and $432.6 million to goodwill. The remaining $102.9 million of the purchase price was allocated to the net acquired tangible assets and liabilities. The allocation of the purchase price is preliminary as we continue to gather information supporting the acquired assets and liabilities. Mobidiag's results of operations are reported in our Diagnostics segment.

Biotheranostics

On February 22, 2021, we completed the acquisition of Biotheranostics, Inc., or Biotheranostics, for a purchase price of $231.3 million. Biotheranostics, located in San Diego, California, manufactures molecular diagnostic tests for breast and metastatic cancers and performs lab testing procedures at its facility. Based on our preliminary valuation, we allocated $162.4 million of the purchase price to the value of intangible assets and $80.9 million to goodwill. The remaining $12.0 million of the purchase price was allocated to the net acquired tangible assets and liabilities. The allocation of the purchase price is

preliminary as we continue to gather information supporting the acquired assets and liabilities. Biotheranostics' results of operations are included in our Diagnostic segment and its revenues are reported within service and other revenues in our consolidated statements of operations.

Diagenode

On March 1, 2021, we completed the acquisition of Diagenode SA, or Diagenode, for a purchase price of $155.1 million. Diagenode, located in Belgium, is a developer and manufacturer of molecular diagnostic assays based on PCR technology to detect infectious diseases of bacterial, viral or parasite origin. Based on our preliminary valuation, we allocated $79.0 million of the purchase price to the value of intangible assets and $83.5 million to goodwill. The remaining $7.4 million of the purchase price was allocated to the net acquired tangible assets and liabilities. The allocation of the purchase price is preliminary as we continue to gather information supporting the acquired assets and liabilities. Diagenode's results of operations are included in our Diagnostics segment.

Somatex Medical Technologies

On December 30, 2020, we completed the acquisition of Somatex Medical Technologies GmbH, or Somatex, for a purchase price of $62.9 million. Somatex, located in Germany, is a manufacturer of biopsy site markers, including the Tumark product line of tissue markers, which were distributed by the Company in the U.S. prior to the acquisition. Based on our preliminary valuation, we allocated $40.1 million of the purchase price to the value of intangible assets and $32.4 million to goodwill. The remaining $9.6 million of the purchase price was allocated to the net acquired tangible assets and liabilities. The allocation of the purchase price is preliminary as we continue to gather information supporting the acquired assets and liabilities. Somatex' results of operations are included in our Breast Health segment.

NXC Imaging

On September 28, 2020, we completed the acquisition of assets from NXC Imaging, for a purchase price of $5.6 million. NXC Imaging was a long-standing distributor of our Breast and Skeletal products in the U.S.

Acessa Health

On August 23, 2020, we completed the acquisition of Acessa Health, Inc., or Acessa for a purchase price of $162.0 million, which included contingent consideration and was estimated at $81.8 million as of the measurement date. Acessa, located in Austin, Texas, manufactures and markets its Acessa ProVu system, a laparoscopic radio frequency ablation system for use in treatment of uterine fibroids. Acessa's results of operations are included in our GYN Surgical segment. The contingent consideration is based on annual incremental revenue growth over a three-year period ending annually in December. The contingent consideration is payable after each annual measurement period. We remeasure the contingent consideration liability on a quarterly basis, and for fiscal year 2021 we recorded a gain of $6.7 million to decrease the liability to its fair value. The reduction in fair value was primarily due to a decrease in forecasted revenues over the measurement period, partially offset by lower discount rates and accretion of the liability. The liability was recorded at $75.1 million at September 25, 2021.

Health Beacons

On February 3, 2020, we completed the acquisition of Health Beacons, Inc., or Health Beacons, for a purchase price of $19.7 million. Health Beacons manufactures the LOCalizer product. Health Beacon's results of operations are reported in our Breast Health segment.

Alpha Imaging

On December 30, 2019, we completed the acquisition of assets from Alpha Imaging, LLC, or Alpha Imaging, for a purchase price of $18.0 million. Alpha Imaging was a long-standing distributor of our Breast and Skeletal products in the U.S.

SuperSonic Imagine

On August 1, 2019, we acquired approximately 46% of the outstanding shares of SuperSonic Imagine SA, or SSI, which is headquartered in France. SSI specializes in ultrasound imaging and designs, develops and markets an ultrasound platform used in the non-invasive care path for the characterization of breast, liver or prostate diseases. We initially accounted for this investment as an equity method investment.

On November 21, 2019, we acquired an additional 7.6 million common shares of SSI for $12.6 million. As a result, we owned approximately 78% of the outstanding shares of SSI at November 21, 2019 and controlled SSI's voting interest and

operations. We performed purchase accounting as of November 21, 2019 and beginning on that date the financial results of SSI are included within our consolidated financial statements within our Breast Health segment. We remeasured the initial investment of 46% of the outstanding shares of SSI to its fair value at the acquisition date, resulting in a gain of $3.2 million in Other income (expense), net in the first quarter of fiscal 2020.

During the third quarter of fiscal 2021, we acquired the remaining 4.8 million shares outstanding of SSI for $8.5 million. As of September 25, 2021, we owned 100% of SSI. Accordingly we recorded an adjustment to our net income for the noncontrolling interest we did not own of $1.8 million and $4.7 million (both of which were losses) for the years ended September 25, 2021 and September 26, 2020, respectively.

Disposition - Medical Aesthetics

On December 30, 2019, we completed the sale of our Medical Aesthetics. At the closing, we received cash proceeds of $153.4 million. The sales price was finalized in the fourth quarter of fiscal 2020, and we repaid $3.4 million, resulting in a final sales price of $150.0 million. As a result of the sale, we recorded a $30.2 million impairment charge in the first quarter of fiscal 2020 to record the asset group at fair value less costs to dispose as it met the assets held-for-sale criteria. For additional information, see Note 15 to our consolidated financial statements included herein. Following the sale of our Medical Aesthetics business, we have not generated any further product revenue related to this business, although additional expenses have been and will be incurred primarily in connection with the indemnification of legal and tax matters that existed as of the date of disposition. In addition, we agreed to provide transition services for a period of up to 15 months, which ended in March 2021.

RESULTS OF OPERATIONS

Fiscal Year Ended September 25, 2021 Compared to Fiscal Year Ended September 26, 2020

Product Revenues

	Fiscal Years Ended					
	September 25, 2021		September 26, 2020		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Product Revenues						
Diagnostics	$ 3,596.1	63.9 %	$ 2,073.8	54.9 %	$ 1,522.3	73.4 %
Breast Health	815.1	14.5 %	672.1	17.8 %	143.0	21.3 %
GYN Surgical	486.8	8.6 %	374.9	9.9 %	111.9	29.8 %
Skeletal Health	69.3	1.2 %	56.5	1.5 %	12.8	22.7 %
Medical Aesthetics	—	— %	49.7	1.3 %	(49.7)	(100.0)%
	$ 4,967.3	88.2 %	$ 3,227.0	85.4 %	$ 1,740.3	53.9 %

We generated a 53.9% increase in product revenues in fiscal 2021 compared to fiscal 2020 primarily due to the increase in the Diagnostics business from a full year of sales of our two COVID-19 assays, one of which was launched near the end of the second quarter of fiscal 2020 and the other in the third quarter of fiscal 2020. Excluding sales of our COVID-19 assays, product revenues in the prior year period were adversely impacted by the COVID-19 pandemic, and product revenues in the current year periods have increased across our divisions. We primarily attribute this increase to recovery of elective procedures and exams, including associated capital equipment spending, as economies were opened back up and restrictions eased, and to a lesser extent a portion of the increase was driven by our current year acquisitions. The increase in product revenues in fiscal 2021 compared to fiscal 2020 was partially offset by no revenues from the Medical Aesthetics business in the current fiscal year as we disposed of this business segment on December 30, 2019, the beginning of our second quarter of fiscal 2020.

Diagnostics product revenues increased 73.4% in fiscal 2021 compared to fiscal 2020 primarily due to increases in Molecular Diagnostics of $1,457.7 million, Cytology and Perinatal of $58.3 million, and an increase in blood-screening of $6.3 million. While we divested our blood screening business in the second quarter of fiscal 2017, we continue to provide long-term access to Panther instrumentation and certain supplies to the purchaser of that business. Molecular Diagnostics product revenue was $3.1 billion in fiscal 2021 compared to $1.6 billion in fiscal 2020. The increase was primarily attributable to revenues of $2.16 billion in fiscal 2021 compared to $929.3 million in fiscal 2020 from our two SARS-CoV-2 assays (primarily the Aptima SARS-CoV-2 assay and to a lesser extent the Panther Fusion SARS-CoV-2 assay), an increase in Panther and Panther Fusion instrument sales due to demand for increased testing capacity for COVID-19, and an increase of $150.2 million in Aptima assays sales, which primarily consist of our CTGC, HPV and Trichomonas vaginalis assays, and related collection kits due to a return to pre-COVID testing levels. Prior fiscal year sales of these assays were adversely impacted by the COVID-19 pandemic and related lockdowns across the globe. In addition, we had an increase of $9.4 million in worldwide sales of our virology products in the current fiscal year. We expect that sales of our COVID-19 assays will decline significantly in fiscal 2022 compared to the current fiscal year primarily due to the continued distribution of vaccines. Cytology & Perinatal product revenue increased $58.3 million in the current fiscal year primarily due to higher ThinPrep test volumes, which we primarily attribute to the recovery of wellness office visits that had previously been delayed or cancelled in the prior year in response to the COVID-19 pandemic, partially offset by lower average selling prices and lower Perinatal product volumes. The inclusion of Diagenode and Mobidiag contributed $29.9 million of product revenue in the current fiscal year. We also experienced an increase in revenue from the favorable foreign currency exchange impact of the weakened U.S. dollar against a number of currencies in current fiscal year.

Breast Health product revenues increased 21.3% in fiscal 2021 compared to fiscal 2020 as product revenues in the prior fiscal year were adversely impacted by the COVID-19 pandemic and related lockdowns across the globe. These increases were primarily due to an increase in sales volume of our digital mammography systems and related workflow products (primarily Intelligent 2D, Clarity HD and SmartCurve), Affirm Prone breast biopsy tables, and our interventional breast solutions products, primarily Eviva, ATEC, and Brevera disposables (relaunched in the fourth quarter of fiscal 2020). In addition, we had higher sales of our breast conserving surgery products and ultrasound imaging products. We primarily attribute the increase in revenues to hospitals and imaging centers purchasing capital equipment following a significant decline in such spending during fiscal 2020 and to the recovery of elective procedures and exams as elective procedures and wellness visits that had previously been delayed or cancelled in the prior year in response to the COVID-19 pandemic. We also experienced an increase in revenue from the favorable foreign currency exchange impact of the weakened U.S. dollar against a number of currencies in the current year.

GYN Surgical product revenues increased 29.8% in fiscal 2021 compared to fiscal 2020, primarily due to the recovery of elective medical visits and procedures that had previously been delayed or cancelled in response to the COVID-19 pandemic and to a lesser extent healthcare providers increasing their inventory levels. These revenue increases were primarily due to increases in the sales volumes of MyoSure systems, NovaSure systems, Fluent Fluid Management systems and to a lesser extent sales of ProVu systems acquired in the Acessa acquisition in the fourth quarter of fiscal 2020. We also experienced an increase in revenue from the favorable foreign currency exchange impact of the weakened U.S. dollar against a number of currencies in the current year.

Skeletal Health product revenues increased 22.7% in fiscal 2021 compared to fiscal 2020 primarily due to an increase in sales volume of both our Insight FD mini C-arm and Horizon DXA systems. We primarily attribute this increase to the increase in wellness visits and healthcare screenings in 2021 as a result of the ongoing recovery from the COVID-19 pandemic.

We divested the Medical Aesthetics segment on December 30, 2019, the beginning of our second quarter of fiscal 2020. We have generated no revenue from the segment since that date.

Product revenues by geography as a percentage of total revenues were as follows:

	Years ended	
	September 25, 2021	September 26, 2020
United States	68.3 %	75.3 %
Europe	21.9 %	15.5 %
Asia-Pacific	6.7 %	6.0 %
Rest of world	3.1 %	3.2 %
	100.0 %	100.0 %

While our product revenue increased in all our geographic regions, our largest proportionate increase was in Europe, which we primarily attribute to strong sales of our SARS-CoV-2 assays in Europe, growth in our Aptima assays in Europe as we expanded our customer base, increased sales from the adoption of co-testing for cervical cancer screening in Germany and to a lesser extent in the UK, as well as the inclusion of revenue from Diagenode, Mobidiag and Somatex, which are predominantly in Europe. Asia-Pacific product revenue as a percentage of total product revenue increased primarily due to an increase in sales of our SARS-CoV-2 assays in the region, an increase in sales of our mammography systems and growth in ThinPrep and Molecular Diagnostics primarily due to the recovery of wellness office visits that had previously been delayed or cancelled in response to the COVID-19 pandemic.

Service and Other Revenues

	Years Ended					
	September 25, 2021		September 26, 2020		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Service and Other Revenues	$ 665.0	11.8 %	$ 549.4	14.5 %	$ 115.6	21.0 %

Service and other revenues are primarily comprised of revenue generated from our field service organization to provide ongoing service, installation and repair of our products. The majority of these revenues are generated within our Breast Health segment. Service and other revenues increased 21.0% in fiscal 2021 compared to fiscal 2020 primarily due to an increase in Breast Health service contract revenue as the Breast Health business continued to convert a high percentage of our installed base of digital mammography systems to service contracts upon expiration of the warranty period, as well as additions from our distributor acquisitions. We also experienced an increase in spare parts revenue in the current fiscal year for services that had previously been delayed or cancelled due to the COVID-19 pandemic. In our Diagnostics business, we had additional royalty revenue in the current fiscal year of $34.4 million from Grifols related to licensing our intellectual property to our COVID-19 assays for their sale in Spain. In addition, the inclusion of Biotheranostics added $33.7 million in the current fiscal year. These increases were partially offset by the sale of the Medical Aesthetics business which contributed $15.6 million of service revenue in the prior fiscal year.

Cost of Product Revenues

	Years Ended							
	September 25, 2021		September 26, 2020		Change	
	Amount	% of Product Sales	Amount	% of Product Sales	Amount	%
Cost of Product Revenues	$ 1,205.1	24.3 %	$ 953.7	29.6 %	$ 251.4	26.4 %
Amortization of Acquired Intangible Assets	276.7	5.5 %	253.2	7.8 %	23.5	9.3 %
Impairment of Intangible Assets and Equipment	—	— %	25.8	0.8 %	(25.8)	(100.0)%
	$ 1,481.8	29.8 %	$ 1,232.7	38.2 %	$ 249.1	20.2 %

Product gross margin was 70.2% in fiscal 2021 compared to 61.8% in fiscal 2020.

Cost of Product Revenues. The cost of product revenues as a percentage of product revenues was 24.3% in the current year compared to 29.6% in the prior year. Cost of product revenues as a percentage of revenue decreased in fiscal 2021 primarily due to sales of our SARS-CoV-2 assays, which have higher gross margins compared to our other Diagnostic products, and comprised 43.5% and 28.8% of total product revenue in fiscal 2021 and fiscal 2020, respectively. Also benefiting gross margin in the current year were higher sales volumes from our other businesses and product lines as they have continued to recover from the COVID-19 pandemic as economies opened back up and restrictions eased and the disposition of Medical Aesthetics, which had lower gross margins compared to our remaining businesses. Partially offsetting these decreases were higher field service costs for our expanded instrument installed base for the Diagnostics business and higher freight costs.

Diagnostics' product costs as a percentage of revenue decreased in fiscal 2021 compared to fiscal 2020 primarily due to higher sales of our SARS-CoV-2 assays and higher overall production of our Aptima assays and ThinPrep Pap Test reducing fixed overhead on a unit basis. These increases were partially offset by increased international freight costs, increased inventory reserves, higher field service costs for our expanded instrument installed base, an increase in amortization of placed instruments, and a slight decline in average selling prices partially driven by geographic mix.

Breast Health's product costs as a percentage of revenue decreased in fiscal 2021 compared to fiscal 2020 primarily due to the impact of the COVID-19 pandemic in the prior year, which resulted in decreased sales volume across the majority of our product lines, period costs for temporary facility shut-downs and reduced manufacturing utilization and higher inventory reserves. In the current fiscal year, sales volumes have increased for our higher margin 3Dimensions systems, higher-margin workflow products (primarily consisting of Intelligent 2D, Clarity HD and SmartCurve), and our breast biopsy and breast conserving surgery disposable products. Increased sales also improved manufacturing utilization.

GYN Surgical's product costs as a percentage of revenue decreased in fiscal 2021 compared to fiscal 2020 primarily due to the impact of the COVID-19 pandemic in the prior year, which resulted in significant decreases in sales volume of our NovaSure and MyoSure devices, period costs for the temporary shutdown of our manufacturing facility and reduced manufacturing utilization. In the current fiscal year, the Surgical business has recovered to pre-COVID levels which significantly improved manufacturing utilization and margins, partially offset by the product mix of higher volumes of lower margin products, including our Fluent Fluid Management systems and Acessa ProVu systems.

Skeletal Health's product costs as a percentage of revenue decreased in fiscal 2021 compared to fiscal 2020 due to higher sales volume of both our Insight FD mini C-arm and Horizon DXA systems and lower inventory reserves in the current year.

We divested the Medical Aesthetics segment on December 30, 2019, the beginning of our second quarter of fiscal 2020.

Amortization of Acquired Intangible Assets. Amortization of intangible assets included in cost of product revenues relates to acquired developed technology, which is generally amortized over its estimated useful life of between 5 and 15 years using a straight-line method or, if reliably determinable, based on the pattern in which the economic benefits of the assets are expected to be consumed. Amortization expense increased in fiscal 2021 compared to fiscal 2020 primarily due to intangible assets acquired in the Mobidiag, Acessa, Biotheranostics, Diagenode and Somatex acquisitions, partially offset by lower amortization of intangible assets acquired in the Cytyc acquisition which reduces over time.

Impairment of Intangible Assets and Equipment. As discussed in Note 2 to the consolidated financial statements, we recorded an aggregate impairment charge of $30.2 million during the first quarter of fiscal 2020. The impairment charge was allocated to the Medical Aesthetics long-lived assets, of which $25.8 million was allocated to developed technology assets and written off to cost of revenues.

Cost of Service and Other Revenues

	Years Ended					
	September 25, 2021		September 26, 2020		Change	
	Amount	% of Service and Other Revenues	Amount	% of Service and Other Revenues	Amount	%
Cost of Service and Other Revenues	$ 354.7	53.3 %	$ 316.2	57.6 %	$ 38.5	12.2 %

Service and other revenues gross margin was 46.7% in fiscal 2021 compared to 42.4% in fiscal 2020. The increase in gross margin was primarily due to additional royalty revenue from Grifols related to licensing our intellectual property related to our COVID-19 assays for their sale in Spain, which has a high margin, and laboratory testing services from Biotheranostics, which has a higher gross margin than our legacy service businesses. In addition, in the current year period the Breast Health business had an increase in service contract revenue which benefited gross margin as service contract revenue has higher margins compared to revenue from spare parts, installation and training.

Operating Expenses

	Years Ended					
	September 25, 2021		September 26, 2020		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Operating Expenses						
Research and development	$ 276.3	4.9 %	$ 222.5	5.9 %	$ 53.8	24.2 %
Selling and marketing	561.2	10.0 %	484.6	12.8 %	76.6	15.8 %
General and administrative	433.2	7.7 %	355.7	9.4 %	77.5	21.8 %
Amortization of acquired intangible assets	42.2	0.7 %	39.7	1.1 %	2.5	6.3 %
Impairment of intangible assets and equipment	—	— %	4.4	0.1 %	(4.4)	(100.0)%
Contingent consideration—fair value adjustments	(6.7)	(0.1) %	0.3	— %	(7.0)	**
Restructuring and divestiture charges	9.3	0.2 %	15.3	0.4 %	(6.0)	(39.2)%
	$ 1,315.5	23.4 %	$ 1,122.5	29.7 %	$ 193.0	17.2 %

** Percentage not meaningful

Research and Development Expenses. Research and development expenses increased 24.2% in fiscal 2021 compared to fiscal 2020 primarily due to higher R&D project spend in Diagnostics, Breast Health and Surgical, the inclusion of expenses from the Mobidiag, Acessa, Biotheranostics, Diagenode and Somatex acquisitions aggregating $14.6 million, higher salary expense from increased headcount in Diagnostics, higher project and consulting spend and increased spending to implement the European Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) requirements. In the current year, we also recorded a $7.0 million charge related to the purchase of intellectual property in Breast Health that has no future alternative use. Partially offsetting these increases in the current year was the reduction of expense due to the disposition of the Medical Aesthetics business which contributed $7.3 million of expense in the prior year. In addition, we recorded a credit to research and development expenses of $11.0 million and $7.1 million in fiscal 2021 and 2020, respectively, from the Biomedical Advanced Research and Development Authority (BARDA) in connection with a grant to expand manufacturing capacity, obtain FDA approval of our SARS-CoV-2 assays and develop sampling pooling capability and other enhancements to our SARS-CoV-2 assays. At any point in time, we have a number of different research projects and clinical trials being conducted and the timing of these projects and related costs can vary from period to period.

Selling and Marketing Expenses. Selling and marketing expenses increased 15.8% in fiscal 2021 compared to fiscal 2020 primarily due inclusion of expenses from the Mobidiag, Acessa, Biotheranostics, Diagenode and Somatex acquisitions aggregating $36.3 million, an increase in commissions in Breast Health, Surgical and Diagnostics from higher revenues, and an increase in marketing initiatives and consulting spend. Partially offsetting these increases in the current year was the disposition of the Medical Aesthetics business which contributed $23.7 million of expense in the prior year, lower travel and trade show expenses in response to the COVID-19 pandemic, decreases in meeting expenses primarily related to cancelling our national sales meeting and not having an in-person RSNA conference as a result of the COVID-19 pandemic, and lower bonus expense.

General and Administrative Expenses. General and administrative expenses increased 21.8% in fiscal 2021 compared to fiscal 2020 primarily due to the inclusion of expenses from the Mobidiag, Acessa, Biotheranostics, Diagenode and Somatex acquisitions aggregating $16.4 million, increased acquisition transaction costs including $11.5 million for a transfer tax related to the Mobidiag acquisition, a $11.2 million non-income tax charge related to an ongoing non-income tax audit, higher expense from our deferred compensation plan, higher litigation and settlement costs, increased consulting spend for corporate initiatives and information system implementation projects, higher charitable donations, higher salary expenses due to an increase in headcount and the cessation of furloughs implemented in April 2020 due to the COVID-19 pandemic before the end of the prior year period, and lower credits in the current year of $3.5 million related to transition services provided to Cynosure. Partially offsetting these increases were lower stock-based compensation and bonuses, lower bad debt expense, the disposition of the Medical Aesthetics business, which contributed $5.5 million of expenses in the prior year, expenses incurred in the prior year to separate and dispose of that business, and a $3.3 million benefit due to reversal of a tax reserve.

Amortization of Acquired Intangible Assets. Amortization of intangible assets results from customer relationships, trade names, distributor relationships and business licenses related to our acquisitions. These intangible assets are generally amortized over their estimated useful lives of between 2 and 30 years using a straight-line method or, if reliably determinable, based on the pattern in which the economic benefits of the assets are expected to be consumed utilizing expected undiscounted future cash flows. Amortization expense increased 6.3% in fiscal 2021 compared to fiscal 2020 primarily due to increases from recent acquisitions, partially offset by assets from older acquisitions becoming fully amortized.

Contingent Consideration Fair Value Adjustments. In connection with the acquisition of Acessa, we are obligated to make contingent earn-out payments. The payments are based on achieving incremental revenue growth over a three-year period ending annually in December. As of the acquisition date for Acessa, we recorded a contingent consideration liability for the estimated fair value of the amount we expected to pay to the former shareholders of the acquired business. This liability is not contingent on future employment, and we recorded our estimate of the fair value of the contingent consideration liability utilizing the Monte Carlo simulation based on future revenue projections of Acessa, comparable company revenue growth rates, implied volatility and applying a risk adjusted discount rate. Increases or decreases in the fair value of contingent consideration liabilities can result from the passage of time, changes in discount rates, and changes in the timing, probabilities and amount of revenue estimates. In the current year, we recorded a gain of $6.7 million to decrease the liability to its fair value. The reduction in fair value was primarily due to a decrease in forecasted revenues over the measurement period, partially offset by a lower discount rate and accretion of the liability based on the passage of time.

Impairment of Intangible Assets and Equipment. As discussed in Note 2 to the consolidated financial statements, we recorded an aggregate impairment charge of $30.2 million during the first quarter of fiscal 2020. The impairment charge was allocated to the Medical Aesthetics long-lived assets of which $4.4 million was written off to operating expenses.

Restructuring and Divestiture Charges. We have implemented various cost reduction initiatives to align our cost structure with our operations and related to integration activities. These actions have primarily resulted in the termination of employees, As a result, we recorded charges of $9.3 million in fiscal 2021 and $15.3 million in fiscal 2020, primarily related to severance benefits. For additional information, please refer to Note 6 to our consolidated financial statements.

Interest Expense

	Years Ended			
	September 25, 2021	September 26, 2020	Change	
	Amount	Amount	Amount	%
Interest Expense	$ (93.6)	$ (116.5)	$ 22.9	(19.7)%

Interest expense in fiscal 2021 and 2020 consists primarily of the cash interest costs and the related amortization of the debt discount and deferred issuance costs on our outstanding debt. Interest expense in fiscal 2021 decreased compared to fiscal 2020 primarily due to a decrease in LIBOR year over year, the basis for determining interest expense under our 2018 Credit Agreement, lower interest rates on our Senior Notes due to issuing our 2029 Senior Notes and paying off our 2025 Senior Notes, and the pay-off of amounts outstanding under our accounts receivable asset securitization agreement in the prior year, partially offset by issuance costs expensed from the issuance of the 2029 Senior Notes and higher interest rate swap expenses.

Debt Extinguishment Loss

	Years Ended			
	September 25, 2021	September 26, 2020	Change	
	Amount	Amount	Amount	%
Debt Extinguishment Loss	$ (21.6)	$ —	$ (21.6)	(100.0)%

In the first quarter of fiscal 2021, we completed a private placement of $950 million aggregate principal amount of our 2029 Senior Notes, The proceeds under the 2029 Senior Notes offering, together with available cash, were used to redeem our 2025 Senior Notes in the same principal amount. In connection with this transaction, we recorded a debt extinguishment loss of $21.6 million in the first quarter of fiscal 2021.

Other Income (Expense), net

	Years Ended			
	September 25, 2021	September 26, 2020	Change	
	Amount	Amount	Amount	%
Other Income (Expense), net	$ (5.4)	$ 9.1	$ (14.5)	(159.3)%

In fiscal 2021, this account primarily consisted of a net foreign currency exchange loss of $17.1 million, partially driven by the mark-to-market and settling of outstanding forward foreign currency exchange and option contracts, and a charge of $1.8 million for the write-off of an equity investment, partially offset by a gain of $13.4 million on the cash surrender value of life insurance contracts related to our deferred compensation plan driven by current year stock market gains.

In fiscal 2020, this account primarily consisted of net foreign currency exchange gains of $3.2 million primarily due to hedging activities, a net gain of $3.2 million to reflect an adjustment to remeasure our initial investment in SSI in connection with purchase accounting and a gain of $2.3 million on the cash surrender value of life insurance contracts related to our deferred compensation plan.

Provision (Benefit) for Income Taxes.

	Years Ended			
	September 25, 2021	September 26, 2020	Change	
	Amount	Amount	Amount	%
Provision (Benefit) for Income Taxes	$ 491.4	$ (108.6)	$ 600.0	**

** Percentage not meaningful

Our effective tax rate for fiscal 2021 was a provision of 20.8%. The effective tax rate was lower than the U.S. statutory tax rate primarily due to the impact of the U.S. deduction for foreign derived intangible income and the geographic mix of income earned by our international subsidiaries, which are taxed at rates lower than the U.S. statutory tax rate, partially offset by state income taxes and the global intangible low-taxed income inclusion.

Our effective tax rate for fiscal 2020 was a benefit of 10.8%. The effective tax rate differed from the U.S. statutory tax rate primarily due to a $313.4 million discrete net tax benefit related to the sale of the Medical Aesthetics business, the impact of the U.S. deduction for foreign derived intangible income, federal and state tax credits, and the geographic mix of income earned by our international subsidiaries, which are taxed at rates lower than the U.S. statutory tax rate, partially offset by state income taxes, reserves for uncertain tax positions net of releases resulting from statute of limitations expirations and favorable audit settlements, the global intangible low-taxed income inclusion, and unbenefited foreign losses.

Segment Results of Operations

We operate in four segments: Diagnostics, Breast Health, GYN Surgical, and Skeletal Health. Until December 30, 2019, our product portfolio included aesthetic and medical treatments systems sold by our former Medical Aesthetic business. We completed the disposition of the Medical Aesthetics segment on December 30, 2019 (the first day of the second quarter of fiscal 2020). The accounting policies of the segments are the same as those described in the footnotes to the accompanying consolidated financial statements contained in Item 15 of this Annual Report. We measure segment performance based on total revenues and operating income (loss). Revenues from product sales of each of these segments are described in further detail above. The discussion that follows is a summary analysis of total revenues and the primary changes in operating income or loss by segment.

Diagnostics

	Years Ended			
	September 25, 2021	September 26, 2020	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 3,695.0	$ 2,102.1	$ 1,592.9	75.8 %
Operating Income	$ 2,140.1	$ 929.7	$ 1,210.4	130.2 %
Operating Income as a % of Segment Revenue	57.9 %	44.2 %		

Diagnostics revenues increased in fiscal 2021 compared to fiscal 2020 primarily due to the increase in product revenues from the recovery of our core product lines, current year acquisitions and sales of our SARS-CoV-2 assays discussed above, an increase in royalty revenue from Grifols related to licensing our intellectual property to our COVID-19 assays for their sale in Spain, and the inclusion of laboratory testing service revenue from Biotheranostics.

Operating income for this business segment increased in fiscal 2021 compared to fiscal 2020 primarily due to an increase in gross profit from higher revenues partially offset by an increase in operating expenses. Gross margin was 73.2% in the current year compared to 65.2% in the prior year. The increase in gross margin was primarily due to increased sales of our SARS-CoV-2 assays, higher overall production of our Aptima assays and ThinPrep Pap Test reducing fixed overhead on a unit basis and increased royalty revenue from Grifols, partially offset by an increase in freight costs to ship product internationally, an increase in inventory reserves, higher field service costs, an increase in amortization of placed Panther instruments as the installed base has increased significantly year over year, and higher intangible asset amortization expense from the Mobidiag, Diagenode and Biotheranostics acquisitions in the current year.

Operating expenses increased in fiscal 2021 compared to fiscal 2020 primarily due to higher compensation and benefits driven by salary, commissions and our deferred compensation plan, an increase in headcount in the operations, service and sales departments, an increase in R&D project spend, higher acquisition transaction expenses, which included $11.5 million for a transfer tax related to the Mobidiag acquisition, higher bad debt expense, an increase in marketing initiatives, a lower BARDA credit of $3.9 million in the current year, and additional expenses from the Mobidiag, Biotheranostics and Diagenode acquisitions. These increases were partially offset by lower bonus expense.

Breast Health

	Years Ended			
	September 25, 2021	September 26, 2020	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 1,352.2	$ 1,151.9	$ 200.3	17.4 %
Operating Income	$ 284.2	$ 192.8	$ 91.4	47.4 %
Operating Income as a % of Segment Revenue	21.0 %	16.7 %		

Breast Health revenues increased in fiscal 2021 compared to fiscal 2020 primarily due to an increase of $143.0 million in product revenue as discussed above and an increase of $57.3 million in service and other revenue. The increase in service revenue is primarily due to an increase in service contract revenue as the Breast Health business continued to convert a high percentage of our installed base of digital mammography systems to service contracts upon expiration of the warranty period, the addition of service contracts from the NXC Imaging acquisition and an increase in spare parts revenue.

Operating income for this business segment increased in fiscal 2021 compared to fiscal 2020 primarily due to an increase in gross profit from higher revenues with higher gross margin, partially offset by an increase in operating expenses. Gross margin was 56.4% in the current year compared to 52.8% in the prior year. The increase in gross profit was primarily due to the increase in product revenue and service revenue discussed above and lower costs related to the step-up in fair value of inventory of $2.3 million for the Somatex acquisition in the current year compared to $6.8 million for the SSI and Health Beacons acquisitions in the prior year. In addition, gross profit in the prior year was impacted by the COVID-19 pandemic, which resulted in decreased sales volume across the majority of our product lines, period costs for temporary facility shut-downs and reduced manufacturing utilization and higher inventory reserves.

Operating expenses increased in fiscal 2021 compared to fiscal 2020 due to due to higher compensation and benefits driven by higher commissions from increased sales and our deferred compensation plan, a $7.0 million charge related to the purchase of intellectual property, an increase in R&D project spend, an increase in consulting spend, an increase in marketing initiatives and the prior year included a benefit from the reversal of acquisition related accruals and a holdback. These increases were partially offset by lower bonus expense, lower stock compensation expense, a decrease in trade show expenses and lower bad debt expense.

GYN Surgical

	Years Ended			
	September 25, 2021	September 26, 2020	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 488.1	$ 376.1	$ 112.0	29.8 %
Operating Income	$ 58.9	$ 42.0	$ 16.9	40.2 %
Operating Income as a % of Segment Revenue	12.1 %	11.2 %		

GYN Surgical revenues increased in fiscal 2021 compared to fiscal 2020 due to the increase in product revenues discussed above.

Operating income for this business segment increased in fiscal 2021 compared to fiscal 2020 primarily due to an increase in gross profit from higher revenues with higher gross margin, partially offset by an increase in operating expenses. Gross margin was 61.0% in the current year, compared to 59.1% in the prior year. The increase in gross margin was primarily due to the increased sales volume in the current year as the GYN Surgical business recovered to pre-COVID levels and the impact of the COVID-19 pandemic on the prior year, which resulted in decreased sales volume, period costs for temporary facility shut-downs and reduced manufacturing utilization. The increase in gross margin was partially offset by an unfavorable product mix of lower margin products, including our Fluent Fluid Management system and Acessa ProVu systems, higher intangible asset amortization expense from the Acessa acquisition, and an increase in inventory reserves.

Operating expenses increased in fiscal 2021 compared to fiscal 2020 primarily due to the inclusion of Acessa expenses of $15.0 million, higher compensation and benefits driven by our deferred compensation plan and commissions from the increase in sales, increased spending on research and development projects, higher travel, marketing initiative spend and consulting, and an increase in bad debt expense partially offset by a gain of $6.7 million related to the fair value adjustments for contingent consideration related to the Acessa acquisition.

Skeletal Health

	Years Ended			
	September 25, 2021	September 26, 2020	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 96.9	$ 81.0	$ 15.9	19.6 %
Operating Loss	$ (2.9)	$ (2.4)	$ (0.5)	20.8 %
Operating Loss as a % of Segment Revenue	(3.0)%	(3.0)%		

Skeletal Health revenues increased in fiscal 2021 compared to fiscal 2020 primarily due to the increase in product revenues discussed above.

Operating loss increased in fiscal 2021 compared to fiscal 2020 primarily due to an increase in operating expenses, partially offset by an increase in gross profit from higher revenues. Gross margin decreased to 31.4% in the current year compared to 33.2% in the prior year primarily due to higher service costs, partially offset by higher sales volume of our products and higher inventory reserves in the prior year.

Operating expenses increased in fiscal 2021 compared to fiscal 2020 primarily due to higher compensation and benefits and an increase in trade show expenses.

Fiscal Year Ended September 26, 2020 Compared to Fiscal Year Ended September 28, 2019

Discussions of year-to-year comparisons between fiscal 2020 and 2019 that are not included in this Form 10-K can be found in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Part II, Item 7 of the Company’s Annual Report on Form 10-K for the fiscal year ended September 26, 2020.

LIQUIDITY AND CAPITAL RESOURCES

At September 25, 2021, we had working capital of $1,841.9 million, and our cash and cash equivalents totaled $1,170.3 million. Our cash and cash equivalents balance increased by $469.3 million during fiscal 2021 principally due to cash generated from operating activities partially offset by cash used in financing and investing activities related to acquisitions of businesses, repurchases of common stock, net repayments of debt and capital expenditures.

In fiscal 2021, our operating activities provided us with $2,330.4 million of cash, primarily due to net income of $1,869.7 million, non-cash charges for depreciation and amortization aggregating $406.9 million, stock-based compensation expense of

$65.0 million and a debt extinguishment loss of $21.6 million. These adjustments to net income were partially offset by a decrease in net deferred tax liabilities of $70.1 million primarily due to the amortization of intangible assets. Cash provided by operations included a net cash inflow of $13.0 million from changes in our operating assets and liabilities. Changes in our operating assets and liabilities were driven primarily by a decrease in accounts receivable of $110.9 million primarily due to payments received from customers that had large balances from COVID-19 assay sales in our Diagnostics division and lower revenues in fourth quarter of fiscal 2021 compared to the fourth quarter of fiscal 2020, an increase in accounts payable of $20.4 million primarily due to the timing of these payments, and an increase in deferred revenue of $14.0 million primarily due to an increase in service contracts as the Breast Health business continues to convert a high percentage of its installed base of digital mammography systems to service contracts upon expiration of the warranty period, and a decrease in prepaid income taxes of $13.0 million. These cash inflows were partially offset by an increase in inventory of $84.1 million primarily due to the increase in raw materials and inventory to continue to support SARS-CoV-2 assay demand and production and an increase in prepaid expenses and other assets of $56.3 million due to an increase in technology implementation capitalized costs and licenses and the timing of value added tax receivables.

In fiscal 2021, our investing activities used cash of $1,329.6 million primarily related to net cash paid for our fiscal 2021 acquisitions of Biotheranostics, Diagenode, Somatex, and Mobidiag of $1,164.7 million and net capital expenditures of $156.2 million, which primarily consisted of purchases of manufacturing equipment primarily to expand the capacity of our molecular diagnostics manufacturing facilities and the placement of equipment under customer usage agreements.

In fiscal 2021, our financing activities used cash of $529.8 million, primarily related to $970.8 million for the repayment of our 2025 Senior Notes, $409.8 million for repurchases of our common stock, $250.0 million for the repayment of amounts borrowed under our revolving credit line, $75.0 million for scheduled principal payments under our 2018 Credit Agreement, $71.5 million for the net repayment of amounts borrowed under our accounts receivable securitization agreement and payments of $47.5 million for employee-related taxes withheld for the net share settlement of vested restricted stock units. Partially offsetting these uses of cash were net proceeds of $936.3 million under our 2029 Senior Notes, $320.0 million of proceeds under the accounts receivable securitization agreement that we restarted in the third quarter of 2021 to partially fund the Mobidiag acquisition, and $51.3 million from our equity plans, primarily from the exercise of stock options.

Debt

We had total recorded debt outstanding of $3.0 billion at September 25, 2021, which was comprised of our term loan under our then existing Credit Agreement of $1.38 billion (principal of $1.39 billion), 2029 Senior Notes of $934.5 million (principal of $950.0 million), and 2028 Senior Notes of $395.4 million (principal of $400.0 million), Securitization Program of $248.5 million, and $64.5 million in debt acquired in the Mobidiag acquisition.

2021 Credit Agreement (Subsequent Event)

On September 27, 2021, we refinanced our existing term loan and revolving credit facility with Bank of America, N.A. in its capacity as Administrative Agent, Swing Line Lender and L/C Issuer, and certain other lenders from time to time party thereto (the "2018 Credit Agreement") by entering into Refinancing Amendment No. 2 dated as of September 27, 2021, to the Amended and Restated Credit and Guaranty Agreement, dated as of October 3, 2017, as amended(the "2021 Credit Agreement"). Substantially all of the proceeds under the 2021 Credit Agreement of $1.5 billion were used to repay the amounts outstanding under the term loan under the 2018 Credit Agreement. Borrowings under the 2021 Credit Agreement are secured by first-priority liens on, and a first priority security interest in (in each case subject to certain liens permitted under the 2021 Credit Agreement), substantially all of our U.S. assets and the assets of the Subsidiary Guarantors. These liens are subject to release during the term of the facilities if we are able to achieve certain corporate or corporate family ratings and other conditions are met. The credit facilities (the "2021 Credit Facilities") under the 2021 Credit Agreement consist of:

- A $1.5 billion secured term loan ("2021 Term Loan") with a stated maturity date of September 25, 2026; and
- A secured revolving credit facility (the "2021 Revolver") under which the Borrowers may borrow up to $2.0 billion, subject to certain sublimits, with a stated maturity date of September 25, 2026.

As of the date of this Annual Report, there have been no borrowings under the 2021 Revolver.

Borrowings under the 2021 Credit Agreement, other than Swing Line Loans (as defined in the 2021 Credit Agreement), bear interest, at our option, at the Base Rate (as defined in the 2021 Credit Agreement), at the Eurocurrency Rate (as defined in the 2021 Credit Agreement), at the Alternative Currency Daily Rate (as defined in the 2021 Credit Agreement), or at the LIBOR Daily Floating Rate (as defined in the 2021 Credit Agreement), in each case plus the Applicable Rate (as defined in the 2021 Credit Agreement).

The Applicable Rate in regards to the Base Rate, the Eurocurrency Rate, the Alternative Currency Daily Rate, the Alternative Currency Term Rate and the LIBOR Daily Floating Rate is subject to change depending on the Total Net Leverage Ratio (as defined in the 2021 Credit Agreement). The borrowings of the Term Loan under the 2021 Credit Facilities initially bear interest at an annual rate equal to the Eurocurrency Rate for a one month interest period plus an Applicable Rate equal to 1.00%.

We are also required to pay a quarterly commitment fee calculated on a daily basis equal to the Applicable Rate as of such day multiplied by the undrawn committed amount available under the Revolver (taking into account any outstanding amounts under the LS Sublimit). This commitment fee is initially 0.15% per annum for the Revolver.

We are required to make scheduled principal payments under the 2021 Term Loan in increasing amounts ranging from $3.750 million per three-month period commencing with the three-month period ending on December 29, 2022 to $18.750 million per three-month period commencing with the three month period ending on December 26, 2025. The remaining scheduled balance of $1.335 billion (or such lesser aggregate principal amount of Term Loans then outstanding) on the 2021 Term Loan and any amounts outstanding under the 2021 Revolver are due at maturity. In addition, subject to the terms and conditions set forth in the 2021 Credit Agreement, we may be required to make certain mandatory prepayments from the net proceeds of specified types of asset sales (subject to certain reinvestment rights), debt issuances and insurance recoveries (subject to certain reinvestment rights). Certain of the mandatory prepayments are subject to reduction or elimination of certain financial covenants are met. These mandatory prepayments are required to be applied first to the 2021 Term Loan, second to any outstanding amount under any Swing Line Loans (as defined in the 2021 Credit Agreement), third to the 2021 Revolver, fourth to prepay any outstanding reimbursement obligations with respect to Letters of Credit (as defined in the 2021 Credit Agreement) and fifth to cash collateralize any Letters of Credit. Subject to certain limitations, we may voluntarily prepay any of the 2021 Credit Facilities without premium or penalty.

The 2021 Credit Agreement contains affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants restricting our ability subject to negotiated exceptions, to incur additional indebtedness and grant additional liens on our assets, engage in mergers or acquisitions or dispose of assets, enter into sale-leaseback transactions, pay dividends or make other distributions, voluntarily prepay other indebtedness, enter into transactions with affiliated persons, make investments, and change the nature of our business. In additions, the 2021 Credit Agreement requires the Borrowers to maintain certain financial ratios. The 2021 Credit Agreement also contains customary representations and warranties and events of default, including payments defaults, breach of representations and warranties, covenant defaults, cross defaults and an event of default upon a change of control of the company.

2028 Senior Notes

As of September 25, 2021, the total aggregate principal balance of the 2028 Senior Notes was $400.0 million. The 2028 Senior Notes are general senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. The 2028 Senior Notes were issued pursuant to an indenture, dated as of January 19, 2018, among the Company, the guarantors and Wells Fargo Bank, National Association, as trustee. The 2028 Senior Notes mature on February 1, 2028 and bear interest at the rate of 4.625% per year, payable semi-annually on February 1 and August 1 of each year, commencing on August 1, 2018. We may redeem the 2028 Senior Notes at any time prior to February 1, 2023 at a price equal to 100% of the aggregate principal amount so redeemed, plus accrued and unpaid interest, if any, to the redemption date and a make-whole premium set forth in the Indenture. We also have the option to redeem the 2028 Senior Notes on or after: February 1, 2023 through February 1, 2024 at 102.312% of par; February 1, 2024 through February 1, 2025 at 101.541% of par; February 1, 2025 through February 1, 2026 at 100.770% of par; and February 1, 2026 and thereafter at 100% of par. In addition, if there is a change of control coupled with a decline in ratings, as provided in the indenture, we will be required to make an offer to purchase each holder’s 2028 Senior Notes at a price equal to 101% of their principal amount, plus accrued and unpaid interest, if any, to the repurchase date.

2029 Senior Notes

On September 28, 2020, we completed a private placement of our 2029 Senior Notes. The total aggregate principal balance of the 2029 Senior Notes is $950.0 million. The 2029 Senior Notes are general senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain of the Company's domestic subsidiaries. The 2029 Senior Notes were issued pursuant to an indenture, dated as of September 28, 2020, among the Company, the guarantors and Wells Fargo Bank, National Association, as trustee. The 2029 Senior Notes mature on February 15, 2029 and bear interest at the rate of 3.250% per year, payable semi-annually on February 15 and August 15 of each year, commencing on February 15, 2021. We may redeem the 2029 Senior Notes at any time prior to September 28, 2023 at a price equal to 100% of the aggregate principal amount so redeemed, plus accrued and unpaid interest, if any, to the redemption date and a make-whole premium set forth in the Indenture. We may also redeem up to 40% of the aggregate principal amount of the 2029 Senior Notes with the net cash proceeds of certain equity offerings at any time and from time to time before September 28, 2023, at a redemption price equal to 103.250% of the aggregate principal amount so redeemed, plus accrued and unpaid interest, if any, to the redemption date. We also have the option to redeem the 2029 Senior Notes on or after: September 28, 2023 through September 27, 2024 at 101.625% of par; September 28, 2024 through September 27, 2025 at 100.813% of par; and September 28, 2025 and thereafter at 100% of par. In addition, if there is a change of control coupled with a decline in ratings, as provided in the indenture, we will be required to make an offer to purchase each holder’s 2029 Senior Notes at a price equal to 101% of their principal amount, plus accrued and unpaid interest, if any, to the repurchase date.

Accounts Receivable Securitization Program

In response to the market uncertainties created by the COVID-19 pandemic, on March 26, 2020, we paid off the total amount outstanding of $250.0 million previously borrowed under our then existing accounts receivable securitization program. On April 13, 2020, we amended the Credit and Security agreement with the lenders, temporarily suspending the ability to borrow and the need to comply with covenants for up to a year. On June 11, 2021, we amended and restated the Credit and Security agreement to restart the Securitization Program (the "Securitization Program") and increase the maximum borrowing amount to $320.0 million. Under the terms of the Securitization Program, we and certain of our wholly-owned subsidiaries sell our customer receivables to a bankruptcy remote special purpose entity, which is wholly-owned by us. The amount that the special purpose entity may borrow at a given point in time is determined based on the amount of qualifying receivables that are present in the special purpose entity at such point in time. The assets of the special purpose entity secure the amounts borrowed and cannot be used to pay our other debts or liabilities. The Securitization Program provides for annual renewals.

Loans outstanding under the Securitization Program bear interest at LIBOR plus an applicable margin for defined tranches. As of September 25, 2021, there was $248.5 million outstanding under this program. The weighted average interest rate under the Securitization Program was 0.8% as of September 25, 2021.

Fiscal 2022 Acquisition

On October 14, 2021, we announced that we entered into an agreement to acquire Bolder Surgical, Inc., or Bolder, a privately held, U.S.-based company that provides advanced energy vessel sealing surgical devices, for approximately $160.0 million, subject to working capital and other customary closing adjustments. The closing is subject to certain regulatory approvals, but we expect the acquisition to close before the end of calendar 2021. The acquisition will add laparoscopic vessel sealing, dividing and dissecting devices to the GYN Surgical portfolio and also will enable Hologic to expand the use of Bolder’s devices to OB/GYN specialists.

Contingent Consideration Earn-Out Payments

In connection with certain of our acquisitions, we have incurred the obligation to make contingent earnout payments tied to performance criteria, principally revenue growth of the acquired business over a specified period. In addition, contractual provisions relating to these contingent earn-out obligations may result in the risk of litigation relating to the calculation of the amount due or our operation of the acquired business. Such litigation could be expensive and divert management attention and resources. Our obligation to make contingent payments may also result in significant operating expenses.

Our contingent consideration arrangements are recorded as either additional purchase price or compensation expense if continuing employment is required to receive such payments. Pursuant to ASC 805, *Business Combinations*, contingent consideration that is deemed to be part of the purchase price is recorded as a liability based on the estimated fair value of the consideration we expect to pay to the former shareholders of the acquired business as of the acquisition date. This liability is re-measured each reporting period with the change in fair value recorded through a separate line item within our Consolidated Statements of Operations. Increases or decreases in the fair value of contingent consideration liabilities can result from changes in discount rates, changes in the timing, probabilities and amount of revenue estimates, and accretion of the liability for the passage of time.

Currently, our primary contingent consideration liability is from our acquisition of Acessa Health. We have an obligation to the former Acessa Health shareholders to make contingent payments based on a multiple of annual incremental revenue growth over a three year period ending annually in December. There is no maximum earnout. Pursuant to ASC 805, the contingent consideration was deemed to be part of the purchase price and we recorded our estimate of the fair value of the contingent consideration liability utilizing the Monte Carlo simulation based on future revenue projections of the business, comparable company revenue growth rates, implied volatility and applying a risk adjusted discount rate. At September 25, 2021 this liability was recorded at $75.1 million and no contingent earnout payments have been earned or made.

Stock Repurchase Program

On December 9, 2020, the Board of Directors authorized a new five-year share repurchase plan, to repurchase up to $1.0 billion of our outstanding common stock. The prior plan was terminated in connection with this new authorization. As of September 25, 2021, $691.6 million remained available under this authorization. Subsequent to September 25, 2021, we repurchased 2.3 million shares of our common stock for $167.0 million.

Future Liquidity Considerations

We expect to continue to review and evaluate potential strategic transactions (both acquisitions and dispositions) and alliances that we believe will complement or enhance our business and stockholder value. Subject to the Risk Factors set forth in Part I, Item 1A of this Annual Report and the general disclaimers set forth in our Special Note Regarding Forward-Looking Statements at the outset of this Annual Report, we believe that our cash and cash equivalents, cash flows from operations, the cash available under our 2021 Revolver and our Securitization Program will provide us with sufficient funds in order to fund our expected normal operations and debt payments over the next twelve months. Our longer-term liquidity is contingent upon future operating performance. We may also require additional capital in the future to fund capital expenditures, repayment of debt, acquisitions including contingent consideration payments, strategic transactions or other investments. As described above, we have significant indebtedness outstanding under our 2021 Credit Agreement, 2028 Senior Notes, 2029 Senior Notes and Securitization Program. These capital requirements could be substantial. Our operating performance may also be affected by matters discussed under the above-referenced Risk Factors set forth elsewhere in this report. These risks, trends and uncertainties may also adversely affect our long-term liquidity.

Legal Contingencies

We are currently involved in certain legal proceedings and claims. In connection with these legal proceedings and claims, management periodically reviews estimates of potential costs to be incurred by us in connection with the adjudication or settlement, if any, of these proceedings. These estimates are based on an analysis of potential litigation outcomes and settlement strategies. In accordance with ASC 450, *Contingencies*, loss contingencies are accrued if, in the opinion of management, an adverse outcome is probable and such outcome can be reasonably estimated. It is possible that future results for any particular quarter or annual period may be materially affected by changes in our assumptions or the effectiveness of our strategies relating to these proceedings.

Guarantees and Other Off-Balance Sheet Arrangements

We do not have guarantees or other off-balance sheet financing arrangements, including variable interest entities, of a magnitude that we believe could have a material impact on our financial condition or liquidity.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition for multiple element arrangements, allowance for doubtful accounts, reserves for excess and obsolete inventories, valuations, purchase price allocations and contingent consideration related to business combinations, expected future cash flows including growth rates, discount rates, terminal values and other assumptions used to evaluate the recoverability of long-lived assets and goodwill, estimated fair values of intangible assets and goodwill, amortization methods and periods, warranty reserves, certain accrued expenses, restructuring and other related charges, stock-based compensation, contingent liabilities, tax reserves and recoverability of our net deferred tax assets and related valuation allowances. We base our estimates on historical experience and various other assumptions that are believed to be reasonable under the circumstances. Actual results could differ from these estimates if past experience or other assumptions do not turn out to be substantially accurate. Any differences may have a material impact on our financial condition and results of operations.

The following is a discussion of what we believe to be the more significant critical accounting policies and estimates used in the preparation of our consolidated financial statements.

Inventory

Our inventories include material, labor and overhead, and are stated at the lower of cost (first-in, first-out) or market. As a developer and manufacturer of high technology medical equipment and diagnostic test kits, we may be exposed to a number of economic and industry factors that could result in portions of our inventory becoming either obsolete or in excess of anticipated usage. Our policy is to establish inventory reserves when conditions exist that suggest that our inventory may be in excess of anticipated demand or is obsolete based upon our assumptions about future demand for our products and market conditions. Although considerable effort is made to ensure the accuracy of our forecasts of future product demand, any significant unanticipated changes in demand or expected usage could have a significant negative impact on the value of our inventory and our operating results.

Business Combinations

We record tangible and intangible assets acquired and liabilities assumed in business combinations under the purchase method of accounting. Amounts paid for each acquisition are allocated to the assets acquired and liabilities assumed based on their fair values at the dates of acquisition. Contingent consideration, which is not deemed to be linked to continuing employment, is recorded at fair value as measured on the date of acquisition using an appropriate valuation model, such as the Monte Carlo simulation model. The value recorded is based on estimates of future financial projections under various potential scenarios, in which the model runs many simulations based on comparable companies' growth rates and their implied volatility. These cash flow projections are discounted with a risk adjusted rate. Each quarter until such contingent amounts are earned, the fair value of the liability is remeasured at each reporting period and adjusted as a component of operating expenses based on changes to the underlying assumptions. The estimates used to determine the fair value of the contingent consideration liability are subject to significant judgment, specifically projected revenues, and given the inherent uncertainties in making these estimates, actual results are likely to differ from the amounts originally recorded and could be materially different.

The fair value of identifiable intangible assets is based on detailed valuations that use information and assumptions provided by management, which consider management’s best estimate of inputs and assumptions that a market participant would use. We allocate any excess purchase price over the fair value of the net tangible and intangible assets acquired and liabilities assumed to goodwill.

We generally use the income approach in which cash flow projections on an after-tax basis are discounted using a risk adjusted rate to determine the estimated fair value of certain identifiable intangible assets including developed technology, in-process research and development projects, customer relationships, and trade names. The significant assumptions used to estimate the fair value of intangible assets include discount rates and certain assumptions that form the basis of the forecasted results specifically revenue growth rates. These significant assumptions are forward looking and could be affected by future economic and market conditions.

With respect to property, plant and equipment, we estimate the fair value of these assets using a combination of the cost and market approaches, depending on the component. Generally, we apply the cost or income approach as the primary methods in estimating the fair value of land and buildings as the market approach is less reliable based on potential significant differences between the property being valued and the potentially comparable sales of similar properties.

Goodwill

We test goodwill at the reporting unit level for impairment on an annual basis and between annual tests if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that could indicate impairment and trigger an interim impairment assessment include, but are not limited to current economic and market conditions, including a decline in market capitalization, a significant adverse change in legal factors, business climate, operational performance of the business or key personnel, and an adverse action or assessment by a regulator. Our annual impairment test date is the first day of our fiscal fourth quarter.

In performing the test, we either use the qualitative assessment permitted by ASC 350, *Intangibles—Goodwill and Other,* or the single step quantitative approach prescribed under ASC 350 including amendments under ASU 2017-04. Under the qualitative approach we consider a number of factors, including the amount by which the previous quantitative test's fair value exceeded the carrying value of the reporting units, the forecasts in our then-current strategic plan compared to the forecasts in the previous quantitative test, an evaluation of discount rates, long-term growth rates including the terminal year rate, if tax rates would have significantly changed, an evaluation of current economic factors for both the worldwide economy and specifically the medical device industry, and any significant changes in customer and supplier relationships. We weigh these factors to determine if it is more likely than not that the fair value of the reporting unit exceeds its carrying value. If after

performing a qualitative assessment, indicators are present, or we identify factors that cause us to believe it is appropriate to perform a more precise calculation of fair value, we would move beyond the qualitative assessment and perform a quantitative impairment test.

Under the quantitative impairment test, we perform a comparison of the reporting unit's carrying value to its fair value. We consider a number of factors to determine the fair value of a reporting unit, including an independent valuation to conduct this test. The valuation is based upon expected future discounted operating cash flows of the reporting unit as well as analysis of recent sales and ratio comparisons of similar companies. We base the discount rate on the weighted average cost of capital, or WACC, of market participants. If the carrying value of a reporting unit exceeds its estimated fair value, we apply the single step approach under ASU 2017-04. As a result of this simplified approach the goodwill impairment is calculated as the amount by which the carrying value of the reporting unit exceeds its fair value to the extent of the goodwill balance.

We conducted our fiscal 2021 annual impairment test on the first day of the fourth quarter and utilized the quantitative approach. We utilized discounted cash flows, or DCF, and market approaches to estimate the fair value of our reporting units as of June 27, 2021 and ultimately used the fair value determined by the DCF in making our impairment test conclusions. We believe we used reasonable estimates and assumptions about future revenue, cost projections, cash flows, market multiples and discount rates as of the measurement date. As a result of completing this analysis, all of our reporting units had fair values exceeding their carrying values.

At September 25, 2021, we believe that our reporting units, with goodwill aggregating $3.3 billion, were not at risk of failing the goodwill impairment test based on its current forecasts and qualitative assessment.

Since the fair value of our reporting units was determined by use of the DCF, and the key assumptions that drive the fair value in this model are the WACC, terminal values, growth rates, and the amount and timing of expected future cash flows, significant judgment is applied in determining fair value. If the current economic environment were to deteriorate, this would likely result in a higher WACC because market participants would require a higher rate of return. In the DCF as the WACC increases, the fair value decreases. The other significant factor in the DCF is our projected financial information (i.e., amount and timing of expected future cash flows and growth rates) and if these assumptions were to be adversely impacted, this could result in a reduction of the fair value of a reporting unit.

Intangible Assets

Intangible assets are initially recorded at fair value and stated net of accumulated amortization and impairments. We amortize intangible assets that have finite lives using either the straight-line method, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be utilized. We evaluate the recoverability of our definite lived intangible assets whenever events or changes in circumstances or business conditions indicate that the carrying value of these assets may not be recoverable based on expectations of future undiscounted cash flows for each asset group. If the carrying value of an asset or asset group exceeds its undiscounted cash flows, the Company estimates the fair value of the assets, generally utilizing a discounted cash flow analysis based on the present value of estimated future cash flows to be generated by the assets using a risk-adjusted discount rate. To estimate the fair value of the assets, the Company uses market participant assumptions pursuant to ASC 820, *Fair Value Measurements*.

Revenue Recognition

We generate revenue from the sale of our products, primarily medical imaging systems and diagnostic and surgical disposable products, and related services, which are primarily support and maintenance services on our medical imaging systems. See Note 3 for further discussion of revenue recognition.

We consider revenue to be earned when all of the following criteria are met: we have a contract with a customer that creates enforceable rights and obligations; promised products or services are identified; the transaction price, or the amount that we expect to receive, including an estimate of uncertain amounts subject to a constraint to ensure revenue is not recognized in an amount that would result in a significant reversal upon resolution of the uncertainty, is determinable; and we have transferred control of the promised items to the customer. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in the contract. The transaction price for the contract is measured as the amount of consideration we expect to receive in exchange for the goods and services expected to be transferred. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, control of the distinct good or service is transferred. Transfer of control for our products is generally at shipment or delivery, depending on contractual terms, but occurs when title and risk of loss transfers to the customer which represents the point in time when the customer obtains the use of and substantially all of the remaining benefit of the product. As such, the performance obligation related to product sales is satisfied at a point in time. Revenue from support and maintenance contracts and extended warranties are recognized over time based on the contract term, which represents a faithful depiction of the transfer of goods and services

given the stand-ready nature of the performance obligations. Service revenue related to professional services for installation, training and repairs is recognized as the services are performed based on the specific nature of the service.

We recognize receivables when we have an unconditional right to payment, which represents the amount we expect to collect in a transaction and is most often equal to the transaction price in the contract. Payment terms are typically 30 days in the U.S. but may be longer in international markets. We treat shipping and handling costs performed after a customer obtains control of the good as a fulfillment cost and record these costs within costs of product revenue when the corresponding revenue is recognized.

Some of our contracts have multiple performance obligations. For contracts with multiple performance obligations, we are required to allocate the transaction price to each performance obligation using our best estimate of the standalone selling price of each distinct good or service in the contract. We determine the best estimate of standalone selling price using average selling prices over 3- to 12-month periods of data depending on the products or nature of the services coupled with current market considerations. If the product or service does not have a history of sales or if sales volume is not sufficient, we rely on prices set by our pricing committees or applicable marketing department adjusted for expected discounts.

We also place instruments (or equipment) at customer sites but retain title to the instrument (for example, the ThinPrep Processor, ThinPrep Imaging System, and the Panther system). The customer has the right to use the instrument for a period of time, and then we recover the cost of providing the instrument through the sales of disposables, namely tests and assays in Diagnostics and handpieces in GYN Surgical. These types of agreements include an embedded operating lease for the right to use an instrument and no instrument revenue is recognized at the time of instrument delivery. We recognize a portion of the revenue allocated to the embedded lease concurrent with the sale of disposables over the term of the agreement.

Income Taxes

We use the asset and liability method for accounting for income taxes in accordance with ASC 740, *Income Taxes*. Under this method, we recognize deferred income tax assets and liabilities for the future tax consequences of differences between the financial statement carrying amount of existing assets and liabilities and their respective tax bases, and also for operating loss and tax credit carry-forwards at each reporting period. We measure deferred tax assets and liabilities using enacted tax rates and laws applicable to the period and jurisdiction in which we expect the differences to affect taxable income. We evaluate both the positive and negative evidence that affects the realizability of net deferred tax assets and assess the need for a valuation allowance. The future benefit to be derived from our deferred tax assets is dependent upon our ability to generate sufficient future taxable income in each jurisdiction of the right type to realize the assets. We establish a valuation allowance when necessary to reduce deferred tax assets to the amounts expected to be realized. To the extent we establish or release a valuation allowance, a tax charge or benefit will be recorded as a component of the income tax provision on the statement of operations in the reporting period that such determination is made.

We have recognized $228.6 million in net deferred tax liabilities at September 25, 2021 and $186.3 million at September 26, 2020. The increase was primarily due to purchase accounting related intangible additions to deferred liabilities in fiscal 2021. The liabilities primarily relate to deferred taxes associated with our acquisitions. The tax assets relate primarily to net operating loss carryforwards, accruals and reserves, stock-based compensation, and research credits.

Accounting for income taxes requires a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if, based on the technical merits, it is more likely than not that the position will be sustained upon audit, including resolutions of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. We evaluate these uncertain tax positions on a quarterly basis. This evaluation is based on factors including, but not limited to, changes in facts or circumstances, changes in tax law, effectively settled issues under audit and new audit activity. Any change in these factors could result in the recognition of a tax benefit or an additional charge to the tax provision.

As of September 25, 2021, we had $212.8 million in gross unrecognized tax benefits excluding interest, of which $197.0 million, if recognized, would reduce our effective tax rate. As of September 26, 2020, we had $197.1 million in gross unrecognized tax benefits excluding interest, of which $184.9 million, if recognized, would have reduced our effective tax rate. The Tax Cuts and Jobs Act subjects a U.S. shareholder to tax on global intangible low-taxed income (“GILTI”) earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company accounts for GILTI in the year the tax is incurred as a period cost.

In the ordinary course of business, there are many transactions and calculations where the ultimate tax outcome is uncertain. Judgment is required in determining our worldwide income tax provision. In our opinion, we have made adequate

provisions for income taxes for all years subject to audit. While we consider our estimates reasonable, no assurance can be given that the final tax outcome will not be different than amounts reflected in our historical income tax provisions and accruals. If our assumptions are incorrect, the differences could have a material impact on our income tax provision and operating results in the period in which such determination is made.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements contained in Item 15 of this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Financial Instruments, Other Financial Instruments, and Derivative Commodity Instruments. Financial instruments consist of cash and cash equivalents, accounts receivable, equity investments, foreign currency derivative contracts, an interest rate swap agreement, insurance contracts, accounts payable and debt obligations. Except for our outstanding 2028 and 2029 Senior Notes, the fair value of these financial instruments approximate their carrying amount. The fair value of our 2028 and 2029 Senior Notes was approximately $424.5 million and $964.7 million, respectively, as of September 25, 2021. Amounts outstanding under our 2018 Credit Agreement of $1.4 billion aggregate principal and Securitization Program of $248.5 million as of September 25, 2021 are subject to variable rates of interest based on current market rates, and as such, we believe the carrying amount of these obligations approximates fair value.

Primary Market Risk Exposures. Our primary market risk exposure is in the areas of interest rate risk and foreign currency exchange rate risk. We incur interest expense on borrowings outstanding under our 2028 and 2029 Senior Notes, 2018 Credit Agreement and Securitization Program. The 2028 and 2029 Senior Notes have fixed interest rates. Borrowings under our 2018 Credit Agreement bore interest at the Eurocurrency Rate (i.e., LIBOR) plus the applicable margin of 1.00% per annum, and borrowings under our Securitization program currently bear interest at LIBOR plus the applicable margin of 0.7%.

As of September 25, 2021, there was $1.6 billion of aggregate principal outstanding under the 2018 Credit Agreement and Securitization Program. Since these debt obligations are variable rate instruments, our interest expense associated with these instruments is subject to change. A hypothetical 10% adverse movement (increase in LIBOR rate) would increase annual interest expense by approximately $0.3 million. We entered into an interest rate swap agreement to help mitigate the interest rate volatility associated with the variable rate interest on the amounts outstanding under the 2018 Credit Agreement. The critical terms of the interest rate swap were designed to mirror the terms of our LIBOR-based borrowings under the 2018 Credit Agreement, and therefore the interest rate swap is highly effective at offsetting the cash flows being hedged. We designated this derivative instrument as a cash flow hedge of the variability of the LIBOR-based interest payments on $1.0 billion of principal. The interest rate swap contract expires on December 17, 2023.

The UK Financial Conduct Authority announced in 2017 that it intends to phase out LIBOR by the end of 2021, which was extended to the end of 2023. If changes are made to the method of calculating LIBOR or LIBOR ceases to exist, we may need to amend certain contracts, including our interest rate swap agreement, and we cannot predict what alternative rate or benchmark would be negotiated or the extent to which this would adversely affect our interest rate and the effectiveness of our interest rate hedging activity.

The return from cash and cash equivalents will vary as short-term interest rates change. A hypothetical 10% increase or decrease in interest rates, however, would not have a material adverse effect on our financial condition.

Foreign Currency Exchange Risk. Our international business is subject to risks, including, but not limited to: unique economic conditions, changes in political climate, differing tax structures, other regulations and restrictions, and foreign exchange rate volatility. Accordingly, our future results could be materially adversely impacted by changes in these or other factors.

We conduct business worldwide and maintain sales and service offices outside the U.S. as well as manufacturing facilities in Costa Rica and the United Kingdom. Our international sales are denominated in a number of currencies, primarily the Euro, U.S. dollar, UK Pound and Chinese Renminbi. The majority of our foreign subsidiaries functional currency is the local currency, although certain foreign subsidiaries functional currency is the U.S. dollar based on the nature of their operations or functions. Fluctuations in the foreign currency rates could affect our sales, cost of goods and operating margins and could result in exchange losses. In addition, currency devaluations can result in a loss if we hold deposits of that currency. We have executed forward foreign currency contracts to hedge a portion of results denominated in the Euro, UK Pound, Australian dollar, Japanese Yen, Canadian dollar and Chinese Renminbi. These contracts do not qualify for hedge accounting. As a result, we may experience volatility in our Consolidated Statements of Operations due to (i) the impact of unrealized gains and losses reported in other income, net on the mark-to-market of outstanding contracts and (ii) realized gains and losses

recognized in other income, net, whereas the offsetting economic gains and losses are reported in the line item of the underlying cash flow, for example, revenue.

We believe that the operating expenses of our international subsidiaries that are incurred in local currencies will not have a material adverse effect on our business, results of operations or financial condition. Our operating results and certain assets and liabilities that are denominated in foreign currencies are affected by changes in the relative strength of the U.S. dollar against those currencies. Our expenses, denominated in foreign currencies, are positively affected when the U.S. dollar strengthens against those currencies and adversely affected when the U.S. dollar weakens. However, we believe that the foreign currency exchange risk is not significant. We believe a hypothetical 10% increase or decrease in foreign currencies that we transact in would not have a material adverse impact on our financial condition or results of operations. During fiscal 2021, we incurred net foreign exchange losses of $17.1 million and in 2020 and 2019, we incurred net foreign exchange gains of $3.4 million and $5.1 million, respectively.

Item 8. Financial Statements and Supplementary Data

Our Consolidated Financial Statements and Supplementary Data are set forth under Part IV, Item 15, which is incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of September 25, 2021, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective.

Report of Management on Internal Control over Financial Reporting

We are responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act, as amended, as a process designed by, or under the supervision of our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and disposition of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting as of September 25, 2021. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (COSO) in Internal Control-Integrated Framework.

Management has excluded from our assessment of and conclusion on the effectiveness of internal control over financial reporting the internal controls of Mobidiag Oy, Diagenode SA, Biotheranostics, Inc., and Somatex Medical Technologies GmbH, which are included in the consolidated financial statements of Hologic, Inc. as of and for the year ended September 25, 2021 and constituted $1.4 billion and $1.1 billion of our total assets and net assets, respectively, as of September 25, 2021 and $77.1 million and $40.3 million of revenues and pre-tax losses, respectively, for the year then ended.

Subject to the foregoing, based on management’s assessment, we believe that, as of September 25, 2021, our internal control over financial reporting is effective at a reasonable assurance level based on these criteria.

Ernst & Young LLP, an independent registered public accounting firm, has issued an attestation report on the effectiveness of our internal control over financial reporting. This report in which they expressed an unqualified opinion is included below.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Hologic, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Hologic, Inc.'s internal control over financial reporting as of September 25, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Hologic, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of September 25, 2021, based on the COSO criteria.

As indicated in the accompanying Report of Management on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Mobidiag Oy, Diagenode SA, Biotheranostics, Inc., and Somatex Medical Technologies GmbH, which are included in the 2021 consolidated financial statements of the Company and constituted $1.4 billion and $1.1 billion of total and net assets, respectively, as of September 25, 2021 and $77.1 million and $40.3 million of revenues and pre-tax losses, respectively, for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of Mobidiag Oy, Diagenode SA, Biotheranostics, Inc., and Somatex Medical Technologies GmbH.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the 2021 consolidated financial statements of the Company and our report dated November 16, 2021 expressed an unqualified opinion thereon.

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 Report of Management 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/ Ernst & Young LLP

Boston, Massachusetts
November 16, 2021

Changes in Internal Control over Financial Reporting

During the quarter ended September 25, 2021, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control 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 Ethics for Senior Financial Officers that applies to our principal executive officer, principal financial officer, and principal accounting officer and controller, and other persons performing similar functions. Our Code of Ethics for Senior Financial Officers is publicly available on our website at *investors.hologic.com* as Appendix A to our Code of Conduct. We intend to satisfy the disclosure requirement under Item 5.05 of Current Report on Form 8-K regarding an amendment to, or waiver from, a provision of this code by posting such information on our website, at the address specified above.

The additional information required by this item is incorporated by reference to our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the SEC within 120 days after the close of our fiscal year.

Item 11. Executive Compensation

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the SEC within 120 days after the close of our fiscal year.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

We maintain a number of equity compensation plans for employees, officers, directors and others whose efforts contribute to our success. The table below sets forth certain information as of the end of our fiscal year ended September 25, 2021 regarding the shares of our common stock available for grant or granted under stock option plans and equity incentives that (i) were approved by our stockholders, and (ii) were not approved by our stockholders.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b) (2)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)	7,127,161	$ 44.66	4,588,412
Equity compensation plans not approved by security holders	—	$ —	—
Total	7,127,161	$ 44.66	4,588,412

(1) Includes 2,958,017 shares that are issuable upon restricted stock units (RSUs), performance stock units (PSUs) and market stock units (MSUs) vesting. The remaining balance consists of outstanding stock option grants.

(2) The weighted average exercise price does not take into account the shares issuable upon vesting of outstanding RSUs, PSUs and MSUs, which have no exercise price.

The additional information required by this item is incorporated by reference to our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the SEC within 120 days after the close of our fiscal year.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the SEC within 120 days after the close of our fiscal year.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the SEC within 120 days after the close of our fiscal year.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this report:

(1) Financial Statements

Report of Independent Registered Public Accounting Firm on Consolidated Financial Statements

Consolidated Statements of Operations for the years ended September 25, 2021, September 26, 2020 and September 28, 2019

Consolidated Statements of Comprehensive Income (Loss) for the years ended September 25, 2021, September 26, 2020 and September 28, 2019

Consolidated Balance Sheets as of September 25, 2021 and September 26, 2020

Consolidated Statements of Stockholders' Equity for the years ended September 25, 2021, September 26, 2020 and September 28, 2019

Consolidated Statements of Cash Flows for the years ended September 25, 2021, September 26, 2020 and September 28, 2019

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

All schedules have been omitted because they are not required or because the required information is given in the Consolidated Financial Statements or Notes thereto.

(b) Listing of Exhibits

		Incorporated by Reference	
Exhibit Number	Exhibit Description	Form	Filing Date/ Period End Date
2.1	Asset Purchase Agreement, dated December 14, 2016, by and among Hologic, Inc., Grifols Diagnostic Solutions Inc. and Grifols, S.A.	8-K	12/15/2016
2.2	Securities Purchase Agreement, dated as of November 20, 2019, by and among Hologic, Inc., Hologic Holdings Limited and Lotus Buyer, Inc.	8-K	11/20/2019
2.3	Share Purchase Agreement, dated as of April 8, 2021, by and among Hologic, Inc. and certain sellers listed therein	8-K	04/08/2021
3.1	Certificate of Incorporation of Hologic, with amendments	10-K	09/30/2017
3.2	Seventh Amended and Restated Bylaws of Hologic, Inc.	8-K	06/25/2019
4.1	Specimen Certificate for Shares of Hologic's Common Stock (filed in paper format)	8-A	01/31/1990
4.2	Indenture, dated September 28, 2020, by and among Hologic, Inc., the guarantors party thereto and Wells Fargo Bank, National Association, as Trustee	8-K	09/28/2020
4.3	First Supplemental Indenture dated as of May 18, 2021 among Hologic, Inc., The Subsidiary Guarantor Party Hereto and Wells Fargo Bank, National Association, as Trustee	Filed herewith	
4.4	Form of 3.250% Senior Note due 2029 (included in Exhibit 4.2)	8-K	09/28/2020
4.5	Indenture dated January 19, 2018, by and among Hologic, the Guarantors party thereto and Wells Fargo Bank, National Association, as Trustee	8-K	01/19/2018

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
4.6	First Supplemental Indenture dated January 19, 2018, by and among Hologic, the Guarantors party thereto and Wells Fargo Bank, National Association, as Trustee	8-K	01/19/2018
4.7	Form of 4.625% Senior Note due 2028 (included in Exhibit 4.5)	8-K	01/19/2018
4.8	Second Supplemental Indenture dated as of November 9, 2018 among Hologic, Inc., The Subsidiary Guarantor Parties Hereto and Wells Fargo Bank, National Association, as Trustee	Filed Herewith	
4.9	Third Supplemental Indenture dated as of January 8, 2019 among Hologic, Inc., the Subsidiary Guarantors Party Hereto and Wells Fargo Bank, National Association, as Trustee	Filed Herewith	
4.10	Fourth Supplemental Indenture dated as of March 14, 2019 among Hologic, Inc., The Subsidiary Guarantor Party Hereto and Wells Fargo Bank, National Association, as Trustee	Filed Herewith	
4.11	Fifth Supplemental Indenture dated as of May 18, 2021 among Hologic, Inc., the Subsidiary Guarantor Party Hereto and Wells Fargo Bank, National Association, as Trustee	Filed Herewith	
4.12	Description of Securities	10-K	09/28/2019
10.1*	The 2003 Incentive Award Plan of Gen-Probe Incorporated as amended and restated.	S-8	08/02/2012
10.2*	Hologic Amended and Restated 2008 Equity Incentive Plan.	8-K	03/15/2018
10.3*	Form of Stock Option Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2016).	8-K	10/14/2015
10.4*	Form of Stock Option Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2017).	8-K	11/09/2016
10.5*	Form of Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2017).	8-K	11/09/2016
10.6*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (relative TSR) (adopted fiscal 2020).	8-K	11/08/2019
10.7*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (ROIC) (adopted fiscal 2020).	8-K	11/08/2019
10.8*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (Free Cash Flow) (adopted fiscal 2020).	8-K	11/08/2019
10.9*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (relative TSR) (adopted fiscal 2021).	8-K	11/06/2020
10.10*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (ROIC) (adopted fiscal 2021).	8-K	11/06/2020
10.11*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (Free Cash Flow) (adopted fiscal 2021).	8-K	11/06/2020
10.12*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (ROIC – Outside US) (adopted fiscal 2021).	8-K	11/06/2020
10.13*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (relative TSR – Outside US) (adopted fiscal 2021).	8-K	11/06/2020
10.14*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (Free Cash Flow – Outside US) (adopted fiscal 2021).	8-K	11/06/2020

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.15*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (relative TSR) (adopted fiscal 2022).	8-K	11/04/2021

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.16*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (ROIC) (adopted fiscal 2022).	8-K	11/04/2021
10.17*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (Free Cash Flow) (adopted fiscal 2022).	8-K	11/04/2021
10.18*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (ROIC – Outside US) (adopted fiscal 2022).	8-K	11/04/2021
10.19*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (relative TSR – Outside US) (adopted fiscal 2022).	8-K	11/04/2021
10.20*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (Free Cash Flow – Outside US) (adopted fiscal 2022).	8-K	11/04/2021
10.21*	Form of Independent Director Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (annual grant).	10-K	09/28/2013
10.22*	Hologic, Inc. 2012 Employee Stock Purchase Plan, as amended	8-K	03/04/2016
10.23*	Hologic Short-Term Incentive Plan, as amended and restated	8-K	11/07/2018
10.24*	Hologic Amended and Restated Deferred Equity Plan	8-K	12/16/2015
10.25*	Rabbi Trust Agreement.	10-K	09/28/2013
10.26*	Form of Indemnification Agreement (as executed with each director of Hologic).	8-K	03/06/2009
10.27*	Employment Agreement dated December 6, 2013 by and between Stephen P. MacMillan and Hologic.	8-K	12/09/2013
10.28*	Amended and Restated Employment Agreement by and between the Company and Stephen P. MacMillan, dated September 18, 2015.	8-K	09/21/2015
10.29*	Amendment No. 1 to Amended and Restated Employment Agreement by and between the Company and Stephen P. MacMillan, dated September 24, 2016.	10-K	11/17/2016
10.30*	Amendment No. 2 to Amended and Restated Employment Agreement by and between the Company and Stephen P. MacMillan, dated October 5, 2020.	8-K	10/06/2020
10.31*	Form of Matching Restricted Stock Unit Award Agreement	8-K	12/09/2013
10.32*	Change of Control Agreement dated December 6, 2013 by and between Stephen P. MacMillan and Hologic.	8-K	12/09/2013
10.33*	Severance and Change of Control Agreement dated July 31, 2018 by and between Karleen M. Oberton and Hologic, Inc.	8-K	07/31/2018
10.34*	Transition Agreement by and between Allison P. Bebo and Hologic, Inc. dated July 2, 2021	10-Q	07/28/2021
10.35*	Severance and Change of Control Agreement dated February 2, 2015 by and between John M. Griffin and Hologic.	10-Q	03/28/2015
10.36*	Severance and Change of Control Agreement dated September 15, 2020 by and between Kevin R. Thornal and Hologic, Inc.	8-K	09/15/2020
10.37*	Severance and Change of Control Agreement by and between Hologic, Inc. and Sean S. Daugherty, dated August 31, 2020	10-K	11/17/2020
10.38*	Amended Contract of Employment between Jan Verstreken and Hologic dated December 11, 2020	10-Q	01/27/2021

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.39*	Severance and Change of Control Agreement dated June 28, 2021 by and between Elisabeth (Lisa) Hellmann and Hologic, Inc.	10-Q	07/28/2021
10.40	Office Lease dated December 31, 2003 between Cytyc and Marlborough Campus Limited Partnership.	Cytyc Corporation 10-K	12/31/2003
10.41	First Amendment to that Office Lease dated December 31, 2003 between Cytyc and Marlborough Campus Limited Partnership, entered into August 23, 2017, by and between Hines Global REIT Marlborough Campus LLC and Hologic, Inc. (1)	10-K	09/30/2017
10.42	Lease Agreement by and between Zona Franca Coyol S.A. and Cytyc Surgical Products Costa Rica S.A. dated April 23, 2007.	10-K	09/29/2007
10.43	Addendum 1 to Lease Agreement by and between Zona Franca Coyol S.A. and Cytyc Surgical Products Costa Rica S.A. dated July 22, 2007. (2) (3)	10-K	09/28/2019
10.44	Addendum 2 to Lease Agreement by and between Zona Franca Coyol S.A. and Cytyc Surgical Products Costa Rica S.A. dated September 22, 2008. (2) (3)	10-K	09/28/2019
10.45	Addendum No. 3 to Current Lease by and Between BCR Fondo de Inversion Inmobiliario and Hologic Surgical Products Costa Rica S.R.L. (1)	10-Q	12/30/2017
10.46	Lease Agreement by and between 445 Simarano Drive, Marlborough LLC and Cytyc dated July 11, 2006.	10-K	09/29/2007
10.47	First Amendment to Lease by and between 445 Simarano Drive Marlborough LLC and Hologic, Inc. dated July 14, 2016. (2)	10-K	09/28/2019
10.48	Lease of land situate at Crewe Road, Wythenshawe in the City of Manchester between the Council of the City of Manchester and V.G. Instruments Group Limited dated February 8, 1988 (2)	Filed Herewith	
10.49	Amended and Restated Credit and Guaranty Agreement, originally dated May 29, 2015, and amended and restated as of October 3, 2017 among Hologic, Hologic GGO 4 Ltd, each Designated Borrower from time to time party thereto, the Guarantors from time to time party thereto, each Lender from time to time party thereto and Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer.	8-K	10/04/2017
10.50	Refinancing Amendment No. 1 dated as of December 17, 2018 to the Amended and Restated Credit and Guaranty Agreement dated as of October 3, 2017.	8-K	12/18/2018
10.51	Refinancing Amendment No. 2, dated as of September 27, 2021, to the Amended and Restated Credit and Guaranty Agreement dated as of October 3, 2017, as amended.	8-K	09/27/2021
10.52	Supply Agreement for Panther Instrument System effective November 22, 2006 between Gen-Probe Incorporated and STRATEC Biomedical Systems AG. (1)	Gen-Probe 10-Q	09/30/2007
10.53	Amendment No. 1 dated June 1, 2011 to Supply Agreement for Panther Instrument System. (1)	10-K	09/24/2016
10.54	Amendment No. 2 dated February 28, 2013 to Supply Agreement for Panther Instrument System. (1)	10-K	09/24/2016
10.55	Intellectual Property License, dated as of January 31, 2017, by and among Hologic, Inc., Gen-Probe Incorporated and Grifols Diagnostics Solutions Inc.	8-K	02/02/2017
10.56	First Amendment, dated as of April 9, 2019, to Intellectual Property License, dated as of January 31, 2017, by and among Hologic, Inc., Gen-Probe Incorporated and Grifols Diagnostic Solutions.	10-Q	05/01/2019

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
21.1	Subsidiaries of Hologic.	Filed herewith	
23.1	Consent of Independent Registered Public Accounting Firm.	Filed herewith	
31.1	Certification of Hologic's CEO pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith	
31.2	Certification of Hologic's CFO pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith	
32.1	Certification of Hologic's CEO pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith	
32.2	Certification of Hologic's CFO pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith	
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	Filed herewith	
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Filed herewith	
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith	
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith	
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith	
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith	
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)	Filed herewith	

* *Indicates management contract or compensatory plan, contract or arrangement.*

(1) *Confidential treatment has been granted with respect to certain portions of this exhibit. A complete version of this exhibit has been filed separately with the SEC.*

(2) *Certain portions of this exhibit are considered confidential and have been omitted as permitted under SEC rules and regulations.*

(3) *Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K.*

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.

HOLOGIC, INC.

By: /S/ STEPHEN P. MACMILLAN

Stephen P. MacMillan

Chairman, President and Chief Executive Officer

Date: November 16, 2021

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/ STEPHEN P. MACMILLAN **STEPHEN P. MACMILLAN**	Chairman, President and Chief Executive Officer (Principal Executive Officer)	November 16, 2021
/S/ KARLEEN M. OBERTON **KARLEEN M. OBERTON**	Chief Financial Officer (Principal Financial Officer)	November 16, 2021
/S/ BENJAMIN J. COHN **BENJAMIN J. COHN**	Vice President, Corporate Controller (Principal Accounting Officer)	November 16, 2021
/S/ SALLY W. CRAWFORD **SALLY W. CRAWFORD**	Lead Independent Director	November 16, 2021
/S/ CHARLES DOCKENDORFF **CHARLES DOCKENDORFF**	Director	November 16, 2021
/S/ SCOTT T. GARRETT **SCOTT T. GARRETT**	Director	November 16, 2021
/S/ LUDWIG N. HANTSON **LUDWIG N. HANTSON**	Director	November 16, 2021
/S/ NAMAL NAWANA **NAMAL NAWANA**	Director	November 16, 2021
/S/ CHRISTIANA STAMOULIS **CHRISTIANA STAMOULIS**	Director	November 16, 2021
/S/ AMY M. WENDELL **AMY M. WENDELL**	Director	November 16, 2021

Hologic, Inc.

Consolidated Financial Statements

Years ended September 25, 2021, September 26, 2020 and September 28, 2019

Contents

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Hologic, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Hologic, Inc. (the Company) as of September 25, 2021 and September 26, 2020, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended September 25, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at September 25, 2021 and September 26, 2020, and the results of its operations and its cash flows for each of the three years in the period ended September 25, 2021, in conformity with U.S. generally accepted accounting principles.

We also have 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 September 25, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated November 16, 2021 expressed an unqualified opinion thereon.

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 Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate 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 consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Income Taxes - Uncertain Tax Positions

Description of the Matter

As described in Note 9 to the consolidated financial statements, at September 25, 2021 the Company had $212.8 million in gross unrecognized tax benefits excluding interest. The Company is a party to many transactions in the ordinary course of business where the ultimate tax outcome is uncertain. To account for this uncertainty, the Company must determine whether each tax position's technical merits are more-likely-than-not to be sustained in an audit by a taxing authority and then measure the amount of tax benefit that qualifies for recognition.

Auditing the recognition and measurement of uncertain tax positions requires significant auditor judgment because the Company's determination of whether a tax position's technical merits are more-likely-than-not to be sustained in an audit is judgmental and is based on interpretations of tax laws and legal rulings. In addition, measuring the amount of tax benefit that qualifies for recognition for each uncertain tax position requires judgment in assessing the potential outcomes that could occur if a tax position undergoes an audit by a taxing authority. These judgments are reassessed each reporting period and can be affected by, among other things, changes in tax law, recent tax rulings, and changes in the status of ongoing tax audits.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's processes to assess and measure uncertain tax positions, including management's controls to determine if a tax position's technical merits are more-likely-than-not to be sustained in an audit and, if so, measure the amount of tax benefit that qualifies for recognition.

To test the Company's assessment and measurement of uncertain tax positions, we involved our tax professionals to assess whether the uncertain tax positions identified by the Company are more-likely-than-not to be sustained upon audit and if so, to assist in testing the assumptions made by the Company in measuring the amount of tax benefit that qualifies for recognition. Our procedures included, among others, assessing the Company's correspondence with the relevant tax authorities and evaluating income tax opinions or other third-party advice obtained by the Company. We also used our knowledge of, and experience with, the application of domestic and international income tax laws by the relevant income tax authorities to evaluate the Company's assessments of whether the uncertain tax position is more-likely-than-not to be sustained and if so, the potential outcomes that could occur upon an audit by a taxing authority. We tested the completeness and accuracy of the data and calculations used to determine the amount of tax benefit to recognize. We also compared the Company's income tax disclosures included in Note 9 to the consolidated financial statements to disclosures required by the relevant accounting guidance.

Product Revenue Recognition

Description of the Matter

As discussed in Note 3 to the consolidated financial statements, the Company generates product revenue from the sale of medical imaging systems, diagnostic and surgical disposable products. The Company's contracts for capital equipment sales generally have multiple performance obligations.

Auditing the timing and amount of revenue recognized for product sales required significant auditor judgment because it involves several subjective management assumptions and estimates including the identification of performance obligations within the contracts, the estimation of the standalone selling price of each performance obligation, the determination of the transaction price and the allocation of the transaction price to each performance obligation, and a determination of the point in time at which those performance obligations were satisfied.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's processes to account for product revenue recognition, including management's controls over determining the transaction price, the identification of performance obligations in revenue contracts, the estimation of the standalone selling price for each performance obligation, the allocation of the transaction price to each performance obligation, and the determination of the point in time at which the Company transferred control of the promised items to the customer.

To test product revenue, we evaluated whether management's revenue recognition policies are appropriate and in accordance with ASC 606, *Revenue from Contracts with Customers*. We tested management's determination of the transaction price by comparing the price to the customer contract for a sample of transactions. We tested management's identification of the performance obligations and the allocation of transaction price to each performance obligation by performing an independent assessment, in comparison to the standard, on a sample of customer contracts. We tested management's estimated standalone selling prices for its identified performance obligations based on actual prices charged for similar products and services sold on a standalone basis. We also tested management's assertion that control was transferred to the customer by inspecting documentation supporting the transfer of control for a sample of contracts. In addition, we performed other procedures which included, among others, analytical procedures over product revenue and testing a sample of revenue transactions that occurred near the end of the fiscal year to evaluate accounting cut-off. We also compared the Company's revenue recognition disclosures included in Note 3 to the consolidated financial statements to disclosures required by the relevant accounting guidance.

Business Combinations

Description of the Matter

As described in Note 5 to the consolidated financial statements, during 2021, the Company completed several business combinations for total consideration of $1,178.9 million. The most significant of these were the acquisition of all the outstanding equity of (1) Mobidiag Oy for total consideration of $729.6 million, (2) Biotheranostics, Inc. for total consideration of $231.3 million, and (3) Diagenode SA for total consideration of $155.1 million. These business combinations resulted in the recognition of intangible assets of $681.4 million. As of September 25, 2021, the Company also recorded within accrued expenses and other long-term liabilities a contingent consideration liability of $75.1 million related to an acquisition completed in 2020.

Auditing the Company's accounting for business combinations was complex due to the significant estimation required by management to determine the fair value of identified intangible assets, which principally consisted of developed technology related to currently marketed products and an in process research and development ("IPR&D") asset, totaling $627.1 million and to determine the fair value of the contingent consideration liability. The Company used an income approach to measure the fair value of the acquired developed technology and IPR&D related intangible assets, and a Monte Carlo simulation model to value the contingent consideration liability. The significant assumptions used to estimate the fair value of these intangible assets and the contingent consideration liability included discount rates and certain assumptions that form the basis of the forecasted results, specifically revenue growth rates. These significant assumptions are forward looking and could be affected by future economic and market conditions.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of the controls over the Company's accounting for business combinations. For example, we tested controls over the identification and valuation of intangible assets and measurement of the contingent consideration liability, including the valuation models and underlying assumptions used to develop such estimates.

To test the estimated fair value of the developed technology and IPR&D assets and the contingent consideration liability, we performed audit procedures that included, among others, evaluating the Company's use of the different valuation models for each estimate and testing the significant assumptions described above that were used in the models. We tested the completeness and accuracy of the underlying data used in each analysis. For example, to evaluate revenue growth rates, we compared the assumptions used to current industry, market and economic trends, to the historical results of the acquired businesses, and to other guideline companies within the same industry. We also performed sensitivity analyses over the significant assumptions used to evaluate the changes in the fair value of each estimate that would result from changes in the assumptions. We involved our valuation professionals to test the models and the significant assumptions noted above. We also compared the Company's disclosures included in Note 5 to the consolidated financial statements to disclosures required by the relevant accounting guidance.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.

Boston, Massachusetts
November 16, 2021

Hologic, Inc.

Consolidated Statements of Operations

(In millions, except number of shares, which are reflected in thousands, and per share data)

	Years ended		
	September 25, 2021	September 26, 2020	September 28, 2019
Revenues:			
Product	$ 4,967.3	$ 3,227.0	$ 2,771.3
Service and other	665.0	549.4	596.0
	5,632.3	3,776.4	3,367.3
Costs of revenues:			
Product	1,205.1	953.7	948.7
Amortization of acquired intangible assets	276.7	253.2	318.5
Impairment of intangible assets and equipment	—	25.8	578.7
Service and other	354.7	316.2	350.5
Gross Profit	3,795.8	2,227.5	1,170.9
Operating expenses:			
Research and development	276.3	222.5	232.2
Selling and marketing	561.2	484.6	564.9
General and administrative	433.2	355.7	332.3
Amortization of acquired intangible assets	42.2	39.7	52.0
Impairment of intangible assets and equipment	—	4.4	106.7
Contingent consideration – fair value adjustments	(6.7)	0.3	—
Restructuring and divestiture charges	9.3	15.3	6.6
	1,315.5	1,122.5	1,294.7
Income (loss) from operations	2,480.3	1,105.0	(123.8)
Interest income	1.4	4.3	4.6
Interest expense	(93.6)	(116.5)	(140.8)
Debt extinguishment losses	(21.6)	—	(0.8)
Other income (expense), net	(5.4)	9.1	3.1
Income (loss) before income taxes	2,361.1	1,001.9	(257.7)
Provision (benefit) for income taxes	491.4	(108.6)	(54.1)
Net income (loss)	$ 1,869.7	$ 1,110.5	$ (203.6)
Net loss attributable to noncontrolling interest	(1.8)	(4.7)	—
Net income (loss) attributable to Hologic	$ 1,871.5	$ 1,115.2	$ (203.6)
Net income (loss) per common share attributable to Hologic:			
Basic	$ 7.28	$ 4.24	$ (0.76)
Diluted	$ 7.21	$ 4.21	$ (0.76)
Weighted average number of shares outstanding:			
Basic	257,046	262,727	269,413
Diluted	259,706	264,613	269,413

See accompanying notes.

Hologic, Inc.

Consolidated Statements of Comprehensive Income (Loss)

(In millions)

	Years ended		
	September 25, 2021	September 26, 2020	September 28, 2019
Net income (loss)	$ 1,869.7	$ 1,110.5	$ (203.6)
Changes in foreign currency translation adjustment	(20.2)	18.5	(14.8)
Changes in pension plans, net of taxes of $0.2 in 2021, $0.1 in 2020, and $0.3 in 2019	0.5	(0.1)	(0.6)
(Loss) gain recognized, net of tax of $2.5 million in 2021 $(8.3) million in 2020, and $1.2 million in 2019 for interest rate swaps	9.4	(27.6)	3.5
Changes in value of hedged interest rate caps, net of tax of $0.2 in 2021, $0.5 in 2020, and $1.1 in 2019			
Loss recognized in other comprehensive income (loss), net	0.4	(0.5)	(8.0)
Loss reclassified from accumulated other comprehensive loss to the statement of operations, net	0.5	2.3	3.1
Other comprehensive loss	(9.4)	(7.4)	(16.8)
Comprehensive income (loss)	$ 1,860.3	$ 1,103.1	$ (220.4)
Components of comprehensive income (loss) attributable to noncontrolling interest:			
Net loss attributable to noncontrolling interest	1.8	4.7	—
Comprehensive loss attributable to noncontrolling interest	1.8	4.7	—
Comprehensive income (loss) attributable to Hologic	$ 1,862.1	$ 1,107.8	$ (220.4)

See accompanying notes.

Hologic, Inc.

Consolidated Balance Sheets

(In millions, except number of shares, which are reflected in thousands, and par value)

	September 25, 2021	September 26, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,170.3	$ 701.0
Accounts receivable	942.7	1,028.9
Inventory	501.2	395.1
Prepaid income taxes	25.7	38.8
Prepaid expenses and other current assets	528.8	58.5
Total current assets	3,168.7	2,222.3
Property, plant and equipment, net	564.7	491.5
Intangible assets, net	1,659.2	1,307.5
Goodwill	3,281.6	2,657.9
Other assets	245.7	516.6
Total assets	$ 8,919.9	$ 7,195.8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 313.0	$ 324.9
Accounts payable	215.9	178.8
Accrued expenses	596.2	547.6
Deferred revenue	198.0	186.1
Finance lease obligations	3.7	1.9
Total current liabilities	1,326.8	1,239.3
Long-term debt, net of current portion	2,712.2	2,713.9
Finance lease obligations, net of current portion	22.8	17.4
Deferred income tax liabilities	250.5	201.8
Deferred revenue, net of current portion	20.3	12.9
Other long-term liabilities	368.7	303.2
Commitments and contingencies (Note 13 and 14)		
Stockholders' equity:		
Preferred stock, $0.01 par value – 1,623 shares authorized; 0 shares issued	—	—
Common stock, $0.01 par value – 750,000 shares authorized; 297,306 and 295,107 shares issued, respectively	3.0	2.9
Additional paid-in-capital	5,965.8	5,904.8
Accumulated earnings (deficit)	298.3	(1,573.2)
Treasury stock, at cost – 43,653 and 37,609 shares, respectively	(1,989.4)	(1,579.6)
Accumulated other comprehensive loss	(59.1)	(49.7)
Total Hologic's stockholders' equity	4,218.6	2,705.2
Noncontrolling interest	—	2.1
Total stockholders' equity	$ 4,218.6	$ 2,707.3
Total liabilities and stockholders' equity	$ 8,919.9	$ 7,195.8

See accompanying notes.

Hologic, Inc.

Consolidated Statements of Stockholders' Equity

(In millions, except number of shares, which are reflected in thousands)

	Common Stock					Treasury Stock			
	Number of Shares	Par Value	Additional Paid-in-Capital	Accumulated Earnings (Deficit)	Accumulated Other Comprehensive Loss	Number of Shares	Amount	Noncontrolling Interest	Total Stockholders' Equity
Balance at September 29, 2018	289,900	$ 2.9	$ 5,671.3	$ (2,494.0)	$ (25.5)	19,812	$ (725.9)	$ —	$ 2,428.8
Accounting standard transition adjustment - ASC 606	—	—	—	6.4	—	—	—	—	6.4
Accounting standard transition adjustment - ASU 2016-16	—	—	—	2.5	—	—	—	—	2.5
Exercise of stock options	1,304	—	32.8		—	—	—	—	32.8
Vesting of restricted stock units, net of shares withheld for employee taxes	645	—	(12.8)	—	—	—	—	—	(12.8)
Common stock issued under the employee stock purchase plan	474	—	16.5	—	—	—	—	—	16.5
Stock-based compensation expense	—	—	62.0	—	—	—	—	—	62.0
Net loss	—	—	—	(203.6)	—	—	—	—	(203.6)
Foreign currency translation adjustment	—	—	—	—	(14.8)	—	—	—	(14.8)
Adjustment to minimum pension liability, net	—	—	—	—	(0.6)	—	—	—	(0.6)
Repurchase of common stock	—	—	—	—	—	4,826	(200.1)	—	(200.1)
Unrealized loss on interest rate cap, net of taxes	—	—	—	—	(8.0)	—	—	—	(8.0)
Unrealized gain on interest rate swap	—	—	—	—	3.5	—	—	—	3.5
Interest cost of interest rate cap reclassified to statement of operations	—	—	—	—	3.1	—	—	—	3.1
Balance at September 28, 2019	292,323	$ 2.9	$ 5,769.8	$ (2,688.7)	$ (42.3)	24,638	$ (926.0)	$ —	$ 2,115.7
Noncontrolling interest created in acquisition	—	—	—	—	—	—	—	8.6	8.6
Accounting standard transition adjustment - ASC 842	—	—	—	0.3	—	—	—	—	0.3
Exercise of stock options	1,761	—	48.3	—	—	—	—	—	48.3
Vesting of restricted stock units, net of shares withheld for employee taxes	611	—	(14.2)	—	—	—	—	—	(14.2)
Common stock issued under the employee stock purchase plan	412	—	17.6	—	—	—	—	—	17.6
Stock-based compensation expense	—	—	83.3	—	—	—	—	—	83.3
Net income (loss)	—	—	—	1,115.2	—	—	—	(4.7)	1,110.5
Foreign currency translation adjustment	—	—	—	—	18.5	—	—	—	18.5
Adjustment to minimum pension liability, net	—	—	—	—	(0.1)	—	—	—	(0.1)
Repurchase of common stock	—	—	—	—	—	9,064	(448.6)	—	(448.6)
Accelerated share repurchase agreement	—	—	—	—	—	3,907	(205.0)	—	(205.0)
Unrealized loss on interest rate cap, net of taxes	—	—	—	—	(0.5)	—	—	—	(0.5)
Unrealized loss on interest rate swap	—	—	—	—	(27.6)	—	—	—	(27.6)
Interest cost of interest rate cap reclassified to statement of operations	—	—	—	—	2.3	—	—	—	2.3
Purchase of non-controlling interest	—	—	—	—	—	—	—	(1.8)	(1.8)
Balance at September 26, 2020	295,107	$ 2.9	$ 5,904.8	$ (1,573.2)	$ (49.7)	37,609	$ (1,579.6)	$ 2.1	$ 2,707.3
Exercise of stock options	857	—	32.9	—	—	—	—	—	32.9
Vesting of restricted stock units, net of shares withheld for employee taxes	980	0.1	(47.6)	—	—	—	—	—	(47.5)
Common stock issued under the employee stock purchase plan	362	—	18.9	—	—	—	—	—	18.9
Stock-based compensation expense	—	—	65.0	—	—	—	—	—	65.0
Net income (loss)	—	—	—	1,871.5	—	—	—	(1.8)	1,869.7
Foreign currency translation adjustment	—	—	—	—	(20.2)	—	—	—	(20.2)
Adjustment to minimum pension liability, net	—	—	—	—	0.5	—	—	—	0.5
Repurchase of common stock	—	—	—	—	—	6,044	(409.8)	—	(409.8)
Unrealized gain on interest rate cap, net of taxes	—	—	—	—	0.4	—	—	—	0.4

Unrealized gain on interest rate swap	—	—	—	—	9.4	—	—	—	9.4
Interest cost of interest rate cap reclassified to statement of operations	—	—	—	—	0.5	—	—	—	0.5
Purchase of non-controlling interest	—	—	(8.2)	—	—	—	—	(0.3)	(8.5)
Balance at September 25, 2021	297,306	$ 3.0	$ 5,965.8	$ 298.3	$ (59.1)	43,653	$ (1,989.4)	$ —	$ 4,218.6

See accompanying notes.

Hologic, Inc.

Consolidated Statements of Cash Flows

(In millions)

	Years ended		
	September 25, 2021	September 26, 2020	September 28, 2019
OPERATING ACTIVITIES			
Net income (loss)	$ 1,869.7	$ 1,110.5	$ (203.6)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation	88.0	83.1	92.5
Amortization	318.9	292.9	370.6
Stock-based compensation expense	65.0	83.3	62.0
Deferred income taxes and other non-cash taxes	(70.1)	(94.4)	(235.7)
Intangible asset and equipment impairment charges	—	30.2	685.4
Debt extinguishment loss	21.6	—	0.8
Other adjustments and non-cash items	24.3	27.3	33.8
Changes in operating assets and liabilities, excluding the effect of acquisitions and dispositions:			
Accounts receivable	110.9	(427.1)	(76.5)
Inventory	(84.1)	(25.3)	(63.0)
Prepaid income taxes	13.0	(3.8)	(3.2)
Prepaid expenses and other assets	(56.3)	(286.2)	(6.0)
Accounts payable	20.4	(4.9)	(5.5)
Accrued expenses and other liabilities	(4.9)	96.0	(16.5)
Deferred revenue	14.0	15.0	14.4
Net cash provided by operating activities	2,330.4	896.6	649.5
INVESTING ACTIVITIES			
Acquisition of businesses, net of cash acquired	(1,164.7)	(119.4)	(110.6)
Net proceeds from sale of business	—	139.3	—
Purchase of equity method investment in SSI	—	—	(18.2)
Loans to SSI	—	—	(28.4)
Purchase of property and equipment	(96.8)	(98.3)	(57.0)
Increase in equipment under customer usage agreements	(59.4)	(58.1)	(52.1)
Purchase of intellectual property	(6.5)	—	(4.5)
Other activity	(2.2)	(5.1)	(9.9)
Net cash used in investing activities	(1,329.6)	(141.6)	(280.7)
FINANCING ACTIVITIES			
Proceeds from long-term debt, net of issuance costs	—	—	1,497.3
Repayment of long-term debt	(75.0)	(45.8)	(1,465.0)
Proceeds from senior notes, net of issuance costs	936.3	—	—
Repayment of senior notes	(970.8)	—	—
Proceeds from revolving credit line	—	750.0	480.0
Repayments under revolving credit line	(250.0)	(500.0)	(780.0)
Proceeds from accounts receivable securitization agreement	320.0	16.0	43.0
Repayments under accounts receivable securitization agreement	(71.5)	(250.0)	(34.0)
Purchase of non-controlling interest	(8.5)	(1.8)	—
Repurchases of common stock	(409.8)	(653.6)	(200.1)
Payment of deferred acquisition consideration	(1.9)	(24.3)	(6.5)
Purchase of interest rate caps	—	—	(1.5)
Net proceeds from issuance of common stock under employee stock plans	51.3	65.6	49.8
Payment of minimum tax withholdings on net share settlements of equity awards	(47.5)	(14.3)	(12.8)
Payments under finance lease obligations	(2.4)	(1.7)	(1.7)
Net cash used in financing activities	(529.8)	(659.9)	(431.5)
Effect of exchange rate changes on cash and cash equivalents	(1.7)	4.1	(2.2)
Net increase (decrease) in cash and cash equivalents	469.3	99.2	(64.9)
Cash and cash equivalents, beginning of period	701.0	601.8	666.7
Cash and cash equivalents, end of period	$ 1,170.3	$ 701.0	$ 601.8

See accompanying notes.

Hologic, Inc.

Notes to Consolidated Financial Statements

(all tabular amounts in millions, except number of shares which are reflected in thousands)

1. Operations

Hologic, Inc. (the "Company" or "Hologic") develops, manufactures and supplies premium diagnostics products, medical imaging systems, and surgical products with an emphasis on women's health and well-being through early detection and treatment. Until December 30, 2019, the Company's product portfolio included light-based aesthetic and medical treatment systems sold by its former Medical Aesthetics business. The Company completed the sale of its Medical Aesthetics segment on December 30, 2019 (the first day of the second quarter of fiscal 2020).

COVID-19 Considerations

The global COVID-19 pandemic has created significant volatility, uncertainty, and economic disruption in the markets the Company sells its products into, primarily the U.S., Europe and Asia-Pacific. Starting in the second quarter of fiscal 2020, the spread of COVID-19 negatively impacted business and healthcare activity globally. In particular, due to government measures, elective procedures and exams were delayed or cancelled, there were significant reductions in physician office visits, and hospitals postponed or canceled capital purchases as well as limited or eliminated services; however, in the second half of the third quarter of fiscal 2020, the Company started to see a recovery of elective procedures and exams as economies were opened back up and restrictions eased, which has continued through the fourth quarter of fiscal 2021. The reductions in testing and procedures had a negative impact on the Company's operating results and cash flows in fiscal 2020, however, the impact of the commercial release of its COVID-19 assays more than offset those negative impacts as the Company generated significant revenue from the sales of these assays starting in the third quarter of fiscal 2020 through the fourth quarter of fiscal 2021.

While the Company's results of operations and cash flows since the third quarter of fiscal 2020 have been positively impacted by the sale of its COVID-19 assays as well the continued recovery of its other primary product lines and businesses to pre-COVID levels, the COVID-19 pandemic could have an adverse impact on its operating results, cash flows and financial condition in the future. The factors that could create such adverse impact include: reduced demand for COVID-19 testing; competition from existing and new COVID-19 testing technologies and products as well as the timing and effectiveness of distributing vaccines; the severity and duration of the COVID-19 pandemic; the resurgence of COVID-19 infections; the emergence of new COVID strain variants; the COVID-19 pandemic's impact on the U.S. and international healthcare systems, the U.S. economy and worldwide economy; and the timing, scope and effectiveness of U.S. and international governmental, regulatory, fiscal, monetary and public health responses to the COVID-19 pandemic and associated economic disruptions. The Company expects that as the current COVID-19 pandemic subsides, there may be a significantly reduced demand for ongoing testing, and thus, for its COVID-19 assays. As expected in the third quarter of fiscal 2021, revenues generated from the sale of its COVID-19 assays decreased significantly in the U.S. compared to the prior year period and the first and second quarters of fiscal 2021 as the population of vaccinated people continues to grow in the U.S. In the fourth quarter of fiscal 2021, COVID-19 assay revenues increased compared to the preceding quarter primarily due to the impact of the delta strain of COVID-19 resulting in higher demand for testing, however COVID-19 assay revenues decreased compared to the corresponding prior year period.

In response to the negative impact of COVID-19 on the Company's business, in April 2020, the Company initiated cost-cutting measures, which included not only reducing discretionary and variable spend, such as travel, marketing programs and the use of contractors, consultants and temporary help, but the Company also implemented employee furloughs, salary cuts primarily in the U.S., reduced hours and in certain instances, effected employee terminations. Further in April 2020, the Company shut down certain manufacturing facilities temporarily and implemented reduced work-week schedules in response to lower near-term demand for many of its products. As of the end of the third quarter of fiscal 2020, substantially all of the Company's employee cost-cutting measures ceased During fiscal 2021, the majority of the impacted manufacturing facilities were back to pre-COVID levels.

The Company has also taken and continue to take measures to ensure the safety of its employees and to comply with governmental orders. These measures could require that the Company's employees continue to work remotely or otherwise refrain from reporting to their normal workplace for extended periods of time, which in turn could result in a decrease in the Company's commercial and marketing activities. In addition, complying with government and customer vaccine mandates that apply to the Company may lead to employee attrition, disruption to the Company's workforce and result in additional costs associated with implementation and on-going compliance, which could have an adverse impact on the Company's operating results, cash flows and financial condition.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation. The Company's fiscal year ends on the last Saturday in September. Fiscal 2021, 2020 and 2019 ended on September 25, 2021, September 26, 2020 and September 28, 2019, respectively. Fiscal 2021, 2020 and 2019 were 52-week years.

Subsequent Events Consideration

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that may require additional disclosure. Subsequent events have been evaluated as required. There were no material recognized or unrecognized subsequent events, except as described below, recorded in the consolidated financial statements as of and for the year ended September 25, 2021. On September 27, 2021, the Company refinanced its term loan and revolving credit facility. For additional information, refer to Note 7. On October 14, 2021, the Company announced that it had entered into an agreement to acquire Bolder Surgical, Inc. ("Bolder Surgical") for a purchase price of approximately $160.0 million. The closing is subject to certain regulatory approvals, but the Company expects to close this acquisition by the end of calendar 2021. Bolder Surgical, located in Louisville, CO, is a developer and manufacturer of energy vessel sealing surgical devices in both laparoscopic and open procedures.

Management's Estimates and Uncertainties

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires management to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions by management affect the Company's revenue recognition for multiple performance obligation arrangements, valuations, purchase price allocations and contingent consideration related to business combinations, expected future cash flows including growth rates, discount rates, terminal values and other assumptions and estimates used to evaluate the recoverability of long-lived assets and goodwill, estimated fair values of intangible assets and goodwill, amortization methods and periods, warranty reserves, certain accrued expenses, restructuring and other related charges, contingent liabilities, tax reserves, deferred tax rates and recoverability of the Company's net deferred tax assets and related valuation allowances, and stock-based compensation.

Although the Company regularly assesses these estimates, actual results could differ materially from these estimates. Changes in estimates are recorded in the period in which they become known. The Company bases its estimates on historical experience and various other assumptions that it believes to be reasonable under the circumstances.

The Company is subject to a number of risks similar to those of other companies of similar size in its industry, including dependence on third-party reimbursements to support the markets of the Company's products, early stage of development of certain products, rapid technological changes, recoverability of long-lived assets (including intangible assets and goodwill), competition, stability of world financial markets, ability to obtain regulatory approvals, changes in the regulatory environment, limited number of suppliers, customer concentration, integration of acquisitions, substantial indebtedness, government regulations, management of international activities, protection of proprietary rights, patent and other litigation, dependence on contract manufacturers and dependence on key individuals.

Cash Equivalents

Cash equivalents are highly liquid investments with insignificant interest rate risk and maturities of three months or less at the time of acquisition.

Concentrations of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents, cost-method investments and trade accounts receivable. The Company invests its cash and cash equivalents with high credit quality financial institutions.

The Company's customers are principally located in the U.S., Europe and Asia. The Company performs ongoing credit evaluations of the financial condition of its customers and generally does not require collateral. Although the Company is

directly affected by the overall financial condition of the healthcare industry, as well as global economic conditions, management does not believe significant credit risk exists as of September 25, 2021. The Company generally has not experienced any material losses related to receivables from individual customers or groups of customers in the healthcare industry. The Company maintains an allowance for doubtful accounts based on accounts past due and historical collection experience.

There were no customers with a balance greater than 10% of accounts receivable as of September 25, 2021. There was one customer with a balance greater than 10% of accounts receivable as of September 26, 2020, at 11.9%. There were no customers that represented greater than 10% of consolidated revenues for fiscal years 2021, 2020 and 2019.

Concentration of Suppliers

The Company purchases certain components of its products from a single or small number of suppliers. A change in or loss of these suppliers could cause a delay in filling customer orders and a possible loss of sales, which could adversely affect results of operations.

Supplemental Cash Flow Statement Information

	Years ended		
	September 25, 2021	September 26, 2020	September 28, 2019
Cash paid during the period for income taxes	$ 615.1	$ 265.9	$ 180.6
Cash paid during the period for interest	$ 93.2	$ 109.5	$ 132.5
Non-Cash Financing Activities:			
Fair value of contingent consideration at acquisition	$ —	$ 82.7	$ —

Inventories

Inventories are valued at the lower of cost or market on a first in, first out basis. Work-in-process and finished goods inventories consist of materials, labor and manufacturing overhead. The valuation of inventory requires management to estimate excess and obsolete inventory. The Company employs a variety of methodologies to determine the net realizable value of its inventory. Provisions for excess and obsolete inventory are primarily based on management's estimates of forecasted sales, usage levels and expiration dates, as applicable for certain disposable products. A significant change in the timing or level of demand for the Company's products compared to forecasted amounts may result in recording additional charges for excess and obsolete inventory in the future. The Company records charges for excess and obsolete inventory within cost of product revenues.

Inventories consisted of the following:

	September 25, 2021	September 26, 2020
Raw materials	$ 163.3	$ 152.3
Work-in-process	53.0	46.5
Finished goods	284.9	196.3
	$ 501.2	$ 395.1

Property, Plant and Equipment

Property, plant and equipment is recorded at cost less allowances for depreciation and impairments. The straight-line method of depreciation is used for all property and equipment.

Property, plant and equipment consisted of the following:

	Estimated Useful Life	September 25, 2021	September 26, 2020
Equipment	3–10 years	$ 467.1	$ 460.7
Equipment under customer usage agreements	3–8 years	484.6	456.8
Buildings and improvements	20–35 years	191.2	167.3
Leasehold improvements	Shorter of the Original Term of Lease or Estimated Useful Life	49.7	44.3
Land		41.3	40.7
Furniture and fixtures	5–7 years	16.8	16.1
Finance lease right-of-use asset		9.9	—
		1,260.6	1,185.9
Less - accumulated depreciation and amortization		(695.9)	(694.4)
		$ 564.7	$ 491.5

Equipment under customer usage agreements primarily consists of diagnostic instrumentation and imaging equipment located at customer sites but owned by the Company. Generally, the customer has the right to use the equipment for a period of time provided they meet certain agreed to conditions. The Company recovers the cost of providing the equipment from the sale of disposables, primarily assays, tests and handpieces. The depreciation costs associated with equipment under customer usage agreements are charged to cost of product revenues over the estimated useful life of the equipment. The costs to maintain the equipment in the field are charged to cost of product revenue as incurred.

In September 2020 and October 2020, the Company was awarded grants of $7.6 million and $119.3 million, respectively, from the Department of Defense Joint Acquisition Task Force ("DOD") to expand production capacity for the Company's two SARS-CoV-2 assays. These grants are specifically to fund the capital equipment and labor investments needed to increase manufacturing capacity to enable the Company to provide a certain amount of COVID-19 tests per month for the U.S. market. The Company is accounting for the funds received under these grants as a reimbursement of the purchased capital equipment. The Company procures and pays for the capital equipment and necessary resources to build out its facility and construct the manufacturing lines to meet the requirements specified in the grant agreement. Subsequent to paying for the capital equipment, the DOD will reimburse the Company upon it meeting certain requirements However, the DOD retains title to assets purchased under the agreement, and title is transferred to the Company upon meeting certain milestones of the manufacturing efforts. As of September 25, 2021, the Company had $95.2 million of capital equipment related to the DOD grant that was awaiting approval. In fiscal 2021, the Company received $21.2 million from the DOD under these grants which has been recorded as a reduction of the cost basis of the purchased equipment. Payments under these grants are subject to satisfaction of the conditions of the grants.

Long-Lived Assets

The Company reviews its long-lived assets, which includes property, plant and equipment and identifiable intangible assets (see below for discussion of intangible assets), for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable in accordance with ASC 360-10-35-15, *Property, Plant and Equipment—Impairment or Disposal of Long-Lived Assets* (ASC 360). Recoverability of these assets is evaluated by comparing the carrying value of the assets to the undiscounted cash flows estimated to be generated by those assets over their remaining economic life. If the undiscounted cash flows are not sufficient to recover the carrying value of the assets, the assets are considered impaired. The impairment loss is measured by comparing the fair value of the assets to their carrying value. Fair value is determined by either a quoted market price, if any, or a value determined by a discounted cash flow technique.

Business Combinations and Acquisition of Intangible Assets

The Company accounts for the acquisition of a business in accordance with ASC 805, *Business Combinations* (ASC 805). Amounts paid to acquire a business are allocated to the assets acquired and liabilities assumed based on their fair values at the date of acquisition. Contingent consideration not deemed to be linked to continuing employment is recorded at fair value as measured on the date of acquisition. The value recorded is based on estimates of future financial projections under various potential scenarios using a Monte Carlo simulation. These cash flow projections are discounted with an appropriate risk adjusted rate. Each quarter until such contingent amounts are earned, the fair value of the liability is remeasured at each reporting period and adjusted as a component of operating expenses based on changes to the underlying assumptions. The

estimates used to determine the fair value of the contingent consideration liability are subject to significant judgment and actual results are likely to differ from the amounts originally recorded. The Company determines the fair value of acquired intangible assets based on detailed valuations that use certain information and assumptions provided by management. The Company allocates any excess purchase price over the fair value of the net tangible and intangible assets acquired to goodwill.

The Company uses the income approach to determine the fair value of developed technology and in-process research and development ("IPR&D") acquired in a business combination. This approach determines fair value by estimating the after-tax cash flows attributable to the respective asset over its useful life and then discounting these after-tax cash flows back to a present value. The Company bases its revenue assumptions on estimates of relevant market sizes, expected market growth rates, expected trends in technology and expected product introductions by competitors. Developed technology represents patented and unpatented technology and know-how. The value of the in-process projects is based on the project's stage of completion, the complexity of the work completed as of the acquisition date, the projected costs to complete, the contribution of core technologies and other acquired assets, the expected introduction date, the estimated cash flows to be generated upon commercial release and the estimated useful life of the technology. The Company believes that the estimated developed technology and IPR&D amounts represent the fair value at the date of acquisition and do not exceed the amount a third-party would pay for the assets. The significant assumptions used to estimate the fair value of intangible assets include discount rates and certain assumptions that form the basis of the forecasted results specifically revenue growth rates. These significant assumptions are forward looking and could be affected by future economic and market conditions.

The Company also uses the income approach, as described above, to determine the estimated fair value of certain other identifiable intangible assets including customer relationships, trade names and business licenses. Customer relationships represent established relationships with customers, which provide a ready channel for the sale of additional products and services. Trade names represent acquired company and product names.

Intangible Assets and Goodwill

Intangible Assets

Intangible assets are initially recorded at fair value and stated net of accumulated amortization and impairments. The Company amortizes its intangible assets that have finite lives using either the straight-line method, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be utilized. Amortization is recorded over the estimated useful lives ranging from 2 to 30 years. The Company evaluates the recoverability of its definite lived intangible assets whenever events or changes in circumstances or business conditions indicate that the carrying value of these assets may not be recoverable based on expectations of future undiscounted cash flows for each asset group. If the carrying value of an asset or asset group exceeds its undiscounted cash flows, the Company estimates the fair value of the assets, generally utilizing a discounted cash flow analysis based on the present value of estimated future cash flows to be generated by the assets using a risk-adjusted discount rate. To estimate the fair value of the assets, the Company uses market participant assumptions pursuant to ASC 820, *Fair Value Measurements*.

Indefinite lived intangible assets, such as IPR&D assets, are required to be tested for impairment annually, or more frequently if indicators of impairment are present. The Company’s annual impairment test date is as of the first day of its fourth quarter.

Intangible assets consisted of the following:

Description	September 25, 2021 Gross Carrying Value	September 25, 2021 Accumulated Amortization	September 26, 2020 Gross Carrying Value	September 26, 2020 Accumulated Amortization
Acquired intangible assets:				
Developed technology	$ 4,597.7	$ 3,184.2	$ 4,054.0	$ 2,907.2
In-process research and development	71.6	—	—	—
Customer relationships	591.7	510.1	549.1	477.8
Trade names	268.1	191.8	245.5	181.2
Non-competition agreements	1.5	1.5	1.5	1.3
Business licenses	2.5	2.5	2.4	2.3
Total acquired intangible assets	$ 5,533.1	$ 3,890.1	$ 4,852.5	$ 3,569.8
Internal-use software	23.5	17.2	51.8	43.2
Capitalized software embedded in products	25.5	15.6	26.8	10.6
Total intangible assets	$ 5,582.1	$ 3,922.9	$ 4,931.1	$ 3,623.6

Medical Aesthetics Impairment

In the first quarter of fiscal 2020, the Company's Medical Aesthetics business met the criteria to be designated as assets held-for-sale. As a result, the Company recorded a $30.2 million charge to record the asset group at fair value less costs to sell. See Note 15 for additional information.

During fiscal 2019, the Company identified indicators of impairment for its Medical Aesthetics reporting unit as a result of reductions in forecasts during the year, and in connection with the Company’s efforts to sell the business that began prior to the end of fiscal 2019. In performing the undiscounted cash flow analysis pursuant to ASC 360, the expected undiscounted cash flows of the asset group were determined using a probability-weighted approach taking into consideration the planned disposition, which was deemed to be highly probable as of the balance sheet date. Based on this analysis, the undiscounted cash flows were not sufficient to recover the carrying value of the asset group. As a result, the Company was required to perform Step 3 of the impairment test and determine the fair value of the asset group. The Company executed a definitive agreement on November 20, 2019 to sell the business. Although this agreement was signed subsequent to the balance sheet date, the Company concluded that it provided evidence regarding the estimate of fair value of the asset group at September 28, 2019 and that there were no events that occurred between September 28, 2019 and the date the Company entered into the definitive agreement that would significantly affect the fair value of the asset group. As a result, the Company recorded total impairment charges of $685.4 million in fiscal 2019. The impairment charge was allocated to the long-lived assets as follows: $576.9 million to developed technology, $22.4 million to customer relationships, $48.6 million to trade names, $27.7 million to distribution agreements and $9.8 million to equipment. On November 20, 2019, this asset group met the assets held-for-sale criteria and was recorded at fair value less the costs to sell as noted above.

Other Activity

During the third quarter of fiscal 2021, the Company acquired Mobidiag Oy and recorded $285.0 million of developed technology, $74.0 million of in-process research and development, $20.9 million of customer relationships and $20.0 million of trade names based on its preliminary purchase accounting.

During the second quarter of fiscal 2021, the Company acquired Biotheranostics, Inc. and recorded $160.3 million of developed technology and $2.1 million of trade names based on its preliminary purchase accounting.

During the second quarter of fiscal 2021, the Company acquired Diagenode SA and recorded $69.8 million of developed technology and $9.2 million of customer relationships based on its preliminary purchase accounting.

During the second quarter of fiscal 2021, the Company acquired Somatex Medical Technologies GmbH and recorded $38.0 million of developed technology, $1.2 million of customer relationships and $0.9 million of trade names based on its preliminary purchase accounting.

During the fourth quarter of fiscal 2020, the Company acquired Acessa Health, Inc. and recorded $127.0 million of developed technology and $1.2 million of trade names.

Amortization expense related to developed technology is classified as cost of product revenues—amortization of intangible assets. Amortization expense related to customer relationships, contracts, trade names, and business licenses is classified as a component of amortization of intangible assets within operating expenses.

The estimated amortization expense at September 25, 2021 for each of the five succeeding fiscal years was as follows:

Fiscal 2022	$	326.5
Fiscal 2023	$	231.3
Fiscal 2024	$	222.3
Fiscal 2025	$	208.9
Fiscal 2026	$	178.1

Goodwill

In accordance with ASC 350, *Intangibles—Goodwill and Other* (ASC 350), the Company tests goodwill for impairment annually at the reporting unit level and between annual tests if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that could indicate impairment and trigger an interim impairment assessment include, but are not limited to, current economic and market conditions, including a decline in market capitalization, a significant adverse change in legal factors, business climate, operational performance of the business or key personnel, and an adverse action or assessment by a regulator.

In performing the impairment test, the Company utilizes the single-step approach prescribed under Accounting Standards Update No. 2017-04, *Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* (ASU 2017-04). This approach requires a comparison of the carrying value of each reporting unit to its estimated fair value and to the extent the carrying value exceeds the fair value a charge is recorded up to the amount of goodwill in the reporting unit. To estimate the fair value of its reporting units, the Company primarily utilizes the income approach. The income approach is based on a DCF analysis and calculates the fair value by estimating the after-tax cash flows attributable to a reporting unit and then discounting the after-tax cash flows to present value using a risk-adjusted discount rate. Assumptions used in the DCF require significant judgment, including judgment about appropriate discount rates and terminal values, growth rates, and the amount and timing of expected future cash flows. The forecasted cash flows are based on the Company's most recent budget and strategic plan and for years beyond this period, the Company's estimates are based on assumed growth rates expected as of the measurement date. The Company believes its assumptions are consistent with the plans and estimates used to manage the underlying businesses. The discount rates used are intended to reflect the risks inherent in future cash flow projections and are based on estimates of the weighted-average cost of capital ("WACC") of market participants relative to each respective reporting unit. The market approach considers comparable market data based on multiples of revenue or earnings before interest, taxes, depreciation and amortization ("EBITDA") and is primarily used as a corroborative analysis to the results of the DCF analysis. The Company believes its assumptions used to determine the fair value of its reporting units are reasonable. If different assumptions were used, particularly with respect to forecasted cash flows, terminal values, WACCs, or market multiples, different estimates of fair value may result and there could be the potential that an impairment charge could result. Actual operating results and the related cash flows of the reporting units could differ from the estimated operating results and related cash flows.

The Company conducted its fiscal 2021 impairment test for its reporting units on the first day of the fourth quarter, and as noted above used DCF and market approaches to estimate the fair value of its reporting units as of June 27, 2021, and ultimately used the fair value determined by the DCF approach in making its impairment test conclusions. The Company believes it used reasonable estimates and assumptions about future revenue, cost projections, cash flows, market multiples and discount rates as of the measurement date. As a result of completing this analysis, all of the Company's reporting units had fair values exceeding their carrying values.

At September 25, 2021, the Company believes that its reporting units, with goodwill aggregating $3.3 billion, were not at risk of failing the goodwill impairment test based on its current forecasts and qualitative assessment.

The Company conducted its fiscal 2020 impairment test for its reporting units on the first day of the fourth quarter, and as noted above used DCF and market approaches to estimate the fair value of its reporting units as of June 28, 2020, and ultimately used the fair value determined by the DCF approach in making its impairment test conclusions. The Company believes it used reasonable estimates and assumptions about future revenue, cost projections, cash flows, market multiples and discount rates as of the measurement date. As a result of completing this analysis, all of the Company's reporting units had fair

values exceeding their carrying values. For illustrative purposes, had the fair value of each of the reporting units been lower by 10%, all of the reporting units would still have passed the goodwill impairment test.

A rollforward of goodwill activity by reportable segment from September 26, 2020 to September 25, 2021 is as follows:

	Diagnostics	Breast Health	GYN Surgical	Skeletal Health	Total
Balance at September 26, 2020	$ 821.6	$ 764.8	$ 1,063.4	$ 8.1	$ 2,657.9
Mobidiag acquisition	432.6	—	—	—	432.6
Diagenode acquisition	83.5	—	—	—	83.5
Biotheranostics acquisition	80.9	—	—	—	80.9
Somatex acquisition	—	32.4	—	—	32.4
Foreign currency and other adjustments	(7.8)	(0.1)	2.2	—	(5.7)
Balance at September 25, 2021	$ 1,410.8	$ 797.1	$ 1,065.6	$ 8.1	$ 3,281.6

Other Assets

Other assets consisted of the following:

	September 25, 2021	September 26, 2020
Other Assets		
Tax receivable	$ 24.7	$ 325.7
Right of use assets	83.6	80.7
Life insurance contracts	64.3	49.3
Deferred tax assets	21.9	15.5
Cost-method equity investments	9.5	11.4
Other	41.7	34.0
	$ 245.7	$ 516.6

The tax receivable in fiscal 2020 primarily related to a discrete tax benefit from the sale of Cynosure in the second quarter of fiscal 2020. This receivable was reclassified to a current asset in fiscal 2021 as the Company filed the carryback claim and expects to receive the refund within the next twelve months, subject to Internal Revenue Service processing times. The right of use assets were recorded in connection with the adoption of ASC 842, *Leases*, and pertains to operating leases. Life insurance contracts were purchased in connection with the Company's Nonqualified Deferred Compensation Plan ("DCP") and are recorded at their cash surrender value (see Note 12 for further discussion).

Research and Software Development Costs

Costs incurred for the research and development of the Company's products are expensed as incurred. Nonrefundable advance payments for goods or services to be received in the future by the Company for use in research and development activities are deferred. The deferred costs are expensed as the related goods are delivered or the services are performed.

The Company accounts for the development costs of software embedded in the Company's products in accordance with ASC 985, *Software.* Costs incurred in the research, design and development of software embedded in products to be sold to customers are charged to expense until technological feasibility of the ultimate product to be sold is established. The Company's policy is that technological feasibility is achieved when a working model, with the key features and functions of the product, is available for customer testing. Software development costs incurred after the establishment of technological feasibility and until the product is available for general release are capitalized, provided recoverability is reasonably assured. Capitalized software development costs are amortized over their estimated useful life and recorded within cost of revenues - product.

Foreign Currency Translation

The financial statements of the Company's foreign subsidiaries are translated in accordance with ASC 830, *Foreign Currency Matters.* The reporting currency for the Company is the U.S. dollar. The functional currency of the Company's foreign subsidiaries is determined based on the guidance in ASC 830. The majority of the Company's foreign subsidiaries' functional currency is the applicable local currency, although certain of the Company's foreign subsidiaries' functional currency

is the U.S. dollar based on the nature of their operations or functions. Assets and liabilities of subsidiaries whose functional currency is the local currency are translated at the exchange rate in effect at each balance sheet date. Before translation, the Company re-measures foreign currency denominated assets and liabilities, including inter-company accounts receivable and payable, into the functional currency of the respective entity, resulting in unrealized gains or losses recorded in other income (expense), net in the Consolidated Statements of Operations. Revenues and expenses are translated using average exchange rates during the respective period. Foreign currency translation adjustments are accumulated as a component of other comprehensive income (loss), which is a separate component of stockholders' equity. Gains and losses arising from transactions denominated in foreign currencies are included in other income (expense), net in the Consolidated Statements of Operations and were not significant in any of the reporting periods presented.

Accumulated Other Comprehensive Income (Loss)

Other comprehensive income (loss) includes certain transactions that have generally been reported in the statement of stockholders' equity. The following tables summarize the components and changes in accumulated balances of other comprehensive loss for the periods presented:

	Year Ended September 25, 2021					Year Ended September 26, 2020				
	Foreign Currency Translation	Pension Plans	Hedged Interest Rate Caps	Hedged Interest Rate Swaps	Total	Foreign Currency Translation	Pension Plans	Hedged Interest Rate Caps	Hedged Interest Rate Swaps	Total
Beginning Balance	$ (22.9)	$ (1.8)	$ (0.9)	$ (24.1)	$ (49.7)	$ (41.4)	$ (1.7)	$ (2.7)	$ 3.5	$ (42.3)
Other comprehensive income (loss) before reclassifications	(20.2)	0.5	0.4	9.4	(9.9)	18.5	(0.1)	(0.5)	(27.6)	(9.7)
Charges (gains) reclassified to statement of operations	—	—	0.5	—	0.5	—	—	2.3	—	2.3
Ending Balance	$ (43.1)	$ (1.3)	$ —	$ (14.7)	$ (59.1)	$ (22.9)	$ (1.8)	$ (0.9)	$ (24.1)	$ (49.7)

Derivatives

Interest Rate Cap - Cash Flow Hedge

The Company is exposed to certain risks arising from both its business operations and economic conditions. The Company manages its exposure to some of its interest rate risk through the use of interest rate caps, which are derivative financial instruments. The Company does not use derivatives for speculative purposes. For a derivative that is designated as a cash flow hedge, changes in the fair value of the derivative are recognized in accumulated other comprehensive income ("AOCI") to the extent the derivative is effective at offsetting the changes in the cash flows being hedged until the hedged item affects earnings. To the extent there is any hedge ineffectiveness, changes in fair value relating to the ineffective portion are immediately recognized in earnings in other income (expense), net in the Consolidated Statements of Operations.

During fiscal 2018, the Company entered into separate interest rate cap agreements with multiple counter-parties to mitigate the interest rate volatility associated with the variable interest rate on its amounts borrowed under the term loan feature of its credit facilities (see Note 7). Interest rate cap agreements provide the right to receive cash if the reference interest rate rises above a contractual rate. The aggregate premium paid for these interest rate cap agreements was $3.7 million, which was the initial fair value of the instruments recorded in the Company's financial statements. During fiscal 2019, the Company entered into additional separate interest rate cap agreements with multiple counter-parties to extend the expiration date of its hedges by an additional year. The aggregate premium paid for these interest cap agreements was $1.5 million, which was the initial fair value of the instruments recorded in the Company's financial statements.

The critical terms of the interest rate caps were designed to mirror the terms of the Company's LIBOR-based borrowings under its Credit Agreement, that has been amended multiple times, and therefore are highly effective at offsetting the cash flows being hedged. The Company designated these derivatives as cash flow hedges of the variability of the LIBOR-based interest payments on $1.0 billion of principal, which ended on December 27, 2019 (the first quarter of fiscal 2020) for the contracts entered into in fiscal 2018, and on December 23, 2020 (the first quarter of fiscal 2021) for the interest rate cap agreements entered into in fiscal 2019.

During fiscal 2021, 2020 and 2019, interest expense of $0.5 million, $2.3 million and $3.1 million, respectively, was reclassified from AOCI to the Company's Consolidated Statements of Operations related to the interest rate cap agreements. The last interest rate cap agreement matured as of December 26, 2020.

Interest Rate Swap - Cash Flow Hedge

In fiscal 2019, in order to hedge a portion of its variable rate debt beyond the contracted period under interest cap agreements, the Company entered into an interest rate swap contract with an effective date of December 23, 2020 and a termination date of December 17, 2023. The notional amount of this swap is $1.0 billion. The interest rate swap effectively fixes the LIBOR component of the variable interest rate on $1.0 billion of the notional amount under the 2018 Credit Agreement at 1.23%. The critical terms of the interest rate swap are designed to mirror the terms of the Company's LIBOR-based borrowings under its credit agreement and therefore are highly effective at offsetting the cash flows being hedged. The Company designated this derivative as a cash flow hedge of the variability of the LIBOR-based interest payments on $1.0 billion of principal. Therefore, changes in the fair value of the swap are recorded in AOCI and net of taxes were a gain of $9.4 million, a loss of $27.6 million and a gain of $3.5 million for fiscal years 2021, 2020, and 2019, respectively. The fair value of this derivative was in a liability position of $18.7 million as of September 25, 2021.

Forward Foreign Currency Contracts and Foreign Currency Option Contracts

The Company enters into forward foreign currency exchange contracts and foreign currency option contracts to mitigate certain operational exposures from the impact of changes in foreign currency exchange rates. Such exposures result from the portion of the Company's cash and operations that are denominated in currencies other than the U.S. dollar, primarily the Euro, the UK Pound, the Australian dollar, the Canadian dollar, the Chinese Yuan and the Japanese Yen. These foreign currency exchange contracts are entered into to support transactions made in the ordinary course of business and are not speculative in nature. The contracts are generally for periods of one year or less. The Company did not elect hedge accounting for these contracts; however, the Company may seek to apply hedge accounting in future scenarios. The change in the fair value of these contracts is recognized directly in earnings as a component of other income, net.

	Years Ended		
	September 25, 2021	**September 26, 2020**	**September 28, 2019**
Amount of realized (loss) gain recognized in income			
Forward foreign currency contracts	$ (3.6)	$ 0.7	$ 11.0
Foreign currency option contracts	(6.1)	(1.9)	—
	$ (9.7)	$ (1.2)	$ 11.0
Amount of unrealized (loss) gain recognized in income			
Forward foreign currency contracts	$ 0.5	$ (0.2)	$ (2.2)
Foreign currency option contracts	(4.0)	4.0	0.1
	$ (3.5)	$ 3.8	$ (2.1)
Amount of gain (loss) recognized in income			
Total	$ (13.2)	$ 2.6	$ 8.9

As of September 25, 2021, the Company had outstanding forward foreign currency contracts that were not designated for hedge accounting and are used to hedge fluctuations in the U.S dollar of certain of the Company's cash balances denominated in the Euro and UK pound, as well as forecasted transactions denominated in the Euro, UK pound, Australian Dollar, Canadian Dollar, Chinese Yuan and Japanese Yen with an aggregate notional amount of $861.5 million.

Financial Instrument Presentation

The table below presents the fair value of the Company's derivative financial instruments as well as their classification on the balance sheet as of September 25, 2021:

	Balance Sheet Location	September 25, 2021	September 26, 2020
Assets:			
Derivatives not designated as hedging instruments:			
Forward foreign currency contracts	Prepaid expenses and other current assets	$ 1.7	$ 1.1
Foreign currency option contracts	Prepaid expenses and other current assets	—	10.1
		$ 1.7	$ 11.2
Liabilities:			
Derivative instruments designated as a cash flow hedge:			
Interest rate swap contract	Accrued expenses	$ 11.1	$ 8.2
Interest rate swap contract	Other long-term liabilities	7.6	23.0
Total		$ 18.7	$ 31.2
Derivatives not designated as hedging instruments:			
Forward foreign currency contracts	Accrued expenses	$ 0.6	$ —

The following table presents the unrealized gain (loss) recognized in AOCI related to the interest rate caps and interest rate swap for the following reporting periods:

	Years Ended		
	September 25, 2021	September 26, 2020	September 28, 2019
Amount of gain (loss) recognized in other comprehensive income (loss), net of taxes:			
Interest rate swap	$ 9.4	$ (27.6)	$ 3.5
Interest rate cap agreements	0.4	(0.5)	(8.0)
Total	$ 9.8	$ (28.1)	$ (4.5)

Trade Receivables and Allowance for Credit Losses

Effective September 27, 2020, the Company adopted ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)*, which requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The expected credit losses are developed using an estimated loss rate method that considers historical collection experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. The estimated loss rates are applied to trade receivables with similar risk characteristics such as the length of time the balance has been outstanding and the location of the customer. In certain instances, the Company may identify individual trade receivable assets that do not share risk characteristics with other trade receivables, in which case the Company records its expected credit losses on an individual asset basis. For example, potential adverse changes to customer liquidity from new macroeconomic events, such as the COVID-19 pandemic, must be taken into consideration. To date, the Company has not experienced significant customer payment defaults, or identified other significant collectability concerns as a result of the COVID-19 pandemic. In connection with assessing credit losses for individual trade receivable assets, the Company considers significant factors relevant to collectability including those specific to the customer such as bankruptcy, length of time an account is outstanding, and the liquidity and financial position of the customer. If a trade receivable asset is evaluated on an individual basis, the Company excludes those assets from the portfolios of trade receivables evaluated on a collective basis.

The following is a rollforward of the allowance for credit losses for fiscal 2021, 2020 and 2019:

	Balance at Beginning of Period	Charged to Costs and Expenses	Divested	Write-offs and Payments	Balance at End of Period
Period Ended:					
September 25, 2021	$ 31.6	$ 15.0	$ —	$ (6.1)	$ 40.5
September 26, 2020	$ 17.8	$ 26.8	$ (5.8)	$ (7.2)	$ 31.6
September 28, 2019	$ 16.2	$ 4.4	$ —	$ (2.8)	$ 17.8

Cost of Service and Other Revenues

Cost of service and other revenues primarily represents payroll and related costs associated with the Company's professional services, employees, consultants, infrastructure costs and overhead allocations, including depreciation, rent and materials consumed in providing the service.

Stock-Based Compensation

The Company accounts for share-based payments in accordance with ASC 718, *Stock Compensation* (ASC 718). As such, all share-based payments to employees, including grants of stock options, restricted stock units, performance stock units and market stock units and shares issued under the Company's employee stock purchase plan, are recognized in the Consolidated Statements of Operations based on their fair values on the date of grant. In addition, all excess tax benefits and deficiencies are recognized as a component of the provision for income taxes on a discrete basis in the period in which the equity awards vest and/or are settled.

Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Diluted net income per share is computed by dividing net income by the weighted average number of common shares and the dilutive effect of potential future issuances of common stock from outstanding stock options and restricted stock units for the period outstanding determined by applying the treasury stock method. In accordance with ASC 718, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of in-the-money stock options and restricted stock units. This results in the assumed buyback of additional shares, thereby reducing the dilutive impact of equity awards.

A reconciliation of basic and diluted share amounts for fiscal 2021, 2020, and 2019 was as follows:

	September 25, 2021	September 26, 2020	September 28, 2019
Basic weighted average common shares outstanding	257,046	262,727	269,413
Weighted average common stock equivalents from assumed exercise of stock options and restricted stock units	2,660	1,886	—
Diluted weighted average common shares outstanding	259,706	264,613	269,413
Weighted-average anti-dilutive shares related to:			
Outstanding stock options and restricted stock units	528	1,158	4,098

In those reporting periods in which the Company has reported net income, anti-dilutive shares generally are comprised of those stock options that either have an exercise price above the average stock price for the period or the stock options' combined exercise price and average unrecognized stock compensation expense upon exercise is greater than the average stock price. In those reporting periods in which the Company has a net loss, anti-dilutive shares are comprised of the impact of those number of shares that would have been dilutive had the Company had net income plus the number of common stock equivalents that would be anti-dilutive had the company had net income.

Product Warranties

The Company generally offers a one-year warranty for its products. The Company provides for the estimated cost of product warranties at the time product revenue is recognized. Factors that affect the Company's warranty reserves include the

number of units sold, historical and anticipated rates of warranty repairs and the cost per repair. The Company periodically assesses the adequacy of the warranty reserve and adjusts the amount as necessary.

Product warranty activity for fiscal 2021 and 2020 was as follows:

	Balance at Beginning of Period	Provisions	Acquired	Divested	Settlements/ Adjustments	Balance at End of Period
Period ended:						
September 25, 2021	$ 9.9	$ 7.7	$ 0.3	$ —	$ (9.1)	$ 8.8
September 26, 2020	$ 13.9	$ 11.7	$ 0.5	$ (6.1)	$ (10.1)	$ 9.9

Advertising Costs

Advertising costs are charged to operations as incurred. The Company does not have any direct-response advertising. Advertising costs, which include trade shows and conventions, were approximately $9.8 million, $15.6 million and $29.5 million for fiscal 2021, 2020 and 2019, respectively, and were included in selling and marketing expense in the Consolidated Statements of Operations.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)* and subsequently a number of improvements. The guidance requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis. The income statement reflects the measurement of credit losses for newly recognized financial assets, as well as the expected credit losses during the period. The measurement of expected credit losses is based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. The Company adopted the standard in the first quarter of fiscal 2021. The adoption of ASU 2016-13 did not have a material effect on the Company's consolidated financial statements.

In November 2019, the FASB issued ASU No. 2019-08, *Compensation - Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606)*. This ASU identifies, evaluates, and improves areas of GAAP for which cost and complexity can be reduced while maintaining or improving the usefulness of the information provided. The amendments in this Update expanded the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The Company adopted the standard in the first quarter of fiscal 2021. The adoption of ASU 2019-08 did not have a material effect on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740) Simplifying the Accounting for Income Taxes.* The FASB issued this Update as part of its initiative to reduce complexity in accounting standards (the Simplification Initiative). For public business entities, the amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, and is applicable to the Company in fiscal 2022. The Company is currently evaluating the impact of the adoption of ASU 2019-12 on its consolidated financial position and results of operations.

In January 2020, the FASB issued ASU No. 2020-01, *Investments - Equity Securities (Topic 321), Investments - Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)*. The FASB issued this Update to clarify certain interactions between the guidance to account for certain equity securities under Topic 321, the guidance to account for investments under the equity method of accounting in Topic 323, and the guidance in Topic 815. This update could change how an entity accounts for an equity security under the measurement alternative or a forward contract or purchased option to purchase securities that, upon settlement of the forward contract or exercise of the purchased option, would be accounted for under the equity method of accounting or the fair value option in accordance with Topic 825, *Financial Instruments*. For entities that have adopted the amendments in Update 2020-01, the updated guidance is effective for annual periods beginning after December 15, 2020, and is applicable to the Company in fiscal 2022. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of ASU 2020-01 on its consolidated financial position and results of operations.

In January 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848)*. The FASB issued this Update as 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. This update will provide optional expedients and exceptions for applying GAAP to

only contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. For entities that have adopted the amendments in Update 2020-04, the updated guidance is effective for all entities as of March 12, 2020 through December 31, 2022. The Company is currently evaluating the impact of the adoption of ASU 2020-04 on its consolidated financial position and results of operations.

In May 2021, the FASB issued ASU No. 2021-05, *Leases (Topic 842), Lessors - Certain Leases with Variable Lease Payments*. This ASU addresses an issue related to a lessor's accounting for certain leases with variable lease payments. The amendments in this Update affect lessors with lease contracts that (1) have variable lease payments that do not depend on a reference index or a rate and (2) would have resulted in the recognition of a selling loss at lease commencement if classified as a sales-type lease or a direct financing lease. For public business entities, the amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021, and is applicable to the Company in fiscal 2023. The Company is currently evaluating the impact of the adoption of ASU 2021-05 on its consolidated financial position and results of operations.

3. Revenue

The Company accounts for revenue pursuant to ASC Update No. 2014-09, *Revenue from Contracts with Customer* (ASC 606) and generates revenue from the sale of its products, primarily medical imaging systems and related components and software, diagnostic tests and assays and surgical disposable products, and related services, which are primarily support and maintenance services on its medical imaging systems, and to a lesser extent installation, training and repairs. Prior to the Cynosure divestiture, the Company also generated revenue from the sale and service of medical aesthetic treatment systems. The Company's products are sold primarily through a direct sales force, and within international markets, there is more reliance on distributors and resellers. Revenue is recorded net of sales tax. The following table provides revenue from contracts with customers by business and geographic region on a disaggregated basis:

	Years Ended								
	September 25, 2021			September 26, 2020			September 28, 2019		
Business (in millions)	**United States**	**Intl.**	**Total**	**United States**	**Intl.**	**Total**	**United States**	**Intl.**	**Total**
Diagnostics:									
Cytology & Perinatal	$ 304.6	$ 169.3	$ 473.9	$ 266.3	$ 143.8	$ 410.1	$ 312.9	$ 159.1	$ 472.0
Molecular Diagnostics	2,038.9	1,132.6	3,171.5	1,272.5	375.9	1,648.4	549.9	125.1	675.0
Blood Screening	49.6	—	49.6	43.6	—	43.6	58.5	—	58.5
Total	2,393.1	1,301.9	3,695.0	1,582.4	519.7	2,102.1	921.3	284.2	1,205.5
Breast Health:									
Breast Imaging	830.4	253.0	1,083.4	722.0	231.6	953.6	853.1	241.5	1,094.6
Interventional Breast Solutions	221.4	47.5	268.9	166.6	31.7	198.3	184.8	34.8	219.6
Total	1,051.8	300.5	1,352.3	888.6	263.3	1,151.9	1,037.9	276.3	1,314.2
GYN Surgical	396.4	91.7	488.1	310.1	66.0	376.1	362.8	74.4	437.2
Skeletal Health	61.0	35.9	96.9	51.2	29.8	81.0	58.6	36.2	94.8
Medical Aesthetics	—	—	—	30.9	34.4	65.3	155.4	160.2	315.6
Total	$ 3,902.3	$ 1,730.0	$ 5,632.3	$ 2,863.2	$ 913.2	$ 3,776.4	$ 2,536.0	$ 831.3	$ 3,367.3

Geographic Regions (*in millions*)	Years Ended September 25, 2021	September 26, 2020	September 28, 2019
United States	$ 3,902.3	$ 2,863.2	$ 2,536.0
Europe	1,201.8	569.8	396.0
Asia-Pacific	365.0	226.8	286.0
Rest of World	163.2	116.6	149.3
	$ 5,632.3	$ 3,776.4	$ 3,367.3

The following table provides revenue recognized by source:

Revenue by type (*in millions*)	Years Ended September 25, 2021	September 26, 2020	September 28, 2019
Disposables	$ 4,198.2	$ 2,561.1	$ 1,786.4
Capital equipment, components and software	769.1	665.9	984.9
Service	598.1	516.6	568.3
Other	66.9	32.8	27.7
	$ 5,632.3	$ 3,776.4	$ 3,367.3

The Company considers revenue to be earned when all of the following criteria are met: the Company has a contract with a customer that creates enforceable rights and obligations; promised products or services are identified; the transaction price, or the amount the Company expects to receive, including an estimate of uncertain amounts subject to a constraint to ensure revenue is not recognized in an amount that would result in a significant reversal upon resolution of the uncertainty, is determinable; and the Company has transferred control of the promised items to the customer. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer, and is the unit of account in the contract. The transaction price for the contract is measured as the amount of consideration the Company expects to receive in exchange for the goods and services expected to be transferred. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, control of the distinct good or service is transferred. Transfer of control for the Company's products is generally at shipment or delivery, depending on contractual terms, but occurs when title and risk of loss transfers to the customer which represents the point in time when the customer obtains the use of and substantially all of the remaining benefit of the product. As such, the Company's performance obligation related to product sales is satisfied at a point in time. Revenue from support and maintenance contracts, extended warranty and professional services for installation, training and repairs is recognized over time based on the period contracted or as the services are performed as these methods represent a faithful depiction of the transfer of goods and services.

The Company recognizes a receivable when it has an unconditional right to payment, which represents the amount the Company expects to collect in a transaction and is most often equal to the transaction price in the contract. Payment terms are typically 30 days in the U.S. but may be longer in international markets. The Company treats shipping and handling costs performed after a customer obtains control of the good as a fulfillment cost and records these costs within costs of product revenue when the corresponding revenue is recognized.

The Company also places instruments (or equipment) at customer sites but retains title to the instrument. The customer has the right to use the instrument for a period of time, and the Company recovers the cost of providing the instrument through the sales of disposables, namely tests and assays in Diagnostics and handpieces in GYN Surgical. These types of agreements include an embedded lease, which is generally an operating lease, for the right to use an instrument and no instrument revenue is recognized at the time of instrument delivery. The Company recognizes a portion of the revenue allocated to the embedded lease concurrent with the sale of disposables over the term of the agreement.

Some of the Company's contracts have multiple performance obligations. For contracts with multiple performance obligations, the Company allocates the transaction price to each performance obligation using its best estimate of the standalone selling price of each distinct good or service in the contract. The Company determines its best estimate of standalone selling price using average selling prices over 3- to 12-month periods of data depending on the products or nature of the services coupled with current market considerations. If the product or service does not have a history of sales or if sales volume is not

sufficient, the Company relies on prices set by its pricing committees or applicable marketing department adjusted for expected discounts.

Variable Consideration

The Company exercises judgment in estimating variable consideration, which includes volume discounts, sales rebates, product returns and other adjustments. These amounts are recorded as a reduction to revenue and classified as a current liability. The Company bases its estimates for volume discounts and sales rebates on historical information to the extent it is reasonable to be used as a predictive tool of expected future rebates. To the extent the transaction price includes variable consideration, the Company applies judgment in constraining the estimated variable consideration due to factors that may cause reversal of revenue recognized. The Company evaluates constraints based on its historical and projected experience with similar customer contracts. The Company's contracts typically do not provide the right to return product. In general, estimates of variable consideration and constraints are not material to the Company's financial statements.

Remaining Performance Obligations

As of September 25, 2021, the estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied was approximately $830.6 million. These remaining performance obligations primarily relate to extended warranty and support and maintenance obligations in the Company's Breast Health and Skeletal Health reportable segments. The Company expects to recognize approximately 40% of this amount as revenue in 2022, 27% in 2023, 18% in 2024, 10% in 2025, and 5% thereafter. The Company has applied the practical expedient to not include remaining performance obligations related to contracts with original expected durations of one year or less in the amounts above.

Contract Assets and Liabilities

The Company discloses accounts receivable separately in the Consolidated Balance Sheets at their net realizable value. Contract assets primarily relate to the Company's conditional right to consideration for work completed but not billed at the reporting date. Contract assets at the beginning and end of the period, as well as the changes in the balance, were immaterial.

Contract liabilities primarily relate to payments received from customers in advance of performance under the contract. The Company records a contract liability, or deferred revenue, when it has an obligation to provide service, and to a much lesser extent product, to the customer and payment is received or due in advance of performance. Deferred revenue primarily relates to support and maintenance contracts and extended warranty obligations within the Company's Breast Health and Skeletal Health reportable segments. Contract liabilities are classified as other current liabilities and other long-term liabilities on the Consolidated Balance Sheets. The Company recognized revenue of $112.1 million and $106.2 million in the years ended September 25, 2021 and September 26, 2020, respectively, that was included in the contract liability balance at September 26, 2020 and September 28, 2019, respectively.

Practical Expedients

The Company applies a practical expedient to expense costs to obtain a contract with a customer as incurred when the amortization period would have been one year or less. These costs solely comprise sales commissions and typically the commissions are incurred at the time of shipment of product and upon billings for support and maintenance contracts.

4. Leases

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, referred to as ASC 842. The purpose of ASU 2016-02 was to increase the transparency and comparability among organizations by recognizing lease assets and liabilities on the balance sheet, including those previously classified as operating leases under GAAP, and disclosing key information about leasing arrangements. ASC 842, as amended, was effective for the Company in fiscal 2020. The Company adopted the standard using the transition method provided by ASC Update No. 2018-11, *Leases (Topic 842): Targeted Improvements*. Under this method, the Company applied the new lease standard on September 29, 2019, rather than at the earliest comparative period presented in the financial statements.

Upon transition, the Company applied the package of practical expedients permitted under ASC 842 transition guidance to its entire lease portfolio at September 29, 2019. As a result, the Company was not required to reassess (i) whether any expired or existing contracts are or contain leases, (ii) the classification of any expired or existing leases, and (iii) initial direct costs for any existing leases. Furthermore, as a lessee the Company elected to combine lease and non-lease components together for the majority of its leases. As a result, for these applicable classes of underlying assets, the Company accounted for each separate lease component and the non-lease components associated with that lease component as a single lease component.

Under ASC 842 as a lessor, in instances where the Company places instruments (or equipment) at customer sites as part of its reagent rental contracts, certain of the Company's reagent rental contracts could be classified as sales-type leases. Under sales-type leases, there is accelerated expense recognition for the cost of the placed equipment and potentially up-front revenue in the event there are fixed rental payments, a portion of which would be allocated to the equipment. The Company does not have a significant amount of sales-type leases. Prior to the adoption of ASC 842, all instruments placed under the Company's reagent rental programs were classified as operating leases and instrument revenue and cost were recognized over the term of the contract.

Upon adoption of the new lease standard, the Company recognized operating lease right-of-use assets and finance lease right-of-use assets of $91.7 million and $10.2 million, respectively, and corresponding operating lease liabilities and finance lease liabilities of $96.6 million and $21.0 million, respectively. This included recording the Company’s existing capital lease as a finance lease at transition. In addition, the Company derecognized $32.6 million of property, plant and equipment and $35.2 million of finance lease obligations recorded in accrued expenses and other long-term liabilities associated with two previously existing build-to-suit lease arrangements. Right-of-use assets and corresponding liabilities for these build-to-suit lease arrangements were included within the total amount recognized upon adoption of the new lease standard.

Lessee Activity - Leases where Hologic is the Lessee

The majority of the Company's facilities are occupied under operating lease arrangements with various expiration dates through 2035, some of which include options to extend the term of the lease, and some of which include options to terminate the lease within one year. The Company has operating leases for office space, land, warehouse and manufacturing space, vehicles and certain equipment. Leases with an initial term of 12 months or less are generally not recorded on the balance sheet and expense for these leases is recognized on a straight-line basis over the lease term. For leases executed in fiscal 2020 and later, the Company accounts for the lease components and the non-lease components as a single lease component. The Company's leases have remaining lease terms of one year to approximately 14 years, some of which may include options to extend the leases for up to 10 years and some include options to terminate early. These options have been included in the determination of the lease liability when it is reasonably certain that the option will be exercised. The Company does not have any leases that include residual value guarantees.

The Company determines whether an arrangement is or contains a lease based on the unique facts and circumstances present at the inception of an arrangement. The right-of-use assets and related liabilities for operating leases are included in other assets, accrued expenses, and other long-term liabilities in the consolidated balance sheet as of September 25, 2021.

Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease contract. Operating and finance lease liabilities and their corresponding right-of-use assets are recorded based on the present value of fixed lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the incremental borrowing rate, which is the estimated rate that would be incurred to borrow on a collateralized basis over a similar term at an amount equal to the lease payments in a similar economic environment. The weighted average discount rate utilized on the Company's operating and finance lease liabilities as of September 25, 2021 was 2.25%.

The following table presents supplemental balance sheet information related to the Company's operating and finance leases:

	Balance Sheet Location	September 25, 2021 Operating Leases	September 25, 2021 Finance Leases	September 26, 2020 Operating Leases	September 26, 2020 Finance Leases
Assets					
Lease right-of-use assets	*Other assets*	$ 83.6	$ —	$ 80.7	$ —
Finance lease right-of-use assets (non-current)	*Property, plant and equipment, net*	$ —	$ 9.3	$ —	$ —
Liabilities					
Operating lease liabilities (current)	*Accrued expenses*	$ 26.8	$ —	$ 23.5	$ —
Finance lease liabilities (current)	*Finance lease obligations - short term*	$ —	$ 3.7	$ —	$ 1.9
Operating lease liabilities (non-current)	*Other long-term liabilities*	$ 66.1	$ —	$ 65.6	$ —
Finance lease liabilities (non-current)	*Finance lease obligations - long term*	$ —	$ 22.8	$ —	$ 17.4

In connection with the Diagenode SA acquisition, the Company acquired two finance leases. The Company accounted for these lease agreements pursuant to ASC 842 and ASC 805 and recorded both an asset and liability at the present value of future lease payments as part of the purchase accounting. The finance leases are for two facilities with remaining lease terms of 7 and 11 years and contain a bargain purchase option of 3% at the end of the lease term.

The following table presents the weighted average remaining lease term and discount rate information related to the Company's operating and finance leases:

	As of September 25, 2021 Operating Leases	As of September 25, 2021 Finance Lease	As of September 26, 2020 Operating Leases	As of September 26, 2020 Finance Lease
Weighted average remaining lease term	4.95	7.52	5.58	7.64
Weighted average discount rate	1.6 %	4.3 %	2.0 %	5.1 %

The following table provides information related to the Company’s operating and finance leases:

	Year Ended September 25, 2021	Year Ended September 26, 2020
Operating lease cost (a)	$ 30.1	$ 27.5
Finance lease cost - amortization of right-of-use assets	$ 0.6	$ 0.3
Finance lease cost - interest cost	$ 1.0	$ 1.0
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	$ 1.0	$ 1.0
Operating cash flows from operating leases	$ 28.2	$ 23.9
Financing cash flows from finance leases	$ 2.4	$ 1.7
Total cash paid for amounts included in the measurement of lease liabilities	$ 31.6	$ 26.6
ROU assets arising from entering into new operating lease obligations	$ 28.6	$ 13.3
ROU assets arising from entering into new finance lease obligations	$ 9.1	$ —

(a) Includes short-term lease expense and variable lease costs, which were immaterial for the year ended September 25, 2021.

Rent expense under FASB ASC Topic 840 was $23.1 million for fiscal 2019.

The following table presents the future minimum lease payments under non-cancellable operating lease liabilities and finance lease as of September 25, 2021:

Fiscal Year	Operating Leases	Finance Lease
2022	$ 28.2	$ 4.4
2023	22.0	4.2
2024	16.4	3.9
2025	11.8	3.9
2026	7.4	3.9
Thereafter	11.7	10.2
Total future minimum lease payments	97.5	30.5
Less: imputed interest	(4.6)	(4.0)
Present value of lease liabilities	$ 92.9	$ 26.5

Lessor Activity - Leases where Hologic is the Lessor

Certain assets, primarily diagnostics instruments, are leased to customers under contractual arrangements that typically include an operating lease and performance obligations for disposables, reagents and other consumables. These contractual arrangements are subject to termination provisions which are evaluated in determining the lease term for lease accounting purposes. Contract terms vary by customer and may include options to terminate the contract or options to extend the contract. Where instruments are provided under operating lease arrangements, some portion or the entire lease revenue may be variable and subject to subsequent non-lease component (e.g., reagent) sales. Sales-type leases are immaterial. The allocation of revenue between the lease and non-lease components is based on stand-alone selling prices. Lease revenue represented less than 5% of the Company's consolidated revenue for all periods presented.

In connection with the disposition of the Medical Aesthetics business in fiscal 2020, the Company entered into an agreement to sublease to Cynosure its U.S. headquarters and manufacturing location. As such, the Company derecognized $10.2 million for the right-of-use asset for the finance lease and recorded a lease receivable, which is $17.4 million as of September 25, 2021.

The Company leases a portion of a building it owns and subleases some of its rented facilities and has received aggregate rental income of $2.6 million, $2.0 million and $2.7 million in fiscal 2021, 2020 and 2019, respectively, which has been recorded as an offset to operating lease costs. The future minimum annual rental income payments under these lease and sublease agreements at September 25, 2021 are as follows:

Fiscal 2022	$ 3.1
Fiscal 2023	3.0
Fiscal 2024	3.0
Fiscal 2025	2.0
Fiscal 2026	0.9
Thereafter	2.3
Total	$ 14.3

5. Business Combinations

During fiscal 2021, 2020, and 2019, the Company completed several business combinations for a total consideration of $1,178.9 million, $269.0 million and $120.1 million, respectively. The business combinations resulted in the recognition of intangible assets, goodwill and other assets and liabilities summarized below. During 2021, the Company also completed an asset acquisition of customer relationship assets of $5.6 million.

Mobidiag Oy

On June 17, 2021, the Company completed the acquisition of Mobidiag Oy ("Mobidiag"), for a purchase price of $729.6 million. Mobidiag, located in Finland, manufactures molecular diagnostic solutions for gastrointestinal infections, antimicrobial resistance management and other infections. Mobidiag's results of operations are reported in the Company's Diagnostics reportable segment from the date of acquisition.

The total purchase price was allocated to Mobidiag's preliminary tangible and identifiable intangible assets and liabilities

based on the estimated fair values as of June 17, 2021, as set forth below.

Cash	$	7.0
Accounts receivable		4.2
Inventory		13.7
Other assets		29.6
Accounts payable and accrued expenses		(19.1)
Other liabilities		(11.7)
Identifiable intangible assets:		
Developed technology		285.0
In-process research and development		74.0
Customer relationships		20.9
Trade names		20.0
Current debt		(66.1)
Deferred income taxes, net		(60.5)
Goodwill		432.6
Purchase Price	$	729.6

In performing the preliminary purchase price allocation, the Company considered, among other factors, the intended future use of acquired assets, analysis of historical financial performance and estimates of future performance of Mobidiag's business. The allocation of the purchase price is preliminary as the Company continues to gather information supporting the acquired assets and liabilities, primarily related to deferred income taxes.

As part of the preliminary purchase price allocation, the Company determined the identifiable intangible assets are development technology, in-process research and development ("IPR&D"), customer relationships and trade names. The preliminary fair value of the intangible assets was estimated using the income approach, and the cash flow projections were discounted using rates ranging from 15.0% to 19.0%. The cash flows were based on estimates used to price the transaction, and the discount rates applied were benchmarked with reference to the implied rate of return from the transaction model and the weighted average cost of capital.

The developed technology assets are comprised of know-how, patents and technologies embedded in Mobidiag's products and relate to currently marketed products. The developed technology assets comprise the primary product families under the Novodiag and Amplidiag technology platforms.

The IPR&D project relates to an in-process project that has not reached technological feasibility as of the acquisition date and has no alternative future use. The primary basis for determining technological feasibility of the project is obtaining regulatory approval to market the underlying product. The asset recorded relates to one project, and the Company expects to complete the project over the next three years. In the fourth quarter of fiscal 2021, the Company updated its valuation of IPR&D assets based on facts that existed at the date of acquisition and recorded a $29.0 million decrease to the IPR&D intangible asset value. Given the uncertainties inherent with product development and introduction, there can be no assurance that the Company's product development efforts will be successful, completed on a timely basis or within budget, if at all. The IPR&D asset was valued using the income approach.

The preliminary estimate of the weighted average life for the developed technology assets range from 8 to 12 years, customer relationships range from 5 to 10 years, and tradenames range from 8 to 12 years. The preliminary calculation of the excess of the purchase price over the estimated fair value of the tangible net assets and intangible assets acquired was recorded to goodwill. Factors contributing to the recognition of the preliminary amount of goodwill were primarily based on anticipated strategic and synergistic benefits that are expected to be realized from the Mobidiag acquisition. These benefits include expanding the Company's molecular diagnostics portfolio into the near-patient testing market and utilizing the Diagnostic's commercial sales, manufacturing and regulatory expertise to drive adoption and revenue growth. None of the goodwill is expected to be deductible for income tax purposes.

Biotheranostics

On February 22, 2021, the Company completed the acquisition of Biotheranostics, Inc. ("Biotheranostics"), for a purchase price of $231.3 million. Biotheranostics, located in San Diego, California, manufactures molecular diagnostic tests for breast and metastatic cancers and performs the lab testing procedures at its facility. Biotheranostics' results of operations are reported in the Company's Diagnostics reportable segment from the date of acquisition and its revenues are reported within service and other revenue in the Company's consolidated statement of income and within service revenue in the disclosure of disaggregated revenue in Note 3.

The total purchase price was allocated to Biotheranostics' preliminary tangible and identifiable intangible assets and liabilities based on the estimated fair values as of February 22, 2021, as set forth below.

Cash	$	9.6
Accounts receivable		6.6
Other assets		6.5
Accounts payable and accrued expenses		(8.2)
Other liabilities		(8.1)
Identifiable intangible assets:		
Developed technology		160.3
Trade names		2.1
Deferred income taxes, net		(18.4)
Goodwill		80.9
Purchase Price	$	231.3

In performing the preliminary purchase price allocation, the Company considered, among other factors, the intended future use of acquired assets, analysis of historical financial performance and estimates of future performance of Biotheranostics' business. The allocation of the purchase price is preliminary as the Company continues to gather information supporting the acquired assets and liabilities.

As part of the preliminary purchase price allocation, the Company determined the identifiable intangible assets are developed technology and trade names. The preliminary fair value of the intangible assets was estimated using the income approach, and the cash flow projections were discounted using a 18.0% rate. The cash flows were based on estimates used to price the transaction, and the discount rate applied was benchmarked with reference to the implied rate of return from the transaction model and the weighted average cost of capital. The weighted average life of developed technology and trade names is 10 years. The preliminary calculation of the excess of the purchase price over the estimated fair value of the tangible net assets and intangible assets acquired was recorded to goodwill. Factors contributing to the recognition of the preliminary amount of goodwill were primarily based on anticipated synergistic benefits of adding Biotheranostics' Clinical Laboratory Improvement Amendments (CLIA) lab to the Company's portfolio of offerings and of utilizing Diagnostic's marketing and regulatory expertise to drive adoption and revenue growth. None of the goodwill is expected to be deductible for income tax purposes.

Diagenode

On March 1, 2021, the Company completed the acquisition of Diagenode SA ("Diagenode") for a purchase price of $155.1 million. Diagenode, located in Belgium, is a developer and manufacturer of molecular diagnostic assays based on PCR (polymerase chain reaction) technology to detect infectious diseases of bacterial, viral or parasite origin. Diagenode's results of operations are reported in the Company's Diagnostics reportable segment from the date of acquisition.

The total purchase price was allocated to Diagenode's preliminary tangible and identifiable intangible assets and liabilities based on the estimated fair values as of March 1, 2021, as set forth below.

Cash	$	5.6
Accounts receivable		9.3
Inventory		9.0
Other assets		13.9
Accounts payable and accrued expenses		(16.7)
Other liabilities		(9.2)
Identifiable intangible assets:		
Developed technology		69.8
Customer relationships		9.2
Deferred income taxes, net		(19.3)
Goodwill		83.5
Purchase Price	$	155.1

In performing the preliminary purchase price allocation, the Company considered, among other factors, the intended future use of acquired assets, analysis of historical financial performance and estimates of future performance of Diagenode's business. The allocation of the purchase price is preliminary as the Company continues to gather information supporting the acquired assets and liabilities, primarily related to deferred income taxes.

As part of the preliminary purchase price allocation, the Company determined the identifiable intangible assets are developed technology and customer relationships. The preliminary fair value of the intangible assets was estimated using the income approach, and the cash flow projections were discounted using a 14.5% rate for developed technology and a 13.5% rate for customer relationships. The cash flows were based on estimates used to price the transaction, and the discount rate applied was benchmarked with reference to the implied rate of return from the transaction model and the weighted average cost of capital. The weighted average life of developed technology and customer relationships is 10 years. The preliminary calculation of the excess of the purchase price over the estimated fair value of the tangible net assets and intangible assets acquired was recorded to goodwill. Factors contributing to the recognition of the preliminary amount of goodwill were based on anticipated synergistic benefits of Diagenode's products broadening the Diagnostics portfolio of molecular diagnostics products primarily in the transplant and acute care gastrointestinal and respiratory space as customers seek a broader menu of tests, utilizing Diagnostic's sales force to drive menu expansion and revenue growth and gaining additional PCR assay development expertise. None of the goodwill is expected to be deductible for income tax purposes.

Somatex Medical Technologies

On December 30, 2020, the Company completed the acquisition of Somatex Medical Technologies GmbH ("Somatex") for a purchase price of $62.9 million. Somatex, located in Germany, is a manufacturer of biopsy site markers, including the Tumark product line of tissue markers, which were distributed by the Company in the U.S. prior to the acquisition. The allocation of the purchase price is based on the Company's preliminary valuation, and it allocated $38.0 million to the preliminary value of developed technology, $1.2 million to customer relationships, $0.9 million to trade names and $32.4 million to goodwill. The remaining $9.6 million of the purchase price was allocated to the net acquired tangible assets and liabilities. The allocation of the purchase price is preliminary as the Company continues to gather information supporting the acquired assets and liabilities, primarily related to deferred income taxes. Somatex' results of operations are reported in the Company's Breast Health reportable segment from the date of acquisition. None of the goodwill is expected to be deductible for income tax purposes.

NXC Imaging

On September 28, 2020, the Company completed the acquisition of assets from NXC Imaging for a purchase price of $5.6 million. NXC Imaging was a long-standing distributor of the Company's Breast and Skeletal Health products in the U.S. The majority of the purchase price was allocated to a customer relationships intangible asset with a useful life of 5 years.

Acessa Health

On August 23, 2020, the Company completed the acquisition of Acessa Health, Inc. ("Acessa") for a purchase price of $162.0 million, which included a hold-back of $3.0 million that was paid in January 2021, and contingent consideration, which the Company estimated the fair value to be $81.8 million as of the measurement date. Acessa, located in Austin, Texas,

manufactures and markets its ProVu system, a laparoscopic radio frequency ablation system for use in treatment of uterine fibroids. Acessa's results of operations are reported in the Company's GYN Surgical reportable segment from the date of acquisition.

The contingent payments are based on a multiple of annual incremental revenue growth over a three-year period ending annually in December. There is no maximum earnout. Pursuant to ASC 805, *Business Combinations,* the Company recorded its estimate of the fair value of the contingent consideration liability utilizing the Monte Carlo simulation based on future revenue projections of Acessa, comparable companies revenue growth rates, implied volatility and applying a risk adjusted discount rate. Each quarter the Company is required to remeasure the fair value of the liability as assumptions change and such adjustments will be recorded in operating expenses. This fair value measurement was based on significant inputs not observable in the market and thus represented a Level 3 measurement as defined in ASC 820, *Fair Value Measurements*. This fair value measurement is directly impacted by the Company's estimate of future incremental revenue growth of the business. Accordingly, if actual revenue growth is higher or lower than the estimates within the fair value measurement, the Company would record additional charges or benefits, respectively. For the year ended September 25, 2021, the Company remeasured the contingent consideration liability and recorded a gain of $6.7 million to record the liability at fair value. The reduction in fair value was primarily due to a decrease in forecasted revenues over the measurement period, partially offset by a lower discount rate and accretion of the liability based on the passage of time. As of September 25, 2021, the Company's contingent consideration liability was $75.1 million, $16.3 million of which was recorded within accrued expenses and $58.8 million was recorded within other long-term liabilities.

The total purchase price was allocated to Acessa's tangible and identifiable intangible assets and liabilities based on the estimated fair values of those assets as of August 23, 2020, as set forth below.

Cash	$	1.2
Inventory		4.0
Other assets		4.4
Accounts payable and accrued expenses		(4.7)
Identifiable intangible assets:		
Developed Technology		127.0
Trade names		1.2
Deferred income taxes, net		(20.2)
Goodwill		49.1
Purchase Price	$	162.0

In performing the purchase price allocation, the Company considered, among other factors, the intended future use of acquired assets, analysis of historical financial performance and estimates of future performance of Acessa's business. As part of the purchase price allocation, the Company determined the identifiable intangible assets were developed technology and trade names. The fair value of the intangible assets was estimated using the income approach, and the cash flow projections were discounted using an 18.0% rate. The cash flows were based on estimates used to price the transaction, and the discount rate applied was benchmarked with reference to the implied rate of return from the transaction model and the weighted average cost of capital. The weighted average life of developed technology and trade names is 10 years. The calculation of the excess of the purchase price over the estimated fair value of the tangible net assets and intangible assets acquired was recorded to goodwill. Factors contributing to the recognition of the amount of goodwill were based on synergistic benefits of Acessa's products being complementary to the GYN Surgical portfolio of products and utilizing the GYN Surgical sales force to drive adoption and revenue growth. None of the goodwill is expected to be deductible for income tax purposes.

Health Beacons

On February 3, 2020, the Company completed the acquisition of Health Beacons, Inc. ("Health Beacons") for a purchase price of $19.7 million, which included hold-backs of $2.3 million that are payable up to eighteen months from the date of acquisition. Health Beacons manufactures the LOCalizer product. Based on the Company's valuation, it allocated $10.7 million to developed technology and $6.2 million to goodwill. The remaining $2.8 million of the purchase price was allocated to acquired tangible assets and liabilities. Health Beacons' results of operations are reported in the Company's Breast Health reportable segment from the date of acquisition.

Alpha Imaging

On December 30, 2019, the Company completed the acquisition of assets from Alpha Imaging, LLC ("Alpha Imaging") for a purchase price of $18.0 million, which included a hold-back of $1.0 million and contingent consideration which the Company estimated at $0.9 million. The contingent consideration was payable upon shipment of backlog orders entered into by Alpha Imaging prior to the acquisition. Alpha Imaging was a long-standing distributor of the Company's Breast and Skeletal Health products in the U.S. The majority of the purchase price was allocated to a customer relationships intangible asset with a useful life of 5 years.

SuperSonic Imagine

On August 1, 2019, the Company purchased 46% of the outstanding shares of SuperSonic Imagine SA ("SSI") for $18.2 million. SSI was a public company located in Aix-en-Provence, France that manufactures and markets ultrasound medical imaging equipment. In September 2019, the Company launched a cash tender offer to acquire the remaining outstanding shares for a price of €1.50 per share in cash. The Company determined that SSI was a Variable Interest Entity ("VIE") but it was not the primary beneficiary as it was not a party to the initial design of the entity nor did it have control over SSI's operations until November 21, 2019 when the Company's ownership of SSI's voting stock exceeded 50%. Accordingly, the Company initially accounted for this investment under the equity method of accounting and included its proportionate share of SSI's net loss of $3.3 million for the two months ended September 28, 2019 within Other income (expense), net.

On November 21, 2019, the Company acquired an additional 7.6 million of SSI's common shares for $12.6 million. As a result, the Company owned approximately 78% of the outstanding common shares at November 21, 2019, and controlled SSI's voting interest and operations. The Company performed purchase accounting as of November 21, 2019 and beginning on that date the financial results of SSI are included within the Company's consolidated financial statements, specifically the Breast Health reportable segment. The Company remeasured the initial investment of 46% of the outstanding shares of SSI to its fair value at the acquisition date, resulting in a gain of $3.2 million recorded to other income (expense), net in the first quarter of fiscal 2020. The total accounting purchase price was $69.3 million, which consisted of $17.9 million for the equity method investment in SSI, $12.6 million for shares acquired on November 21, 2019, $30.2 million for loans the Company provided to SSI prior to the acquisition to pay-off pre-existing loans and fund operations that are considered forgiven, and $8.6 million representing the fair value of the noncontrolling interest as of November 21, 2019. The Company purchased an additional 1.1 million outstanding shares in fiscal 2020 for $1.8 million. In the third quarter of fiscal 2021, the Company purchased the remaining 4.8 million shares outstanding for $8.5 million and as of September 25, 2021, the Company owned 100% of the outstanding shares of SSI.

The total purchase price was allocated to SSI's tangible and identifiable intangible assets and liabilities based on the estimated fair values of those assets as of November 21, 2019, as set forth below.

Cash	$	2.6
Accounts receivable		7.1
Inventory		10.0
Property, plant and equipment		6.5
Other assets		4.3
Accounts payable and accrued expenses		(24.5)
Deferred revenue		(1.8)
Short and long-term debt		(8.8)
Other liabilities		(3.8)
Identifiable intangible assets:		
Developed technology		38.3
Customer relationships		4.0
Trade names		3.0
Deferred income taxes, net		(1.9)
Goodwill		34.3
Purchase Price	$	69.3

In performing the purchase price allocation, the Company considered, among other factors, the intended future use of acquired assets, analysis of historical financial performance and estimates of future performance of SSI's business. As part of

the purchase price allocation, the Company determined the identifiable intangible assets were developed technology, customer relationships, and trade names. The fair value of the intangible assets was estimated using the income approach, and the cash flow projections were discounted using a 12.0% rate. The cash flows were based on estimates used to price the transaction, and the discount rates applied were benchmarked with reference to the implied rate of return from the transaction model and the weighted average cost of capital. The weighted average life for the developed technology is 9 years, customer relationships is 9 years and trade names is 8.6 years. The calculation of the excess of the purchase price over the estimated fair value of the tangible net assets and intangible assets acquired was recorded to goodwill. Factors contributing to the recognition of the amount of goodwill were based on anticipated synergistic benefits of SSI's products being complementary to Breast Health's 3D mammography systems and using the Company's existing U.S. sales force as SSI's presence in the U.S. is limited. None of the goodwill is expected to be deductible for income tax purposes.

Focal Therapeutics

On October 1, 2018, the Company completed the acquisition of Focal Therapeutics, Inc. ("Focal") for a purchase price of $120.1 million, which included hold-backs of $14.0 million payable up to one year from the date of acquisition. In the second quarter of fiscal 2019, $1.5 million of the hold-back was paid, and the remaining $12.5 million was paid in the first quarter of fiscal 2020. Focal, headquartered in California, manufactures and markets its BioZorb marker, which is an implantable three-dimensional marker that helps clinicians overcome certain challenges in breast conserving surgery. Focal's results of operations are reported in the Company's Breast Health reportable segment from the date of acquisition.

The total purchase price was allocated to Focal's tangible and identifiable intangible assets and liabilities based on the estimated fair values of those assets as of October 1, 2018, as set forth below:

Cash	$	2.2
Accounts receivable		2.0
Inventory		7.9
Other assets		0.5
Accounts payable and accrued expenses		(5.6)
Long-term debt		(2.5)
Identifiable intangible assets:		
Developed technology		83.1
In-process research and development		11.4
Trade names		2.7
Deferred income taxes, net		(12.7)
Goodwill		31.1
Purchase Price	$	120.1

In performing the purchase price allocation, the Company considered, among other factors, the intended future use of acquired assets, analysis of historical financial performance and estimates of future performance of Focal's business. As part of the purchase price allocation, the Company determined the identifiable intangible assets were developed technology, in-process research and development, and trade names. The fair value of the intangible assets was estimated using the income approach, and the cash flow projections were discounted using rates ranging from 15.5% to 16.5%. The cash flows were based on estimates used to price the transaction, and the discount rates applied were benchmarked with reference to the implied rate of return from the transaction model and the weighted average cost of capital. The weighted average life of developed technology and trade names was 11 years and 13 years, respectively. The calculation of the excess of the purchase price over the estimated fair value of the tangible net assets and intangible assets acquired was recorded to goodwill. The factors contributing to the recognition of the amount of goodwill were based on synergistic benefits that are expected to be realized from this acquisition. Benefits include the expectation of broadening the Company's Breast Health portfolio of products and technology. None of the goodwill is expected to be deductible for income tax purposes.

6. Restructuring and Divestiture Charges

The Company evaluates its operations for opportunities to improve operational effectiveness and efficiency, including facility and operations consolidation, and to better align expenses with revenues. As a result of these assessments, the Company has undertaken various restructuring actions which are described below. The following table displays charges taken related to restructuring actions in fiscal 2021, 2020 and 2019 and a rollforward of the charges to the accrued balances as of September 25, 2021:

	Fiscal 2021 Actions	Fiscal 2020 Actions	Fiscal 2019 Actions	Other	Total
Restructuring Charges					
Fiscal 2019 charges:					
Workforce reductions	$ —	$ —	$ 4.0	$ 1.4	$ 5.4
Facility closure costs	—	—	—	1.2	1.2
Fiscal 2019 restructuring charges	$ —	$ —	$ 4.0	$ 2.6	$ 6.6
Fiscal 2020 charges:					
Workforce reductions	$ —	$ 13.2	$ 0.3	$ (0.1)	$ 13.4
Facility closure costs	—	1.9	—	—	1.9
Fiscal 2020 restructuring charges	$ —	$ 15.1	$ 0.3	$ (0.1)	$ 15.3
Fiscal 2021 charges:					
Workforce reductions	$ 8.7	$ 0.6	$ —	$ —	$ 9.3
Fiscal 2021 restructuring charges	$ 8.7	$ 0.6	$ —	$ —	$ 9.3

	Fiscal 2021 Actions	Fiscal 2020 Actions	Fiscal 2019 Actions	Fiscal 2018 Actions	Previous Other Charges	Total
Rollforward of Accrued Restructuring						
Balance as of September 29, 2018	$ —	$ —	$ —	$ 4.3	$ 4.8	$ 9.1
Fiscal 2019 restructuring charges	$ —	$ —	$ 4.0	$ 1.2	$ 1.4	$ 6.6
Severance payments and adjustments	—	—	(3.0)	(3.9)	(0.8)	(7.7)
Other payments	—	—	—	(0.5)	(1.6)	(2.1)
Balance as of September 28, 2019	$ —	$ —	$ 1.0	$ 1.1	$ 3.8	$ 5.9
Fiscal 2020 restructuring charges	$ —	$ 15.1	$ 0.3	$ (0.1)	$ —	$ 15.3
Stock-based compensation	—	(7.5)	—	—	—	(7.5)
Severance payments and adjustments	—	(4.4)	(1.3)	(0.2)	—	(5.9)
Other payments and adjustments (1)	—	0.5	—	—	(3.8)	(3.3)
Balance as of September 26, 2020	$ —	$ 3.7	$ —	$ 0.8	$ —	$ 4.5
Fiscal 2021 restructuring charges	$ 8.7	$ 0.6	$ —	$ —	$ —	$ 9.3
Stock-based compensation	(0.9)	—	—	—	—	(0.9)
Severance payments and adjustments	(4.6)	(3.4)	—	(0.8)	—	(8.8)
Balance as of September 25, 2021	$ 3.2	$ 0.9	$ —	$ —	$ —	$ 4.1

(1) In fiscal 2020, as part of the adoption of ASC 842, the Company reclassified $3.8 million from a lease liability to offset the right of use asset on the Company's consolidated balance sheet.

Fiscal 2021 Actions

During fiscal 2021, the Company made various decisions to terminate certain individuals across all divisions in multiple departments and close certain manufacturing facilities for minor product lines. The Company recorded $8.7 million for severance and benefits related to these actions, which occurred in the U.S. and various international locations. The charges were recorded pursuant to ASC 712, *Compensation-Nonretirement Postemployment Benefits* (ASC 712) or ASC 420, *Exit or Disposal Cost Obligations* (ASC 420), depending on the employee.

Fiscal 2020 Actions

During fiscal 2020, the Company made various decisions to terminate certain personnel across all divisions in multiple departments, transfer production and close certain manufacturing facilities for minor product lines. The Company recorded charges totaling $13.4 million for severance and benefits related to these actions. The charges were recorded pursuant to ASC 712 or ASC 420, depending on the employee. Included within this charge was $5.0 million related to the modification of equity awards for a certain executive. These actions are complete.

During the second quarter of fiscal 2020, the Company recorded net divestiture charges of $1.9 million. The charge included $1.3 million to dispose of the Company's life sciences testing business located in the UK, which performed research testing for pharmaceutical companies. Separately, in connection with the Cynosure divestiture, the Company accelerated stock compensation expense and other benefits of $2.6 million, partially offset by other adjustments of $2.0 million.

Fiscal 2019 Actions

During fiscal 2019, the Company decided to transfer certain shared services positions to its Costa Rica facility from its Marlborough location and announced the termination of certain personnel and implemented other employee termination actions. The charges for these actions were recorded pursuant to ASC 420 for one-time termination benefits. The Company recorded severance benefits charges of $4.0 million in fiscal 2019 related to these actions and this action was completed in the first quarter of fiscal 2020. The Company also recorded $1.0 million of severance charges in fiscal 2019 related to 2018 actions that were recorded pursuant to ASC 420.

Other

In connection with the closure of the Bedford location during the first quarter of fiscal 2017, the Company recorded $3.5 million for lease obligation charges related to the first floor of the facility as the Company determined it had met the cease-use date criteria. The Company made certain assumptions regarding the time period it would take to obtain a subtenant and the sublease rates it could obtain. During the third quarter of fiscal 2017, the Company updated its assumption regarding the time period it would take to obtain a subtenant at the Bedford location and as a result recorded an additional $1.3 million lease obligation charge. During the third quarter of fiscal 2018, the Company further adjusted its assumptions and lowered the estimate of the sublease income rate and extended the time period to obtain a sub-tenant. As a result, the Company recorded an additional charge of $1.6 million. During the third quarter of fiscal 2019, the Company further updated its assumption regarding its ability to sublet the first floor and recorded an additional lease obligation charge of $1.4 million. These estimates may vary from the actual sublease agreements executed, if any, resulting in an adjustment to the charge. The Company has vacated other portions of the building but not the entire facility, and at this time does not meet the cease-use date criteria to record additional restructuring charges. In connection with the adoption of ASC 842, the Company reclassified the remaining accrued lease balance of $3.8 million from restructuring to offset the right of use assets on the consolidated balance sheet.

7. Borrowings and Credit Agreements

The Company's borrowings consisted of the following:

	September 25, 2021	September 26, 2020
Current debt obligations, net of debt discount and deferred issuance costs:		
Term Loan	$ —	$ 74.9
Revolver	—	250.0
Securitization Program	248.5	—
Other	64.5	—
Total current debt obligations	$ 313.0	$ 324.9
Long-term debt obligations, net of debt discount and issuance costs:		
Term Loan	1,382.3	1,379.9
2025 Senior Notes	—	939.4
2028 Senior Notes	395.4	394.6
2029 Senior Notes	934.5	—
Total long-term debt obligations	2,712.2	2,713.9
Total debt obligations	$ 3,025.2	$ 3,038.8

The debt maturity schedule for the Company's obligations as of September 25, 2021 was as follows:

	2022	2023	2024	2025	2026	2027 and Thereafter	Total
Term Loan*	$ 75.0	$ 112.5	$ 1,200.0	$ —	$ —	$ —	$ 1,387.5
Securitization Program	248.5	—	—	—	—	—	248.5
2028 Senior Notes	—	—	—	—	—	400.0	400.0
2029 Senior Notes	—	—	—	—	—	950.0	950.0
Other	64.5	—	—	—	—	—	64.5
	$ 388.0	$ 112.5	$ 1,200.0	$ —	$ —	$ 1,350.0	$ 3,050.5

*The Term Loan debt maturity schedule herein represents the 2018 Credit Agreement as of September 25, 2021. The Company amended the credit agreement on September 27, 2021, which resulted in a change in the principal maturity schedule.

2018 Amended and Restated Credit Agreement

On December 17, 2018, the Company and certain of its subsidiaries refinanced its term loan and revolving credit facility by entering into an Amended and Restated Credit and Guaranty Agreement as of December 17, 2018 (the "2018 Credit Agreement") with Bank of America, N.A. in its capacity as Administrative Agent, Swing Line Lender and L/C Issuer, and certain other lenders. The 2018 Credit Agreement amended and restated the Company's prior credit and guaranty agreement as of October 3, 2017 ("2017 Credit Agreement").

The credit facilities under the 2018 Credit Agreement consisted of:

- A $1.5 billion secured term loan ("2018 Term Loan") with a maturity date of December 17, 2023; and
- A secured revolving credit facility ("2018 Revolver") under which the Company could borrow up to $1.5 billion, subject to certain sublimits, with a maturity date of December 17, 2023.

Borrowings under the 2018 Credit Agreement bore interest, at the Company's option and in each case plus an applicable margin as follows:

- *2018 Term Loan*: at the Base Rate, Eurocurrency Rate or LIBOR Daily Floating Rate,
- *2018 Revolver*: if funded in U.S. dollars, the Base Rate, Eurocurrency Rate, or LIBOR Daily Floating Rate, and, if funded in an alternative currency, the Eurocurrency Rate; and if requested under the swing line sublimit, the Base Rate.

As of September 25, 2021, the Company had no amounts outstanding under the 2018 Revolver and the interest rate under the 2018 Term Loan was 1.08%.

The applicable margin to the Base Rate, Eurocurrency Rate, or LIBOR Daily Floating Rate was subject to specified changes depending on the total net leverage ratio as defined in the 2018 Credit Agreement. The borrowings of the 2018 Term Loan initially bore interest at an annual rate equal to the Eurocurrency Rate (i.e., the LIBOR rate) plus an Applicable Rate equal to 1.00%. The borrowings of the 2018 Revolver initially bore interest at a rate equal to the LIBOR Daily Floating Rate plus an Applicable Rate, which was 1.00% at September 25, 2021. The Company was also required to pay a quarterly commitment fee calculated on the undrawn committed amount available under the 2018 Revolver.

The Company was required to make scheduled principal payments under the 2018 Term Loan in increasing amounts ranging from $9.375 million per three-month period commencing with the three-month period ending on December 27, 2019 to $28.125 million per three-month period commencing with the three-month period ending on December 29, 2022 and ending on September 29, 2023. The remaining balance of the 2018 Term Loan after the scheduled principal payments, which was $1.2 billion, and any amounts outstanding under the 2018 Revolver were due at maturity. In addition, subject to the terms and conditions set forth in the 2018 Credit Agreement, the Company could have been required to make certain mandatory prepayments from the net proceeds of specified types of asset sales (subject to certain reinvestment rights), debt issuances and insurance recoveries (subject to certain reinvestment rights). These mandatory prepayments were required to be applied by the Company, first, to the 2018 Term Loan, second, to any outstanding amount under any Swing Line Loans, third, to the 2018 Revolver, fourth to prepay any outstanding reimbursement obligations with respect to Letters of Credit and fifth, to cash collateralize any Letters of Credit. Subject to certain limitations, the Company could have voluntarily prepaid any of the 2018 Credit Facilities without premium or penalty.

The 2018 Credit Agreement contained affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants restricting the ability of the Company, subject to negotiated exceptions, to incur additional indebtedness and grant additional liens on its assets, engage in mergers or acquisitions or dispose of assets, enter into sale-leaseback transactions, pay dividends or make other distributions, voluntarily prepay other indebtedness, enter into transactions with affiliated persons, make investments, and change the nature of their businesses. In addition, the 2018 Credit Agreement required the Company to maintain certain financial ratios. The 2018 Credit Agreement also contained customary representations and warranties and events of default, including payment defaults, breach of representations and warranties, covenant defaults, cross defaults and an event of default upon a change of control of the Company.

Borrowings were secured by first-priority liens on, and a first-priority security interest in, substantially all of the assets of the Company and its U.S. subsidiaries, with certain exceptions. The 2018 Credit Agreement contained total net leverage ratio and interest coverage ratio financial covenants measured as of the last day of each fiscal quarter. The total net leverage ratio covenant was 5.00:1.00 beginning on the Company's fiscal quarter ended December 29, 2018, and would have remained as such until it decreased to 4.50:1.00 for the quarter ending June 25, 2022. The interest coverage ratio covenant was 3.75:1.00 beginning on the Company's fiscal quarter ended December 29, 2018, and remained as such for each quarter thereafter. The total net leverage ratio was defined as the ratio of the Company's consolidated net debt as of the quarter end to its consolidated adjusted EBITDA (as defined in the 2018 Credit Agreement) for the four-fiscal quarter period ending on the measurement date. The interest coverage ratio was defined as the ratio of the Company's consolidated adjusted EBITDA for the prior four-fiscal quarter period ending on the measurement date to adjusted consolidated cash interest expense (as defined in the 2018 Credit Agreement) for the same measurement period. The Company was in compliance with these covenants as of September 25, 2021.

The Company evaluated the 2018 Credit Agreement for derivatives pursuant to ASC 815, *Derivatives and Hedging*, and identified embedded derivatives that required bifurcation as the features were not clearly and closely related to the host instrument. The embedded derivatives were a default provision, which could require additional interest payments, and a provision requiring contingent payments to compensate the lenders for changes in tax deductions. The Company determined that the fair value of these embedded derivatives was nominal as of September 25, 2021.

Pursuant to ASC 470, *Debt* (ASC 470), the accounting related to entering into the 2018 Credit Agreement and using the proceeds to pay off the 2017 Credit Agreement was evaluated on a creditor-by-creditor basis to determine whether each transaction should be accounted for as a modification or extinguishment. Certain creditors under the 2017 Credit Agreement did not participate in this refinancing transaction and ceased being creditors of the Company. As a result, the Company recorded a debt extinguishment loss of $0.8 million in the first quarter of fiscal 2019. For the remainder of the creditors, this transaction was accounted for as a modification because on a creditor-by-creditor basis the present value of the cash flows between the two debt instruments before and after the transaction was less than 10%.

Interest expense, non-cash interest expense, the weighted average interest rate, and the interest rate at the end of period under the 2018 Credit Agreement and the 2017 Credit Agreement was as follows:

	Years Ended		
	September 25, 2021	September 26, 2020	September 28, 2019
Interest expense (1)	$ 22.0	$ 46.6	$ 67.0
Non-cash interest expense	$ 2.5	$ 2.5	$ 2.6
Weighted average interest rate	1.13 %	2.25 %	3.79 %
Interest rate at end of period	1.08 %	1.40 %	3.43 %

(1) Interest expense includes non-cash interest expense related to the amortization of the deferred issuance costs and accretion of the debt discount.

2021 Credit Agreement - Subsequent Event

On September 27, 2021, the Company and certain of its subsidiaries refinanced its term loan and revolving credit facility under the 2018 Credit Agreement by entering into Refinancing Amendment No. 2 dated as of September 27, 2021, to the Amended and Restated Credit and Guaranty Agreement as of October 3, 2017, as amended (the "2021 Credit Agreement") with Bank of America, N.A. in its capacity as Administrative Agent, Swing Line Lender and L/C Issuer, and certain other lenders. The 2021 Credit Agreement amends the Company's 2018 Credit Agreement. Substantially all of the proceeds under the 2021 Credit Agreement of $1.5 billion were used to repay the amounts outstanding under the 2018 Credit Agreement. Borrowings under the 2021 Credit Agreement are secured by first-priority liens on, and a first-priority security interest in (in each case subject to certain liens permitted under the 2021 Credit Agreement), substantially all of the Company's U.S. assets of the Subsidiary Guarantors. These liens are subject to release during the term of the facilities if the Company is able to achieve certain corporate or corporate family ratings and other conditions are met. The credit facilities under the 2021 Credit Agreement consist of:

- A $1.5 billion secured term loan ("2021 Term Loan") with a maturity date of September 25, 2026; and
- A secured revolving credit facility ("2021 Revolver") under which the Company may borrow up to $2.0 billion, subject to certain sublimits, with a maturity date of September 25, 2026.

Borrowings under the 2021 Credit Agreement, other than Swing Line Loans (as defined in the 2021 Credit Agreement), bear interest, at the Company's option, at the Base Rate (as defined in the 2021 Credit Agreement), at the Eurocurrency Rate (as defined in the 2021 Credit Agreement), at the Alternative Currency Daily Rate (as defined in the 2021 Credit Agreement), or at the LIBOR Daily Floating Rate (as defined in the 2021 Credit Agreement), in each case plus the Applicable Rate (as defined in the 2021 Credit Agreement).

The Applicable Rate in regards to the Base Rate, the Eurocurrency Rate, the Alternative Currency Daily Rate, the Alternative Currency Term Rate, and the LIBOR Daily Floating Rate is subject to change depending on the Total Net Leverage Ratio (as defined in the 2021 Credit Agreement). The borrowings of the Term Loan under the 2021 Credit Facilities initially bear interest at an annual rate equal to the Eurocurrency Rate for a one month interest period plus an Applicable Rate equal to 1.00%.

The Company is also required to pay a quarterly commitment fee calculated on daily basis equal to the Applicable Rate as of such day multiplied by the undrawn committed amount available under the Revolver (taking into account any outstanding amounts under the LC Sublimit). This commitment fee is initially 0.15% per annum for the Revolver.

The Company is required to make scheduled principal payments under the 2021 Term Loan in increasing amounts ranging from $3.75 million per three-month period commencing with the three-month period ending on December 29, 2022 to $18.75 million per three-month period commencing with the three month period ending on December 26, 2025. The remaining balance of $1.335 billion (or such lesser aggregate principal amount of Term Loans then outstanding) on the 2021 Term Loan and any amounts outstanding under the 2021 Revolver are due at maturity. In addition, subject to the terms and conditions set forth in the 2021 Credit Agreement, the Company is required to make certain mandatory prepayments from the net proceeds of specified types of asset sales (subject to certain reinvestment rights), debt issuances and insurance recoveries (subject to certain reinvestment rights). Certain of the mandatory prepayments are subject to reduction or elimination if certain financial covenants are met. These mandatory prepayments are required to be applied by the Company, first to the 2021 Term Loan, second to any outstanding amount under any Swing Line Loans, third to the 2021 Revolver, fourth to prepay any outstanding reimbursement obligations with respect to Letters of Credit and fifth to cash collateralize any Letters of Credit. Subject to certain limitations, the Company may voluntarily prepay any of the 2021 Credit Facilities without premium or penalty.

The 2021 Credit Agreement contains affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants restricting the ability of the Company, subject to negotiated exceptions, to incur additional indebtedness and grant additional liens on its assets, engage in mergers or acquisitions or dispose of assets, enter into sale-leaseback transactions, pay dividends or make other distributions, voluntarily prepay other indebtedness, enter into transactions with affiliated persons, make investments, and change the nature of their businesses. In addition, the 2021 Credit Agreement requires the Borrowers to maintain certain financial ratios. The 2021 Credit Agreement also contains customary representations and warranties and events of default, including payment defaults, breach of representations and warranties, covenant defaults, cross defaults and an event of default upon a change of control of the Company.

Senior Notes

2028 Senior Notes

On January 19, 2018, the Company completed a private placement of $1.0 billion aggregate principal amount of senior notes and allocated $400 million in aggregate principal amount to its 4.625% Senior Notes due 2028 (the "2028 Senior Notes") at an offering price of 100% of the aggregate principal amount of the 2028 Senior Notes. The 2028 Senior Notes are general senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain domestic subsidiaries. The 2028 Senior Notes mature on February 1, 2028 and bear interest at the rate of 4.625% per year, payable semi-annually on February 1 and August 1 of each year, commencing on August 1, 2018.

The Company may redeem the 2028 Senior Notes at any time prior to February 1, 2023 at a price equal to 100% of the aggregate principal amount so redeemed, plus accrued and unpaid interest, if any, to the redemption date and a make-whole premium set forth in the indenture. The Company has the option to redeem the 2028 Senior Notes on or after: February 1, 2023 through February 1, 2024 at 102.312% of par; February 1, 2024 through February 1, 2025 at 101.541% of par; February 1, 2025 through February 1, 2026 at 100.770% of par; and February 1, 2026 and thereafter at 100% of par. In addition, if the Company undergoes a change of control coupled with a decline in ratings, as provided in the indenture, the Company will be required to make an offer to purchase each holder’s 2028 Senior Notes at a price equal to 101% of their principal amount, plus accrued and unpaid interest, if any, to the repurchase date.

The Company evaluated the 2028 Senior Notes for derivatives pursuant to ASC 815 and did not identify any embedded derivatives that require bifurcation. All features were deemed to be clearly and closely related to the host instrument.

2029 Senior Notes

On September 28, 2020, the Company completed a private placement of $950 million aggregate principal amount of its 3.250% Senior Notes due 2029 (the "2029 Senior Notes") at an offering price of 100% of the aggregate principal amount of the 2029 Senior Notes. The 2029 Senior Notes are general senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain domestic subsidiaries. The 2029 Senior Notes mature on February 15, 2029 and bear interest at the rate of 3.250% per year, payable semi-annually on February 15 and August 15 of each year, commencing on February 15, 2021.

The Company may redeem the 2029 Senior Notes at any time prior to September 28, 2023 at a price equal to 100% of the aggregate principal amount so redeemed, plus accrued and unpaid interest, if any, to the redemption date and a make-whole premium set forth in the indenture. The Company may also redeem up to 40% of the aggregate principal amount of the 2029 Senior Notes with the net cash proceeds of certain equity offerings at any time and from time to time before September 28, 2023, at a redemption price equal to 103.250% of the aggregate principal amount so redeemed, plus accrued and unpaid

interest, if any, to the redemption date. The Company also has the option to redeem the 2029 Senior Notes on or after: September 28, 2023 through September 27, 2024 at 101.625% of par; September 28, 2024 through September 27, 2025 at 100.813% of par; and September 28, 2025 and thereafter at 100% of par. In addition, if the Company undergoes a change of control coupled with a decline in ratings, as provided in the indenture, the Company will be required to make an offer to purchase each holder's 2029 Senior Notes at a price equal to 101% of their principal amount, plus accrued and unpaid interest, if any, to the repurchase date.

The Company evaluated the 2029 Senior Notes for derivatives pursuant to ASC 815, *Derivatives and Hedging*, and did not identify any embedded derivatives that require bifurcation. All features were deemed to be clearly and closely related to the host instrument.

2025 Senior Notes

The Company had 4.375% Senior Notes due 2025 (the "2025 Senior Notes") outstanding and bore interest at the rate of 4.375% per year, payable semi-annually on April 15 and October 15 of each year. The Company used the net proceeds of the 2029 Senior Notes offering in the first quarter of fiscal 2021 to redeem in full the 2025 Senior Notes in the aggregate principal amount of $950.0 million on October 15, 2020 at an aggregate redemption price of $970.8 million, which included a premium payment of $20.8 million. Since the Company planned to use the proceeds from the 2029 Senior Notes offering to redeem the 2025 Senior Notes, the Company evaluated the accounting for this transaction under ASC 470 to determine modification versus extinguishment accounting on a creditor-by-creditor basis. Certain 2025 Senior Note holders either did not participate in this refinancing transaction or reduced their holdings and these transactions were accounted for as extinguishments. As a result, the Company recorded a debt extinguishment loss in the first quarter of fiscal 2021 of $21.6 million, which comprised pro-rata amounts of the premium payment, debt discount and debt issuance costs. For the remaining 2025 Senior Notes holders who participated in the refinancing, these transactions were accounted for as modifications because on a creditor-by-creditor basis the present value of the cash flows between the debt instruments before and after the transaction was less than 10%. The Company recorded a portion of the transaction expenses of $5.8 million to interest expense pursuant to ASC 470, subtopic 50-40. The remaining debt issuance costs of $7.9 million and debt discount of $6.4 million related to the modified debt are being amortized over the new term of the 2029 Senior Notes using the effective interest method.

Interest expense for the 2029 Senior Notes, 2028 Senior Notes and 2025 Senior Notes was as follows:

		Years Ended					
		September 25, 2021		September 26, 2020		September 28, 2019	
	Interest Rate	Interest Expense (1)	Non-Cash Interest Expense	Interest Expense (1)	Non-Cash Interest Expense	Interest Expense (1)	Non-Cash Interest Expense
2029 Senior Notes	3.250 %	$ 32.7	$ 2.1	$ —	$ —	$ —	$ —
2028 Senior Notes	4.625 %	19.2	0.7	19.2	0.7	19.2	0.7
2025 Senior Notes	4.375 %	2.3	0.1	43.5	2.1	43.5	2.1
Total		$ 54.2	$ 2.9	$ 62.7	$ 2.8	$ 62.7	$ 2.8

(1) Interest expense includes non-cash interest expense related to the amortization of the deferred issuance costs and accretion of the debt discount.

Accounts Receivable Securitization Program

On April 25, 2016, the Company entered into a one-year $200.0 million accounts receivable securitization program (the "Securitization Program") with several of its wholly owned subsidiaries and certain financial institutions, which provides for annual renewals. Under the terms of the Securitization Program, the Company and certain of its wholly-owned subsidiaries sell their respective customer receivables to a bankruptcy remote special purpose entity, which is also a wholly-owned subsidiary of the Company. In addition, the Company also contributed a portion of its customer receivables to the special purpose entity in connection with its establishment. The Company retains servicing responsibility. The special purpose entity, as borrower, and the Company, as servicer, entered into a Credit and Security Agreement with several lenders pursuant to which the special purpose entity, at that time, could borrow up to $200.0 million from the lenders, with the loans secured by the receivables. The amount that the special purpose entity may borrow at a given point in time is determined based on the amount of qualifying receivables that are present in the special purpose entity at such point in time. Borrowings outstanding under the Securitization Program bear interest at LIBOR plus the applicable margin of 0.8% and are included as a component of current liabilities in the Company's consolidated balance sheet, while the accounts receivable securing these obligations remain as a component of net receivables in the Company's consolidated balance sheet. The Company and the special purpose entity are operated and maintained as separate legal entities. The assets of the special purpose entity secure the amounts borrowed and cannot be used to pay other debts or liabilities of the Company. In subsequent years, the Company amended the agreement to extend it for one-year periods and increased the borrowing capacity up to $250.0 million and lowered the applicable margin to 0.7%.

In response to the market uncertainties created by the COVID-19 pandemic, on March 26, 2020, the Company paid off the total amount outstanding of $250.0 million previously borrowed. On April 13, 2020, the Company amended the Credit and Security Agreement with the lenders, temporarily suspending the ability to borrow and the need to comply with covenants for up to a year. On June 11, 2021, the Company amended and restated the Credit and Security Agreement to restart the Securitization Program and increased the maximum borrowing amount to $320.0 million. As of September 25, 2021, there was $248.5 million outstanding under this program.

Borrowings under the Securitization Program for fiscal 2021 had a weighted-average interest rate of 0.8%. Interest expense under the Securitization Program was $0.9 million, $3.1 million and $7.1 million for fiscal 2021, 2020 and 2019, respectively. The interest rate on the amounts outstanding at September 25, 2021 was 0.8%.

The Credit and Security Agreement contains customary representations and warranties and events of default, including payment defaults, breach of representations and warranties, covenant defaults, and an event of default upon a change of control of the Company. In addition, it contains financial covenants consistent with that of the Credit Agreement. As of September 25, 2021, the Company was not required to be in compliance with the Credit and Security Agreement covenants.

Other

Other represents debt acquired in the Mobidiag acquisition, which is primarily with the European Investment Bank ("EIB"). Multiple tranches were withdrawn under the agreement and were primarily used to fund research and development projects and expansion efforts. The debt agreement contains change-in-control provisions allowing the EIB to call the debt at any time after a change-in-control, which occurred as a result of Hologic acquiring Mobidiag. Accordingly, the Company has classified the debt as current. The tranches withdrawn under this agreement have interest rates ranging from 6.0% to 7.0%. The debt agreement includes additional payments to the EIB based on revenues generated by products developed under the funding as well as prepayment penalties.

8. Fair Value Measurements

The Company applies the provisions of ASC 820 for its financial assets and liabilities that are re-measured and reported at fair value each reporting period and its nonfinancial assets and liabilities that are re-measured and reported at fair value on a non-recurring basis. Fair value is the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining fair value, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the asset or liability.

Fair Value Hierarchy

ASC 820 establishes a three-level valuation hierarchy for disclosure of fair value measurements. Financial assets and liabilities are categorized within the valuation hierarchy based upon the lowest level of input that is significant to the measurement of fair value. The three levels of the hierarchy are defined as follows:

- Level 1—Inputs to the valuation methodology are quoted market prices for identical assets or liabilities.

- Level 2—Inputs to the valuation methodology are other observable inputs, including quoted market prices for similar assets or liabilities and market-corroborated inputs.
- Level 3—Inputs to the valuation methodology are unobservable inputs based on management's best estimate of inputs market participants would use in pricing the asset or liability at the measurement date, including assumptions about risk.

Assets/Liabilities Measured and Recorded at Fair Value on a Recurring Basis

The Company has investments in derivative instruments comprised of an interest rate swap, forward foreign currency contracts and foreign currency option contracts, which are valued using analyses obtained from independent third-party valuation specialists based on market observable inputs, representing Level 2 assets. The fair values of these derivative contracts represent the estimated amounts the Company would receive or pay to terminate the contracts. Refer to Note 2 for further discussion and information on these derivative contracts. In addition, the Company has contingent consideration liabilities that are recorded at fair value and are based on Level 3 inputs. The contingent consideration liability as of September 25, 2021 and September 26, 2020 was related to the Acessa acquisition (see Note 5).

Assets and liabilities measured and recorded at fair value on a recurring basis consisted of the following:

		Fair Value Measurements at September 25, 2021		
	Carrying Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Forward foreign currency contracts	$ 1.7	$ —	$ 1.7	—
Total	$ 1.7	$ —	$ 1.7	$ —
Liabilities:				
Contingent consideration	$ 75.1	$ —	$ —	$ 75.1
Interest rate swaps - derivative	18.7	—	18.7	—
Forward foreign currency contracts	0.6	—	0.6	—
Total	$ 94.4	$ —	$ 19.3	$ 75.1

		Fair Value Measurements at September 26, 2020		
	Carrying Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Forward currency option contracts	$ 10.1	$ —	$ 10.1	$ —
Forward foreign currency contracts	1.1	—	$ 1.1	—
Total	$ 11.2	$ —	$ 11.2	$ —
Liabilities:				
Contingent consideration	$ 81.8	$ —	$ —	$ 81.8
Interest rate swaps - derivative	31.2	—	31.2	—
Total	$ 113.0	$ —	$ 31.2	$ 81.8

Changes in the fair value of recurring fair value measurements using significant unobservable inputs (Level 3), which solely consisted of contingent consideration liabilities, during the years ended September 25, 2021, September 26, 2020, and September 28, 2019 were as follows:

	Years Ended		
	2021	2020	2019
Balance at beginning of period	$ 81.8	$ 9.1	$ 7.8
Contingent consideration recorded at acquisition	—	82.7	—
Fair value adjustments	(6.7)	0.3	1.7
Payments/Accruals	—	(10.3)	(0.4)
Balance at end of period	$ 75.1	$ 81.8	$ 9.1

Assets Measured and Recorded at Fair Value on a Nonrecurring Basis

The Company remeasures the fair value of certain assets and liabilities upon the occurrence of certain events. Such assets are comprised of equity investments and long-lived assets, including property, plant and equipment, intangible assets and goodwill. During the first quarter of fiscal 2020, the Company's Medical Aesthetics division met the criteria to be classified as assets-held-for sale, and the Company recorded a $30.2 million loss to record the asset group at its fair value less costs to sell. This is a level 1 measurement. During the second quarter of fiscal 2019, the Company identified indicators of impairment related to its long-lived assets of its Medical Aesthetics reportable segment and recorded impairment charges of $685.4 million, of which $675.6 million was allocated to intangible assets and $9.8 million was allocated to equipment. This was a level 3

measurement. During the fourth quarter of fiscal 2021, the Company recorded an impairment charge of $1.8 million to record an equity investment to its fair value. There were no such remeasurements in fiscal 2020 and 2019. Refer to Note 6 for disclosure of the nonrecurring fair value measurement related to the debt extinguishment losses recorded in fiscal 2021 and 2019.

Disclosure of Fair Value of Financial Instruments

The Company's financial instruments mainly consist of cash and cash equivalents, accounts receivable, cost-method equity investments, an interest rate swap, forward foreign currency contracts, foreign currency option contracts, insurance contracts, accounts payable and debt obligations. The carrying amounts of the Company's cash and cash equivalents, accounts receivable and accounts payable approximate their fair value due to the short-term nature of these instruments. The Company's interest rate swap, forward foreign currency contracts and foreign currency option contracts are recorded at fair value. The carrying amount of the insurance contracts are recorded at the cash surrender value, as required by U.S. GAAP, which approximates fair value. The Company believes the carrying amounts of its cost-method equity investments approximate fair value.

Amounts outstanding under the Company's 2018 Credit Agreement of $1.39 billion aggregate principal as of September 25, 2021 are subject to variable rates of interest based on current market rates, and as such, the Company believes the carrying amount of these obligations approximates fair value. The Company's 2028 Senior Notes and 2029 Senior Notes had fair values of approximately $424.5 million and $964.7 million, respectively, as of September 25, 2021 based on their trading price, representing a Level 1 measurement.

9. Income Taxes

The Company's income (loss) before income taxes consisted of the following:

	Years ended		
	September 25, 2021	September 26, 2020	September 28, 2019
Domestic	$ 2,267.8	$ 921.1	$ (174.3)
Foreign	93.3	80.8	(83.4)
	$ 2,361.1	$ 1,001.9	$ (257.7)

The provision (benefit) for income taxes contained the following components:

	Years ended		
	September 25, 2021	September 26, 2020	September 28, 2019
Federal:			
Current	$ 453.6	$ (62.1)	$ 142.9
Deferred	(45.6)	(76.6)	(189.9)
	408.0	(138.7)	(47.0)
State:			
Current	84.7	33.9	22.1
Deferred	(11.9)	(12.5)	(41.0)
	72.8	21.4	(18.9)
Foreign:			
Current	23.2	14.0	16.5
Deferred	(12.6)	(5.3)	(4.7)
	10.6	8.7	11.8
	$ 491.4	$ (108.6)	$ (54.1)

The income tax provision (benefit) differed from the tax provision (benefit) computed at the U.S. federal statutory rate due to the following:

	Years ended		
	September 25, 2021	September 26, 2020	September 28, 2019
Income tax (benefit) provision at federal statutory rate	21.0 %	21.0 %	(21.0) %
Increase (decrease) in tax resulting from:			
Loss on sale of Cynosure	—	(31.3)	—
State income taxes, net of federal benefit	2.7	2.9	(0.7)
U.S. tax on foreign earnings	(2.7)	(2.6)	(2.1)
Internal restructuring	—	—	(3.8)
Tax credits	(0.3)	(0.6)	(3.3)
Tax reform	—	—	2.0
Unrecognized tax benefits	0.3	—	(0.1)
Compensation	0.1	0.4	0.8
Foreign rate differential	(0.7)	(1.2)	(5.4)
Change in deferred tax rate	(0.3)	(0.6)	—
Change in valuation allowance	—	1.3	9.5
Other	0.7	(0.1)	3.1
	20.8 %	(10.8) %	(21.0) %

The Company’s effective tax rate for fiscal 2021 was lower than the U.S. statutory tax rate primarily due to the impact of the U.S. deduction for foreign derived intangible income and the geographic mix of income earned by the Company's international subsidiaries, which are taxed at rates lower than the U.S. statutory tax rate, partially offset by state income taxes and the global intangible low-taxed income inclusion.

The Company’s effective tax rate for fiscal 2020, which was a net benefit, differed from the U.S. statutory tax rate primarily due to a $313.4 million net tax benefit related to the sale of the Medical Aesthetics business, which was recorded in other assets net of unrecognized tax benefits, the impact of the U.S. deduction for foreign derived intangible income, federal and state tax credits, and the geographic mix of income earned by the Company's international subsidiaries, which are taxed at rates lower than the U.S. statutory tax rate, partially offset by state income taxes, reserves for uncertain tax positions net of releases resulting from statute of limitations expirations and favorable audit settlements, the global intangible low-taxed income inclusion, and unbenefited foreign losses.

The Company’s effective tax rate for fiscal 2019, which was applied to an overall pre-tax loss resulting in a tax benefit, was equal to the U.S. statutory tax rate primarily due to the offsetting impacts of a discrete tax benefit related to an internal

restructuring, the geographic mix of income earned by the Company's international subsidiaries which are taxed at rates lower than the U.S. statutory tax rate, reserves for uncertain tax positions, reserve releases resulting from statute of limitations expirations and favorable audit settlements, a valuation allowance resulting from the Medical Aesthetics impairment charge, and finalizing the impact of the enactment of the Tax Cuts and Jobs Act in the first quarter of fiscal 2019.

The Company uses the asset and liability method to account for income taxes in accordance with ASC 740, *Accounting for Income Taxes*. Under this method, deferred income tax assets and liabilities are recognized for the future tax consequences of differences between the financial statement carrying amount of existing assets and liabilities and their respective tax bases and also for operating loss and tax credit carry-forwards at each reporting period. Deferred income taxes are based on enacted tax laws and statutory tax rates applicable to the period and jurisdiction in which these differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company’s significant deferred tax assets and liabilities were as follows:

	September 25, 2021	September 26, 2020
Deferred tax assets		
Net operating loss carryforwards	$ 91.5	$ 81.1
Capital losses	52.0	57.0
Non-deductible accruals	34.9	24.9
Non-deductible reserves	41.8	33.2
Stock-based compensation	17.6	18.6
Tax credits	10.0	10.2
Nonqualified deferred compensation plan	16.8	14.4
Lease liability	16.2	17.3
Other temporary differences	17.4	25.2
	298.2	281.9
Less: valuation allowance	(121.3)	(118.5)
	$ 176.9	$ 163.4
Deferred tax liabilities		
Depreciation and amortization	$ (389.7)	$ (333.9)
Right of use asset	(15.8)	(15.8)
	$ (405.5)	$ (349.7)
	$ (228.6)	$ (186.3)

Under ASC 740, the Company can only recognize the future benefit of deferred tax assets to the extent that it is “more likely than not” that these assets will be realized. After considering all available positive and negative evidence, the Company established a valuation allowance against specifically identified deferred tax assets because it is more-likely-than-not that these assets will not be realized. In making this determination, the Company considered numerous factors including historical profitability, estimated future taxable income and the character of such income. The valuation allowance increased $2.8 million in fiscal 2021 from fiscal 2020 primarily due to loss carryforwards and increases in foreign statutory tax rates, partially offset by the liquidation of a foreign subsidiary, attribute expiration, and valuation allowance releases.

At September 25, 2021, the Company had $89.1 million, $135.0 million, and $263.2 million in gross federal, state, and foreign net operating losses, respectively, $4.3 million, $6.0 million, and $0.5 million in federal, state, and foreign credit carryforwards, respectively, and $26.2 million, and $33.0 million in gross state and foreign capital loss carryforwards, respectively. These losses, credits, and capital loss carryforwards expire between 2022 and 2041, except for $235.4 million in losses, $2.3 million in credits, and $33.0 million in capital loss carryforwards that have unlimited carryforward periods. The federal, state, and foreign net operating losses include $1.7 million, $48.0 million, and $0.9 million, respectively, and the state capital loss carryforwards include $26.2 million, that the Company expects will expire unutilized.

As of September 25, 2021, the Company had $212.8 million in gross unrecognized tax benefits excluding interest, of which $197.0 million, if recognized, would reduce the Company's effective tax rate. As of September 26, 2020, the Company had $197.1 million in gross unrecognized tax benefits excluding interest, of which $184.9 million, if recognized, would have reduced the Company's effective tax rate. The $15.7 million increase in gross unrecognized tax benefits from fiscal 2020 was primarily related to intercompany transfer pricing for ordinary business operations, capital losses, federal and state carryback

claims, acquisition related reserves, and other current year positions, partially offset by reserve releases resulting from statute of limitations expirations. In the next twelve months it is reasonably possible that the Company will reduce its gross unrecognized tax benefits excluding interest by up to $13.0 million due to expiring statutes of limitations.

The Company's unrecognized income tax benefits activity for fiscal 2021 and 2020 was as follows:

	2021	2020
Balance at beginning of fiscal year	$ 197.1	$ 101.6
Tax positions related to current year:		
Additions	8.0	109.6
Reductions	—	—
Tax positions related to prior years:		
Additions related to change in estimate	7.9	1.5
Reductions	(0.3)	(0.7)
Payments	—	—
Lapses in statutes of limitations	(1.7)	(15.6)
Acquired tax positions:		
Additions related to reserves acquired from acquisitions	1.8	0.7
Balance as of the end of the fiscal year	$ 212.8	$ 197.1

The Company's policy is to include accrued interest and penalties related to unrecognized tax benefits and income tax liabilities, when applicable, as a component of income tax expense. As of September 25, 2021, and September 26, 2020, gross accrued interest was $13.7 million and $11.9 million, respectively, and accrued penalties were immaterial.

The Company and its subsidiaries are subject to examination by U.S. federal, state, and foreign tax authorities. The Company's U.S. federal and state income tax returns are generally no longer subject to examination prior to fiscal year 2017. The Company is undergoing tax examinations in California (fiscal years 2017-2018), Massachusetts (fiscal years 2016-2017), and the United Kingdom (fiscal years 2016-2019). The Massachusetts income tax examination for fiscal years 2014-2015 was settled and the amount assessed was not material.

The Company filed federal and state carryback claims during the fourth quarter of fiscal 2021 and as a result, has reclassified $310.0 million from its long-term receivable account, of which $404.9 million was recorded as a current tax receivable and included in prepaid expenses and other current assets in the Consolidated Balance Sheet and the remainder of which was recorded as a long-term tax payable and included in other long-term liabilities in the Consolidated Balance Sheet.

The Company has determined that unremitted foreign earnings are not considered indefinitely reinvested to the extent foreign earnings can be distributed without a significant tax cost. As such, the Company records foreign withholding tax liabilities related to the future repatriation of such earnings. The Company continues to indefinitely reinvest all other outside basis differences to the extent reversal would incur a significant tax liability. It is not practicable for the Company to calculate the unrecognized deferred tax liability related to such incremental tax costs on those outside basis differences.

Other Tax Accounting Pronouncements

On October 24, 2016, the FASB issued ASU 2016-16, which removes the prohibition in ASC 740 against the immediate recognition of the current and deferred income tax effects of intra-entity transfers of assets other than inventory. Under ASU 2016-16, the selling (transferring) entity is required to recognize a current tax expense or benefit upon transfer of the asset. Similarly, the purchasing (receiving) entity is required to recognize a deferred tax asset or deferred tax liability, as well as the related deferred tax benefit or expense, upon receipt of the asset. The Company adopted ASU 2016-16 in the first quarter of fiscal 2019 on a modified retrospective basis as of September 30, 2018, the first day of fiscal 2019.

The Company was required to account for an internal restructuring under ASU 2016-16 and recorded a $27.8 million increase to income tax expense and income tax liabilities and a decrease of $37.7 million to deferred tax expense and net deferred tax liabilities for the fiscal year ended September 28, 2019. The net result was a reduction to net loss of $9.9 million, or $0.04 to diluted net loss per share.

Non-Income Tax Matters

The Company is subject to tax examinations for value added, sales-based, payroll and other non-income tax items. A number of these examinations are ongoing in various jurisdictions. The Company takes certain non-income tax positions in the jurisdictions in which it operates and records loss contingencies pursuant to ASC 450. In the normal course of business, the Company's positions and conclusions related to its non-income tax positions could be challenged, resulting in assessments by governmental authorities. While the Company believes estimated losses previously recorded are reasonable, certain audits are still ongoing and additional charges could be recorded in the future.

During the fourth quarter of fiscal 2021, based in part on developments in an ongoing tax audit as well as ongoing operations, the Company determined that it was probable it had incurred a loss related to a non-income tax issue. The Company estimated the probable amount of additional loss to be $11.2 million for all open years and recorded this charge to general and administrative expenses. While the Company believes its estimate is reasonable and appropriate, this matter is still ongoing and additional charges could be recorded in the future.

10. Stockholders' Equity and Stock-Based Compensation

Stock Repurchase Program

On June 13, 2018, the Board of Directors authorized the repurchase of up to $500.0 million of the Company's outstanding common stock. This share repurchase plan was effective August 1, 2018 and expired March 27, 2020. Under this authorization, during fiscal 2019, the Company repurchased 4.8 million shares of its common stock for total consideration of $200.1 million. During the first and second quarters of fiscal 2020, the Company repurchased 3.9 million shares of its common stock for a total consideration of $210.9 million. As of March 28, 2020, the Company had completed this authorization.

On December 11, 2019, the Board of Directors authorized a new share repurchase plan to repurchase up to $500.0 million of the Company's outstanding common stock, effective at the beginning of the third quarter of fiscal 2020. On March 2, 2020 the Board of Directors approved accelerating the effective date of the new share repurchase plan from March 27, 2020 to March 2, 2020. Under this revised authorization during fiscal 2020, the Company repurchased 5.1 million shares of its common stock for a total consideration of $237.7 million. During the first quarter of fiscal 2021, the Company repurchased 1.5 million shares of its common stock under this plan for a total consideration of $101.3 million.

On December 9, 2020, the Board of Directors authorized a new five-year share repurchase plan to repurchase up to $1.0 billion of the Company's outstanding common stock. The prior plan was terminated in connection with this new authorization. Under the new authorization, during fiscal 2021, the Company repurchased 4.6 million shares of its common stock for a total consideration of $308.5 million. As of September 25, 2021 $691.6 million remained available under this authorization. Subsequent to September 25, 2021, the Company repurchased 2.3 million shares of its common stock for $167.0 million.

On November 19, 2019, the Board of Directors authorized the Company to repurchase up to $205 million of its outstanding shares pursuant to an accelerated share repurchase ("ASR") agreement. On November 22, 2019, the Company executed the ASR agreement with Goldman Sachs & Co. ("Goldman Sachs") pursuant to which the Company repurchased $205 million of the Company's common stock. The initial delivery of approximately 80% of the shares under the ASR was 3.3 million shares for which the Company initially allocated $164.0 million of the $205 million paid to Goldman Sachs during the first quarter of fiscal 2020. The Company evaluated the nature of the forward contract aspect of the ASR under ASC 815 and concluded equity classification was appropriate. Final settlement of the transaction under the ASR occurred in the second quarter of fiscal 2020. At settlement, Goldman Sachs delivered an additional 0.6 million shares of the Company's common stock.

Stock-Based Compensation

Equity Compensation Plans

The Company has one share-based compensation plan pursuant to which awards are currently being issued—the 2008 amended and restated Equity Incentive Plan ("2008 Equity Plan"). The purpose of the 2008 Equity Plan is to provide stock options, restricted stock units and other equity interests in the Company to employees, officers, directors, consultants and advisors of the Company and any other person who is determined by the Board of Directors to have made (or is expected to make) contributions to the Company. The 2008 Equity Plan is administered by the Board of Directors of the Company, and a total of 31.5 million shares were reserved for issuance under this plan. As of September 25, 2021, the Company had 4.6 million shares available for future grant under the 2008 Equity Plan.

The following presents stock-based compensation expense in the Company's Consolidated Statements of Operations in fiscal 2021, 2020 and 2019:

	2021	2020	2019
Cost of revenues	$ 8.0	$ 6.7	$ 7.1
Research and development	7.7	8.0	9.2
Selling and marketing	9.5	10.2	10.2
General and administrative	38.9	50.9	35.5
Restructuring	0.9	7.5	—
	$ 65.0	$ 83.3	$ 62.0

Grant-Date Fair Value

The Company uses a binomial model to determine the fair value of its stock options. The Company considers a number of factors to determine the fair value of options including the assistance of an outside valuation adviser. Information pertaining to stock options granted during fiscal 2021, 2020 and 2019 and related assumptions are noted in the following table:

	Years ended		
	September 25, 2021	September 26, 2020	September 28, 2019
Options granted (in millions)	0.6	1.0	1.0
Weighted-average exercise price	$ 68.62	$ 45.96	$ 41.36
Weighted-average grant date fair value	$ 19.86	$ 13.92	$ 13.54
Assumptions:			
Risk-free interest rates	0.4 %	1.7 %	3.0 %
Expected life (in years)	4.8	4.8	4.8
Expected volatility	35.0 %	33.6 %	34.3 %
Dividend yield	—	—	—

The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. In projecting expected stock price volatility, the Company uses a combination of historical stock price volatility and implied volatility from observable market prices of similar equity instruments. The Company estimated the expected life of stock options based on historical experience using employee exercise and option expiration data.

Stock-Based Compensation Expense Attribution

The Company uses the straight-line attribution method to recognize stock-based compensation expense for stock options and restricted stock units ("RSUs"). The vesting term of stock options is generally four years with annual vesting of 25% per year on the anniversary of the grant date, and RSUs generally vest over three years with annual vesting at 33% per year on the anniversary of the grant date.

The amount of stock-based compensation recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. Under ASC 718, the Company's accounting policy is to estimate forfeitures at the time awards are granted and revise, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Based on an analysis of historical forfeitures, the Company has determined a specific forfeiture rate for certain employee groups and has applied forfeiture rates ranging from 0% to 6.0% as of September 25, 2021 depending on the specific employee group. This analysis is re-evaluated annually and the forfeiture rate adjusted as necessary. Ultimately, the actual stock-based compensation expense recognized will only be for those stock options and RSUs that vest.

Stock-based compensation expense related to stock options was $13.0 million, $15.5 million, and $14.1 million in fiscal 2021, 2020 and 2019, respectively. Stock compensation expense related to stock units, including RSUs, performance stock units ("PSUs"), free cash flow performance stock units ("FCFs") and market stock units ("MSUs") was $46.1 million, $63.3 million, and $43.7 million in fiscal 2021, 2020 and 2019, respectively. The related tax benefit recorded in the Consolidated Statements of Operations was $7.9 million, $9.5 million and $8.9 million in fiscal 2021, 2020 and 2019, respectively. At September 25, 2021, there was $15.8 million and $50.3 million of unrecognized compensation expense related to stock options and RSUs, respectively, to be recognized over a weighted average period of 2.3 years and 1.8 years, respectively.

Share Based Payment Activity

The following table summarizes all stock option activity under the Company's stock option plans for the year ended September 25, 2021:

	Number of Shares (in millions)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value (in millions)
Options outstanding at September 26, 2020	4.6	$ 40.37	7.0	$ 109.5
Granted	0.6	68.62		
Canceled/ forfeited	(0.2)	49.67		
Exercised	(0.8)	38.46		30.4
Options outstanding at September 25, 2021	4.2	$ 44.66	6.6	$ 132.7
Options exercisable at September 25, 2021	2.3	$ 39.29	5.7	$ 85.4
Options vested and expected to vest at September 25, 2021 (1)	4.1	$ 44.60	6.6	$ 132.2

(1) This represents the number of vested stock options as of September 25, 2021 plus the unvested outstanding options at September 25, 2021 expected to vest in the future, adjusted for estimated forfeitures.

During fiscal 2020 and 2019, the total intrinsic value of options exercised (i.e., the difference between the market price on the date of exercise and the price paid by the employee to exercise the options) was $44.8 million and $26.1 million, respectively.

A summary of the Company's RSU, PSU, FCF and MSU activity during the year ended September 25, 2021 is presented below:

Non-vested Shares	Number of Shares (in millions)	Weighted-Average Grant-Date Fair Value
Non-vested at September 26, 2020	2.4	$ 44.22
Granted	1.1	69.14
Vested	(1.7)	43.94
Forfeited	(0.1)	52.57
Non-vested at September 25, 2021	1.7	$ 54.21

The number of RSUs vested includes shares withheld on behalf of employees to satisfy minimum statutory tax withholding requirements. The Company pays the minimum statutory tax withholding requirement on behalf of its employees. During fiscal 2021, 2020 and 2019 the total fair value of RSUs vested was $73.1 million, $34.9 million and $34.6 million, respectively.

The Company granted 0.5 million, 0.6 million and 0.9 million RSUs during fiscal 2021, 2020 and 2019, respectively. In addition, included in the above chart, the Company also granted 0.1 million, 0.1 million and 0.1 million PSUs during fiscal 2021, 2020, and 2019 respectively, to members of the Company's senior management team, which includes additional shares issued upon achieving metrics within the performance criteria. The PSUs were valued at $68.51, $45.38 and $40.97 per share based on the ending stock price on the date of grant in fiscal 2021, 2020 and 2019, respectively. Each recipient of the PSUs is eligible to receive between zero and 200% of the target number of shares of the Company's common stock at the end of three

year performance period provided the Company's defined Return on Invested Capital metrics are achieved. The Company also granted 0.1 million and 0.1 million of PSUs based on a one-year free cash flow measure (FCF) to its senior management team in fiscal 2021 and 2020, respectively. Each recipient of FCF PSUs is eligible to receive between zero and 200% of the target number of shares of the Company's common stock at the end of the one-year measurement period, but the FCF PSUs vest at the end of the three year service period. The PSUs and FCF PSUs cliff-vest three years from the date of grant, and the Company recognizes compensation expense ratably over the required service period based on its estimate of the number of shares will vest upon achieving the measurement criteria. If there is a change in the estimate of the number of shares that are probable of vesting, the Company will cumulatively adjust compensation expense in the period that the change in estimate is made. The Company also granted 0.1 million, 0.1 million and 0.1 million MSUs during fiscal 2021, 2020 and 2019, respectively, to its senior management team. Each recipient of MSUs is eligible to receive between zero and 200% of the target number of shares of the Company's common stock at the end of three year performance period based upon achieving a certain total shareholder return relative to a defined peer group. The MSUs were valued at $82.31, $43.54 and $55.13 per share using the Monte Carlo simulation model in fiscal 2021, 2020 and 2019, respectively. These awards cliff-vest three years from the date of grant, and the Company recognizes compensation expense for the MSUs ratably over the service period.

Employee Stock Purchase Plan

The Hologic, Inc. 2012 Employee Stock Purchase Plan ("2012 ESPP") provides for the granting of up to 2.5 million shares of the Company's common stock to eligible employees. The 2012 ESPP plan period is semi-annual and allows participants to purchase the Company's common stock at 85% of the lower of (i) the market value per share of the common stock on the first day of the offering period or (ii) the market value per share of the common stock on the purchase date. Stock-based compensation expense in fiscal 2021, 2020 and 2019 was $5.9 million, $4.5 million and $4.2 million, respectively.

The Company uses the Black-Scholes model to estimate the fair value of shares to be issued as of the grant date using the following weighted average assumptions:

	September 25, 2021	September 26, 2020	September 28, 2019
Assumptions:			
Risk-free interest rates	0.26 %	1.32 %	2.27 %
Expected life (in years)	0.5	0.5	0.5
Expected volatility	34.1 %	26.9 %	27.1 %
Dividend yield	—	—	—

11. 401(k) Plan

The Company's U.S. employees have access to a qualified 401(k) defined contribution plan. The Company made contributions of $20.9 million, $19.6 million and $19.2 million for fiscal 2021, 2020 and 2019, respectively.

12. Deferred Compensation Plans

Nonqualified Deferred Compensation Plan

Effective March 15, 2006, the Company adopted its Nonqualified Deferred Compensation Plan ("DCP") to provide non-qualified retirement benefits to a select group of executive officers, senior management and highly compensated employees of the Company. Eligible employees may elect to contribute up to 75% of their annual base salary and 100% of their annual bonus to the DCP and such employee contributions are 100% vested. In addition, the Company may elect to make annual discretionary contributions on behalf of participants in the DCP. Each Company contribution is subject to a three-year vesting schedule, such that each contribution vests one third annually. Employee contributions are recorded within accrued expenses.

Upon enrollment into the DCP, employees make investment elections for both their voluntary contributions and discretionary contributions, if any, made by the Company. Earnings and losses on contributions based on these investment elections are recorded as a component of compensation expense in the period earned.

Annually, the Compensation Committee of the Board of Directors has approved a discretionary cash contribution to the DCP for each year. Discretionary contributions by the Company to the DCP are held in a Rabbi Trust. The Company records compensation expense for the DCP discretionary contributions ratably over the three-year vesting period of each annual contribution, unless the participant meets the plan retirement provision of reaching a certain age and years of service criteria in which case the expense is accelerated to match the required service period to receive such benefit. Under the DCP, the Company recorded compensation expense related to Company contributions of $3.2 million, $3.1 million and $2.7 million in fiscal 2021, 2020 and 2019, respectively. The full amount of the discretionary contribution, net of forfeitures, along with employee deferrals is recorded within accrued expenses and totaled $76.1 million and $57.7 million at September 25, 2021 and September 26, 2020, respectively.

The Company has purchased Company-owned group life insurance contracts, in which both voluntary and discretionary Company DCP contributions are invested, to partially fund payment of the Company's obligation to the DCP participants. The total amount invested at September 25, 2021 and September 26, 2020 was $64.3 million and $49.3 million, respectively. The values of these life insurance contracts are recorded in other long-term assets. Changes in the cash surrender value of life insurance contracts, which were not significant in fiscal 2021, 2020 and 2019, are recorded within other income (expense), net.

Deferred Equity Plan

Effective September 17, 2015, the Company adopted the Hologic, Inc. Deferred Equity Plan (the "DEP"). The DEP is designed to allow executives and non-employee Directors to accumulate Company stock in a tax-efficient manner to meet their long-term equity accumulation goals and shareholder ownership guidelines. Under the DEP, eligible participants may elect to defer the settlement of RSUs and PSUs granted under the 2008 Equity Plan until separation from service or separation from service plus a fixed number of years. Participants may defer settlement by vesting tranche. Although the equity will vest on schedule, if deferral of settlement is elected, no shares are issued until the settlement date. The settlement date is the earlier of death, disability, change in control of the Company or separation from service plus the number of years of deferral elected by the participant. While these shares upon vesting are not distributed to the individuals and are not outstanding, these shares are included in basic weighted average shares outstanding used to calculate earnings per share.

13. Non-cancelable Purchase Commitments

The Company has certain non-cancelable purchase obligations primarily related to inventory purchases and diagnostics instruments, primarily Panther systems, and to a lesser extent other operating expense commitments. These obligations are not recorded in the Consolidated Balance Sheets. For reasons of quality assurance, sole source availability or cost effectiveness, certain key components and raw materials and instruments are available only from a sole supplier and the Company has certain long-term supply contracts to assure continuity of supply. At September 25, 2021, non-cancelable purchase commitments are as follows:

Fiscal 2022	290.3
Fiscal 2023	16.4
Fiscal 2024	9.2
Fiscal 2025	4.1
Fiscal 2026	1.7
Thereafter	0.4
Total	$ 322.1

14. Litigation and Related Matters

On November 6, 2015, the Company filed a suit against Minerva Surgical, Inc. (“Minerva”) in the United States District Court for the District of Delaware, alleging that Minerva’s endometrial ablation device infringes U.S. Patent 6,872,183 (the '183 patent), U.S. Patent 8,998,898 and U.S. Patent 9,095,348 (the '348 patent). On January 25, 2016, the Company amended the complaint to include claims against Minerva for unfair competition, deceptive trade practices and tortious interference with business relationships. On February 5, 2016, the Company filed a second amended complaint to additionally allege that Minerva’s endometrial ablation device infringes U.S. Patent 9,247,989 (the '989 patent). On March 4, 2016, Minerva filed an answer and counterclaims against the Company, seeking declaratory judgment on the Company’s claims and asserting claims against the Company for unfair competition, deceptive trade practices, interference with contractual relationships, breach of contract and trade libel. On June 2, 2016, the Court denied the Company’s motion for a preliminary injunction on its patent claims and denied Minerva’s request for preliminary injunction related to the Company’s alleged false and deceptive statements regarding the Minerva product. On June 28, 2018, the Court granted the Company's summary judgment motions on infringement and no invalidity with respect to the ‘183 and ‘348 patents. The Court also granted the Company’s motion for summary judgment on assignor estoppel, which bars Minerva’s invalidity defenses or any reliance on collateral findings regarding invalidity from *inter partes* review proceedings. The Court also denied all of Minerva’s defenses, including its motions for summary judgment on invalidity, non-infringement, no willfulness, and no unfair competition. On July 27, 2018, after a two-week trial, a jury returned a verdict that: (1) awarded the Company $4.8 million in damages for Minerva’s infringement; (2) found that Minerva’s infringement was not willful; and (3) found for the Company regarding Minerva’s counterclaims. Damages continued to accrue as Minerva continued its infringing conduct. On May 2, 2019, the Court issued rulings that denied the parties' post-trial motions, including the Company's motion for a permanent injunction seeking to prohibit Minerva from selling infringing devices. Both parties appealed the Court's rulings regarding the post-trial motions. On March 4, 2016, Minerva filed two petitions at the USPTO for *inter partes* review of the '348 patent. On September 12, 2016, the PTAB declined both petitions to review patentability of the ‘348 patent. On April 11, 2016, Minerva filed a petition for *inter partes* review of the '183 patent. On October 6, 2016, the PTAB granted the petition and instituted a review of the '183 patent. On December 15, 2017, the PTAB issued a final written decision invalidating all claims of the ‘183 patent. On February 9, 2018 the Company appealed this decision to the United States Court of Appeals for the Federal Circuit ("Court of Appeals"). On April 19, 2019, the Court of Appeals affirmed the PTAB's final written decision regarding the '183 patent. On July 16, 2019, the Court of Appeals denied the Company’s petition for rehearing in the appeal regarding the '183 patent. On April 22, 2020, the Court of Appeals affirmed the district court’s summary judgment ruling in favor of the Company of no invalidity and infringement, and summary judgment that assignor estoppel bars Minerva from challenging the validity of the ‘348 patent. The Court of Appeals also denied the Company’s motion for a permanent injunction and ongoing royalties for infringement of the ‘183 patent. The Court of Appeals denied Minerva’s arguments for no damages or, alternatively, a new trial. On May 22, 2020 both parties petitioned for en banc review of the Court of Appeals decision. On July 22, 2020, the Court of Appeals denied both parties' petitions for en banc review. On August 28, 2020, the district court entered final judgment against Minerva but stayed execution pending resolution of Minerva’s petition for Supreme Court review. On September 30, 2020, Minerva filed a petition requesting Supreme Court review on the issue of assignor estoppel. On November 5, 2020, the Company filed a cross- petition requesting Supreme Court review on the issue of assignor estoppel. On January 8, 2021, the Supreme Court granted Minerva's petition to address the issue of assignor estoppel and denied the Company's petition. Oral argument before the Supreme Court was held on April 21, 2021. On June 29, 2021, the Supreme Court ruled 5-4 to uphold the assignor estoppel but limited its application to situations in which an assignor's claim of invalidity contradicts a prior representation the assignor made in assigning the patent. The Court also vacated the ruling of the Court of Appeals and remanded the case for further proceedings consistent with its opinion.

On April 11, 2017, Minerva filed suit against the Company and Cytyc Surgical Products, LLC (“Cytyc”) in the United States District Court for the Northern District of California alleging that the Company’s and Cytyc’s NovaSure ADVANCED endometrial ablation device infringes Minerva’s U.S. patent 9,186,208 (the '208 patent). Minerva is seeking a preliminary and permanent injunction against the Company and Cytyc from selling this NovaSure device as well as enhanced damages and interest, including lost profits, price erosion and/or royalty. On January 5, 2018, the Court denied Minerva's motion for a preliminary injunction. On February 2, 2018, at the parties’ joint request, this action was transferred to the District of Delaware. On March 26, 2019, the Magistrate Judge issued a claims construction ruling regarding the disputed terms in the patent, which the District Court Judge adopted in all respects on October 21, 2019. The original trial date of July 20, 2020 was vacated. On October 21, 2020, the trial court scheduled a 10 day trial beginning on August 9, 2021. On July 27. 2021, the Delaware district court granted Hologic's motion for summary judgment on invalidity of the '208 patent and entered judgment in favor of the Company. On August 24, 2021, Minerva appealed this and the other rulings to the Court of Appeals. At this time, based on available information regarding this litigation, the Company is unable to reasonably assess the ultimate outcome of this case or determine an estimate, or a range of estimates, of potential losses.

As described in Note 15, the Company has agreed to indemnify CD&R for certain legal matters related to the Medical Aesthetics business that existed at the date of disposition. The Company currently has $8.5 million accrued for such matters as of September 25, 2021. While the Company believes the estimated amounts accrued are reasonable, certain matters are still ongoing and additional accruals could be recorded in the future.

The Company is a party to various other legal proceedings and claims arising out of the ordinary course of its business. The Company believes that except for those matters described above there are no other proceedings or claims pending against it the ultimate resolution of which could have a material adverse effect on its financial condition or results of operations. In all cases, at each reporting period, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under ASC 450, *Contingencies*. Legal costs are expensed as incurred.

15. Disposition

Sale of Medical Aesthetics

On November 20, 2019, the Company entered into a definitive agreement to sell its Medical Aesthetics business to Clayton Dubilier & Rice ("CD&R") for a sales price of $205.0 million in cash, less certain adjustments. The sale was completed on December 30, 2019, and the Company received cash proceeds of $153.4 million in the second quarter of fiscal 2020. The sale price was subject to adjustment pursuant to the terms of the definitive agreement, and the parties agreed to a final sales price of $150.0 million in the fourth quarter of fiscal 2020. The Company agreed to provide certain transition services for three to fifteen months, depending on the nature of the service. The Company also agreed to indemnify CD&R for certain legal and tax matters that existed as of the date of disposition. In connection with its accounting for the sale, the Company recorded indemnification liabilities of $10.9 million within accrued expenses associated with its obligations under the sale agreement.

As a result of this transaction, the Medical Aesthetics asset group was designated as assets held-for-sale in the first quarter of fiscal 2020. Pursuant to ASC 360, *Impairment and Disposal of Long-Lived Assets,* asset groups under this designation are required to be recorded at fair value less costs to sell. The Company determined that this disposal did not qualify as a discontinued operation as the sale of the Medical Aesthetics business was deemed to not be a strategic shift having or that will have a major effect on the Company's operations and financial results. Based on the terms in the agreement of the sales price and formula for net working capital and related adjustments, its estimate of the fair value for transition services and the amount that must be carved out of the sale proceeds, and liabilities the Company will retain or for which it has agreed to indemnify CD&R, the Company recorded an impairment charge of $30.2 million in the first quarter of fiscal 2020. The impairment charge was allocated to Medical Aesthetics long-lived assets, of which $25.8 million was allocated to cost of product revenues and $4.4 million to operating expenses.

Loss from operations of the disposed business presented below represents the operating loss of the business as it was operated prior to the date of disposition. The operating expenses include only those that were incurred directly by and were retained by the disposed business. As noted above, the Company had performed a number of transition services and the financial impact from these services are not included in the amounts presented below. In addition, the Company will continue to incur expenses related to this business under the indemnification provisions primarily related to legal and tax matters that existed as of the date of disposition. Subsequent to the disposition, the Company recorded additional expenses of $6.2 million in fiscal 2020 primarily for accelerated stock compensation, inventory reserves under the manufacturing supply agreement, and legal expenses and settlements, which are not included in the below amounts. Loss from operations of the disposed business for fiscal 2020 and 2019 was as follows:

	Years Ended	
	September 26, 2020	September 28, 2019
Loss from operations	$ (46.5)	$ (781.2)

16. Business Segments and Geographic Information

The Company reports segment information in accordance with ASC 280, *Segment Reporting.* Operating segments are identified as components of an enterprise about which separate, discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions about how to allocate resources and assess performance. The Company's chief operating decision maker is its chief executive officer, and the Company's reportable segments have been identified based on the types of products manufactured and the end markets to which the products are sold. Each reportable segment generates revenue from either the sale of medical equipment and related services and/or sale of disposable supplies, primarily used for diagnostic testing and surgical procedures. During fiscal 2021, the Company had four reportable segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health. During the first quarter of fiscal 2020 and

fiscal 2019, the Company had five reportable segments: Diagnostics, Breast Health, Medical Aesthetics, GYN Surgical and Skeletal Health. The Company completed the sale of its Medical Aesthetics business on December 30, 2019. The Company measures and evaluates its reportable segments based on segment revenues and operating income adjusted to exclude the effect of non-cash charges, such as intangible asset amortization expense, goodwill and intangible asset impairment charges, transaction and integration expenses for acquisitions, restructuring, consolidation and divestiture charges, litigation charges, and other one-time or unusual items.

Identifiable assets for the reportable segments consist of inventories, intangible assets, goodwill, and property, plant and equipment. The Company fully allocates depreciation expense to its reportable segments. The Company has presented all other identifiable assets as corporate assets. There were no intersegment revenues. Segment information for fiscal 2021, 2020, and 2019 was as follows:

	Years ended		
	September 25, 2021	September 26, 2020	September 28, 2019
Total revenues:			
Diagnostics	$ 3,695.0	$ 2,102.1	$ 1,205.5
Breast Health	1,352.3	1,151.9	1,314.2
GYN Surgical	488.1	376.1	437.2
Skeletal Health	96.9	81.0	94.8
Medical Aesthetics	—	65.3	315.6
	$ 5,632.3	$ 3,776.4	$ 3,367.3
Operating income (loss):			
Diagnostics	$ 2,140.1	$ 929.7	$ 163.1
Breast Health	284.2	192.8	399.3
GYN Surgical	58.9	42.0	99.2
Skeletal Health	(2.9)	(2.4)	(4.2)
Medical Aesthetics	—	(57.1)	(781.2)
	$ 2,480.3	$ 1,105.0	$ (123.8)
Depreciation and amortization:			
Diagnostics	$ 260.4	$ 237.3	$ 246.6
Breast Health	52.7	48.8	36.8
GYN Surgical	93.1	85.1	87.7
Skeletal Health	0.7	0.7	0.6
Medical Aesthetics	—	4.1	91.4
	$ 406.9	$ 376.0	$ 463.1
Capital expenditures:			
Diagnostics	$ 126.2	$ 110.7	$ 59.2
Breast Health	14.2	22.4	18.3
GYN Surgical	14.5	17.9	15.7
Skeletal Health	0.3	0.2	1.2
Medical Aesthetics	—	1.4	7.0
Corporate	1.0	3.8	7.7
	$ 156.2	$ 156.4	$ 109.1
Identifiable assets:			
Diagnostics	$ 3,348.8	$ 2,161.4	$ 2,276.6
Breast Health	1,233.9	1,200.9	1,127.8
GYN Surgical	1,369.7	1,438.7	1,328.6
Skeletal Health	31.9	38.9	27.3
Medical Aesthetics	—	—	159.3
Corporate	2,935.6	2,355.9	1,522.5
	$ 8,919.9	$ 7,195.8	$ 6,442.1

The Company operates in the following major geographic areas as noted in the below chart. Revenue data is based upon customer location. Other than the United States, no single country accounted for more than 10% of consolidated revenues. The Company's sales in Europe are predominantly derived from France, the United Kingdom and Germany. The Company's sales in Asia-Pacific are predominantly derived from China, Australia and Japan. The "Rest of world" designation includes Canada, Latin America and the Middle East.

Revenues by geography as a percentage of total revenues were as follows:

	Years ended		
	September 25, 2021	September 26, 2020	September 28, 2019
United States	69.3 %	75.8 %	75.3 %
Europe	21.3 %	15.1 %	11.8 %
Asia-Pacific	6.5 %	6.0 %	8.5 %
Rest of world	2.9 %	3.1 %	4.4 %
	100.0 %	100.0 %	100.0 %

The Company's property, plant and equipment, net were geographically located as follows:

	September 25, 2021	September 26, 2020	September 28, 2019
United States	$ 403.2	$ 383.0	$ 355.5
Europe	122.9	77.5	64.4
Costa Rica	26.9	20.8	33.0
Rest of world	11.7	10.2	18.0
	$ 564.7	$ 491.5	$ 470.9

17. Accrued Expenses and Other Long-Term Liabilities

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

	September 25, 2021	September 26, 2020
Accrued Expenses		
Compensation and employee benefits	$ 297.2	$ 262.7
Income and other taxes	70.9	125.3
Contingent consideration	16.3	—
Operating leases	26.8	23.5
Accrued interest	16.9	22.1
Other	168.1	114.0
	$ 596.2	$ 547.6

	September 25, 2021	September 26, 2020
Other Long-Term Liabilities		
Reserve for income tax uncertainties	$ 210.0	$ 103.7
Contingent consideration	58.8	81.8
Operating leases	66.1	65.6
Interest rate swap	7.6	23.0
Pension liabilities	10.0	11.1
Other	16.2	18.0
	$ 368.7	$ 303.2

18. Pension and Other Employee Benefits

The Company has certain defined benefit pension plans covering the employees of its Hitec Imaging German subsidiary (the "Pension Benefits"). As of September 25, 2021 and September 26, 2020, the Company's pension liability was $10.3 million and $10.9 million, respectively, which is primarily recorded as a component of long-term liabilities in the Consolidated Balance Sheets. Under German law, there are no rules governing investment or statutory supervision of the pension plan. As such, there is no minimum funding requirement imposed on employers. Pension benefits are safeguarded by the Pension Guaranty Fund, a form of compulsory reinsurance that guarantees an employee will receive vested pension benefits in the event of insolvency. The pension plans were closed on December 31, 1997 and only eligible employees at that date could participate in the plans prior to closing to new participants.

The tables below provide a reconciliation of benefit obligations, plan assets, funded status, and related actuarial assumptions of the Company's German Pension Benefits.

	Years ended		
Change in Benefit Obligation	**September 25, 2021**	**September 26, 2020**	**September 28, 2019**
Benefit obligation at beginning of year	$ (10.9)	$ (10.0)	$ (9.7)
Service cost	—	—	—
Interest cost	(0.1)	(0.1)	(0.2)
Plan participants' contributions	—	—	—
Actuarial gain (loss)	0.5	(0.5)	(1.0)
Foreign exchange gain	(0.1)	(0.7)	0.6
Benefits paid	0.3	0.4	0.3
Benefit obligation at end of year	(10.3)	(10.9)	(10.0)
Plan assets	—	—	—
Benefit obligation at end of year	$ (10.3)	$ (10.9)	$ (10.0)

The tables below outline the components of the net periodic benefit cost and related actuarial assumptions of the Company's German Pension Benefits.

	Years ended		
Components of Net Periodic Benefit Cost	**September 25, 2021**	**September 26, 2020**	**September 28, 2019**
Service cost	$ —	$ —	$ —
Interest cost	0.1	0.1	0.2
Expected return on plan assets	—	—	—
Amortization of prior service cost	—	—	—
Recognized net actuarial gain	0.3	0.2	0.1
Net periodic benefit cost	$ 0.4	$ 0.3	$ 0.3

Weighted-Average Net Periodic Benefit Cost Assumptions	**2021**	**2020**	**2019**
Discount rate	1.00 %	0.80 %	1.10 %
Expected return on plan assets	— %	— %	— %
Rate of compensation increase	— %	— %	— %

The projected benefit obligation for the German Pension Benefits with projected benefit obligations in excess of plan assets was $10.3 million and $10.9 million at September 25, 2021 and September 26, 2020, respectively, and the accumulated benefit obligation for the German Pension Benefits was $10.3 million and $10.9 million at September 25, 2021 and September 26, 2020, respectively.

The Company is also obligated to pay long-term service award benefits under the German Pension Benefits. The projected benefit obligation for long-term service awards was $0.1 million at both September 25, 2021 and September 26, 2020, respectively.

The table below reflects the total Pension Benefits expected to be paid for the German Pension Benefits each fiscal year as of September 25, 2021:

2022	$	0.4
2023	$	0.4
2024	$	0.4
2025	$	0.4
2026	$	0.4
2027 to 2031	$	2.2

The Company also maintains additional contractual pension benefits for its top German executive officers in the form of a defined contribution plan. These contributions were insignificant in fiscal 2021, 2020 and 2019.

FIRST SUPPLEMENTAL INDENTURE

dated as of May 18, 2021

among

Hologic, Inc.,

The Subsidiary Guarantor Party Hereto

and

Wells Fargo Bank, National Association,
as Trustee

3.250% Senior Notes due 2029

This FIRST SUPPLEMENTAL INDENTURE (this "**Supplemental Indenture**"), entered into as of May 18, 2021, among HOLOGIC, INC., a Delaware corporation (the "**Company**"), Biotheranostics Inc., a Delaware corporation (the "**New Guarantor**"), and Wells Fargo Bank, National Association, as trustee (the "**Trustee**").

RECITALS

WHEREAS, the Company, the Subsidiary Guarantors party thereto and the Trustee entered into the Indenture, dated as of September 28, 2020 (the "**Indenture**"), relating to the Company's 3.250% Senior Notes due 2029 (the "**Notes**");

WHEREAS, as a condition to the Trustee entering into the Indenture and the purchase of the Notes by the Holders, the Company agreed pursuant to the Indenture to cause its Restricted Subsidiaries to provide Guarantees in certain circumstances;

WHEREAS, on April 2, 2021, the New Guarantor entered into a Guarantee of the Senior Secured Credit Facilities;

WHEREAS, pursuant to Section 4.10 of the Indenture, if any Wholly Owned Subsidiary (other than a Receivables Entity or an Excluded Disregarded Entity) that is a Restricted Subsidiary (other than a Subsidiary Guarantor, a Receivables Entity, an Excluded Disregarded Entity or an Unrestricted Subsidiary) provides a guarantee of the Senior Secured Credit Facilities, then, within 60 days after such Restricted Subsidiary provides such guarantee, such Restricted Subsidiary will execute a Supplemental Indenture providing for a Subsidiary Guarantee by such Restricted Subsidiary;

WHEREAS, in order to comply with Section 4.10 of the Indenture, the New Guarantor is required to become a Subsidiary Guarantor under the Indenture; and

WHEREAS, the New Guarantor has agreed to become a Subsidiary Guarantor under the Indenture, and to be bound by the terms of the Indenture applicable to Subsidiary Guarantors.

AGREEMENT

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained and intending to be legally bound, the parties to this Supplemental Indenture hereby agree as follows:

Section 1. Capitalized terms used herein and not otherwise defined herein are used as defined in the Indenture.

Section 2. The New Guarantor, by its execution of this Supplemental Indenture, agrees to be a Subsidiary Guarantor under the Indenture and to be bound by the terms of the Indenture applicable to Subsidiary Guarantors, including, but not limited to, Article 10 thereof.

Section 3. THE INTERNAL LAW OF THE STATE OF NEW YORK WILL GOVERN AND BE USED TO CONSTRUE THIS SUPPLEMENTAL INDENTURE, AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS SUPPLEMENTAL INDENTURE, WITHOUT GIVING EFFECT TO APPLICABLE PRINCIPLES OF CONFLICTS OF LAW TO THE EXTENT THAT THE APPLICATION OF THE LAWS OF ANOTHER JURISDICTION WOULD BE REQUIRED THEREBY.

EACH OF THE COMPANY, THE NEW GUARANTOR AND THE TRUSTEE HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS SUPPLEMENTAL INDENTURE, THE INDENTURE, THE NOTES, THE SUBSIDIARY GUARANTEES OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

Section 4. This Supplemental Indenture may be signed in various counterparts that together will constitute one and the same instrument. The exchange of copies of this Supplemental Indenture and of signature pages by facsimile or portable document format (".pdf") transmission shall constitute effective execution and delivery of this Supplemental Indenture as to the parties hereto and may be used in lieu of the original Supplemental Indenture for all purposes. Signatures of the parties hereto transmitted by facsimile or .pdf shall be deemed to be their original signatures for all purposes.

Section 5. This Supplemental Indenture is an amendment supplemental to the Indenture and the Indenture and this Supplemental Indenture will henceforth be read together.

Section 6. The Trustee shall not be responsible in any manner whatsoever for or in respect of the validity or sufficiency of this Supplemental Indenture, the Subsidiary Guarantee of the New Guarantor or for or in respect of the recitals contained herein, all of which recitals are made solely by the Company and the New Guarantor. All of the provisions contained in the Indenture in respect of the rights, privileges, immunities, powers, and duties of the Trustee shall be applicable in respect of this Supplemental Indenture as fully and with like force and effect as though fully set forth in full herein.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this First Supplemental Indenture to be duly executed as of the date first above written.

HOLOGIC, INC., as Issuer

By: /s/ Marci J. Lerner
Name: Marci J. Lerner
Title: Vice President, Treasurer

BIOTHERANOSTICS, INC.
By: /s/ Marci J. Lerner
Name: Marci J. Lerner
Title: Vice President, Treasurer

WELLS FARGO BANK, NATIONAL ASSOCIATION, as Trustee

By: /s/ Tina D. Gonzalez
Name: Tina D. Gonzalez
Title: Vice President

Execution Version

SECOND SUPPLEMENTAL INDENTURE

dated as of November 9, 2018 among
Hologic, Inc.,

The Subsidiary Guarantor Parties Hereto and
Wells Fargo Bank, National Association, as Trustee

4.625% Senior Notes due 2028

THIS SECOND SUPPLEMENTAL INDENTURE (this "**Supplemental Indenture**"), entered into as of November 9, 2018, among HOLOGIC, INC., a Delaware corporation (the "**Company**"), Bioptics, Inc., an Arizona corporation ("**Bioptics**") and Faxitron Bioptics, LLC, a Delaware limited liability company ("**Faxitron**", and together with Bioptics, each a "**New Guarantor**" and collectively, the "**New Guarantors**"), and Wells Fargo Bank, National Association, as trustee (the "**Trustee**").

RECITALS

WHEREAS, the Company, the Subsidiary Guarantors party thereto and the Trustee entered into the Indenture, dated as of January 19, 2018 (as supplemented by that certain First Supplemental Indenture dated as of May 8, 2018, the "**Indenture**"), relating to the Company's 4.625% Senior Notes due 2028 (the "**Notes**");

WHEREAS, as a condition to the Trustee entering into the Indenture and the purchase of the Notes by the Holders, the Company agreed pursuant to the Indenture to cause its Restricted Subsidiaries to provide Guarantees in certain circumstances;

WHEREAS, on September 12, 2018, the New Guarantors entered into a Guarantee of the Senior Secured Credit Facilities;

WHEREAS, pursuant to Section 4.10 of the Indenture, if any Wholly Owned Subsidiary (other than a Receivables Entity or an Excluded Disregarded Entity) that is a Restricted Subsidiary (other than a Subsidiary Guarantor, a Receivables Entity, an Excluded Disregarded Entity or an Unrestricted Subsidiary) and that is not a Subsidiary Guarantor (other than a Receivables Entity or an Excluded Disregarded Entity) provides a guarantee of the Senior Secured Credit Facilities, then, within 60 days after such Restricted Subsidiary provides such guarantee, such Restricted Subsidiary will execute a Supplemental Indenture providing for a Subsidiary Guarantee by such Restricted Subsidiary;

WHEREAS, in order to comply with Section 4.10 of the Indenture, the New Guarantors are each required to become a Subsidiary Guarantor under the Indenture; and

WHEREAS, the New Guarantors have each agreed to become a Subsidiary Guarantor under the Indenture, subject to the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained and intending to be legally bound, the parties to this Supplemental Indenture hereby agree as follows:

Section 1. Capitalized terms used herein and not otherwise defined herein are used as defined in the Indenture.

Section 2. Each New Guarantor, by its execution of this Supplemental Indenture, agrees to be a Subsidiary Guarantor under the Indenture and to be bound by the terms of the Indenture applicable to Subsidiary Guarantors, including, but not limited to, Article 10 thereof.

Section 3. THE INTERNAL LAW OF THE STATE OF NEW YORK WILL GOVERN AND BE USED TO CONSTRUE THIS SUPPLEMENTAL INDENTURE, AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS SUPPLEMENTAL INDENTURE, WITHOUT GIVING EFFECT TO APPLICABLE PRINCIPLES OF CONFLICTS OF LAW TO THE EXTENT THAT THE APPLICATION OF THE LAWS OF ANOTHER JURISDICTION WOULD BE REQUIRED THEREBY.

EACH OF THE COMPANY, THE NEW GUARANTORS AND THE TRUSTEE HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS SUPPLEMENTAL INDENTURE, THE INDENTURE, THE NOTES, THE SUBSIDIARY GUARANTEES OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

Section 4. This Supplemental Indenture may be signed in various counterparts that together will constitute one and the same instrument. The exchange of copies of this Supplemental Indenture and of signature pages by facsimile or portable document format ("PDF") transmission shall constitute effective execution and delivery of this Supplemental Indenture as to the parties hereto and may be used in lieu of the original Supplemental Indenture for all purposes. Signatures of the parties hereto transmitted by facsimile or PDF shall be deemed to be their original signatures for all purposes.

Section 5. This Supplemental Indenture is an amendment supplemental to the Indenture and the Indenture and this Supplemental Indenture will henceforth be read together.

Section 6. The Trustee shall not be responsible in any manner whatsoever for or in respect of the validity or sufficiency of this Supplemental Indenture, the Subsidiary Guarantee of the New Guarantors or for or in respect of the recitals contained herein, all of which recitals are made solely by the Company and the New Guarantors. All of the provisions contained in the Indenture in respect of the rights, privileges, immunities, powers, and duties of the Trustee shall be applicable in respect of this Supplemental Indenture as fully and with like force and effect as though fully set forth in full herein.

IN WITNESS WHEREOF, the parties hereto have caused this Second Supplemental Indenture to be duly executed as of the date first above written

HOLOGIC, INC., as Issuer

/s/ Marci J. Lerner
Name: Marci J. Lerner
Title: Vice President, Treasurer

BIOPTICS, INC.

/s/ Marci J. Lerner
Name: Marci J. Lerner
Title: Vice President and Treasurer

FAXITRON BIOPTICS, LLC

/s/ Marci J. Lerner
Name: Marci J. Lerner
Title: Vice President and Treasurer

WELLS FARGO BANK, NATIONAL ASSOCIATION, as Trustee
By: /s/ Tina D. Gonzalez
Name: Tina D. Gonzalez
Title: Vice President

THIRD SUPPLEMENTAL INDENTURE

dated as of January 8, 2019

among

Hologic, Inc.,

The Subsidiary Guarantors Party Hereto

and

Wells Fargo Bank, National Association,
as Trustee

4.625% Senior Notes due 2028

THIS THIRD SUPPLEMENTAL INDENTURE (this "**Supplemental Indenture**"), entered into as of January 8, 2019, among HOLOGIC, INC., a Delaware corporation (the "**Company**"), Focal Therapeutics, Inc., a Delaware corporation (the "**New Guarantor**"), and Wells Fargo Bank, National Association, as trustee (the "**Trustee**").

RECITALS

WHEREAS, the Company, the Subsidiary Guarantors party thereto and the Trustee entered into the Indenture, dated as of January 19, 2018 (as amended by the First Supplemental Indenture dated as of May 8, 2018 and the Second Supplemental Indenture dated as of November 9, 2018, the "**Indenture**"), relating to the Company's 4.625% Senior Notes due 2028 (the "**Notes**");

WHEREAS, as a condition to the Trustee entering into the Indenture and the purchase of the Notes by the Holders, the Company agreed pursuant to the Indenture to cause its Restricted Subsidiaries to provide Guarantees in certain circumstances;

WHEREAS, on November 14, 2018, the New Guarantor entered into a Guarantee of the Senior Secured Credit Facilities;

WHEREAS, pursuant to Section 4.10 of the Indenture, if any Wholly Owned Subsidiary (other than a Receivables Entity or an Excluded Disregarded Entity) that is a Restricted Subsidiary (other than a Subsidiary Guarantor, a Receivables Entity, an Excluded Disregarded Entity or an Unrestricted Subsidiary) and that is not a Subsidiary Guarantor (other than a Receivables Entity or an Excluded Disregarded Entity) provides a guarantee of the Senior Secured Credit Facilities, then, within 60 days after such Restricted Subsidiary provides such guarantee, such Restricted Subsidiary will execute a Supplemental Indenture providing for a Subsidiary Guarantee by such Restricted Subsidiary;

WHEREAS, in order to comply with Section 4.10 of the Indenture, the New Guarantor is required to become a Subsidiary Guarantor under the Indenture; and

WHEREAS, the New Guarantor has agreed to become a Subsidiary Guarantor under the Indenture, subject to the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained and intending to be legally bound, the parties to this Supplemental Indenture hereby agree as follows:

Section 1. Capitalized terms used herein and not otherwise defined herein are used as defined in the Indenture.

Section 2. The New Guarantor, by its execution of this Supplemental Indenture, agrees to be a Subsidiary Guarantor under the Indenture and to be bound by the terms of the Indenture applicable to Subsidiary Guarantors, including, but not limited to, Article 10 thereof.

Section 3. THE INTERNAL LAW OF THE STATE OF NEW YORK WILL GOVERN AND BE USED TO CONSTRUE THIS SUPPLEMENTAL INDENTURE, AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS SUPPLEMENTAL INDENTURE, WITHOUT GIVING EFFECT TO APPLICABLE PRINCIPLES OF CONFLICTS OF LAW TO THE EXTENT THAT THE APPLICATION OF THE LAWS OF ANOTHER JURISDICTION WOULD BE REQUIRED THEREBY.

EACH OF THE COMPANY, THE NEW GUARANTOR AND THE TRUSTEE HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS SUPPLEMENTAL INDENTURE, THE INDENTURE, THE NOTES, THE SUBSIDIARY GUARANTEES OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

Section 4. This Supplemental Indenture may be signed in various counterparts that together will constitute one and the same instrument. The exchange of copies of this Supplemental Indenture and of signature pages by facsimile or portable document format ("PDF") transmission shall constitute effective execution and delivery of this Supplemental Indenture as to the parties hereto and may be used in lieu of the original Supplemental Indenture for all purposes. Signatures of the parties hereto transmitted by facsimile or PDF shall be deemed to be their original signatures for all purposes.

Section 5. This Supplemental Indenture is an amendment supplemental to the Indenture and the Indenture and this Supplemental Indenture will henceforth be read together.

Section 6. The Trustee shall not be responsible in any manner whatsoever for or in respect of the validity or sufficiency of this Supplemental Indenture, the Subsidiary Guarantee of the New Guarantor or for or in respect of the recitals contained herein, all of which recitals are made solely by the Company and the New Guarantor. All of the provisions contained in the Indenture in respect of the rights, privileges, immunities, powers, and duties of the Trustee shall be applicable in respect of this Supplemental Indenture as fully and with like force and effect as though fully set forth in full herein.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Third Supplemental Indenture to be duly executed as of the date first above written.

HOLOGIC, INC., as Issuer

By: /s/ Marci J. Lerner
Name: Marci J. Lerner
Title: Vice President and Treasurer

FOCAL THERAPEUTICS, INC.

By: /s/ Marci J. Lerner
Name: Marci J. Lerner
Title: Vice President and Treasurer

WELLS FARGO BANK, NATIONAL ASSOCIATION, as Trustee

By: /s/ Tina D. Gonzalez
Name: Tina D. Gonzalez
Title: Vice President

[Signature Page to Supplemental Indenture (2028) – Focal Therapeutics]

FOURTH SUPPLEMENTAL INDENTURE

dated as of March 14, 2019

among

Hologic, Inc.,

The Subsidiary Guarantor Party Hereto

and

Wells Fargo Bank, National Association,
as Trustee

4.625% Senior Notes due 2028

THIS FOURTH SUPPLEMENTAL INDENTURE (this "**Supplemental Indenture**"), entered into as of March 14, 2019, among HOLOGIC, INC., a Delaware corporation (the "**Company**"), Cynosure, LLC, a Delaware limited liability company (the "**New Guarantor**"), and Wells Fargo Bank, National Association, as trustee (the "**Trustee**").

RECITALS

WHEREAS, the Company, the Subsidiary Guarantors party thereto and the Trustee entered into the Indenture, dated as of January 19, 2018 (as amended by the First Supplemental Indenture dated as of May 8, 2018, the Second Supplemental Indenture dated as of November 9, 2018 and the Third Supplemental Indenture dated as of January 8, 2019, the "**Indenture**"), relating to the Company's 4.625% Senior Notes due 2028 (the "**Notes**");

WHEREAS, as a condition to the Trustee entering into the Indenture and the purchase of the Notes by the Holders, the Company agreed pursuant to the Indenture to cause its Restricted Subsidiaries to provide Guarantees in certain circumstances;

WHEREAS, Cynosure, Inc. was a Subsidiary Guarantor, and on December 28, 2018, Cynosure, Inc. converted into Cynosure, LLC, a Delaware limited liability company (the "**Conversion**");

WHEREAS, in accordance with Section 4.10 of the Indenture, a Subsidiary Guarantor shall be automatically released upon the sale or disposition of such Subsidiary in a transaction that is not prohibited under the Indenture such that such Subsidiary ceases to be a Subsidiary;

WHEREAS, upon completion of the Conversion, Cynosure, Inc. was automatically released as a Subsidiary Guarantor pursuant to Section 4.10 of the Indenture;

WHEREAS, on February 8, 2019, the New Guarantor entered into a Guarantee of the Senior Secured Credit Facilities;

WHEREAS, pursuant to Section 4.10 of the Indenture, if any Wholly Owned Subsidiary (other than a Receivables Entity or an Excluded Disregarded Entity) that is a Restricted Subsidiary (other than a Subsidiary Guarantor, a Receivables Entity, an Excluded Disregarded Entity or an Unrestricted Subsidiary) and that is not a Subsidiary Guarantor (other than a Receivables Entity or an Excluded Disregarded Entity) provides a guarantee of the Senior Secured Credit Facilities, then, within 60 days after such Restricted Subsidiary provides such guarantee, such Restricted Subsidiary will execute a Supplemental Indenture providing for a Subsidiary Guarantee by such Restricted Subsidiary;

WHEREAS, in order to comply with Section 4.10 of the Indenture, the New Guarantor is required to become a Subsidiary Guarantor under the Indenture; and

WHEREAS, the New Guarantor has agreed to become a Subsidiary Guarantor under the Indenture, subject to the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained and intending to be legally bound, the parties to this Supplemental Indenture hereby agree as follows:

Section 1. Capitalized terms used herein and not otherwise defined herein are used as defined in the Indenture.

Section 2. The New Guarantor, by its execution of this Supplemental Indenture, agrees to be a Subsidiary Guarantor under the Indenture and to be bound by the terms of the Indenture applicable to Subsidiary Guarantors, including, but not limited to, Article 10 thereof.

Section 3. Upon completion of the Conversion, Cynosure, Inc. was automatically released as a Subsidiary Guarantor under the Indenture (and from all of the obligations of a Subsidiary Guarantor under the Indenture) pursuant to Section 4.10.

Section 4. THE INTERNAL LAW OF THE STATE OF NEW YORK WILL GOVERN AND BE USED TO CONSTRUE THIS SUPPLEMENTAL INDENTURE, AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS SUPPLEMENTAL INDENTURE, WITHOUT GIVING EFFECT TO APPLICABLE PRINCIPLES OF CONFLICTS OF LAW TO THE EXTENT THAT THE APPLICATION OF THE LAWS OF ANOTHER JURISDICTION WOULD BE REQUIRED THEREBY.

EACH OF THE COMPANY, THE NEW GUARANTOR AND THE TRUSTEE HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS SUPPLEMENTAL INDENTURE, THE INDENTURE, THE NOTES, THE SUBSIDIARY GUARANTEES OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

Section 5. This Supplemental Indenture may be signed in various counterparts that together will constitute one and the same instrument. The exchange of copies of this Supplemental Indenture and of signature pages by facsimile or portable document format ("PDF") transmission shall constitute effective execution and delivery of this Supplemental Indenture as to the parties hereto and may be used in lieu of the original Supplemental Indenture for all purposes. Signatures of the parties hereto transmitted by facsimile or PDF shall be deemed to be their original signatures for all purposes.

Section 6. This Supplemental Indenture is an amendment supplemental to the Indenture and the Indenture and this Supplemental Indenture will henceforth be read together.

Section 7. The Trustee shall not be responsible in any manner whatsoever for or in respect of the validity or sufficiency of this Supplemental Indenture, the Subsidiary Guarantee of the New Guarantor or for or in respect of the recitals contained herein, all of which recitals are made solely by the Company and the New Guarantor. All of the provisions contained in the Indenture in respect of the rights, privileges, immunities, powers, and duties of the Trustee shall

be applicable in respect of this Supplemental Indenture as fully and with like force and effect as though fully set forth in full herein.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Fourth Supplemental Indenture to be duly executed as of the date first above written.

HOLOGIC, INC., as Issuer

By: /s/ Marci J. Lerner
Name: Marci J. Lerner
Title: Vice President and Treasurer

CYNOSURE, LLC

By: /s/ Marci J. Lerner
Name: Marci J. Lerner
Title: Vice President and Treasurer

WELLS FARGO BANK, NATIONAL ASSOCIATION, as Trustee

By: /s/ Tina D. Gonzalez
Name: Tina D. Gonzalez
Title: Vice President

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[Signature Page to Supplemental Indenture (2028) – Cynosure, LLC]

FIFTH SUPPLEMENTAL INDENTURE

dated as of May 18, 2021

among

Hologic, Inc.,

The Subsidiary Guarantor Party Hereto

and

Wells Fargo Bank, National Association,
as Trustee

4.625% Senior Notes due 2028

This FIFTH SUPPLEMENTAL INDENTURE (this "**Supplemental Indenture**"), entered into as of May 18, 2021, among HOLOGIC, INC., a Delaware corporation (the "**Company**"), Biotheranostics Inc., a Delaware corporation (the "**New Guarantor**"), and Wells Fargo Bank, National Association, as trustee (the "**Trustee**").

RECITALS

WHEREAS, the Company, the Subsidiary Guarantors party thereto and the Trustee entered into the Indenture, dated as of January 19, 2018 (as supplemented by the First Supplemental Indenture dated as of May 8, 2018, the Second Supplemental Indenture dated as of November 9, 2018, the Third Supplemental Indenture dated as of January 8, 2019, and the Fourth Supplemental Indenture dated as of March 14, 2019, the "**Indenture**"), relating to the Company's 4.625% Senior Notes due 2028 (the "**Notes**");

WHEREAS, as a condition to the Trustee entering into the Indenture and the purchase of the Notes by the Holders, the Company agreed pursuant to the Indenture to cause its Restricted Subsidiaries to provide Guarantees in certain circumstances;

WHEREAS, on April 2, 2021, the New Guarantor entered into a Guarantee of the Senior Secured Credit Facilities;

WHEREAS, pursuant to Section 4.10 of the Indenture, if any Wholly Owned Subsidiary (other than a Receivables Entity or an Excluded Disregarded Entity) that is a Restricted Subsidiary (other than a Subsidiary Guarantor, a Receivables Entity, an Excluded Disregarded Entity or an Unrestricted Subsidiary) provides a guarantee of the Senior Secured Credit Facilities, then, within 60 days after such Restricted Subsidiary provides such guarantee, such Restricted Subsidiary will execute a Supplemental Indenture providing for a Subsidiary Guarantee by such Restricted Subsidiary;

WHEREAS, in order to comply with Section 4.10 of the Indenture, the New Guarantor is required to become a Subsidiary Guarantor under the Indenture; and

WHEREAS, the New Guarantor has agreed to become a Subsidiary Guarantor under the Indenture, and to be bound by the terms of the Indenture applicable to Subsidiary Guarantors.

AGREEMENT

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained and intending to be legally bound, the parties to this Supplemental Indenture hereby agree as follows:

Section 1. Capitalized terms used herein and not otherwise defined herein are used as defined in the Indenture.

Section 2. The New Guarantor, by its execution of this Supplemental Indenture, agrees to be a Subsidiary Guarantor under the Indenture and to be bound by the terms of the Indenture applicable to Subsidiary Guarantors, including, but not limited to, Article 10 thereof.

Section 3. THE INTERNAL LAW OF THE STATE OF NEW YORK WILL GOVERN AND BE USED TO CONSTRUE THIS SUPPLEMENTAL INDENTURE, AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS SUPPLEMENTAL INDENTURE, WITHOUT GIVING EFFECT TO APPLICABLE PRINCIPLES OF CONFLICTS OF

LAW TO THE EXTENT THAT THE APPLICATION OF THE LAWS OF ANOTHER JURISDICTION WOULD BE REQUIRED THEREBY.

EACH OF THE COMPANY, THE NEW GUARANTOR AND THE TRUSTEE HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS SUPPLEMENTAL INDENTURE, THE INDENTURE, THE NOTES, THE SUBSIDIARY GUARANTEES OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

Section 4. This Supplemental Indenture may be signed in various counterparts that together will constitute one and the same instrument. The exchange of copies of this Supplemental Indenture and of signature pages by facsimile or portable document format (".pdf") transmission shall constitute effective execution and delivery of this Supplemental Indenture as to the parties hereto and may be used in lieu of the original Supplemental Indenture for all purposes. Signatures of the parties hereto transmitted by facsimile or .pdf shall be deemed to be their original signatures for all purposes.

Section 5. This Supplemental Indenture is an amendment supplemental to the Indenture and the Indenture and this Supplemental Indenture will henceforth be read together.

Section 6. The Trustee shall not be responsible in any manner whatsoever for or in respect of the validity or sufficiency of this Supplemental Indenture, the Subsidiary Guarantee of the New Guarantor or for or in respect of the recitals contained herein, all of which recitals are made solely by the Company and the New Guarantor. All of the provisions contained in the Indenture in respect of the rights, privileges, immunities, powers, and duties of the Trustee shall be applicable in respect of this Supplemental Indenture as fully and with like force and effect as though fully set forth in full herein.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Fifth Supplemental Indenture to be duly executed as of the date first above written.

HOLOGIC, INC., as Issuer

By: /s/ Marci J. Lerner
Name: Marci J. Lerner
Title: Vice President, Treasurer

BIOTHERANOSTICS, INC.
By: /s/ Marci J. Lerner
Name: Marci J. Lerner
Title: Vice President, Treasurer

WELLS FARGO BANK, NATIONAL ASSOCIATION, as Trustee

By: /s/ Tina D. Gonzalez
Name: Tina D. Gonzalez
Title: Vice President

CERTAIN INFORMATION HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS (I) NOT MATERIAL, AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. OMISSIONS ARE MARKED [*******].

DATED 8th February 1988

THE COUNCIL OF THE CITY

OF MANCHESTER

- and -

V.G. INSTRUMENTS GROUP LIMITED

LEASE

-of-

land situate at

Crewe Road Wythenshawe

in the City of Manchester

Town Clerk

Town Hall

Manchester

M60 2LA

LC/EM3/CP/55936

1103CMM/SP

H.M. LAND REGISTRY

land Registration Acts - 1925 to 1971

County - Greater Manchester

District - City of Manchester Registered Title No.

land situate at Crewe Road Wythenshawe in the

City of Manchester

Parties

THIS LEASE made the eighth day of February 1988 Between (1) THE COUNCIL OF THE CITY OF MANCHESTER ("the Lessors") and (2) V G INSTRUMENTS GROUP LIMITED having its Regjstered Office at 29 Brighton Road Crawley West Sussex Rh10 6AE ("the Lessee")

Interpretation

1. 0 IN THIS LEASE where the context so requires or admits

1.1 "the Lessors" includes the persons for the time being entitled to the reversion expectant on the determination of the term hereby granted

1.2 "the Lessee" includes the persons deriving title under the Lessee

l. 3 "the Plot of land" means All that plot of land fronting to

Crewe Road and Wythenshawe Road Wythenshawe in the City of Manchester containing an area of 1.455 hectares or thereabouts and delineated and described on the plan annexed hereto numbered A2652/6 and thereon edged red

1.4 "the building" means the building with the outbuildings boundary fences or hedges forecourt hedges or fences and other appurtenances thereto recently erected at the expense of the Lessee on the plot of land

1.5 “the demised premises” means both the plot of land and the building together with any alterations or additions thereto

2.0 WITNESSETH as follows:

Demise/Parcels/Reservations/Term

2.1 In consideration of the sum of [*******] paid by the Lessee to the Lessors (the receipt of which sum is hereby acknowledged) and in consideration of the yearly rent hereinafter reserved and of the Covenants by the Lessee and the conditions hereinafter contained the Lessors in Exercise of all powers enabling them hereby demise unto the Lessee ALL THAT the plot of land Except thereout any public sewers laid therein TOGETHER with (by way of demise and not of exception) the building AND TOGETHER WITH (a) a right of way for the Lessee the owners or occupiers for the time being of the demised premises and their respective servants and licensees (in common with he Lessors and all other persons having the like right) at all times with or without vehicles for all purposes connected with the use and enjoyment of the demised premises (but not for any other purpose whatsoever) to pass and repass along the roadway leading from Moor Road to the said plot of land known as Crewe Road and shown

coloured yellow on the plan (b) the free passage and running of water soil gas and electricity through the pipes sewers drains watercourses cables and services now being in or under the adjoining land known as Crewe Road and shown coloured yellow on the plan annexed hereto and the right to make connections thereto or any of them for the purpose of exercising the said right including full rights of access thereto to all times after seven days previous notice in writing to the Lessors (except in the case of emergency) for the purpose of inspecting maintaining renewing repairing and cleansing the same annexed hereto EXCEPT AND RESERVING to the Lessors ALL mines minerals and mineral substances (other than coal and mines of coal as defined by the Coal Act 1938) in or under the plot of land belongs to the Lessors with full power to work and get such mines minerals and mineral substances by underground workings only and without any obligations to leave any subjacent or lateral support for the surface or any buildings for the time being erected thereon or for any adjoining minerals and from time to time or at any time to do all acts and things necessary or proper for working or getting such mines minerals and mineral substances and any adjoining mines minerals and mineral substances but so nevertheless that nothing herein contained shall confer on the Lessors any right to enter on the surface and that proper compensation shall be paid to the Lessee for any damage to the surface or to any buildings thereon by reason of the exercise of the powers and rights hereby reserved by the amount of such compensation in case of dispute to be settled by one independent person to be appointed in accordance with the provisions of the Arbitration Act 1950 to 1979 or any statutory modification or re-enactment thereof AND ALSO EXCEPT AND RESERVING

to the Lessors free passage and drainage of water sewage and soil coming from or off any land or buildings erected and built or to be erected and built contiguous or near to the demised premises through the sewers drains pipes conduits and watercourses which are now or may within the period of eighty years from the date hereof (which shall be the perpetuity period applicable hereto) be in or under the plot of land TO HOLD (except and reserved as aforesaid) unto the Lessee for the term of 150 years from the first day of December 1988 (SUBJECT to the covenants and otherwise as more particularly contained in a Conveyance dated the 7th day of March 1927 made between (1) Robert Henry Grenville Tatton (2) Thomas Francis Egerton Sir Harry Stapleton Mainwaring and (3) The Lord Mayor Aldermen and Citizens of the City of Manchester so far as the same relate to or affect the demised premises and remain enforceable And subject also to:

(i) the term of years reserved by an Underlease dated the 2nd day of January 1987 made between (1) the Lessors and (2) The North West Electricity Board in respect of the land situated within and forming part of the plot of land and which is more particularly delineated and described on the plan annexed hereto and numbered A2662/6 and thereon edged purple

(ii) the respective user rights of The North West Water Authority and the North West Electricity Board in respect of the sewers and electricity cables laid in the parts of the plot of land hatched brown hatched purple horizontally hatched purple and shaded mauve respectively on the plan annexed hereto and numbered A2662/6

(iii) the respective rights of the said Authority and the said Board to enter the land hereinbefore mentioned (whichever may

be the case) to inspect maintain cleanse repair renew divert conduct work or manage such sewers or electricity cables and sub-station fencing making good any damage or loss caused by the exercise of such rights or any of them and restoring the surface of the said land YIELDING AND PAYING unto the Lessors throughout the said term the yearly rent of a [*******] if demanded

Lessees covenants

3.0 THE Lessee hereby covenants with the Lessors as follows:

Rent /rates and taxes

3.1 To pay the yearly rent hereby reserved at the times and in the manner hereinbefore appointed and also to pay and discharge all rates taxes assessments charges duties impositions and outgoings whatsoever which now are or during the said term shall be charged assessed or imposed on the demised premises or the landlord or the tenant in respect thereof except tax payable by the Lessors as a result of any dealing with any reversion immediately or mediately expectant on the term hereby granted

Easement Area

3. 2 Not without the previous consent in writing of the Lessorsto (a) erect any building or projection whatsoever on the parts of the plot of land shown as a brown line hatched brown hatched purple horizontally hatched purple and shaded respectively on the plan annexed hereto or do or permit to be done anything which could damage or impede the maintenance rights or the function of the surface water sewer and electricity cable laid in such land or

Proportion of site to be occupied by buildings

(b) build over the plot of land to a greater than one third

thereof nor erect any part of the building nearer than 3 metres from the side and rear boundaries of the plot of land

To repair

3.3 From time to time and at all times during the said term at the expense of the Lessee well and substantially to repair maintain and cleanse and in all respects keep in good and substantial repair and condition the demised premises and the fixtures and the same so repaired maintained cleansed and kept at the end or sooner determination of the said term peaceably to surrender and yield up unto the Lessors

To paint

3.4 Once in every four years of the said term properly to paint to the reasonable satisfaction of the Lessors all such parts of the outside of all buildings and any fences railings or other erections on the plot of land as are usually painted and once in every seven years of the said term properly to paint and decorate to the reasonable satisfaction of the Lessors all such parts of the inside of such buildings as are usually painted and decorated

To keep demised premises in order etc.

3.5 To keep all parts of the demised premises generally in proper and neat order and condition and properly to maintain keep satisfaction of the Lessors any grass lawns flowering shrubs bushes and dwarf hedges within the demised premises

No alterations

3. 6 Not without the consent in writing of the Lessors such consent not to be unreasonably withheld to make any addition improvement or alteration to the demised premises such as to

change the character exterior design or appearance of the same or of any addition thereto or affect the load bearing capacity of the structure of the demised premises nor without the previous consent in writing of the Lessors such consent not to be unreasonably withheld to erect or maintain or suffer to be erected or maintained upon the said plot of land any building erection wall or fence of any kind whatsoever other than and except the demised premises and if any consent shall be given under this sub-clause to carry out all such additions improvements or alterations in accordance with plans sections elevations and specifications to be prepared by a Registered Architect (who shall supervise the work throughout to completion) and with materials previously approved of in writing by the Lessors (such approval not to be unreasonably withheld)

User

3. 7 For to use the plot of land for any other purpose than as the site of the building nor without the consent in writing of the Lessors (such consent not to be unreasonably withheld) use the building for any purpose other than the manufacture assembly and testing of mass spectrometers

Nuisance

3.8 Not to let or use the demised premises or any part or parts thereof or permit or suffer the same to be let or used for a club or for the manufacture distribution sale or supply of intoxicating liquors for consumption on or off the demised premises nor for any noxious offensive noisy or dangerous trade business pursuit or occupation or for any purpose or in any manner which may be deemed by the Lessors to be a nuisance damage grievance or annoyance to the Lessors or their tenants or to the

owenrs lessee or lessees tenant or tenants of any of the adjoining property or the neighbourhood or to be detrimental to the neighbourhood Provided that the carrying on in a proper manner of the trade or business referred to in the last proceding sub-clause hereof shall not be deemed to be a breach of this covenant

Not to store in open

3. 9 Not at any time without the consent in writing of the Lessors to use any part of the plot of land not occupied by the building for the open storage of goods or materials of any nature whatsoever and to comply with any conditions subject to which any such consent may be given

Encroachments

3.10 To take all necessary steps to prevent any encroachment upon the demised premises or the acquisition of any new right to light passage drainage or other easement over under or upon the demised premises which shall come to the knowledge of the Lessee and to give notice to the Lessors of any threatened encroachments or attempt to acquire any such easement and to cooperate in all reasonable respects with the Lessors in taking any measures the Lessors may deem necessary (including legal action) to resist such encroachment or the acquisition of any such easement

As to waste material

3.11 Not to deposit place or store any bins crates cartons boxes or any receptacle for waste nor any such waste material in such manner as to be visible from any part of the street or road but maintain any such receptacles or material as aforesaid within the boundary walls of the demised premises

To preserve tress

3.12 Not to damage or cut down or remove any trees or shrubs

growing on the said plot of land without first obtaining the written consent of the Lessors other than pruning or the removal of dead timber and/or shrubs

Smokeless fuel

3.13 (a) Not to erect or install in or upon the demised premises any furnace boiler or other fuel burning apparatus (other than domestic apparatus consuming gas or electricity) without the previous written consent of the Lessors and to use and maintain any apparatus so installed and any alteration or addition thereto to the reasonable satisfaction of the Lessors

(b) Not to use or suffer to be used negligently inefficiently improperly any furnace boiler or other fue1 burning apperatus so as to cause or permit any noxious or offensive smoke effluvia gas vapor or grit to be emitted from the same

(c) Not to claim exemption under any Smoke Control Order or any similar order regulation bye-law or enactment made by the Lessors in t heir capacity of the Local Authority or by another proper Authority

No advertising or billposting station

3.14 Not to use any walls gable ends of buildings fences upon or enclosing the plot of land or any notice board sign or hoarding for the posting of bills or advertisements and not to use the demised premises for the purpose of an advertising or billposting station and in case of any breach of this covenant the Lessors shall in addition to any other remedy they may possess have the right at any time without notice to the Lessee or the occupier or occupiers to enter upon the demised premises and to remove any bills advertisements or posters displayed or exhibited in contravention of this convenant Provided always that the Lessors

shall not refuse their consent to the display on the demised premises of one advertisement indicating the Lessee's nature of business unless such advertisement shall be of such a nature as the Lessors shall take objection to on the ground of unsightliness or disfigurement of the neighbourhood or on other reasonable grounds

Compliance with acts

3.15 To execute all such works as are or may under or in pursuance of any Act of Parliament already or hereafter to be passed be directed or required by any local or public authority to be executed at any time during the said term upon or in respect of the demised premises whether by the Lessors or the Lessee and to comply with all Acts of Parliament and observe and perform all the regulations and byelaws and other requirements of any public authority in respect of the demised premises

Inspection

3.16 To permit the Lessors by their officers and servants with or without workmen or others at reasonable times upon prior written notice save in the case of emergency to enter upon the demised premises to view the state and condition thereof and also at any reasonable time upon prior written notice during the last seven years of the said term to take a schedule of the Landlord’s fixtures therein and to repair and make good all defects and wants of reparation which shall on any such inspection be discovered for which the Lessee is responsible under the provisions of this Lease and of which notice in writing shall be given to the Lessee or left for the Lessee at or upon the demised premises within two calendar months after the fiving of such notice Provided that in case the Lessee makes default in complying with the requirements

of any notice given by the Lessors within the aforesaid period then in addition to any other remedy they may possess it shall be lawful for the Lessors to enter into and upon the demised premise and to execute or cause to be executed the works comprised or referred to in the said notice and to recover from the Lessee the actual costs thereof and charges incurred in connection therewith as rent in arrear

Insurance

3.17 (a) To insure the demised premises from loss or damage by fire explosion lightning storm tempest and aircraft including articles dropped therefrom and any other risks from time to time reasonably required by the Lessors to the full replacement value thereof in the joint names of the Lessee and the Lessors as co-insureds in some well-established insurance office in Great Britain approved of in writing by the Lessors and during the said term to keep the same so insured and to pay all premiums necessary for that purpose within fourteen days after the same shall have become due and upon the request of the Lessors from time to time to produce the policy of such insurance and the receipt for the premium for the then current year

(b) If the demised premises *or* any part or parts shall be destroyed or damaged and as often as the same shall be so destroyed or damaged forthwith to lay out the money received in respect of such insurance in rebuilding and reinstating the Same under the direction and to the reasonable satisfaction of the Lessors and in case such money shall be insufficient for such purpose to make good such deficiency

(c) If the Lessee shall at any time fail to insure or keep insured the demised premises or to produce the policy of insurance

and the receipt for the current year's premium as hereinbefore provided the Lessors may do all things necessary to effect or maintain such insurance and all money expended by the Lessors for that purpose shall be repaid by the Lessee to the Lessors on demand with interest while unpaid in accordance with Clause 4.5 hereof and such money and interest and all incidental costs incurred by the Lessors shall until payment be recoverable as rent in arrear

(d) If at any time the Lessee desires to effect an insurance on the demised premises otherwise than in compliance with the terms of this Lease the Lessee shall first obtain the consent in writing of the Lessors and shall hold all money received by the Lessee in respect of any such insurance in trust for the Lessors to be paid to the Lessors and to be applied by them (so far as may be required) in reinstatement of the demised premises

(e) Not to do or suffer to be done anything which may prejudice any such insurance as aforesaid nor without the consent in writing of the Lessors (which consent shall not be unreasonably withheld) to keep or permit to be kept on the demised premises materials of a dangerous or explosive nature or do or suffer to be done anything whereby the insurance premium for adjacent premises shall require to be increased

Not to assign etc.

3.18 (a) not to assign part only (as opposed to the whole) of the demised premises

(b) Not to part with or share the possession or occupation of all or any part of the demised premises for all or any part of the term save as permitted pursuant to the provisions of sub-clause (c) below PROVIDED ALWAYS that the occupation

of the demised premises or any part thereof by a wholly owned subsidiary or associated company of the lessee shall not constitute a breach of this Clause

(c) Not to assign the whole of the demised premises nor to sub-demise the whole or any part of the demised premises without the previous written consent of the Lessors provided always that every permitted underlease shall contain covenants on the part of the underlessee or underlessees as follows

(i) An absolute covenant not to assign part only (as opposed to the whole) of the underlet premises or to part with or share possession or occupation of the whole or any part thereof other than in accordance with sub-clause (ii) hereof

(ii) A qualified covenant not to assign the whole of the underlet premises or underlet the whole or any part of the underlet premises without the consent in writing of the I,essors

Notice of assignment

3.19 Upon every assignment or sub-demise (except by way of mortgage) or devolution of the demised premises or any part thereof within one calendar month afater the assignment sub-demise or devolution to give to the Town Clerk of the Lessors notice in writing thereof specifying the name and address of the assignee sub-lessee or personal representative or other person in whom the term or any part thereof may have become vested and to produce the assignment sub-demise or evidence of devolution at at the Office of the said Town Clerk for registration and for such consent and registration to pay a reasonable fee

Acquisition of rights

3.20 That the Lessee shall not (save as herein provided or under a written agreement of the Lessors) acquire any right of light

air way support watercourse drainage or other easement over under or through any adjoining or neighbouring land of the Lessors

Indemnify re covenants

3.21 For the purpose of affording to the Lessors a full and sufficient indemnity but not further or otherwise at all times during the said term to duly observe and perform the covenants and the conditions subject to which this demise is made so far as all such covenants and conditions are still subsisting and capable of being enforced and relate to or affect the demised premises and to keep the Lessors indemnified from and against all actions proceedings costs damages claims and demands whatsoever in respect of the non-observance or non-performance thereof

Cost of LPA notices

3.22 To pay all reasonable expenses including legal costs and Surveyor's fees incurred by the Lessors incidental to the preparation and service of a Notice under Section 146 of the Law of Property Act 1925 or incurred in or in contemplation of proceedings under Section 146 or 147 of that Act notwithstanding in any such case forfeiture is avoided otherwise than by relief by the Court

To comply with statues etc.

3.23 At all times during the said term to comply in all respects with the provisions and requirements of the Town and Country Planning Acts and all other Acts of Parliament hereafter enacted related to Town Planning and all regulations or orders made thereunder whether as to the permitted use hereunder or otherwise and to indemnify and keep the Lessors indemnified against all liability in respect of any acts or omissions by the Lessee in contravention hereof including costs and expenses in

respect of such matters and forthwith to produce to the Lessors on receipt of notice thereof any notice order or proposal therefor made given or issued to the Lessee by a Planning Authority under or by virtue of the said Acts or any of them affecting or relating to the demised premises

Costs in abating nuisance etc.

3.24 To pay all costs charges and expenses incurred by the Lessors in abating a nuisance and executing all such works as may be necessary for abating a nuisance or for remedying any other matter in connection with the demised premises in obedience to any notice served by any local or public authority

Costs for consents licenses etc.

3.25 Save where otherwise provided in this Lease to pay to the Lessors all reasonable Solicitors' costs and Surveyors' fees incurred by the Lessors attendant upon or incidental to every application made by the Lessee for a consent or license herein required or made necessary whether the same be granted or refused or or proffered subject to any lawful qualification or condition or whether the application be withdrawn

Load bearing

3.26 Not to install or bring or leave upon the demised premises any article of any description whatsoever which would cause any greater strain to be placed upon any part of the demised premises than that which the demised premises are capable of bearing

Not to obstruct drains

3.27 Not to stop up or obstruct or permit or suffer to be stopped up or obstructed or permit or suffer oil grease or other deleterious matter to enter the drains and sewers pipes channels

and watercourses of the demised premises

To indemnify Lessors

3. 28 To indemnify the Lessors against all actions cost claims demands and liability whatsoever in respect of injury (including fatal injury) or damage to any person or property due to or arising from the act default or negligence of the Lessee or the Lessee's agents or servants or licensees or trustees of the Lessee

3.29 During the subsistence of the term hereby granted to rebuild or replace or cause to be rebuilt or replaced once and in accordance with plans sections elevations specifications and Detailed drawings and of materials previously approved by the Lessors (such approval not to be unreasonably withheld) to the reasonable satisfaction of the Lessors expressed in writing the building

4.0 PROVIDED ALWAYS that: -

Lessors may obstruct lights etc.

4.1 It shall be lawful for the Lessors their lessee or lessees tenant or tenants at any time during the said term to erect rebuild or alter any buildings or erections facing adjoining or near to the demised premises to any extent and in any manner they may think fit notwithstanding that the buildings so erected rebuilt or altered may obstruct or interfere with any light or air for the time being appertaining to or enjoyed with the demised premises or any part thereof

Sale or Lease of adjoining

4. 2 The Lessors may sell or lease any land adjoining or near to the demised premises free from any obligations or restrictions similar to the obligations or restrictions hereby imposed and any obligations or restrictions in relation to any adjoining or

neighbouring land may be wholly or partially released or any breach thereof waived without thereby releasing the Lessee from any of the covenants or provisions herein contained or giving to the Lessee any right of action against the Lessors or any other person or persons

Re-entry

4.3 If there shall be any breach non-performance or non-observance of any of the covenants herein contained and on the Lessee's part to be observed and performed then and in every such case it shall be lawful for the Lessors into and upon the demised premises for the time being thereon or any part thereof in the name of the whole to re-enter and thereupon this demise shall absolutely determine without prejudice to any right of action or remedy of the Lessors in respect of any breach non-performance or non-observance of any of the covenants by the Lessee herein contained

Avoidance of doubt re Lessors' Powers

4.4 For the avoidance of doubt nothing herein contained or implied shall prejudice or affect the Lessors rights powers duties and obligations in the exercise of their functions as a local auathority planning authority or in any other capacity whatsoever nor relieve the Lessee from the necessity to obtain all such approvals or consents as may from time to time be requisite from the Lessors in any such capacity as aforesaid and the rights powers duties and obligations of the Lessors under all public and local statutes bye-laws orders and regulations may be as fully and effectually exercised in relation to the demised premises or any part thereof as if they were not the reversioners and this Lease had not been executed by

Interest on unpaid sums

4.5 All sums payable hereunder by the Lessee to the Lessors shall from the date due to the date paid carry interest while unpaid at a rate equivalent to two per cent above the base rate charged by the Lessors Bankers from time to time and this clause shall operate notwithstanding and without prejudice to the Lessors rights or re-entry and to determine this Lease for non-payment of such sums or breach of covenant

Lessors covenant for quiet enjoyment

5.0 THE LESSORS hereby covenant with Lessee (i) that the Lessee paying the rent hereby reserved and observing and performing the covenants and conditions herein contained and on the part of the Lessee to be observed and performed may quietly possess and enjoy the demised premises during the said term without any lawful interruption from or by the Lessors or any person rightly claiming from or under them (ii) until the same shall be adopted as maintainable at the public expense to light and comport all ways roads pavements (including the roadway shown coloured yellow on the plan annexed hereto) sewers drains pipes channels watercourses wires and cables which shall form part of or serve or be used by the demised premises in common with other adjoining or neighbouring premises

Notices

6.0 THE regulations as to notices contained in Section 196 of the Law of Property Act 1925 as amended by the Recorded Delivery Service Act 1962 apply to this Lease

Marginal notes

7.0 THE marginal notes shall not affect the construction hereof

IN WITNESS whereof the Lessors and the Lessee have hereunto affixed their respective Common Seals the day and year first before written

THE COMMON SEAL of THE COUNCIL
OF THE CITY 0F MANCHESTER was
hereunto affixed in pursuance
of an Order of the Council of
the *said* City:-

/s/

Authorised Signatory

Exhibit 21.1

Subsidiaries of Hologic*	Jurisdiction of Incorporation or Organization
Acessa Health Inc.	Delaware
Beijing Hologic Technology Co., Ltd.	China
Benassar Diagnostica-Equipamientos Medicos Unipessoal, Lda.	Portugal
BioLucent, LLC	Delaware
Bioptics, Inc.	Arizona
Biotheranostics, Inc.	Delaware
Cytyc Corporation	Delaware
Cytyc Prenatal Products Corp.	Delaware
Cytyc Surgical Products, LLC	Massachusetts
Diagenode Co., Ltd.	Japan
Diagenode SA	Belgium
Diagenode SPA	Chile
Diagenode, LLC	Delaware
Direct Radiography Corp.	Delaware
Emsor, Sociedad de responsabilidad limitada	Spain
Faxitron Bioptics, LLC	Delaware
Genewave SAS	France
Gen-Probe Incorporated	Delaware
Gen-Probe Prodesse, Inc.	Wisconsin
Gen-Probe Sales & Service, Inc.	Delaware
Health Beacons, Inc.	Washington
Hologic (Australia & New Zealand) Pty Ltd.	Australia
Hologic (MA), LLC	Massachusetts
Hologic ASE, LLC	Delaware
Hologic Asia Limited	Hong Kong
Hologic Asia Pacific Limited	Hong Kong
Hologic Austria GmbH	Austria
Hologic BV	Belgium
Hologic Bermuda Limited	Bermuda
Hologic Canada ULC	Canada
Hologic Caribbean (Barbados) SRL	Barbados
Hologic Denmark ApS	Denmark
Hologic Deutschland GmbH	Germany
Hologic Espana S.A.	Spain
Hologic Finance Ltd.	Bermuda
Hologic France SARL	France
Hologic GGO 2, LLC	Delaware
Hologic GGO 3 LLP	United Kingdom
Hologic GGO 4 LTD	United Kingdom
Hologic Global Holding LTD	United Kingdom
Hologic Hitec-Imaging GmbH	Germany
Hologic Holdings Limited	United Kingdom
Hologic HUB LTD	United Kingdom
Hologic Iberia, S.L.	Spain

Subsidiaries of Hologic*	Jurisdiction of Incorporation or Organization
Hologic India LLP	India
Hologic International Holdings B.V.	Netherlands
Hologic IP LTD	United Kingdom
Hologic Ireland Limited	Ireland
Hologic Italia S.r.l.	Italy
Hologic Japan KK	Japan
Hologic Latin America (Servicos Em Marketing E Negocios) Ltda.	Brazil
Hologic Ltd.	United Kingdom
Hologic Malaysia SDN. BHD.	Malaysia
Hologic Medical Technologies (Beijing) Co., Ltd.	China
Hologic Medicor GmbH	Germany
Hologic Medicor Suisse GmbH	Switzerland
Hologic Netherlands B.V.	Netherlands
Hologic Nordic Holdings Oy	Finland
Hologic (Shanghai) Medical Supplies Co., Ltd.	China
Hologic Singapore Pte. Ltd	Singapore
Hologic Suisse SA	Switzerland
Hologic Surgical Products Costa Rica, S.R.L.	Costa Rica
Hologic Sweden AB	Sweden
Hologic Taiwan Ltd.	Taiwan
Hologic UK Finance Ltd.	United Kingdom
Hologic US Finance Co LLC	Delaware
Mobidiag Oy	Finland
Mobidiag UK Ltd.	United Kingdom
Navigation Three Limited	Hong Kong
NXT-Dx SCRL	Belgium
Somatex (HK) Limited	China
Somatex Medical Technologies GmbH	Germany
Somatex USA Inc.	Delaware
SuperSonic Imagine SA	France
SuperSonic Imagine GmbH	Germany
SuperSonic Imagine Ltd	United Kingdom
SuperSonic Imagine Srl	Italy
SuperSonic Imagine HK Ltd	Hong Kong
SuperSonic Imagine (Shanghai) Medical Devices Co., Ltd.	China
Suros Surgical Systems, Inc.	Delaware
TCT International Co., Ltd.	British Virgin Islands
Tridaho LLC	Delaware

*Subsidiaries not included in the list are omitted because, in aggregate, they are insignificant as defined by Item 601(b((21) of Regulation S-K.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3ASR No. 333-235287) pertaining to Hologic, Inc.'s shelf registration statement for common stock, preferred stock, debt securities, rights, warrants, purchase contracts, units or any combination of the foregoing, and

(2) Registration Statements (Form S-8 Nos. 333-79167, 333-60046, 333-112222, 333-121111, 333-130170, 333-139341, 333-150796, 333-181126, 333-183019, 333-188468, 333-224613, 333-210968) pertaining to the equity incentive plans and employee stock purchase plan of Hologic, Inc.;

of our reports dated November 16, 2021, with respect to the consolidated financial statements of Hologic, Inc. and the effectiveness of internal control over financial reporting of Hologic, Inc., included in this Annual Report (Form 10-K) of Hologic, Inc. for the year ended September 25, 2021.

/s/ Ernst & Young LLP

Boston, Massachusetts
November 16, 2021

Exhibit 31.1

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

I, Stephen P. MacMillan, certify that:

1. I have reviewed this annual report on Form 10-K of Hologic, Inc.;

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

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

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

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

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

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: November 16, 2021

/s/ Stephen P. MacMillan

Stephen P. MacMillan
Chairman, President and Chief Executive Officer

Exhibit 31.2

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

I, Karleen M. Oberton, certify that:

1. I have reviewed this annual report on Form 10-K of Hologic, Inc.;

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

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

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

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

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

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: November 16, 2021

/s/ Karleen M. Oberton

Karleen M. Oberton
Chief Financial Officer

Exhibit 32.1

Certification
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

I, Stephen P. MacMillan, Chief Executive Officer of Hologic, Inc., a Delaware corporation (the "Company"), do hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), that:

(1) The Annual Report on Form 10-K for the year ended September 25, 2021 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 16, 2021

/s/ Stephen P. MacMillan

Stephen P. MacMillan
Chairman, President and Chief Executive Officer

A SIGNED ORIGINAL OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 HAS BEEN PROVIDED TO HOLOGIC, INC. AND WILL BE RETAINED BY HOLOGIC, INC. AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

Exhibit 32.2

Certification
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

I, Karleen M. Oberton, Chief Financial Officer of Hologic, Inc., a Delaware corporation (the "Company"), do hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), that:

(1) The Annual Report on Form 10-K for the year ended September 25, 2021 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 16, 2021

/s/ Karleen M. Oberton

Karleen M. Oberton
Chief Financial Officer

A SIGNED ORIGINAL OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 HAS BEEN PROVIDED TO HOLOGIC, INC. AND WILL BE RETAINED BY HOLOGIC, INC. AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.