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

FORM 10-K

(Mark One)

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

For the fiscal year ended: September 26, 2020

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, $.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 28, 2020 was $8,530,248,376 based on the price of the last reported sale on NASDAQ Global Select Market on that date.

As of November 12, 2020, 257,009,683 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 26, 2020 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 26, 2020

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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 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 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 current trade war between the U.S. and other nations, most notably China, and the impending impact of tariffs on the sale of our products in those countries and potential increased costs we may incur to purchase materials from our suppliers to manufacture our products;
- the development of new competitive technologies and products, and the impact and anticipated benefits of completed acquisitions;
- 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;
- strategic alliances and the ability of the Company to realize anticipated benefits of those alliances;
- 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;
- 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 the end of 2021; 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 U.S. Securities and Exchange Commission (the "SEC") including those set forth under “Risk Factors” set forth in Part I, Item 1A of this annual report on Form 10-K. 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 Pro Vu, AccuProbe, Aixplorer, Affirm, Affirm Prone, Alpha Imaging, Aptima, ATEC, BioZorb, Brevera, Celero, Cervista, 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, LOCalizer, Medicor, MyoSure, NovaSure, Panther, Panther Fusion, Progensa, 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 offering circular 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 light-based 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, certain high-risk strains of human papillomavirus, or HPV, and *Trichomonas vaginalis*, the parasite that causes trichomoniasis. In addition, in 2017 and 2018 we introduced the Aptima quantitative viral load tests for HIV, Hepatitis C and Hepatitis B. 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 2020, in response to the COVID-19 global 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 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. In January 2017, we sold our blood screening business to Grifols. We have continued to provide Grifols with instrumentation and certain raw materials, manufacture assays, and perform research and development services to support the blood screening business Grifols acquired from us.

Our Breast Health segment offers a broad portfolio of solutions for breast cancer care for radiology, pathology and surgery. These solutions include breast imaging and analytics, such as our 2D and 3D digital mammography systems and reading workstations, minimally invasive breast biopsy guidance systems and devices, breast biopsy site markers and localization, specimen radiology, ultrasound and connectivity solutions and breast conserving surgery products. Our most advanced breast imaging platforms, Selenia Dimensions and 3Dimensions, utilize a technology called tomosynthesis to produce 3D images that show multiple contiguous slice images of the breast, which we refer to as the Genius 3D Mammography exam, as well as conventional 2D full field digital mammography images. Our clinical results for FDA approval demonstrated that conventional 2D digital mammography with the addition of 3D tomosynthesis is superior to 2D digital mammography alone for both screening and diagnostics for women of all ages and breast densities. With the acquisition of SuperSonic Imagine in the first quarter of fiscal 2020, we now offer premium ultrasound imaging, further connecting Hologic capabilities across the continuum of breast care from screening to diagnosis and treatment.

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 multiple 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 and procedures. We completed the sale of our Medical Aesthetic business on December 30, 2019.

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 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. Hologic has used, and intends 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 its 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 on Form 10-K 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 Products

Molecular Diagnostic Assay Portfolio

Aptima Family of Molecular Diagnostic Assays. The 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, certain high-risk strains of human papillomavirus, or HPV, and *Trichomonas vaginalis*, the parasite that causes trichomoniasis. 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. 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 2020, in response to the COVID-19 global pandemic, we developed and launched our Aptima SARS-CoV-2 assays 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 that increase assay performance, improve laboratory efficiency and reduce laboratory costs. 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 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 "light 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 global pandemic, in 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 both 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 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 fiscal 2017, we released our new Panther Fusion system and related Fusion assays for flu and respiratory testing, which extends the capabilities of the existing Panther system by adding the flexibility of PCR, functionality to our existing TMA-based technology, all as a modular in-lab upgrade to the existing 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 Imaging System, 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.

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 System, the screening process has been automated to combine the power of computer imaging technology and human interpretive skills. Prior to human review, the ThinPrep Imaging System rapidly scans, locates and highlights areas of interest for review. By directing the cytotechnologist to areas of interest on a slide, the system 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.

Breast Health Products

Mammography Solutions

Our Dimensions platform includes the Selenia Dimensions and 3Dimensions gantries capable of performing both 2D and tomosynthesis image acquisition and display, which is referred to as 3D. 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. Our Synthesized 2D product has two offerings: C-View and Intelligent 2D. These software products provide a 2D image that is mathematically synthesized from the data within a tomosynthesis exam. Our current recommended clinical practice involves what we refer to as a "combo" exam involving a tomosynthesis exam and a conventional digital 2D exam, but performed under the same breast compression. The C-View product allows for the mathematical construction of a 2D image in standard resolution format from the tomosynthesis data, without the need for an actual 2D exposure. Elimination of the 2D exposure reduces the breast compression time and patient dose compared to the current combo exam.

Our new Intelligent 2D product, allows for the mathematical construction of a 2D image in high resolution format. Intelligent 2D is constructed from Clarity HD 3D images. Clarity HD high-resolution imaging is designed to clearly reveal subtle lesions and fine calcifications to help pinpoint cancers early. Our recently released 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 Clarity HD and Intelligent 2D study size by an estimated over 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 and Unifi Workspace, approved for interpretation of digital mammograms from most vendors as well as images from other diagnostic breast modalities. We also offer computer-aided detection, or CAD, software tools for our mammography products. Mammography CAD is used by radiologists as "a second pair of eyes" when reading a woman's mammogram. Use of this technology provides reviewers with the potential to detect findings 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 upright or prone systems for breast biopsy by offering two minimally invasive stereotactic breast biopsy guidance systems: Affirm Prone breast biopsy table and the Affirm upright attachment. The Affirm upright attachment is employed 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. To address this need, we acquired SuperSonic Imagine in the first quarter of fiscal 2020 following our equity method investment in fiscal 2019. 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 systems. The Supersonic Mach 40 ultrasound systems offers integration benefits with our existing breast health portfolio. We also offer a full line of ultraportable wireless solutions for breast and general imaging applications via a partnership with Clarius Mobile Health.

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 device which has a slimmer diameter. This device is 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 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.

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 2020, 2019, and 2018, 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% of our Diagnostics segment revenue. Comparatively, in fiscal 2019 and 2018 revenues from only one customer accounted for more than 10% of our Diagnostics segment revenue, at 14.5% and 14.2%, respectively. These 10% 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 2020, 2019, or 2018.

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 include 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. However, this product could 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 laboratory-developed tests, or LDTs.

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 and Cervista HPV tests compete 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, Koninklijke Philips NV, or Philips, Planmed Oy, or Planmed, Carestream Health, Inc., FUJIFILM Holdings Corporation, or Fuji, 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 Health'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 Boston Scientific Corporation, or Boston Scientific, 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's TruClear device and Boston Scientific's 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.

Skeletal Health. GE is our primary competitor in the bone densitometry market, and we also compete with Orthoscan 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 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 Diagnostics Corporation, 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, Cervista, 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 on Form 10-K.

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 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 global 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. 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.

The laboratories that purchase certain of our products, including the 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.

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 will have until May 2021 to meet the requirements of the EU MDR and 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. For example, the NMPA recently approved the Selenia 3Dimensions imaging product.

The regulatory environment in China is evolving, 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, patient need for our products and procedures, and, other than for our Medical Aesthetics products, 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 Resources

As of September 26, 2020, we had 5,814 full-time employees, including 1,655 in manufacturing operations, 706 in research and development, 2,827 in marketing, sales and support services, and 626 in general administration. As of that date, the 54 employees (53 non-management and one management) of our Hitec-Imaging subsidiary located in Germany are represented by a union and are subject to collective bargaining agreements. In addition, Hitec-Imaging's German employees are represented by a works council, a Betriebsrat, with respect to various shop agreements for social matters and working conditions. We believe that our relationship with our employees is good. Except as described herein, none of our other employees are represented by a union.

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 as 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 on Form 10-K 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

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

We have developed assays to detect the novel strain of coronavirus, which causes the infectious disease known as COVID-19 ("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, including governmental and quasi-governmental entities, away from us and toward other companies. Moreover, the dangers posed by COVID-19 may subside over time. We expect that, if and when the current COVID-19 pandemic subsides, there may be a significantly reduced demand for ongoing testing, and thus, for our COVID-19 assays. There is no guarantee that current or anticipated demand will continue, or if demand does continue, 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 uptick in our other businesses could have a material, adverse effect on our results of operations, cash flow and financial position.

Additional resources allocated to our Diagnostics business may negatively impact our other development programs or production capacities.

Given the significant current demand for our COVID-19 assays as well as for our Panther systems on which the assays run, we have devoted significant financial resources and personnel to scaling up production of the assay and our Panther systems. This resource allocation may cause delays in or otherwise negatively impact our other development programs or production capacities. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and that could dissipate.

The COVID-19 pandemic and associated economic disruptions have adversely affected and could in the future continue to have a material adverse impact on the demand for many of our products.

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. As healthcare systems respond to the increasing 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 are responding to the fears 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 are increasing from initially depressed levels, anticipated unemployment increases will result in more uninsured patients in the U.S. which will likely lead to fewer elective procedures, including screenings. The reduction in elective procedures, exams and capital purchases has had, and we believe will continue to have, a significant negative impact on the sales of most of our products (other than our COVID-19 assays and related systems) 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 believe that COVID-19's adverse impact on our operating results, cash flows and financial condition will be primarily driven by the severity and duration of the COVID-19 pandemic; 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 responses to the COVID-19 pandemic and associated economic disruptions.

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

The COVID-19 pandemic and associated economic disruptions could have 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. Although we have not experienced significant manufacturing or supply chain difficulties as a result of COVID-19, we may in the future. A reduction or interruption in any of our manufacturing processes could have a material adverse effect on our business.

GLOBAL CHALLENGES

Continuing worldwide political and social uncertainty, as well as existing tariffs and trade wars 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 2018, 2019 and 2020, the U.S. imposed tariffs on goods imported from China and certain other countries, which has resulted in retaliatory tariffs by China and other countries. Additional 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. There is also uncertainty surrounding the impact of U.S. presidential and congressional elections in 2020 on existing and future healthcare legislation; changes in such legislation could have a material adverse impact on our business.

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 2020, 24.2% 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 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 Diagnostics Corporation, 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. 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), 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 facilities could harm our business.

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, disruptions caused by the COVID-19 pandemic, or other reasons, could reduce, delay or prevent the production of our products. Our manufacturing 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. Manufacturing 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, 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, a material portion of product sales in our Diagnostics segment comes from (and we anticipate will continue to come from) a limited number of customers, two of which accounted for 12.5% and 10.9% 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.

BUSINESS DEVELOPMENT AND COMPETITION

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

As part of our long-term strategy, we are engaged in business development activities including evaluating 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. Further, once we develop a product or acquire a business, any inability to successfully integrate the new product or business, decreases in customer loyalty or product orders, failure to retain or develop the acquired workforce, 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 new products or 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. 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 other 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. Any corporate collaboration may divert management time and resources. In some instances, we have entered into 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.

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 they have 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 new 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.

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 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, 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 may also increase our exposure to cybersecurity breaches and failures. Additionally, we 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.

REGULATORY AND LEGAL

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 or product 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 2021 to meet the requirements of the EU MDR and 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.

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 various foreign jurisdictions. 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. 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, a change in our geographic earnings mix, or a change in the measurement of our deferred taxes.

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 do issue 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 COVID-19 assays 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 26, 2020, we had approximately $3.0 billion aggregate principal of indebtedness outstanding (exclusive of an additional $1.25 billion that would be available to draw under our revolver and any funds that we may draw under our temporarily suspended accounts receivable securitization program). We also have other contractual obligations and deferred tax liabilities, which as of September 26, 2020, are described under “Management’s Discussion and Analysis of Financial Condition and Results of Operation—Contractual Obligations.” 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 26, 2020, approximately $1.7 billion aggregate principal of our indebtedness, which represented the outstanding principal under our Amended and Restated Credit Facilities, was subject to floating interest rates. We currently have limited hedging arrangements in place to mitigate the impact of higher interest rates, including interest rate cap agreements and an interest rate swap agreement. These interest rate cap agreements expire through December 23, 2020, and the interest rate swap contract expires on December 17, 2023. We may not be able to extend these at an attractive economic price.

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 by the end of 2021. 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, including our Credit Agreement and related interest rate swap agreements, 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

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

We continue to assess the key personnel that we believe are essential to our long-term success. Following the recent retirement of the President of our Breast and Skeletal Health division, we established the role of Group President, Breast and Skeletal Health and Surgical and appointed a new President for each of the Breast and Skeletal Health and Surgical divisions. All of these roles were filled with internal candidates. As we promote from within, we must fill the roles that are left vacant due to the promotions. If we fail to effectively manage our ongoing organizational and 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. Additionally, 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. Also, 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. 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 during the current health and economic uncertainties may adversely impact job performance and employee retention. The loss of any of our key personnel, particularly 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.

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
Warstein, Germany	Manufacturing operations, research and development and administrative functions
Livingston, UK	Manufacturing operations and research and development
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

Material Properties Leased:	Primary Use	Lease Expiration (fiscal year)	Renewals
Danbury, CT	Manufacturing facility	2022	4, five-yr. periods
Danbury, CT	Manufacturing operations and research and development	2021	1, five-yr. period
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

The Company also leases various administrative and customer support centers throughout the world including in Brussels, Belgium, Kerpen, Germany, Madrid, Spain, Suzhou, China, Wiesbaden, Germany, and also maintains specialized research and development and manufacturing operations at various additional locations.

Item 3. Legal Proceedings

For a discussion of legal matters as of September 26, 2020, 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 12, 2020, there were approximately 930 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, 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 2020.

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) (3)
June 28, 2020 – July 25, 2020	705	$ 56.97	—	$ —	$ 362.6
July 26, 2020 – August 22, 2020	22,395	69.78	—	—	362.6
August 23, 2020 – September 26, 2020	260	59.22	1,668,422	60.04	262.4
Total	23,360	$ 69.28	1,668,422	$ 60.04	$ 262.4

(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 deemed 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.

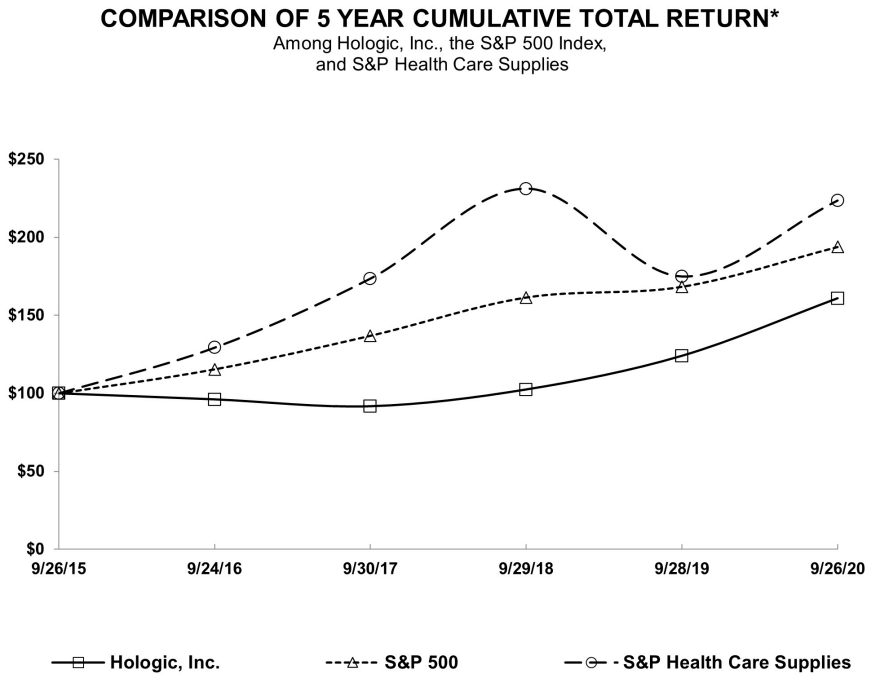
(2) On June 13, 2018, the Company's Board of Directors authorized a share repurchase plan to repurchase up to $500.0 million of our outstanding common stock. This share repurchase plan, which replaced the prior plan, was effective August 1, 2018 and expired on March 27, 2020. On December 11, 2019, the Board of Directors authorized a new share repurchase plan to repurchase up to $500.0 million of our 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.

(3) On November 22, 2019, the Company's Board of Directors authorized the further repurchase of up to $205 million of our outstanding shares pursuant to an accelerated share repurchase ("ASR") agreement with Goldman Sachs. Under the ASR, Hologic agreed to purchase $205 million of Hologic’s common stock. The initial delivery was 3.3 million shares for which the Company has initially allocated $164.0 million of the $205 million paid to Goldman Sachs, based on the then current market price of $50.02 per share. The ASR was completed 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 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 26, 2015 with the cumulative total return of the Standard & Poor's Health Care Supplies Index. This graph assumes the investment of $100 on September 26, 2015 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 9/26/15 in stock or index, including reinvestment of dividends.
Fiscal year ending September 26.

Item 6. Selected Financial Data

The following selected financial data should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K, beginning on page F-1.

In the second quarter of fiscal 2017, we divested our blood screening business and acquired the Medical Aesthetics business, which consisted of Cynosure, Inc., and in the third quarter of fiscal 2017 we acquired Medicor. In the first and fourth quarters of fiscal 2018, we acquired Emsor and Faxitron, respectively. In the first quarter of fiscal 2019, we acquired Focal Therapeutics. In the first quarter of fiscal 2020, we divested Cynosure. In the first and fourth quarters of fiscal 2020, we acquired SuperSonic Imagine and Acessa Health, respectively. Results of operations for these businesses are included in our consolidated financial statements from the date of acquisition.

	Fiscal Years Ended				
	September 26, 2020 (5)	September 28, 2019 (4)	September 30, 2018 (3)	September 24, 2017 (2)	September 26, 2016 (1)
	(In millions, except per share data)				
Consolidated Statement of Operations Data					
Total revenues	$ 3,776.4	$ 3,367.3	$ 3,217.9	$ 3,058.8	$ 2,832.7
Total operating costs and expenses	$ 2,671.4	$ 3,491.1	$ 3,455.8	$ 1,688.6	$ 2,284.1
Net income (loss) attributable to Hologic	$ 1,115.2	$ (203.6)	$ (111.3)	$ 755.5	$ 330.8
Basic net income (loss) per common share attributable to Hologic	$ 4.24	$ (0.76)	$ (0.40)	$ 2.70	$ 1.18
Diluted net income (loss) per common share attributable to Hologic	$ 4.21	$ (0.76)	$ (0.40)	$ 2.64	$ 1.16
Consolidated Balance Sheet Data					
Working capital	$ 983.0	$ 723.0	$ 320.6	$ (386.9)	$ 424.7
Total assets	$ 7,195.8	$ 6,442.1	$ 7,230.9	$ 7,979.6	$ 7,317.0
Long-term debt obligations, less current portion (6)	$ 2,731.3	$ 2,812.3	$ 2,736.1	$ 2,198.9	$ 3,058.7
Total Hologic's stockholders' equity	$ 2,705.2	$ 2,115.7	$ 2,428.8	$ 2,784.7	$ 2,142.7

(1) Fiscal 2016 total operating costs and expenses include restructuring and divestiture charges of $10.5 million. Included in net income was a gain on the sale of a marketable security of $25.1 million partially offset by a debt extinguishment loss of $5.3 million.
(2) Fiscal 2017 total operating costs and expenses include a gain on sale of the blood screening business of $899.7 million (reduces operating costs and expenses), inventory step-up costs of $39.7 million, transaction expenses for acquisitions of $23.2 million, and restructuring charges of $13.3 million.
(3) Fiscal 2018 total operating costs and expenses include a goodwill impairment charge of $685.7 million, an intangible asset impairment charge of $46.0 million, a legal settlement charge of $34.8 million and restructuring charges of $14.2 million. Included in net loss was a debt extinguishment loss of $45.9 million and related transaction costs of $4.3 million.
(4) Fiscal 2019 total operating costs and expenses include an intangible assets and equipment impairment charge of $685.4 million, inventory step-up costs of $7.1 million, a net legal settlement charge of $4.5 million and restructuring charges of $6.6 million. Included in net loss was a $3.3 million loss for the Company's proportionate share of its equity method investment in SuperSonic Imagine.
(5) Fiscal 2020 total operating costs and expenses include an intangible assets and equipment impairment charge of $30.2 million, restructuring charges of $15.3 million, and inventory step-up costs of $6.8 million.
(6) Long-term obligations are net of unamortized debt discounts and deferred issuance costs aggregating $23.6 million, $29.0 million, $32.9 million, $27.9 million and $62.9 million for fiscal years 2020, 2019, 2018, 2017, and 2016, respectively.

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 report and our Special Note Regarding Forward-Looking Statements at the outset of this report.

OVERVIEW

We are a developer, manufacturer and supplier of premium diagnostics products, medical imaging systems and surgical products with an emphasis 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, certain high-risk strains of human papillomavirus, or HPV, and *Trichomonas vaginalis*, the parasite that causes trichomoniasis. In addition, in 2017 and 2018 we introduced the Aptima quantitative viral load tests for HIV, Hepatitis C and Hepatitis B. 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 2020, in response to the COVID-19 global 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 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. In January 2017, we sold our blood screening business to Grifols. We have continued to provide Grifols with instrumentation and certain raw materials, manufacture assays, and perform research and development services to support the blood screening business Grifols acquired from us.

Our Breast Health segment offers a broad portfolio of solutions for breast cancer care for radiology, pathology and surgery. These solutions include breast imaging and analytics, such as our 2D and 3D digital mammography systems and reading workstations, minimally invasive breast biopsy guidance systems and devices, breast biopsy site markers and localization, specimen radiology, ultrasound and connectivity solutions and breast conserving surgery products. Our most advanced breast imaging platforms, Selenia Dimensions and 3Dimensions, utilize a technology called tomosynthesis to produce 3D images that show multiple contiguous slice images of the breast, which we refer to as the Genius 3D Mammography exam, as well as conventional 2D full field digital mammography images. Our clinical results for FDA approval demonstrated that conventional 2D digital mammography with the addition of 3D tomosynthesis is superior to 2D digital mammography alone for both screening and diagnostics for women of all ages and breast densities. With the acquisition of SuperSonic Imagine in the first quarter of fiscal 2020, we now offer premium ultrasound imaging, further connecting Hologic capabilities across the continuum of breast care from screening to diagnosis and treatment.

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 pandemic caused by the spread of the novel strain of coronavirus disease 2019 ("COVID-19") has created significant volatility, uncertainty and economic disruption in the markets we sell our products into, primarily the U.S., Europe and Asia-Pacific. In the second, third and fourth quarters of fiscal 2020, the spread of COVID-19 has negatively impacted business and healthcare activity globally. As healthcare systems respond to the increasing 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 are responding to the fears of contracting COVID-19. In particular, elective procedures and exams have been and continue to be delayed or cancelled, there has been a significant reduction in physician office visits, and hospitals have 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, which continued into the fourth quarter. The reductions in testing and procedures have had, and we believe will continue to have, a negative impact on our operating results and cash flows. However, the impact of the commercial release of our COVID-19 assays more than offset these negative impacts as we generated significant revenue from the sales of these assays in the third and fourth quarters of fiscal 2020.The negative effects of COVID-19 and the associated economic disruptions were felt primarily beginning in the second half of March in many of our end-markets and earlier in Asia, primarily China, and the impact to our legacy products in the third fiscal quarter was significant. The impact to our legacy products was less severe in the fourth quarter.

While our results of operations and cash flows in the third and fourth quarters of fiscal 2020 were positively impacted by the sale of our COVID-19 assays, 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: the severity and duration of the COVID-19 pandemic; continued demand for COVID-19 testing; competition from existing and new COVID-19 testing technologies and products; 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 responses to the COVID-19 pandemic and associated economic disruptions.

In addition to adversely affecting demand for our products, other than our COVID-19 assays, COVID-19 and associated economic disruptions could continue to have an adverse impact on our supply chains and distribution systems, including as a result of impacts associated with preventive and precautionary measures that we, other businesses and governments have taken and will take. A reduction or interruption in any of our manufacturing processes could have a material adverse effect on our business.

We believe that the uncertainty surrounding global financial markets and deteriorating worldwide macroeconomic conditions resulting from the pandemic have caused and may continue to cause the purchasers of medical equipment to decrease their medical equipment purchasing and procurement activities. Additionally, the pandemic has caused and may further cause constrictions in world credit markets that have caused and could cause our customers to experience increased difficulty in paying their existing obligations to us or in securing the financing necessary to purchase our products. Economic uncertainty has resulted and may continue to result in cost-conscious consumers focusing on acute care rather than wellness, which may also continue to adversely affect demand for our products (other than our COVID-19 assays).

As we assessed the potential longer term economic and capital market uncertainties resulting from the COVID-19 pandemic, at the end of March 2020 we suspended our accounts receivable securitization program and borrowed $750.0 million under our revolver. We used $250.0 million of these proceeds to pay off all amounts then owed under our accounts receivable securitization agreement, and retained the balance as cash reserve. As of the end of fiscal 2020, the Company repaid $500.0 million of the $750.0 million borrowed under its revolver. As of September 26, 2020 the Company had an additional $1.25 billion available under its revolver and $701.0 million of cash on hand.

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, 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, and the majority of the impacted manufacturing facilities were back to pre-COVID-19 pandemic levels.

We have also taken 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.

Acquisitions and Disposition

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

Acquisitions

Acessa Health

On August 23, 2020, we completed the acquisition of Acessa Health, Inc., or Acessa for a purchase price of $161.3 million, which included a hold-back of $3.0 million payable up to 5 months from the date of acquisition, and contingent consideration, which we 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. 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. Based on our preliminary purchase price allocation, we have allocated $128.2 million of the purchase price to the preliminary value of intangible assets and $48.4 million to goodwill. The allocation of the purchase price is preliminary as we continue to gather information supporting the acquired assets and liabilities. Acessa's results of operations are reported in our Surgical segment from the date of acquisition.

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, which included hold-backs of $2.3 million that are payable up to 18 months from the date of acquisition. Health Beacons manufactures the LOCalizer product. Based on our preliminary valuation, we have allocated $10.7 million of the purchase price to the preliminary value of developed technology and $6.2 million to goodwill. The remaining $2.8 million of the purchase price has been allocated to 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. Health Beacon's results of operations are reported in our Breast Health reportable segment from the date of acquisition.

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, which included a hold-back of $1.0 million and contingent consideration estimated at $0.9 million. The contingent consideration was payable upon shipment of certain backlog orders entered into by Alpha Imaging prior to the acquisition. Alpha Imaging was a long-standing distributor of our Breast and Skeletal products in the U.S. Based on our preliminary valuation, the majority of the purchase price was allocated to a customer relationships intangible asset. The allocation of the purchase price is preliminary as we continue to gather information supporting the acquired assets and liabilities.

SuperSonic Imagine

On August 1, 2019, we acquired approximately 46% of the outstanding shares of SuperSonic Imagine S. A., or SSI. SSI, headquartered in France, 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 common 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, specifically 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 the first quarter of fiscal 2020. The total 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 we provided to SSI prior to the acquisition that are considered forgiven, and $8.6 million representing the fair value of the noncontrolling interests as of November 21, 2019. Based on our preliminary purchase price allocation, we have allocated $45.3 million of the purchase price to the preliminary value of intangible assets and $34.3 million to goodwill. The allocation of the purchase price is preliminary as we continue to gather information supporting the acquired assets and liabilities, primarily income taxes and recognition of uncertain tax positions, to finalize the purchase price allocation.

As of September 26, 2020, we owned approximately 81% of SSI, and accordingly we have recorded an adjustment to our net income for the non-controlling interest we do not own of $4.7 million in the current year.

Focal Therapeutics

On October 1, 2018, we completed the acquisition of Focal Therapeutics, Inc., or 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 on October 1, 2019. 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. Based on our valuation, we allocated $97.2 million of the purchase price to the value of intangible assets and $31.1 million to goodwill. Focal's results of operations are reported in our Breast Health reportable segment from the date of acquisition.

Faxitron

On July 31, 2018, we completed the acquisition of Faxitron Bioptics, LLC, or Faxitron, for a purchase price of $89.5 million, which included hold-backs of $11.7 million that were payable up to one year from the date of acquisition, and contingent consideration, which we estimated at $2.9 million as of the measurement date. The contingent consideration was payable upon meeting certain revenue growth metrics. In fiscal 2019, the continent consideration liability was increased, and we paid $5.0 million in the second quarter of fiscal 2020. In fiscal 2019, we paid $6.5 million of the hold-back and withheld the remaining $5.2 million under the indemnification provisions of the purchase agreement, which the former shareholders had disputed. We resolved this dispute in the first quarter of fiscal 2020 and made a $4.1 million payment to the former shareholders. Based on our valuation, we allocated $53.2 million of the purchase price to the value of intangible assets and $45.6 million to goodwill. Faxitron, headquartered in Tucson, Arizona, develops, manufactures, and markets digital radiography systems. Faxitron's results of operations are reported in our Breast Health reportable segment from the date of acquisition.

Emsor, S.A.

On December 11, 2017, we completed the acquisition of Emsor S.A., or Emsor, a distributor of our Breast and Skeletal Health products in Spain and Portugal, for a purchase price of $16.3 million, which included contingent consideration estimated at $4.9 million as of the measurement date. The contingent consideration was payable upon Emsor achieving predefined amounts of cumulative revenue over a two-year period from the date of acquisition. The contingent consideration was paid in the second quarter of fiscal 2020.

Disposition

On December 30, 2019, we completed the sale of our Medical Aesthetics business to Clayton Dubilier & Rice ("CD&R"). At the closing, the Company received cash proceeds of $153.4 million. The sales price was finalized in the fourth quarter of fiscal 2020, and the Company paid $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 received any further product revenue related to this business, although additional expenses 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.

RESULTS OF OPERATIONS

The following table sets forth, for the periods indicated, the percentage of total revenues represented by items as shown in our Consolidated Statements of Operations. All dollar amounts in tables are presented in millions.

	Fiscal Years Ended	
	September 26, 2020	September 28, 2019
Revenues:		
Product	85.5 %	82.3 %
Service and other	14.5 %	17.7 %
	100.0 %	100.0 %
Costs of revenues:		
Product	25.3 %	28.2 %
Amortization of intangible assets	6.7 %	9.5 %
Impairment of intangible assets and equipment	0.7 %	17.2 %
Service and other	8.4 %	10.4 %
Gross Profit	58.9 %	34.7 %
Operating expenses:		
Research and development	5.9 %	6.9 %
Selling and marketing	12.8 %	16.8 %
General and administrative	9.4 %	9.9 %
Amortization of intangible assets	1.1 %	1.5 %
Impairment of intangible assets and equipment	0.1 %	3.2 %
Restructuring charges	0.4 %	0.2 %
	29.7 %	38.5 %
Income (loss) from operations	29.3 %	(3.7) %
Interest income	0.1 %	0.1 %
Interest expense	(3.1) %	(4.2) %
Debt extinguishment losses	— %	— %
Other income, net	0.2 %	0.1 %
Income (loss) before income taxes	26.5 %	(7.7) %
Provision (benefit) for income taxes	(2.9) %	(1.6) %
Net income (loss)	29.4 %	(6.1) %

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

Product Revenues

	Fiscal Years Ended					
	September 26, 2020		September 28, 2019		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Product Revenues						
Diagnostics	$ 2,073.8	54.9 %	$ 1,179.9	35.0 %	$ 893.9	75.8 %
Breast Health	672.1	17.8 %	836.8	24.9 %	(164.7)	(19.7)%
GYN Surgical	374.9	9.9 %	436.2	13.0 %	(61.3)	(14.1)%
Skeletal Health	56.5	1.5 %	65.5	1.9 %	(9.0)	(13.7)%
Medical Aesthetics	49.7	1.3 %	252.9	7.5 %	(203.2)	(80.3)%
	$ 3,227.0	85.4 %	$ 2,771.3	82.3 %	$ 455.7	16.4 %

We generated a 16.4% increase in product revenues in fiscal 2020 compared to fiscal 2019 primarily due to the increase in the Diagnostics business from sales of our newly introduced COVID-19 assays that were partially offset by reduced sales of our legacy products. We had decreases in our Breast Health, GYN Surgical and Skeletal Health segments which we attribute primarily to the impact of the COVID-19 pandemic across our businesses. We disposed of the Medical Aesthetics business segment on December 30, 2019, the beginning of our second quarter of fiscal 2020, and generated no Medical Aesthetics revenue after that sale.

Diagnostics product revenues increased 75.8% in fiscal 2020 compared to fiscal 2019 primarily due to increases in Molecular Diagnostics (excluding blood screening) of $965.6 million, partially offset by decreases in Cytology & Perinatal of $62.7 million and a decrease of $9.0 million in blood screening. 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 (excluding blood screening) was $1.6 billion in fiscal 2020 compared to $665.4 million in fiscal 2019. The increase was primarily attributable to revenues of $929.3 million 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) and an increase in Panther and Panther Fusion instrument sales due to demand for increased testing capacity for COVID-19. We are actively working to increase capacity production to meet worldwide demand of these assays. These increases were partially offset by decreases in our Aptima women's health assays of $10.7 million on a worldwide basis in the current fiscal year primarily due to lower volumes, which we attribute primarily to the impact of the COVID-19 pandemic resulting in a reduction in physician office visits and hospitals limiting services. In addition, we had an increase of $8.1 million in worldwide sales of our virology products in the current fiscal year. Cytology & Perinatal product revenue decreased $62.7 million in the current fiscal year primarily due to lower ThinPrep test volumes, which we attribute primarily to the reduction in wellness office visits in response to the COVID-19 pandemic, and to a lesser extent lower Perinatal product volumes. 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. Most recently, in July 2020, the American Cancer Society recommended using a primary human papillomavirus (HPV) test, rather than a Pap test, for cervical cancer screening. While the impact of the COVID-19 pandemic has negatively impacted our legacy product lines, we have experienced an increase in revenues sequentially from the third quarter of fiscal 2020 to the fourth quarter indicating strength in a recovery of these end markets. We expect the market for our legacy diagnostics products to continue to be challenging in the first quarter of 2021 and beyond as the COVID-19 pandemic continues and wellness visits continue to be delayed or cancelled. In the first two months of fiscal 2021, there has been an increase in the volume of reported positive COVID-19 cases.

Breast Health product revenues decreased 19.7% in fiscal 2020 compared to fiscal 2019 primarily due to a decrease in sales volume of our 3D and 2D digital mammography systems and related workflow products (primarily Intelligent 2D, Clarity HD and SmartCurve), Affirm Prone breast biopsy tables and our interventional breast solutions Eviva, ATEC and Celero handpieces. We primarily attribute the decline in revenues to the COVID-19 pandemic. In particular, in the U.S. as hospitals and imaging centers either slowed down purchases or delayed orders and installations of capital equipment units in order to focus their efforts towards COVID-19 patients and concerns on maintaining their cash and liquidity, as well as from the impact of delayed or cancelled elective imaging exams and procedures in response to the pandemic. While the impact of the COVID-19 pandemic has negatively impacted these product lines, we have experienced an increase in revenues sequentially from the third quarter of fiscal 2020 to the fourth quarter indicating strength in a recovery of these end markets. These decreases were partially offset by the inclusion of revenues from SSI which contributed $18.8 million of product revenue in fiscal 2020. We obtained control of SSI and began consolidating their results for the last fiscal month of the first quarter of fiscal 2020. We expect the market for our Breast Health products to continue to be challenging in the first quarter of fiscal 2021 and beyond to

the extent the COVID-19 pandemic continues and hospitals and healthcare centers continue to restrict access and wellness visits and elective medical procedures, and hospital and healthcare center capital expenditures continue to be delayed or cancelled.

GYN Surgical product revenues decreased 14.1% in fiscal 2020 compared to fiscal 2019, which we primarily attribute to reduced sales volumes resulting from the impact of the COVID-19 pandemic. MyoSure system sales decreased $21.5 million, and NovaSure system sales decreased $44.5 million. While the impact of the COVID-19 pandemic has negatively impacted these product lines, we have experienced an increase in revenues sequentially from the third quarter of fiscal 2020 to the fourth quarter indicating strength in a recovery of these end markets. Partially offsetting the decreases in fiscal 2020 compared to fiscal 2019 was an increase in Fluent system and disposable sales of $9.2 million. We expect the market for our GYN Surgical products to continue to be challenging in the first quarter of fiscal 2021 and beyond to the extent the COVID-19 pandemic continues and hospitals and healthcare centers continue to restrict access and elective medical procedures continue to be delayed or cancelled.

Skeletal Health product revenues decreased 13.7% in fiscal 2020 compared to fiscal 2019 which we attribute primarily to the impact of the COVID-19 pandemic resulting in a decrease in sales volume of our Horizon DXA systems and Insight FD mini C-arm system. While the impact of the COVID-19 pandemic has negatively impacted these product lines, we have experienced an increase in revenues sequentially from the third quarter of fiscal 2020 to the fourth quarter indicating strength in a recovery of these end markets. We expect a continued reduced demand for our Skeletal products in the first quarter of fiscal 2021 and beyond to the extent the COVID-19 pandemic continues and hospitals and healthcare centers continue to restrict access, wellness and elective medical procedures continue to be delayed or cancelled and hospital and healthcare center capital expenditures continue to be delayed or cancelled.

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 26, 2020	September 28, 2019
United States	75.3 %	74.6 %
Europe	15.5 %	12.0 %
Asia-Pacific	6.0 %	8.8 %
Rest of world	3.2 %	4.6 %
	100.0 %	100.0 %

The slight increase in the percentage of U.S. revenues in fiscal 2020 was primarily driven by sales of our SARS-CoV-2 assays, the majority of which were sold domestically. The increase in the percentage of product revenue derived from Europe was primarily due to sales of our SARS-CoV-2 assays in fiscal 2020, and also included growth in Molecular Diagnostics as we expanded our customer base and increased sales from the adoption of co-testing for cervical cancer screening in Germany, as well as, the inclusion of SSI revenues, which are predominantly in Europe. Asia-Pacific product revenue as a percentage of total product revenue decreased primarily due to lower sales in China in fiscal 2020, which we primarily attribute to the effect of the COVID-19 pandemic disrupting wellness visits and the disposition of Medical Aesthetics.

Service and Other Revenues

	Years Ended					
	September 26, 2020		September 28, 2019		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Service and Other Revenues	$ 549.4	14.5 %	$ 596.0	17.7 %	$ (46.6)	(7.8)%

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, and to a lesser extent, our Medical Aesthetics business prior to its disposition in the beginning of the second quarter of fiscal 2020. Service and other revenues decreased 7.8% in fiscal 2020 compared to fiscal 2019 primarily due to the disposition of Medical Aesthetics, resulting in a decrease in revenue of $47.0 million in fiscal 2020. The Breast Health business continues to convert a high percentage of our installed base of digital mammography systems to service contracts upon expiration of the warranty period, and Breast Health service contract revenue increased by $19.6 million in the current fiscal year. This increase

was partially offset by the decline in installation, spare parts and training revenue as hospitals and healthcare centers restricted access and capital expenditures continue to be delayed or cancelled due to the COVID-19 pandemic. In the current year, we generated additional royalty revenue from Grifols related to licensing intellectual property related to our COVID-19 assays for their sale in Spain. Additionally, we generated less service revenue in blood screening from Grifols in the current year and the prior year period included additional one-time license revenue in Breast Health.

Cost of Product Revenues

	Years Ended											
	September 26, 2020				September 28, 2019				Change			
	Amount		% of Product Sales		Amount		% of Product Sales		Amount		%	
Cost of Product Revenues	$	953.7	29.6	%	$	948.7	34.2	%	$	5.0	0.5	%
Amortization of Intangible Assets		253.2	7.8	%		318.5	11.5	%		(65.3)	(20.5)	%
Impairment of Intangible Assets and Equipment		25.8	0.8	%		578.7	20.9	%		(552.9)	(95.5)	%
	$	1,232.7	38.2	%	$	1,845.9	66.6	%	$	(613.2)	(33.2)	%

Product gross margin was 61.8% in fiscal 2020 compared to 33.4% in fiscal 2019. Excluding the impairment of intangible assets and equipment included in cost of product revenues in both fiscal 2020 and 2019, product gross margin increased by 8.3% in fiscal 2020 compared to fiscal 2019.

Cost of Product Revenues. The cost of product revenues as a percentage of product revenues was 29.6% in the current year compared to 34.2% in the prior year. Cost of product revenues as a percentage of revenue decreased in fiscal 2020 primarily due to sales of our SARS-CoV-2 assays, which have higher gross margins compared to our other diagnostic products, and comprised 28.8% of total product revenue in fiscal 2020. Also benefiting gross margin was the disposition of Medical Aesthetics, which had lower gross margins compared to our remaining businesses. Partially offsetting these decreases was an increase in inventory reserves, higher freight costs and the step-up in fair value of inventory acquired in the SSI and Health Beacons acquisitions resulting in additional costs of $6.8 million.

Diagnostics' product costs as a percentage of revenue decreased in fiscal 2020 compared to fiscal 2019 primarily due to sales of our SARS-CoV-2 assays and higher overall production reducing fixed overhead on a unit basis, partially offset by lower volumes of ThinPrep, an increase in inventory reserves, higher field service costs for the instrument installed base and an increase in freight charges internationally.

Breast Health’s product costs as a percentage of revenue increased in fiscal 2020 compared to fiscal 2019 primarily due to decreased sales volume across the majority of its product lines, period costs for temporary facility shut-downs and reduced manufacturing utilization, an increase in inventory reserves and the step-up in fair value of inventory acquired in the SSI and Health Beacons acquisitions resulting in additional costs of $6.8 million. We attribute these decreases primarily to the COVID-19 global pandemic as hospitals and imaging centers either slowed down purchases or delayed orders and installations of capital equipment units in order to focus their efforts towards COVID-19 patients and concerns on maintaining their cash and liquidity, as well as from the impact of delayed or cancelled elective imaging exams, screenings and procedures as described above.

GYN Surgical’s product costs as a percentage of revenue increased in fiscal 2020 compared to fiscal 2019 primarily due to the significant decrease in sales volume of our NovaSure and MyoSure devices, period costs for the temporary shutdown of our manufacturing facility and reduced manufacturing utilization, higher Fluent disposable sales at lower margins, as well as the continued product mix shift to a higher percentage of sales of MyoSure devices, which have lower margins than NovaSure devices.

Skeletal Health’s product costs as a percentage of revenue increased in fiscal 2020 compared to fiscal 2019 due to lower sales volume and an increase in inventory reserves.

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

Amortization of 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 decreased in fiscal 2020 compared to fiscal 2019 primarily due to lower amortization of $63.5 million from intangible assets acquired in the Cynosure acquisition as a result of impairment charges (partially offset by shortening lives of certain assets) in fiscal 2019, the classification of the Medical Aesthetics business as assets held-for-sale in November 2019 and its subsequent disposition on December 30, 2019, and lower amortization of intangible assets acquired in the Cytyc acquisition which reduce over time. These decreases were partially offset by amortization expense in the current fiscal year related to intangible assets primarily acquired in the SSI acquisition of $3.6 million.

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. During fiscal 2019, we identified indicators of impairment for our Medical Aesthetics reporting unit as a result of reductions in forecasts during the year, and in connection with our efforts to sell the business that began prior to the end of fiscal 2019. As a result of these indicators of impairment, we recorded total impairment charges of $685.4 million in fiscal 2019, which was allocated to developed technology for $576.9 million and equipment assets for $1.8 million, which is included in cost of revenues.

Cost of Service and Other Revenues

	Years Ended					
	September 26, 2020		September 28, 2019		Change	
	Amount	% of Service and Other Revenues	Amount	% of Service and Other Revenues	Amount	%
Cost of Service and Other Revenues	$ 316.2	57.6 %	$ 350.5	58.8 %	$ (34.3)	(9.8)%

Service and other revenues gross margin was 42.4% in fiscal 2020 compared to 41.2% in fiscal 2019. The increase in gross margin was primarily due to the disposition of Medical Aesthetics as service margins for Medical Aesthetics were lower compared to the Breast Health business, which generated the majority of our service revenues. In addition, in the current year, the Breast Health business had lower warranty and repair costs, including personnel costs, as hospitals and healthcare centers restricted access. The decrease in revenue from installation, spare parts and training also benefited gross margin as these services have lower margins compared to service contract revenue. In addition, the Diagnostics business had higher royalty revenue in fiscal 2020, which has higher margins. Partially offsetting these increases was lower license revenue in Breast Health in the current year, as the prior year period included additional one-time license revenue.

Operating Expenses

	Years Ended					
	September 26, 2020		September 28, 2019		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Operating Expenses						
Research and development	$ 222.5	5.9 %	$ 232.2	6.9 %	$ (9.7)	(4.2)%
Selling and marketing	484.6	12.8 %	564.9	16.8 %	(80.3)	(14.2)%
General and administrative	356.0	9.4 %	332.3	9.9 %	23.7	7.1 %
Amortization of intangible assets	39.7	1.1 %	52.0	1.5 %	(12.3)	(23.7)%
Impairment of intangible assets and equipment	4.4	0.1 %	106.7	3.2 %	(102.3)	(95.9)%
Restructuring charges	15.3	0.4 %	6.6	0.2 %	8.7	131.8 %
	$ 1,122.5	29.7 %	$ 1,294.7	38.5 %	$ (172.2)	(13.3)%

Research and Development Expenses. Research and development expenses decreased 4.2% in fiscal 2020 compared to fiscal 2019 primarily due to the disposition of the Medical Aesthetics business in the beginning of the second quarter of fiscal 2020. As a result, we had a $19.8 million decrease in research and development expenses for that segment in fiscal 2020. Partially offsetting this decrease was higher compensation and benefits driven by higher bonus and expense from our deferred

compensation plan as the expense is primarily driven by the mark-to-market of the value of the underlying investments, the addition of SSI expenses, increased spending to implement the European Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) requirements, and higher software development costs. These increases were partially offset by a decrease in R&D consulting and project spend across the divisions as cuts or deferred spending actions were implemented in response to the effects of the COVID-19 pandemic and resources in Diagnostics were focused on the development and approval of our SARS-CoV-2 assays. In addition, during the current fiscal year, we recorded a reduction to research and development expenses of $7.1 million attributable to our grant from the Biomedical Advanced Research and Development Authority (BARDA) 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. The prior fiscal year included a $4.5 million charge related to the purchase of intellectual property in the third quarter of fiscal 2019. 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 decreased 14.2% in fiscal 2020 compared to fiscal 2019 primarily due to the disposition of the Medical Aesthetics business. As a result, we had a $86.9 million decrease in sales and marketing expenses for that segment in fiscal 2020. In addition, in fiscal 2020, there were decreases in travel, commissions, third party commissions, trade shows and consulting, partially offset by an increase in marketing initiatives spending primarily for the Diagnostics segment and to a lesser extent corporate initiatives, an increase in bonus expense and the inclusion of SSI expenses in the current fiscal year of $15.3 million.

General and Administrative Expenses. General and administrative expenses increased 7.1% in fiscal 2020 compared to fiscal 2019 primarily due to higher compensation and benefits driven by higher bonus, stock compensation and expense from our deferred compensation plan, charitable donations of $15.0 million, an increase in bad debt expense, higher facilities and infrastructure costs, and the addition of $6.9 million of SSI expenses. Partially offsetting these increases were lower expenses of $10.6 million in fiscal 2020 from the disposition of the Medical Aesthetics business, credits related to services provided under the transition services agreement with Cynosure, lower travel, and lower legal expenses as the prior year period included higher litigation and settlement costs related to the Fuji, Enzo and Minerva lawsuits. In addition, in fiscal 2020 expenses were higher due to project expenses related to the Medical Aesthetics disposition including accelerated stock compensation, partially offset by acquisition-related hold-back and accrual reversals.

Amortization of 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 5 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 decreased 23.7% in fiscal 2020 compared to fiscal 2019 primarily due to lower amortization from intangible assets acquired in the Cynosure acquisition as a result of impairment charges (partially offset by shortening lives of certain assets) in fiscal 2019 and the classification of the Medical Aesthetics business as assets held-for-sale in November 2019 and its subsequent disposition on December 30, 2019.

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. As discussed above, we recorded aggregate impairment charges of $685.4 million during fiscal 2019. The impairment charges were allocated to the long-lived assets and written off to operating expenses in the amounts of $22.4 million to customer relationships, $48.6 million to trade names, $27.7 million to distribution agreements and $8.0 million to equipment.

Restructuring Charges. We have implemented various cost reduction initiatives to align our cost structure with our operations and related to integration activities. In addition, we have recorded divestiture charges. These actions have primarily resulted in the termination of employees. As a result, we recorded charges of $15.3 million in fiscal 2020 and $6.6 million in fiscal 2019, primarily related to severance benefits. For additional information, please refer to Note 6 to our consolidated financial statements.

Interest Expense

	Years Ended			
	September 26, 2020	September 28, 2019	Change	
	Amount	Amount	Amount	%
Interest Expense	$ (116.5)	$ (140.8)	$ 24.3	(17.3)%

Interest expense in fiscal 2020 and 2019 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 2020 decreased compared to fiscal 2019 primarily due to a decrease in LIBOR year over year, the basis for determining interest expense under our 2018 Credit Agreement and lower interest expense from the Securitization Program which was paid-off in full in the second quarter of fiscal 2020, partially offset by interest expense on net borrowings on our revolver and lower proceeds received under our interest rate cap agreements that hedge the variable interest rate under our credit facilities in fiscal 2020 compared to fiscal 2019.

Debt Extinguishment Losses

	Years Ended			
	September 26, 2020	September 28, 2019	Change	
	Amount	Amount	Amount	%
Debt Extinguishment Losses	$ —	$ (0.8)	$ 0.8	(100.0)%

In the first quarter of fiscal 2019, we entered into the 2018 Credit Agreement with Bank of America, N.A. The proceeds under the 2018 Agreement were used to pay off the term loan and revolver outstanding under the 2017 Credit Agreement. In connection with this transaction, we recorded a debt extinguishment loss of $0.8 million in the first quarter of fiscal 2019.

Other Income, net

	Years Ended			
	September 26, 2020	September 28, 2019	Change	
	Amount	Amount	Amount	%
Other Income, net	$ 9.1	$ 3.1	$ 6.0	193.5 %

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 plans.

In fiscal 2019, this account primarily consisted of net foreign currency exchange gains of $5.1 million primarily due to hedging activities, a gain of $0.9 million on the sale of an investment and a gain of $0.4 million on the cash surrender value of life insurance contracts related to our deferred compensation plans, partially offset by a $3.3 million loss related to our proportionate share of investment in SSI, which is being accounted for an equity method investment.

Benefit for Income Taxes.

	Years Ended			
	September 26, 2020	September 28, 2019	Change	
	Amount	Amount	Amount	%
Benefit for Income Taxes	$ (108.6)	$ (54.1)	$ (54.5)	100.7 %

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.

Our effective tax rate for fiscal 2019 was 21.0%. The effective tax rate, applied to an overall pre-tax loss resulting in a benefit, was equal to the statutory tax rate primarily due to the offsetting impacts of a discrete benefit related to an internal restructuring, earnings in jurisdictions subject to lower tax rates, reserves for uncertain tax positions and 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 (the "Act") in the first quarter of fiscal 2019.

As of December 29, 2018, we completed our accounting for the tax effects of enactment of the Act, recording a benefit reduction of $5.0 million in the three months ended December 29, 2018. We recognized a final net benefit amount of $341.2 million related to the Act, which was included as a component of income tax expense.

Segment Results of Operations

Until the divestiture of our Medical Aesthetics segment, we reported our business in five segments: Diagnostics, Breast Health, Medical Aesthetics, GYN Surgical and Skeletal Health. 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. 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 26, 2020	September 28, 2019	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 2,102.1	$ 1,205.5	$ 896.6	74.4 %
Operating Income	$ 929.7	$ 163.1	$ 766.6	470.0 %
Operating Income as a % of Segment Revenue	44.2 %	13.5 %		

Diagnostics revenues increased in fiscal 2020 compared to fiscal 2019 primarily due to the increase in product revenues associated with the commercial launch of our SARS-CoV-2 assays discussed above.

Operating income for this business segment increased in fiscal 2020 compared to fiscal 2019 primarily due to an increase in gross profit from higher revenues partially offset by an increase in operating expenses. Gross margin was 65.2% in the current year compared to 47.3% in the prior year. The increase in gross margin was primarily due to sales of our SARS-CoV-2 assays, higher overall production reducing fixed overhead on a unit basis and royalty revenue from Grifols, partially offset by lower volumes of ThinPrep, an increase in inventory reserves, higher field service costs for the instrument installed base and an increase in freight charges internationally.

Operating expenses increased in fiscal 2020 compared to fiscal 2019 primarily due to an increase in research and development expenses from higher compensation and benefits driven by higher bonus expense, increased project spend and software development costs partially offset by the BARDA $7.1 million credit, higher compensation across other functions due to focus on the development and approval of our SARS-CoV-2 assays, an increase in marketing initiatives, an increase in bad debt expense and an allocated portion of charitable donations. These increases were partially offset by a reduction in travel, consulting and trade shows. The increase in the current year period was also partially offset as a result of the prior year period including a $10.5 million settlement charge related to the Enzo litigation.

Breast Health

	Years Ended			
	September 26, 2020	September 28, 2019	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 1,151.9	$ 1,314.2	$ (162.3)	(12.3)%
Operating Income	$ 192.8	$ 399.3	$ (206.5)	(51.7)%
Operating Income as a % of Segment Revenue	16.7 %	30.4 %		

Breast Health revenues decreased in fiscal 2020 compared to fiscal 2019 primarily due to a decrease of $164.7 million in product revenue as discussed above, partially offset by an increase of $2.4 million in service and other revenue. The increase in service revenue is primarily due to continued conversion of a high percentage of the installed base of digital mammography systems to service contracts upon expiration of the warranty period, partially offset by lower installation, spare parts and training revenue as hospitals and healthcare centers continue to restrict access and capital expenditures continue to be delayed or cancelled due to the COVID-19 pandemic, and the prior year period including additional one-time license revenue.

Operating income for this business segment decreased in fiscal 2020 compared to fiscal 2019 primarily due to a decrease in gross profit from lower revenues with lower gross margin and an increase in operating expenses. Gross margin was 52.8% in the current fiscal year, compared to 57.8% in the prior fiscal year. The decrease in gross margin was primarily due to decreased sales volume of our products, period costs related to temporary facility shut-downs and reduced manufacturing utilization, an increase in inventory reserves, the step-up in fair value of inventory acquired in the SSI and Health Beacons acquisitions resulting in additional costs of $6.8 million and higher intangible asset amortization expense.

Operating expenses increased in fiscal 2020 compared to fiscal 2019 due to higher compensation and benefits driven by higher bonus expense and increased stock compensation expenses, an increase in bad debt expense, restructuring charges, an allocated portion of charitable donations and the inclusion in the current period of SSI expenses of $26.1 million. These increases were partially offset by a decrease in travel expenses, trade shows, R&D project spend, commissions and third party commissions. The increase is also driven as a result of the prior year period included a benefit from settling the Fuji litigation, partially offset by the reversal of acquisition related accruals and a hold-back in fiscal 2020.

GYN Surgical

	Years Ended			
	September 26, 2020	September 28, 2019	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 376.1	$ 437.2	$ (61.1)	(14.0)%
Operating Income	$ 42.0	$ 99.2	$ (57.2)	(57.7)%
Operating Income as a % of Segment Revenue	11.2 %	22.7 %		

GYN Surgical revenues decreased in fiscal 2020 compared to fiscal 2019 due to the decrease in product revenues discussed above.

Operating income for this business segment decreased in fiscal 2020 compared to fiscal 2019 primarily due to a decrease in gross profit from lower revenues with lower gross margins, partially offset by a decrease in operating expenses. Gross margin was 59.1% in the current fiscal year, compared to 64.3% in the prior year. The decrease in gross margin was primarily due to a decrease in sales volume of our products and period costs from the temporary facility shut-down and reduced manufacturing utilization.

Operating expenses decreased in fiscal 2020 compared to fiscal 2019 primarily due to lower commissions from the decrease in sales, lower marketing initiative spend, decreased spending on research and development projects and a decrease in travel, partially offset by higher bonus, increased stock compensation expenses, transaction expenses, and an allocated portion of charitable donations.

Skeletal Health

	Years Ended			
	September 26, 2020	September 28, 2019	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 81.0	$ 94.8	$ (13.8)	(14.6)%
Operating Loss	$ (2.4)	$ (4.2)	$ 1.8	(42.9)%
Operating Loss as a % of Segment Revenue	(3.0) %	(4.4) %		

Skeletal Health revenues decreased in fiscal 2020 compared to fiscal 2019 primarily due to the decrease in product revenues discussed above.

Operating loss decreased in fiscal 2020 compared to the prior year primarily due to a decrease in operating expenses, partially offset by a decrease in gross profit from lower revenues with lower gross margins. Gross margin decreased to 33.2% in the current year compared to 37.4% in the prior year primarily due to lower sales volume of our products and an increase in inventory reserves.

Operating expenses decreased in fiscal 2020 compared to fiscal 2019 primarily due to a decrease in travel expenses, a decrease in trade show expenses, and lower commissions, partially offset by higher compensation and benefits driven by higher bonus and stock compensation expense.

Medical Aesthetics

	Years Ended			
	September 26, 2020	September 28, 2019	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 65.3	$ 315.6	$ (250.3)	(79.3)%
Operating Loss	$ (57.1)	$ (781.2)	$ 724.1	(92.7)%
Operating Loss as a % of Segment Revenue	(87.4) %	(247.5)%		

Medical Aesthetics revenue and operating loss decreased in fiscal 2020 compared to fiscal 2019 primarily due to the divestiture of the Medical Aesthetics segment on December 30, 2019, the first day of our second quarter of fiscal 2020. We will continue to incur expenses related to legal and tax matters that we have agreed to retain. The operating loss in the current fiscal year and the corresponding period in the prior year included intangible assets and equipment impairment charges of $30.2 million recorded in the first quarter of fiscal 2020 and $443.8 million and $241.6 million recorded in the second and fourth quarter of fiscal 2019, respectively.

Fiscal Year Ended September 28, 2019 Compared to Fiscal Year Ended September 29, 2018

Discussions of year-to-year comparisons between fiscal 2019 and 2018 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 28, 2019.

LIQUIDITY AND CAPITAL RESOURCES

At September 26, 2020, we had working capital of $983.0 million, and our cash and cash equivalents totaled $701.0 million. Our cash and cash equivalents balance increased by $99.2 million during fiscal 2020 principally due to cash generated from operating activities partially offset by cash used in financing and investing activities related to net repayments of debt, repurchases of common stock and capital expenditures.

As we assessed the potential longer term economic and capital market uncertainties resulting from the COVID-19 pandemic, in March 2020 we suspended our accounts receivable securitization program and borrowed $750.0 million under our revolver. We used $250.0 million of these proceeds to pay off all amounts then owed under our accounts receivable securitization agreement, and retained the balance as cash reserves. In the third and fourth quarters of fiscal 2020, we repaid a total of $500.0 million on amounts borrowed under our revolver. As of September 26, 2020, we had $1.25 billion available under our revolver.

In fiscal 2020, our operating activities provided us with $896.6 million of cash, primarily due to net income of $1,110.5 million, non-cash charges for depreciation and amortization aggregating $376.0 million, stock-based compensation expense of $83.3 million, and non-cash intangible asset and equipment impairment charges aggregating $30.2 million. These adjustments to net income were partially offset by a decrease in net deferred tax liabilities of $94.4 million primarily due to the amortization

of intangible assets and the intangible assets impairment charge. Cash provided by operations included a net cash outflow of $636.3 million from changes in our operating assets and liabilities. Changes in our operating assets and liabilities were driven primarily by an increase in accounts receivable of $427.1 million primarily due to increased sales of our SARS-CoV-2 assays, an increase in prepaid expenses and other assets of $286.2 million, primarily due to recording a $313.4 million tax refund receivable in connection with carrying back the Medical Aesthetics' loss, and an increase in inventory of $25.3 million primarily due to lower Breast Health sales than anticipated due to the COVID-19 pandemic and increased raw materials and inventory to support SARS-CoV-2 assay demand. Partially offsetting these cash outflows was an increase in accrued expenses of $96.0 million primarily due to an increase in accrued bonus, federal income taxes and other taxes, and an increase in deferred revenue of $15.0 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.

In fiscal 2020, our investing activities used cash of $141.6 million primarily related to acquisition payments of $119.4 million primarily for the Acessa Health, Alpha Imaging and Health Beacons acquisitions and $156.4 million for capital expenditures, which consisted of the placement of equipment under customer usage agreements and purchases of manufacturing equipment primarily to expand the capacity of our molecular diagnostics manufacturing facilities. These uses of cash were primarily offset by net proceeds received from the sale of the Medical Aesthetics business of $139.3 million.

In fiscal 2020, our financing activities used cash of $659.9 million, primarily for payments of $653.6 million for repurchases of our common stock on the open market, $234.0 million for the net repayment of amounts borrowed under our accounts receivable securitization agreement, $37.5 million for scheduled principal payments under our 2018 Credit Agreement, payment of $24.3 million for hold-back and contingent consideration payments related to the Focal, Faxitron and Emsor acquisitions, and payments of $14.3 million for employee-related taxes withheld for the net share settlement of vested restricted stock units. Partially offsetting these uses of cash were $250.0 million of net proceeds on amounts borrowed under our revolving credit line and $65.6 million from our equity plans, primarily the exercise of stock options.

Debt

We had total recorded debt outstanding of $3.0 billion at September 26, 2020, which was comprised of our term loan under our 2018 Credit Agreement of $1.45 billion (principal of $1.46 billion), our revolver under our 2018 Credit Agreement of $250.0 million (principal of $250.0 million), 2025 Senior Notes of $939.4 million (principal of $950.0 million), and 2028 Senior Notes of $394.6 million (principal of $400.0 million)

2018 Credit Agreement

On December 17, 2018, we refinanced our term loan and revolving credit facility by entering into an Amended and Restated Credit and Guaranty Agreement, dated 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 our prior credit and guaranty agreement, dated as of October 3, 2017 ("2017 Credit Agreement").

The credit facilities under the 2018 Credit Agreement consist 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"; together with the 2018 Term Loan, the "Amended Credit Facilities") under which the Company may borrow up to $1.5 billion, subject to certain sublimits, with a maturity date of December 17, 2023.

The borrowings on the 2018 Term Loan bear interest at an annual rate equal to the Eurocurrency Rate (i.e., the LIBOR rate) plus an Applicable Rate, which was equal to 1.25% as of September 26, 2020. The borrowings of the 2018 Amended Revolver bear interest at a rate equal to the LIBOR Daily Floating Rate plus an Applicable Rate equal to 1.25% as of September 26, 2020. At September 26, 2020, borrowings under the 2018 Term Loan were subject to an interest rate of 1.40%.

Borrowings made under the 2018 Credit Agreement, bear interest, at a variable rate plus an applicable margin. The applicable margin is based upon our total net leverage ratio as defined in the 2018 Credit Agreement.

We are 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 is $1.2

billion as of September 26, 2020, and any amounts outstanding under the 2018 Revolver are due at maturity. In addition, subject to the terms and conditions set forth in the 2018 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). These mandatory prepayments are required to be applied by us, 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 may voluntarily prepay any of the 2018 Credit Facilities without premium or penalty.

Borrowings are 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. For example, borrowings under the 2018 Credit Agreement are not secured by those accounts receivable that are transferred to the special purpose entity under our Accounts Receivable Securitization program.

The 2018 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 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 requires us to maintain certain financial ratios. The 2018 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.

The 2018 Credit Agreement contains two financial covenants (a total net leverage ratio and an interest coverage ratio) measured as of the last day of each fiscal quarter. As of September 26, 2020, we were in compliance with these covenants.

2025 Senior Notes

As of September 26, 2020, we had 2025 Senior Notes outstanding in the total aggregate principal of $950.0 million. On September 28, 2020 (in the first quarter of fiscal 2021), we completed a private placement of $950 million aggregate principal amount of our 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 proceeds from this offering and cash on hand were used to redeem the 2025 Senior Notes in full on October 15, 2020, a redemption price of approximately $970.8 million (equal to 102.2% of the aggregate principal amount of the 2025 Senior Notes). See "Subsequent Event - 2029 Senior Notes" for further discussion.

2028 Senior Notes

As of September 26, 2020, 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 may also redeem up to 35% of the aggregate principal amount of the 2028 Senior Notes with the net cash proceeds of certain equity offerings at any time and from time to time before February 1, 2021, at a redemption price equal to 104.625% 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 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.

Accounts Receivable Securitization Program

On April 25, 2016, we entered into a one-year $200.0 million accounts receivable securitization program (the "Securitization Program") with several of our wholly owned subsidiaries and certain financial institutions, which provides for annual renewals.

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 special purpose entity, as borrower, and we, as servicer, have entered into a Credit and Security Agreement with several lenders pursuant to which the special purpose entity may borrow from the lenders up to the maximum borrowing amount allowed, 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. The assets of the special purpose entity secure the amounts borrowed and cannot be used to pay our other debts or liabilities.

Effective April 18, 2019, we entered into an amendment to extend the Securitization Program an additional year to April 17, 2020. Under the amendment, the maximum borrowing amount increased from $225.0 million to $250.0 million. 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 the 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. As of September 26, 2020, we did not have any borrowings under this program.

Borrowings outstanding under the Securitization Program bear interest at LIBOR plus the applicable margin of 0.7% and are included as a component of current liabilities in our consolidated balance sheet, while the accounts receivable securing these obligations remain as a component of net receivables in our consolidated balance sheet. We 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 our other debts or liabilities.

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. In addition, it contains financial covenants consistent with that of the Credit Agreement. As of September 26, 2020, the Company had amended the Credit and Security Agreement, temporarily suspending the need to comply with the financial covenants for up to one year.

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, 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.

Contingent Consideration Earn-Out Payments

In connection with certain of our acquisitions, we have incurred the obligation to make contingent earn-out 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, 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.

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 companies revenue growth rates, implied volatility and applying a risk adjusted discount rate. At September 26, 2020 this liability was recorded at $81.8 million and no contingent payments have earned or been made.

Stock Repurchase Program

On December 11, 2019, the Board of Directors authorized a new share repurchase plan to repurchase up to $500.0 million of our 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. As of September 26, 2020, $262.4 million remained available under this authorization. Subsequent to September 26, 2020, we have repurchased 1.1 million shares of our common stock for $74.8 million.

Contractual Obligations

The following table summarizes our contractual obligations and commitments as of September 26, 2020:

	Payments Due by Period				
Contractual Obligations	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**	**Total**
Long-Term Debt Obligations	$ 325.0	$ 187.5	$ 2,150.0	$ 400.0	$ 3,062.5
Interest on Long-Term Debt Obligations	83.7	165.6	124.1	45.5	418.9
Operating Leases	25.0	34.1	19.6	16.0	94.7
Finance Leases	2.8	6.0	6.1	8.4	23.3
Purchase Obligations (1)	267.7	10.9	1.1	0.1	279.8
Pension Obligations (2)	0.4	0.8	0.8	8.9	10.9
Total Contractual Obligations	$ 704.6	$ 404.9	$ 2,301.7	$ 478.9	$ 3,890.1

(1) Purchase obligations primarily represent minimum purchase commitments for inventory and instruments and, to a lesser extent, other operating expense commitments.

(2) Pension obligations do not include our obligation under our deferred compensation plans of $57.7 million at September 26, 2020, which is recorded as a current liability. Deferred compensation plan benefits are generally paid out at retirement or termination of employment.

The above table does not reflect our long-term liabilities associated with reserves for uncertain tax positions recorded under ASC 740, *Income Taxes* totaling $103.7 million. Due to the complexity associated with tax uncertainties, we cannot reasonably make a reliable estimate of the period in which we expect to settle these non-current liabilities. See Note 9 to our consolidated financial statements contained in Item 15 of this Annual Report for more information on our unrecognized tax benefits.

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 2018 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 2018 Credit Agreement, 2028 Senior Notes, and 2029 Senior Notes. 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 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.

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 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 5 year 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 2020 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 28, 2020 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. For illustrative purposes, had the fair value of each of our reporting units been lower by 10%, all of our reporting units would still have passed the goodwill impairment test.

At September 26, 2020, we believe that our reporting units, with goodwill aggregating $2.6 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.

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 $186.3 million in net deferred tax liabilities at September 26, 2020 and $258.1 million at September 28, 2019. The reduction was primarily due to intangible asset amortization recorded in fiscal 2020. 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 26, 2020, we had $197.1 million in gross unrecognized tax benefits excluding interest, of which $184.9 million, if recognized, would reduce our effective tax rate. As of September 28, 2019, we had $101.6 million in gross unrecognized tax benefits excluding interest, of which $87.3 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 cost-method investments, foreign currency contracts, interest rate cap and interest rate swap agreements, insurance contracts, accounts payable and debt obligations. Except for our outstanding 2025 and 2028 Senior Notes, the fair value of these financial instruments approximate their carrying amount. The fair value of our 2025 and 2028 Senior Notes was approximately $971.5 million and $419.1 million, respectively, as of September 26, 2020. Amounts outstanding under our 2018 Credit Agreement of $1.71 billion aggregate principal as of September 26, 2020 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 2025 and 2028 Senior Notes and 2018 Credit Agreement. The 2025 and 2028 Senior Notes have fixed interest rates. Borrowings under our 2018 Credit Agreement currently bear interest at the Eurocurrency Rate (i.e., Libor) plus the applicable margin of 1.25% per annum. Borrowings under our accounts receivable securitization program currently bear interest at Libor plus the applicable margin of 0.7%.

As of September 26, 2020, there was $1.71 billion of aggregate principal outstanding under the 2018 Credit Agreement aggregate principal outstanding. Since these debt obligations are variable rate instruments, our interest expense associated with these instruments is subject to change. A 10% adverse movement (increase in LIBOR rate) would increase annual interest expense by approximately $0.3 million. We entered into multiple interest rate cap agreements and an interest rate swap agreement to help mitigate the interest rate volatility associated with the variable rate interest on the amounts outstanding. The critical terms of the interest rate caps and interest rate swap were designed to mirror the terms of our LIBOR-based borrowings under the 2018 Credit Agreement, and therefore the interest rate caps and interest rate swap are highly effective at offsetting the cash flows being hedged. We designated these derivatives as cash flow hedges of the variability of the Libor-based interest payments on $1.0 billion of principal. The interest rate cap contract expires on December 23, 2020, and 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. If changes are made to the method of calculating LIBOR or LIBOR ceases to exist, we may need to amend certain contracts, including our 2018 Credit Agreement and related interest rate cap and swap agreements, 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 United States 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 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 and foreign currency option 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 2020, 2019 and 2018, we incurred net foreign exchange gains (losses) of $3.4 million, $5.1 million and $5.9 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 26, 2020, 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 26, 2020. 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 Acessa Health, Inc. acquired on August 23, 2020, which is included in the consolidated financial statements of Hologic, Inc. as of and for the year ended September 26, 2020 and constituted less than 1% of our total assets and net assets as of September 26, 2020 and less than 1% of revenues and pre-tax income for the year then ended.

Subject to the foregoing, based on management’s assessment, we believe that, as of September 26, 2020, 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 26, 2020, 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 26, 2020, 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 Acessa Health, Inc., which is included in the 2020 consolidated financial statements of the Company and constituted less than 1% of total and net assets, respectively, as of September 26, 2020 and less than 1% of revenues and pre-tax income, 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 Acessa Health, Inc.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the 2020 consolidated financial statements of the Company and our report dated November 17, 2020 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 17, 2020

Changes in Internal Control over Financial Reporting

During the quarter ended September 26, 2020, 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 26, 2020 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)	8,231,820	$ 40.37	5,673,843
Equity compensation plans not approved by security holders	—	$ —	—
Total	8,231,820	$ 40.37	5,673,843

(1) Includes 3,664,256 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 26, 2020, September 28, 2019 and September 29, 2018

Consolidated Statements of Comprehensive Income (Loss) for the years ended September 26, 2020, September 28, 2019 and September 29, 2018

Consolidated Balance Sheets as of September 26, 2020 and September 28, 2019

Consolidated Statements of Stockholders' Equity for the years ended September 26, 2020, September 28, 2019 and September 29, 2018

Consolidated Statements of Cash Flows for the years ended September 26, 2020, September 28, 2019 and September 29, 2018

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
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	Form of 3.250% Senior Note due 2029 (included in Exhibit 4.2)	8-K	09/28/2020
4.4	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
4.5	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
4.6	Form of 4.625% Senior Note due 2028 (included in Exhibit 4.5)	8-K	01/19/2018
4.7	Description of Securities	10-K	09/28/2019

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.1*	Second Amended and Restated 1999 Equity Incentive Plan.	10-Q	03/25/2006
10.2*	Amendment No. 1 to Second Amended and Restated 1999 Equity Incentive Plan.	S-8	10/23/2007
10.3*	Amendment No. 2 to Second Amended and Restated 1999 Equity Incentive Plan.	8-K	10/22/2007
10.4*	Amendment No. 3 to Second Amended and Restated 1999 Equity Incentive Plan.	8-K	12/12/2008
10.5*	The 2003 Incentive Award Plan of Gen-Probe Incorporated as amended and restated.	S-8	08/02/2012
10.6*	Hologic Amended and Restated 2008 Equity Incentive Plan.	8-K	03/15/2018
10.7*	Form of Stock Option Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2016).	8-K	10/14/2015
10.8*	Form of Stock Option Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2017).	8-K	11/09/2016
10.9*	Form of Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2017).	8-K	11/09/2016
10.10*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (relative TSR) (adopted fiscal 2019).	8-K	11/07/2018
10.11*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (ROIC) (adopted fiscal 2019).	8-K	11/07/2018
10.12*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (relative TSR) (adopted fiscal 2020).	8-K	11/08/2019
10.13*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (ROIC) (adopted fiscal 2020).	8-K	11/08/2019
10.14*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (Free Cash Flow) (adopted fiscal 2020).	8-K	11/08/2019
10.15*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (relative TSR) (adopted fiscal 2021).	8-K	11/06/2020
10.16*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (ROIC) (adopted fiscal 2021).	8-K	11/06/2020
10.17*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (Free Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (Free Cash Flow) (adopted fiscal 2021). Flow) (adopted fiscal 2021).	8-K	11/06/2020
10.18*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (ROIC – Outside US) (adopted fiscal 2021).	8-K	11/06/2020
10.19*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (relative TSR – Outside US) (adopted fiscal 2021).	8-K	11/06/2020
10.20*	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
10.21*	Form of Independent Director Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (annual grant).	10-K	09/28/2013

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
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*	Severance and Change of Control Agreement dated September 13, 2017 by and between Allison Bebo and Hologic.	10-K	09/30/2017
10.35*	Offer Letter dated January 6, 2015 by and between John M. Griffin and Hologic.	10-Q	03/28/2015
10.36*	Severance and Change of Control Agreement dated February 2, 2015 by and between John M. Griffin and Hologic.	10-Q	03/28/2015
10.37*	Severance and Change of Control Agreement dated September 15, 2020 by and between Kevin R. Thornal and Hologic, Inc.	8-K	09/15/2020
10.38*	Retirement and Separation Agreement by and between Hologic, Inc. and Peter J. Valenti, III, dated August 25, 2020	8-K	08/25/2020
10.39*	Severance and Change of Control Agreement by and between Hologic, Inc. and Sean S. Daugherty, dated August 31, 2020	Filed Herewith	
10.40	Facility Lease (Danbury) dated December 20, 1995 by and among Melvin J. Powers and Mary P. Powers D/B/A M&N Realty and Lorad (filed in paper format).	Trex Medical Corporation S-1	03/29/1996
10.41	First Addendum to Lease Agreement by and between Melvyn J. Powers and Mary P. Powers d/b/a M&M Realty and Lorad, a Division of Trex-Medical Corporation dated as of March 1, 1996.	10-K	09/28/2019
10.42	Second Addendum to Lease Agreement by and between Melvyn J. Powers and Mary P. Powers d/b/a M&M Realty and Lorad, a Division of Trex-Medical Corporation dated as of April 1, 1996.	10-K	09/28/2019
10.43	Third Addendum to Lease Agreement by and between Melvyn J. Powers and Mary P. Powers d/b/a M&M Realty and Lorad, a Division of Trex-Medical Corporation dated as of May 1, 1996. (2)	10-K	09/28/2019

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.44	Notice of Lease by Commerce Park Realty, LLC, successor-in-interest to Melvyn J. Powers and Mary P. Powers d/b/a M&M Realty and Hologic, Inc. dated as of October 7, 2005 and Fourth Addendum to Lease. (2)	10-K	09/28/2019
10.45	Fifth Addendum to Agreement of Lease by and between Commerce Park Realty, LLC and Hologic, Inc. dated as of March 2012. (2)	10-K	09/28/2019
10.46	Sixth Addendum to Agreement of Lease by and between Commerce Park Realty, LLC and Hologic, Inc. dated as of July 2016. (2)	10-K	09/28/2019
10.47	Lease Agreement (Danbury and Bedford) by and between BONE (DE) QRS 15-12, INC., and Hologic dated August 28, 2002.	10-K	09/28/2002
10.48	First Amendment to Lease Agreement (Danbury and Bedford) by and between BONE (DE) QRS 15-12, INC., and Hologic dated October 29, 2007.	10-K	09/29/2007
10.49	Office Lease dated December 31, 2003 between Cytyc and Marlborough Campus Limited Partnership.	Cytyc Corporation 10-K	12/31/2003
10.50	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
10.51	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
10.52	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
10.53	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
10.54	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
10.55	Lease Agreement by and between 445 Simarano Drive, Marlborough LLC and Cytyc dated July 11, 2006.	10-K	09/29/2007
10.56	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
10.57	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
10.58	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
10.59	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
10.60	Amendment No. 1 dated June 1, 2011 to Supply Agreement for Panther Instrument System. (1)	10-K	09/24/2016
10.61	Amendment No. 2 dated February 28, 2013 to Supply Agreement for Panther Instrument System. (1)	10-K	09/24/2016

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.62	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
10.63	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
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 17, 2020

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 17, 2020
/S/ KARLEEN M. OBERTON **KARLEEN M. OBERTON**	Chief Financial Officer (Principal Financial Officer)	November 17, 2020
/S/ BENJAMIN J. COHN **BENJAMIN J. COHN**	Vice President, Corporate Controller (Principal Accounting Officer)	November 17, 2020
/S/ SALLY W. CRAWFORD **SALLY W. CRAWFORD**	Lead Independent Director	November 17, 2020
/S/ CHARLES DOCKENDORFF **CHARLES DOCKENDORFF**	Director	November 17, 2020
/S/ SCOTT T. GARRETT **SCOTT T. GARRETT**	Director	November 17, 2020
/S/ LUDWIG N. HANTSON **LUDWIG N. HANTSON**	Director	November 17, 2020
/S/ NAMAL NAWANA **NAMAL NAWANA**	Director	November 17, 2020
/S/ CHRISTIANA STAMOULIS **CHRISTIANA STAMOULIS**	Director	November 17, 2020
/S/ AMY M. WENDELL **AMY M. WENDELL**	Director	November 17, 2020

Hologic, Inc.

Consolidated Financial Statements

Years ended September 26, 2020, September 28, 2019 and September 29, 2018

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 26, 2020 and September 28, 2019, 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 26, 2020, 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 26, 2020 and September 28, 2019, and the results of its operations and its cash flows for each of the three years in the period ended September 26, 2020, 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 26, 2020, 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 17, 2020 expressed an unqualified opinion thereon.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases in the year ended September 26, 2020 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases*, (Topic 842), and the related amendments.

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 26, 2020 the Company had $197.1 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 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 when a tax position undergoes an audit by a taxing authority.

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 both the determination of the tax basis of certain assets and liabilities underlying uncertain tax positions as well as the positions taken. Our procedures included 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 transaction price (including collectability) and the allocation of 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 and assessing collectability, 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 and assessments of collectability by comparing the price to the contract and performing an independent assessment of collectability using available evidence of the customer's financial condition and payment history. We also 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 on a sample of contracts. In addition, we performed other analytical procedures over product revenue and tested a higher volume of revenue transactions that occurred near the end of the fiscal year to evaluate accounting cut-off.

Business Combinations

Description of the Matter

As described in Note 5 to the consolidated financial statements, during 2020, the Company completed the acquisition of all outstanding equity of Acessa Health, Inc. ("Acessa") for consideration of approximately $161.3 million, net of cash acquired. In connection with the acquisition of Acessa, the Company recognized a contingent consideration liability for acquisition consideration that is payable based on a multiple of annual incremental revenue growth over a three-year period for which there is no maximum earnout. The Company recorded its estimate of the fair value of the contingent consideration liability utilizing the Monte Carlo simulation both as part of the initial purchase price allocation, and as of September 26, 2020. As of September 26, 2020, the amount accrued for future estimated contingent consideration is $81.8 million. The Company also recognized the fair value of intangible technology assets of $127.0 million using an income approach.

Auditing the Company's accounting for the Acessa business combination was complex due to the significant estimation required by management to determine the fair value of the intangible technology assets and to determine the fair value of the Acessa contingent consideration arrangement. The significant assumptions used to determine the fair value of contingent consideration included forecasted revenue projections, revenue volatility based on the comparable peer companies, and a risk adjusted discount rate. The significant assumptions used to estimate the value of the developed technology assets included a discount rate and forecasted revenue assumptions. 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 calculation of the estimated fair values of the intangible technology assets and the contingent consideration. For example, we tested controls over the valuation models and underlying assumptions used to develop such estimates. To test the estimated fair value of the developed technology assets and the contingent consideration liability, we performed audit procedures that included, among others, evaluating the Company's use of the different valuation methods and testing the significant assumptions described above that were used in the models. In testing the valuation of contingent consideration, we assessed, among other things, the terms of the arrangement and the conditions that must be met for the amounts to become payable. We evaluated the completeness and accuracy of the underlying data used in the analyses. We compared the significant assumptions to current industry, market and economic trends, to the assumptions used to value similar assets in other acquisitions, to the historical results of the acquired business and to other comparable companies within the same industry. We involved our valuation professionals to test the Monte Carlo simulation used to fair value the contingent consideration liability and to test the certain significant assumptions, including the discount rate and volatility of future revenue. We also involved our valuation professionals to test the income approach used to fair value the intangible technology assets and to test the discount rate used in the valuation.

/s/ Ernst & Young LLP

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

Boston, Massachusetts
November 17, 2020

Hologic, Inc.

Consolidated Statements of Operations

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

	Years ended		
	September 26, 2020	September 28, 2019	September 29, 2018
Revenues:			
Product	$ 3,227.0	$ 2,771.3	$ 2,643.9
Service and other	549.4	596.0	574.0
	3,776.4	3,367.3	3,217.9
Costs of revenues:			
Product	953.7	948.7	886.6
Amortization of intangible assets	253.2	318.5	319.4
Impairment of intangible assets and equipment	25.8	578.7	—
Service and other	316.2	350.5	315.2
Gross Profit	2,227.5	1,170.9	1,696.7
Operating expenses:			
Research and development	222.5	232.2	218.7
Selling and marketing	484.6	564.9	544.6
General and administrative	356.0	332.3	366.1
Amortization of intangible assets	39.7	52.0	59.3
Impairment of intangible assets and equipment	4.4	106.7	46.0
Impairment of goodwill	—	—	685.7
Restructuring and divestiture charges	15.3	6.6	14.2
	1,122.5	1,294.7	1,934.6
Income (loss) from operations	1,105.0	(123.8)	(237.9)
Interest income	4.3	4.6	6.3
Interest expense	(116.5)	(140.8)	(148.7)
Debt extinguishment losses	—	(0.8)	(45.9)
Other income, net	9.1	3.1	7.6
Income (loss) before income taxes	1,001.9	(257.7)	(418.6)
Benefit for income taxes	(108.6)	(54.1)	(307.3)
Net income (loss)	$ 1,110.5	$ (203.6)	$ (111.3)
Net loss attributable to noncontrolling interest	(4.7)	—	—
Net income (loss) attributable to Hologic	$ 1,115.2	$ (203.6)	$ (111.3)
Net income (loss) per common share attributable to Hologic:			
Basic	$ 4.24	$ (0.76)	$ (0.40)
Diluted	$ 4.21	$ (0.76)	$ (0.40)
Weighted average number of shares outstanding:			
Basic	262,727	269,413	275,105
Diluted	264,613	269,413	275,105

See accompanying notes.

Hologic, Inc.

Consolidated Statements of Comprehensive Income (Loss)

(In millions)

	Years ended		
	September 26, 2020	September 28, 2019	September 29, 2018
Net income (loss)	$ 1,110.5	$ (203.6)	$ (111.3)
Changes in foreign currency translation adjustment	18.5	(14.8)	(8.1)
Changes in unrealized holding gains and losses on available-for-sale securities, net of tax of $0.2 in 2018:			
Loss (gain) reclassified from accumulated other comprehensive income (loss) to the statement of operations	—	—	0.4
Changes in pension plans, net of taxes of $ 0.1 in 2020, $0.3 in 2019, and $(0.6) in 2018	(0.1)	(0.6)	0.5
(Loss) gain recognized, net of tax of $(8.3) million in 2020 and $1.2 million in 2019 for interest rate swaps	(27.6)	3.5	—
Changes in value of hedged interest rate caps, net of tax of $ 0.5 in 2020, $1.1 in 2019, and $(5.0) in 2018			
Loss recognized in other comprehensive income (loss), net	(0.5)	(8.0)	(5.7)
Loss reclassified from accumulated other comprehensive loss to the statement of operations, net	2.3	3.1	3.6
Other comprehensive loss	(7.4)	(16.8)	(9.3)
Comprehensive income (loss)	$ 1,103.1	$ (220.4)	$ (120.6)
Components of comprehensive income (loss) attributable to noncontrolling interest:			
Net loss attributable to noncontrolling interest	4.7	—	—
Comprehensive loss attributable to noncontrolling interest	4.7	—	—
Comprehensive income (loss) attributable to Hologic	$ 1,107.8	$ (220.4)	$ (120.6)

See accompanying notes.

Hologic, Inc.

Consolidated Balance Sheets

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

	September 26, 2020	September 28, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 701.0	$ 601.8
Accounts receivable, less reserves of $31.6 and $17.8, respectively	1,028.9	648.7
Inventory	395.1	444.9
Prepaid income taxes	38.8	34.9
Prepaid expenses and other current assets	58.5	62.8
Total current assets	2,222.3	1,793.1
Property, plant and equipment, net	491.5	470.9
Intangible assets, net	1,307.5	1,459.8
Goodwill	2,657.9	2,563.7
Other assets	516.6	154.6
Total assets	$ 7,195.8	$ 6,442.1
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 324.9	$ 271.4
Accounts payable	178.8	186.5
Accrued expenses	547.6	430.9
Deferred revenue	186.1	179.5
Finance lease obligation (capital lease obligation in 2019)	1.9	1.8
Total current liabilities	1,239.3	1,070.1
Long-term debt, net of current portion	2,713.9	2,783.6
Finance lease obligation - long term (capital lease obligation in 2019)	17.4	19.2
Deferred income tax liabilities	201.8	275.3
Deferred revenue	12.9	15.8
Other long-term liabilities	303.2	162.4
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; 295,107 and 292,323 shares issued, respectively	2.9	2.9
Additional paid-in-capital	5,904.8	5,769.8
Accumulated deficit	(1,573.2)	(2,688.7)
Treasury stock, at cost – 37,609 and 24,639 shares, respectively	(1,579.6)	(926.0)
Accumulated other comprehensive loss	(49.7)	(42.3)
Total Hologic's stockholders' equity	2,705.2	2,115.7
Noncontrolling interest	2.1	—
Total stockholders' equity	$ 2,707.3	$ 2,115.7
Total liabilities and stockholders' equity	$ 7,195.8	$ 6,442.1

See accompanying notes.

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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 Deficit	Accumulated Other Comprehensive Loss	Number of Shares	Amount	Noncontrolling Interest	Total Stockholders' Equity
Balance at September 30, 2017	287,853	$ 2.9	$ 5,630.8	$ (2,382.7)	$ (16.2)	12,560	$ (450.1)	$ —	$ 2,784.7
Exercise of stock options	795	—	17.3	—	—	—	—	—	17.3
Vesting of restricted stock units, net of shares withheld for employee taxes	804	—	(16.7)	—	—	—	—	—	(16.7)
Common stock issued under the employee stock purchase plan	448	—	15.6	—	—	—	—	—	15.6
Stock-based compensation expense	—	—	65.0	—	—	—	—	—	65.0
Reacquisition of equity component from convertible notes repurchase, net of taxes	—	—	(40.7)	—	—	—	—	—	(40.7)
Net loss	—	—	—	(111.3)	—	—	—	—	(111.3)
Foreign currency translation adjustment	—	—	—	—	(8.1)	—	—	—	(8.1)
Adjustment to minimum pension liability, net	—	—	—	—	0.5	—	—	—	0.5
Repurchase of common stock	—	—	—	—	—	7,252	(275.8)	—	(275.8)
Unrealized losses on derivatives, net of taxes	—	—	—	—	(5.7)	—	—	—	(5.7)
Interest cost of interest rate cap reclassified to statement of operations	—	—	—	—	3.6	—	—	—	3.6
Net realized loss on marketable securities reclassified out of accumulated other comprehensive loss	—	—	—	—	0.4	—	—	—	0.4
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 derivatives, 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									

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 derivatives, 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

See accompanying notes.

Hologic, Inc.

Consolidated Statements of Cash Flows

(In millions)

	Years ended		
	September 26, 2020	September 28, 2019	September 29, 2018
OPERATING ACTIVITIES			
Net income (loss)	$ 1,110.5	$ (203.6)	$ (111.3)
Adjustments to reconcile net income (loss) income to net cash provided by operating activities:			
Depreciation	83.1	92.5	101.6
Amortization	292.9	370.6	378.7
Stock-based compensation expense	83.3	62.0	65.0
Deferred income taxes and other non-cash taxes	(94.4)	(235.7)	(477.3)
Goodwill impairment charge	—	—	685.7
Intangible asset and equipment impairment charges	30.2	685.4	46.0
Debt extinguishment losses	—	0.8	45.9
Other adjustments and non-cash items	27.3	33.8	24.8
Changes in operating assets and liabilities, excluding the effect of acquisitions and dispositions:			
Accounts receivable	(427.1)	(76.5)	(38.2)
Inventory	(25.3)	(63.0)	(50.6)
Prepaid income taxes	(3.8)	(3.2)	(9.4)
Prepaid expenses and other assets	(286.2)	(6.0)	(4.2)
Accounts payable	(4.9)	(5.5)	23.9
Accrued expenses and other liabilities	96.0	(16.5)	53.8
Deferred revenue	15.0	14.4	(1.5)
Net cash provided by operating activities	896.6	649.5	732.9
INVESTING ACTIVITIES			
Acquisition of businesses, net of cash acquired	(119.4)	(110.6)	(76.5)
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	(98.3)	(57.0)	(58.4)
Increase in equipment under customer usage agreements	(58.1)	(52.1)	(47.2)
Purchase of cost-method investment	—	(3.0)	(6.0)
Purchases of insurance contracts	(2.4)	—	—
Purchase of intellectual property	—	(4.5)	—
Other activity	(2.7)	(6.9)	(7.1)
Net cash (used in) provided by investing activities	(141.6)	(280.7)	(195.2)
FINANCING ACTIVITIES			
Proceeds from long-term debt	—	1,500.0	1,500.0
Repayment of long-term debt	(37.5)	(1,462.5)	(1,359.4)
Proceeds from senior notes	—	—	1,350.0
Repayment of senior notes	—	—	(1,037.7)
Payments to extinguish convertible notes	—	—	(546.2)
Payoff of acquired long-term debt	(8.3)	(2.5)	(3.3)
Proceeds from revolving credit line	750.0	480.0	1,150.0
Repayments under revolving credit line	(500.0)	(780.0)	(1,195.0)
Proceeds from accounts receivable securitization agreement	16.0	43.0	34.0
Repayments under accounts receivable securitization agreement	(250.0)	(34.0)	(9.0)
Purchase of non-controlling interest	(1.8)	—	—
Repurchases of common stock	(653.6)	(200.1)	(275.8)
Payment of debt issuance costs	—	(2.7)	(23.5)
Payment of deferred acquisition consideration	(24.3)	(6.5)	—
Purchase of interest rate caps	—	(1.5)	(3.7)
Net proceeds from issuance of common stock under employee stock plans	65.6	49.8	33.2
Payment of minimum tax withholdings on net share settlements of equity awards	(14.3)	(12.8)	(16.7)
Payments under finance lease obligations	(1.7)	(1.7)	(1.7)
Net cash used in financing activities	(659.9)	(431.5)	(404.8)
Effect of exchange rate changes on cash and cash equivalents	4.1	(2.2)	(6.8)
Net increase (decrease) in cash and cash equivalents	99.2	(64.9)	126.1
Cash and cash equivalents, beginning of period	601.8	666.7	540.6
Cash and cash equivalents, end of period	$ 701.0	$ 601.8	$ 666.7

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). During the second, third and fourth quarters of fiscal 2020, the Company operated in four segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health.

COVID-19 Considerations

The pandemic caused by the spread of the novel strain of coronavirus disease 2019 ("COVID-19") 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. In the second, third and fourth quarters of fiscal 2020, the spread of COVID-19 has negatively impacted business and healthcare activity globally.

As healthcare systems respond to the increasing 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 are responding to the fears of contracting COVID-19. In particular, elective procedures and exams have been and continue to be delayed or cancelled, there has been a significant reduction in physician office visits, and hospitals have postponed or cancelled 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, which continued into the fourth quarter. The reductions in testing and procedures have had, and the Company believes will continue to have, a negative impact on the Company's operating results and cash flows. However, the impact of the Company's commercial release of its COVID-19 assays more than offset these negative impacts, as the Company generated significant revenue from the sales of these assays in the third and fourth quarters of fiscal 2020. The negative effects of COVID-19 and the associated economic disruptions were felt primarily beginning in the second half of March in many of the Company's end-markets and earlier in Asia, primarily China, and the impact to the Company's legacy products in the third fiscal quarter was significant. The impact to its legacy products was less severe in the fourth quarter.

While the Company's results of operations and cash flows in the third and fourth quarter of fiscal 2020 were positively impacted by the sale of its COVID-19 assays, 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: the severity and duration of the COVID-19 pandemic; continued demand for COVID-19 testing; competition from existing and new COVID-19 testing technologies and products; the COVID-19 pandemic’s impact on the U.S. and international healthcare system, the U.S. economy and worldwide economy; and the timing, scope and effectiveness of U.S. and international governmental responses to the COVID-19 pandemic and associated economic disruptions.

In addition to adversely affecting demand for the Company's products, other than its COVID-19 assays, COVID-19 and associated economic disruptions could continue to have an adverse impact on the Company's supply chains and distribution systems, including as a result of impacts associated with preventive and precautionary measures that it, other businesses and governments have taken and will take. A reduction or interruption in any of the Company's manufacturing processes could have a material adverse effect on its business.

The Company believes that the uncertainty surrounding global financial markets and deteriorating worldwide macroeconomic conditions resulting from the pandemic have caused and may continue to cause the purchasers of medical equipment to decrease their medical equipment purchasing and procurement activities. Additionally, the pandemic has caused and may further cause constrictions in world credit markets that have caused and could cause its customers to experience increased difficulty in paying their existing obligations to the Company or in securing the financing necessary to purchase the Company's products. Economic uncertainty has resulted and may continue to result in cost-conscious consumers focusing on acute care rather than wellness, which may also continue to adversely affect demand for the Company's products (other than the Company's COVID-19 assays).

As the Company assessed the potential longer term economic and capital market uncertainties resulting from the COVID-19 pandemic, at the end of March 2020 the Company suspended its accounts receivable securitization program and borrowed $750.0 million under its revolver. The Company used $250.0 million of these proceeds to pay off all amounts then

owed under its accounts receivable securitization agreement and retained the balance as cash reserve. As of the end of fiscal 2020, the Company repaid $500.0 million of the $750.0 million borrowed under its revolver. As of September 26, 2020 the Company had an additional $1.25 billion available under its revolver and $ 701.0 million of cash on hand.

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 employee terminations. Further, in April 2020, the Company had 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, and the majority of the impacted manufacturing facilities are back to pre-COVID levels.

The Company has also taken 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 its commercial and marketing activities.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned and majority 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 2020, 2019 and 2018 ended on September 26, 2020, September 28, 2019 and September 29, 2018, respectively. Fiscal 2020, 2019 and 2018 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 recorded in the consolidated financial statements as of and for the year ended September 26, 2020. Subsequent to September 26, 2020, the Company's issued its 2029 Notes on September 28, 2020 and used the proceeds and cash on hand to pay off its 2025 Notes. For additional information, refer to Note 7.

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.

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 United States, 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 26, 2020. 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 was one customer with a balance greater than 10% of accounts receivable as of September 26, 2020, at 11.9%. There were no customers with a balance greater than 10% of accounts receivable as of September 28, 2019. There were no customers that represented greater than 10% of consolidated revenues for fiscal years 2020, 2019 and 2018 .

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; however, management believes that suitable replacement suppliers could be obtained in such an event.

Supplemental Cash Flow Statement Information

	Years ended		
	September 26, 2020	September 28, 2019	September 29, 2018
Cash paid during the period for income taxes	$ 265.9	$ 180.6	$ 178.2
Cash paid during the period for interest	$ 109.5	$ 132.5	$ 122.1
Non-Cash Financing Activities:			
Fair value of contingent consideration at acquisition	$ 82.7	$ —	$ 7.8

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 26, 2020	September 28, 2019
Raw materials	$ 152.3	$ 166.1
Work-in-process	46.5	54.5
Finished goods	196.3	224.3
	$ 395.1	$ 444.9

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 26, 2020	September 28, 2019
Equipment	3–10 years	$ 460.7	$ 379.2
Equipment under customer usage agreements	3–8 years	456.8	427.5
Buildings and improvements	20–35 years	167.3	196.7
Leasehold improvements	Shorter of the Original Term of Lease or Estimated Useful Life	44.3	61.7
Land		40.7	46.3
Furniture and fixtures	5–7 years	16.1	17.5
		1,185.9	1,128.9
Less - accumulated depreciation and amortization		(694.4)	(658.0)
		$ 491.5	$ 470.9

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.

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 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:

	September 26, 2020		September 28, 2019	
Description	Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Acquired intangible assets:				
Developed technology	$ 4,054.0	$ 2,907.2	$ 3,927.7	$ 2,654.8
Customer relationships	549.1	477.8	525.5	447.5
Trade names	245.5	181.2	245.4	171.1
Distribution agreement	—	—	2.5	—
Non-competition agreements	1.5	1.3	1.4	0.9
Business licenses	2.4	2.3	2.3	2.2
Total acquired intangible assets	$ 4,852.5	$ 3,569.8	$ 4,704.8	$ 3,276.5
Internal-use software	51.8	43.2	53.9	43.4
Capitalized software embedded in products	26.8	10.6	27.9	6.9
Total intangible assets	$ 4,931.1	$ 3,623.6	$ 4,786.6	$ 3,326.8

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. In addition, developed technology, customer lists, trade names, and distribution agreement related to Medical Aesthetics of $24.1 million, $0.9 million, $2.0 million, and $1.2 million, respectively, were reclassified accordingly in the Company's Consolidated Balance Sheet to assets held-for-sale as of December 28, 2019 and subsequently disposed of in the second quarter of fiscal 2020. 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. See Note 15.

During the second quarter of fiscal 2018, the Company abandoned an in-process research and development project acquired in the Cynosure acquisition and recorded an impairment charge of $46.0 million. The Company abandoned the project as a result of unsuccessful clinical results.

Other Activity

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 based on its preliminary purchase accounting.

During the first quarter of fiscal 2019, the Company acquired Focal Therapeutics, Inc. and recorded $ 83.1 million of developed technology, $11.4 million of in-process research and development and $ 2.7 million of trade names. In the fourth quarter of fiscal 2019, the Company obtained FDA approval for the in-process research and development project and reclassified this value to developed technology. During fiscal 2019, the two in-process research and development projects acquired in the Faxitron acquisition aggregating $5.5 million were completed and reclassified to developed technology.

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, distribution agreements, and business licenses is classified as a component of amortization of intangible assets within operating expenses.

The estimated amortization expense at September 26, 2020 for each of the five succeeding fiscal years was as follows:

Fiscal 2021	$	283.5
Fiscal 2022	$	273.1
Fiscal 2023	$	176.0
Fiscal 2024	$	164.6
Fiscal 2025	$	151.1

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 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.

At September 26, 2020, the Company believes that its reporting units, with goodwill aggregating $ 2.6 billion, were not at risk of failing the goodwill impairment test based on its current forecasts and qualitative assessment.

In fiscal 2019, the Company used the qualitative approach as of June 29, 2019 to assess its goodwill for impairment. Under this approach the Company considered 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 the Company's strategic plan compared to the forecast used 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. The Company weighed these factors to determine if it was more likely than not that the fair value of the reporting unit exceeded its carrying value. If after performing a qualitative assessment, indicators are present, or the Company identified factors that cause it to believe it is appropriate to perform a more precise calculation of fair value, the Company would have moved beyond the qualitative assessment and perform a quantitative impairment test. As a result of completing the qualitative assessment for each of its reporting units for fiscal 2019, the Company concluded that it was more likely than not that the fair value of each reporting exceeded its carrying value by a significant amount and a quantitative test was unnecessary.

During the second quarter of fiscal 2018, in connection with commencing its company-wide annual budgeting and strategic planning process, evaluating its current operating performance of its Medical Aesthetics reporting unit, and abandoning an in-process research and development project, the Company reduced its short term and long term revenue and operating income forecasts and determined that indicators of impairment existed in its Medical Aesthetics reporting unit. The Medical Aesthetics reporting unit was solely comprised of the Cynosure business, which the Company acquired on March 22, 2017. The updated forecast reflected significantly reduced volume and market penetration projections resulting in lower short-term and long-term profitability than expected at the time of the Cynosure acquisition. As a result of those events and circumstances at that time, the Company determined that it was more likely than not that this change would reduce the fair value of the reporting unit below its carrying amount. To estimate the fair value of the reporting unit, the Company utilized the DCF analysis. The forecasted cash flows were based on the Company's most recent budget and strategic plan and for period beyond the strategic plan, the Company's estimates were based on assumed growth rates expected as of the measurement date. The Company believed its assumptions were consistent with the plans and estimates used to manage the underlying business. The discount rate used is intended to reflect the risks inherent in future cash flow projections and was based on an estimate of the weighted average cost of capital (WACC) of market participants relative to the reporting unit. The basis of fair value for Medical Aesthetics assumed the reporting unit would be purchased or sold in a non-taxable transaction, and the discount rate of 12.0% applied to the after-tax cash flows was consistent with that used in the purchase accounting performed in fiscal 2017. As a result of this analysis, the fair value of the Medical Aesthetic reporting unit was significantly below its carrying value, and the Company recorded a goodwill impairment charge of $685.7 million during the second quarter of fiscal 2018.

In connection with the goodwill impairment test in the second quarter of fiscal 2018, the Company also performed an impairment test of this reporting unit's long-lived assets. This impairment evaluation was based on expectations of future undiscounted cash flows compared to the carrying value of the long-lived assets. The Company's cash flow estimates were consistent with those used in the goodwill impairment test discussed above. Based on this analysis, the undiscounted cash flows

of the Medical Aesthetics long-lived assets were in excess of their carrying value and thus deemed to not be impaired. The Company believed its procedures for estimating future cash flows were reasonable and consistent with market conditions at the time of estimation.

The Company conducted its 2018 impairment test 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 July 1, 2018 and ultimately used the fair value determined by the DCF approach in making its impairment test conclusions. As a result of completing Step 1, all of the Company's reporting units had fair values exceeding their carrying values, and as such, Step 2 of the impairment test was not required.

A rollforward of goodwill activity by reportable segment from September 28, 2019 to September 26, 2020 is as follows:

	Diagnostics	Breast Health	GYN Surgical	Skeletal Health	Total
Balance at September 28, 2019	$ 819.2	$ 722.2	$ 1,014.2	$ 8.1	$ 2,563.7
SuperSonic Imagine acquisition	—	34.3	—	—	34.3
Health Beacons acquisition	—	6.2	—	—	6.2
Acessa Health acquisition	—	—	48.4	—	48.4
Foreign currency and other adjustments	2.4	2.1	0.8	—	5.3
Balance at September 26, 2020	$ 821.6	$ 764.8	$ 1,063.4	$ 8.1	$ 2,657.9

Other Assets

Other assets consisted of the following:

	September 26, 2020	September 28, 2019
Other Assets		
Tax receivable	$ 325.7	$ —
Right of use assets	80.7	—
Life insurance contracts	49.3	44.6
Deferred tax assets	15.5	17.2
Cost-method equity investments	11.4	11.4
Equity-method investment and loans to SSI (Note 5)	—	42.7
Other	34.0	38.7
	$ 516.6	$ 154.6

The tax receivable primarily relates to a discrete tax benefit from the sale of Cynosure in the second quarter of fiscal 2020. 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 estimate 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, 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) as a separate component of stockholders' equity. Gains and losses arising from transactions denominated in foreign currencies are included in other income, 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 26, 2020					Year Ended September 28, 2019				
	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	$ (41.4)	$ (1.7)	$ (2.7)	$ 3.5	$ (42.3)	$ (26.6)	$ (1.1)	$ 2.2	$ —	$ (25.5)
Other comprehensive loss before reclassifications	18.5	(0.1)	(0.5)	(27.6)	(9.7)	(14.8)	(0.6)	(8.0)	3.5	(19.9)
Charges (gains) reclassified to statement of operations	—	—	2.3	—	2.3	—	—	3.1	—	3.1
Ending Balance	$ (22.9)	$ (1.8)	$ (0.9)	$ (24.1)	$ (49.7)	$ (41.4)	$ (1.7)	$ (2.7)	$ 3.5	$ (42.3)

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, 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 for the contracts entered into in fiscal 2018, and which will end on December 23, 2020 for the interest rate cap agreements entered into in fiscal 2019.

As of September 26, 2020, the Company determined that the existence of hedge ineffectiveness, if any, was immaterial and all changes in the fair value of the interest rate caps were recorded within AOCI.

During fiscal 2020, 2019 and 2018, interest expense of $ 2.3 million, $3.1 million and $3.6 million, respectively, was reclassified from AOCI to the Company's Consolidated Statements of Operations related to the interest rate cap agreements. The Company expects to similarly reclassify approximately $0.5 million from AOCI to the Consolidated Statements of Operations in the next twelve months.

The aggregate fair value of these interest rate caps was $ 0.0 million and $0.1 million at September 26, 2020 and September 28, 2019, respectively, and is included in both Prepaid expenses and other current assets and Other assets on the Company's Consolidated Balance Sheet. Refer to Note 8 "Fair Value Measurements" for related fair value disclosures.

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 accumulated other comprehensive income (loss) and were a loss, net of taxes, of $27.6 million and a gain, net of taxes, of $ 3.5 million for the years ended September 26, 2020 and September 28, 2019, respectively. The fair value of this derivative was in a liability position of $31.2 million as of September 26, 2020.

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 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 26, 2020	September 28. 2019	September 29. 2018
Amount of realized (loss) gain recognized in income			
Forward foreign currency contracts	$ 0.7	$ 11.0	$ (1.3)
Foreign currency option contracts	(1.9)	—	—
Total	$ (1.2)	$ 11.0	$ (1.3)
Amount of unrealized gain (loss) recognized in income			
Forward foreign currency contracts	$ (0.2)	$ (2.2)	$ 6.6
Foreign currency option contracts	4.0	0.1	—
Total	$ 3.8	$ (2.1)	$ 6.6

As of September 26, 2020, 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 forecasted transactions denominated in the Australian Dollar, Canadian Dollar, Chinese Yuan and Japanese Yen with a notional amount of $172.6 million. As of September 26, 2020, the Company had outstanding foreign currency option contracts that were not designated for hedge accounting and are used to hedge fluctuations in the U.S dollar of forecasted transactions denominated in the Euro and UK Pound with a notional amount of $380.2 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 26, 2020:

	Balance Sheet Location	September 26, 2020	September 28, 2019
Assets:			
Derivative instruments designated as a cash flow hedge:			
Interest rate cap agreements	Prepaid expenses and other current assets	$ —	$ 0.1
Interest rate swap contract	Other assets	$ —	$ 4.7
		$ —	$ 4.8
Derivatives not designated as hedging instruments:			
Forward foreign currency contracts	Prepaid expenses and other current assets	$ 1.1	$ 0.9
Foreign currency option contracts	Prepaid expenses and other current assets	10.1	2.0
		$ 11.2	$ 2.9
Liabilities:			
Derivative instruments designated as a cash flow hedge:			
Interest rate swap contract	Accrued expenses	$ 8.2	$ —
Interest rate swap contract	Other long-term liabilities	23.0	—
Total		$ 31.2	$ —
Derivatives not designated as hedging instruments:			
Forward foreign currency contracts	Accrued expenses	$ —	$ 0.1

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 26, 2020	September 28, 2019	September 29, 2018
Amount of gain (loss) recognized in other comprehensive income (loss), net of taxes:			
Interest rate swap	$ (27.6)	$ 3.5	$ —
Interest rate cap agreements	(0.5)	(8.0)	(5.7)
Total	$ (28.1)	$ (4.5)	$ (5.7)

The following table presents the adjustment to fair value (realized and unrealized) recorded within the Consolidated Statements of Operations for derivative instruments for which the Company did not elect hedge accounting:

Derivatives not classified as hedging instruments	Years Ended			Location of Gain Recognized in Income
	September 26, 2020	September 28, 2019	September 29, 2018	
Forward foreign currency contracts	$ 0.5	$ 8.8	$ 5.3	Other income, net
Foreign currency option contracts	2.1	0.1	—	Other income, net
	$ 2.6	$ 8.9	$ 5.3	

Accounts Receivable and Reserves

The Company records reserves for doubtful accounts based upon a specific review of all outstanding invoices, known collection issues and historical experience. The Company regularly evaluates the collectability of its trade accounts receivables and performs ongoing credit evaluations of its customers and adjusts credit limits based upon payment history and its assessment of the customer's current credit worthiness.

Accounts receivable reserve activity for fiscal 2020, 2019 and 2018 was as follows:

	Balance at Beginning of Period	Charged to Costs and Expenses	Divested	Write-offs and Payments	Balance at End of Period
Period Ended:					
September 26, 2020	$ 17.8	$ 26.8	$ (5.8)	$ (7.2)	$ 31.6
September 28, 2019	$ 16.2	$ 4.4	$ —	$ (2.8)	$ 17.8
September 29, 2018	$ 9.8	$ 7.0	$ —	$ (0.6)	$ 16.2

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, as a result of the adoption of ASU 2016-09 in fiscal 2017, 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, restricted stock units and convertible debt 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 2020, 2019, and 2018 was as follows:

	September 26, 2020	September 28, 2019	September 29, 2018
Basic weighted average common shares outstanding	262,727	269,413	275,105
Weighted average common stock equivalents from assumed exercise of stock options and restricted stock units	1,886	—	—
Diluted weighted average common shares outstanding	264,613	269,413	275,105
Weighted-average anti-dilutive shares related to:			
Outstanding stock options and stock units	1,158	4,098	5,073
Convertible notes	—	—	703

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 2020 and 2019 was as follows:

	Balance at Beginning of Period	Provisions	Acquired	Divested	Settlements/ Adjustments	Balance at End of Period
Period ended:						
September 26, 2020	$ 13.9	$ 11.7	$ 0.5	$ (6.1)	$ (10.1)	$ 9.9
September 28, 2019	$ 15.9	$ 14.1	$ —	$ —	$ (16.1)	$ 13.9

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 $15.6 million, $29.5 million and $26.9 million for fiscal 2020, 2019 and 2018, respectively, and were included in selling and marketing expense in the Consolidated Statements of Operations.

Recently Adopted Accounting Pronouncements

In August 2017, the FASB issued ASU No. 2017-12, *Derivatives and Hedging* (Topic 815): Targeted Improvements to Accounting for Hedging Activities. The guidance requires certain changes to the presentation of hedge accounting in the financial statements and also simplifies the application of hedge accounting and expands the strategies that qualify for hedge accounting. The Company adopted the standard in the first quarter of fiscal 2020. The adoption of ASU 2017-12 did not have a material effect on the Company's consolidated financial statements.

Recently Issued 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 updated guidance is effective for annual periods beginning after December 15, 2019, and is applicable to the Company in fiscal 2021. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of ASU 2016-13, as well as all codification improvements in ASU 2019-04, ASU 2019-10, ASU 2019-11 and ASU 2020-03, on its consolidated financial position and results of operations. The Company expects the adoption to primarily be applicable to its accounts receivable and does not believe the impact will be material to its 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)*. The guidance 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 that Update expanded the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. For entities that have adopted the amendments in Update 2018-07, the updated guidance is effective for annual periods beginning after December 15, 2019, and is applicable to the Company in fiscal 2021. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of ASU 2019-08 on its consolidated financial position and results of operations but does not expect the adoption to have a material impact to its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740) Simplifying the Accounting for Income Taxes.* The Board is issuing 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. 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 Board is issuing 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. 2020-03, *Codification Improvements to Financial Instruments*. The Board is issuing this Update to clarify or improve the Codification, as well as, make the Codification easier to understand and apply by eliminating inconsistencies. This update is to improve various financial instruments Topics in the Codification to increase stakeholder awareness of the amendments and to expedite the improvement process. For entities that have adopted the amendments in Update 2020-03, the updated guidance is effective for all entities beginning in fiscal 2021. The Company is currently evaluating the impact of the adoption of ASU 2020-03 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 Board is issuing 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 generally accepted accounting principles (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.

3. Revenue

In May 2014, the FASB issued ASC 606. The Company adopted the standard, which superseded ASC Topic 605, *Revenue Recognition* (ASC 605), as of September 30, 2018 using the modified retrospective method for contracts that were not complete as of September 30, 2018. Under this method, the Company recognized the cumulative effect of initially applying the standard to its open contracts and recorded an adjustment to decrease the opening balance of accumulated deficit within stockholders' equity by $6.4 million, which is net of taxes of $2.4 million, as of September 30, 2018 (the first day of fiscal 2019). The cumulative effect adjustment was primarily due to the Company applying the principles of ASC 606 to contracts for which the Company had deferred revenue as of September 29, 2018 for collectability uncertainty and providing extended payment terms resulting in the fee not being fixed or determinable under ASC 605. Under ASC 606, revenue from certain arrangements may be recognized earlier than under ASC 605 as a result of the ability to apply additional judgment in evaluating collectability and the elimination of the requirement to assess whether a fee is fixed or determinable, specifically as it relates to providing customers with extended payment terms. Results for reporting periods beginning September 30, 2018 and after are presented in accordance with ASC 606. Prior period results were not adjusted and will continue to be reported in accordance with the legacy GAAP requirements of ASC 605. As the adoption of this standard did not have a material impact on the Company’s revenue recorded for the years ended September 28, 2019 and September 29, 2018, transitional disclosures have not been presented.

The Company 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:

Business (in millions)	Years Ended September 26, 2020 United States	Intl.	Total	September 28, 2019 United States	Intl.	Total	September 29, 2018 United States	Intl.	Total
Diagnostics:									
Cytology & Perinatal	$ 266.3	$ 143.8	$ 410.1	$ 312.9	$ 159.1	$ 472.0	$ 322.9	$ 157.4	$ 480.3
Molecular Diagnostics	1,272.5	375.9	1,648.4	549.9	125.1	675.0	503.4	108.4	611.8
Blood Screening	43.6	—	43.6	58.5	—	58.5	55.3	—	55.3
Total	1,582.4	519.7	2,102.1	921.3	284.2	1,205.5	881.6	265.8	1,147.4
Breast Health:									
Breast Imaging	722.0	231.6	953.6	853.1	241.5	1,094.6	782.0	234.5	1,016.5
Interventional Breast Solutions	166.6	31.7	198.3	184.8	34.8	219.6	169.4	32.3	201.7
Total	888.6	263.3	1,151.9	1,037.9	276.3	1,314.2	951.4	266.8	1,218.2
GYN Surgical	310.1	66.0	376.1	362.8	74.4	437.2	352.8	69.2	422.0
Skeletal Health	51.2	29.8	81.0	58.6	36.2	94.8	59.4	31.8	91.2
Medical Aesthetics	30.9	34.4	65.3	155.4	160.2	315.6	172.4	166.7	339.1
Total	$ 2,863.2	$ 913.2	$ 3,776.4	$ 2,536.0	$ 831.3	$ 3,367.3	$ 2,417.6	$ 800.3	$ 3,217.9

Geographic Regions (*in millions*)	Years Ended September 26, 2020	September 28, 2019	September 29, 2018
United States	$ 2,863.2	$ 2,536.0	$ 2,417.6
Europe	569.8	396.0	377.5
Asia-Pacific	226.8	286.0	275.6
Rest of World	116.6	149.3	147.2
	$ 3,776.4	$ 3,367.3	$ 3,217.9

The following table provides revenue recognized by source:

Revenue by type (*in millions*)	Years Ended September 26, 2020	September 28, 2019	September 29, 2018
Disposables	$ 2,561.1	$ 1,786.4	$ 1,666.7
Capital equipment, components and software	665.9	984.9	977.2
Service	516.6	568.3	551.8
Other	32.8	27.7	22.2
	$ 3,776.4	$ 3,367.3	$ 3,217.9

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 26, 2020, the estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied was approximately $635.6 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 39% of this amount as revenue in 2021, 28% in 2022, 19% in 2023, 10% in 2024, and 4% 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 and, until December 30, 2019, the divested Medical Aesthetics segment. Contract liabilities are classified as other current liabilities and other long-term liabilities on the Consolidated Balance Sheets. The Company recognized revenue of $106.2 million and $158.9 million in the years ended September 26, 2020 and September 28, 2019, respectively, that was included in the contract liability balance at September 28, 2019 and September 29, 2018, respectively.

Practical Expedients

With the adoption of ASC 606, the Company elected to apply certain permitted practical expedients. In evaluating the cumulative-effect adjustment to retained earnings, the Company adopted the standard only for contracts that were not complete as of the date of adoption. For contracts that were modified prior to the adoption date, the Company elected to present the aggregate effect of all contract modifications in determining the transaction price and for the allocation to the satisfied and unsatisfied performance obligations.

The Company applies a practical expedient to expense costs as incurred for costs to obtain a contract with a customer 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.

Revenue Recognition under ASC 605 (prior to the adoption of ASC 606, which applies to fiscal 2018)

Under ASC 605, the Company recognized product revenue upon shipment provided that there was persuasive evidence of an arrangement, there were no uncertainties regarding acceptance, the sales price was fixed or determinable, and collection of the resulting receivable was reasonably assured. Generally, the Company’s product arrangements for capital equipment sales, primarily in its Breast Health, Medical Aesthetics and Skeletal Health reporting segments, were multiple-element arrangements, including services, such as installation, training and support and maintenance, and multiple products. Based on the terms and conditions of the product arrangements, the Company believed that these services and undelivered products could be accounted for separately from the delivered product element as the Company’s delivered products have value to its customers on a stand-alone basis. Accordingly, revenue for services not yet performed at the time of product delivery were deferred and recognized as such services were performed. The relative selling price of any undelivered products was also deferred at the time of shipment and recognized as revenue when these products were delivered. There was no customer right of return in the Company’s sales agreements for its capital equipment.

Service revenues primarily consist of amounts recorded under service and maintenance contracts and repairs not covered under warranty, installation and training, and shipping and handling costs billed to customers. Service and maintenance contract revenues were recognized ratably over the term of the contract. Other service revenues were recognized as the services were completed using the specific performance method. Service and other revenue also included royalties which were recognized in the period the payments were due to the Company.

For revenue arrangements with multiple deliverables, the Company recorded revenue as separate units of accounting if the delivered items had value to the customer on a stand-alone basis and the delivery or performance of the undelivered items was considered probable and substantially within the Company’s control. Some of the Company’s products have both software and non-software components that function together to deliver the product’s essential functionality. The Company determined that except for its computer-aided detection (“CAD”) products and C-View and Intelligent 2D products, the software element in its other products was not within the scope of the software revenue recognition rules, ASC 985-605, *Software—Revenue Recognition*. The Company determined that given the significance of the software component’s functionality to its CAD, C-View and Intelligent 2D components, which are sold by its Breast Health segment, these products were within the scope of the software revenue recognition rules. The Company evaluated the appropriate revenue recognition treatment of it hardware products, including its Dimensions digital mammography systems, which had both software and non-software components that function together to deliver the products’ essential functionality (i.e., it is a tangible product), and determined they were not within the scope of ASC 985-605.

The Company was required to allocate revenue to its multiple element arrangements based on the relative fair value of each element's selling price. The Company typically determined the selling price of its products based on its best estimate of selling prices ("ESP") and services based on vendor-specific objective evidence of selling price ("VSOE"). The Company determined VSOE based on its normal pricing and discounting practices for the specific product or service when sold on a stand-alone basis. In determining VSOE, the Company's policy was to require a substantial majority of selling prices for a product or service to be within a reasonably narrow range. The Company also considered the class of customer, method of distribution, and the geographies into which its products and services were sold when determining VSOE. If VSOE could not be established, which could occur in instances when a product or service had not been sold separately, stand-alone sales were too infrequent, or product pricing was not within a relatively narrow range, the Company would generally establish the selling price using ESP to allocate arrangement consideration. The objective of ESP was to determine the price at which the Company would typically transact a stand-alone sale of the product or service. ESP was determined by considering a number of factors including Company pricing policies, internal costs and gross margin objectives, method of distribution, information gathered from experience in customer negotiations, market research and information, recent technological trends, competitive landscape and geographies.

For those arrangements accounted for under the software revenue recognition rules, ASC 985-605 generally required revenue earned on software arrangements involving multiple elements to be allocated to each element based on their relative VSOE of fair value. If VSOE did not exist for a delivered element, the residual method was applied in which the arrangement consideration was allocated to the undelivered elements based on their VSOE with the remaining consideration recognized as revenue for the delivered elements. For multiple-element software arrangements where VSOE of fair value of Post-Contract Customer Support ("PCS") had been established, the Company recognized revenue using the residual method at the time all other revenue recognition criteria were met.

While the majority of its instruments are placed at customer sites, in certain instances the Company sold instruments to its clinical diagnostics customers and recorded sales of these instruments upon shipment or delivery, depending on the terms of the arrangement.

Within its Diagnostics business, and to a lesser extent, its GYN Surgical business, the Company provided its instrumentation (for example, the ThinPrep Processor, ThinPrep Imaging System, and the Panther and Tigris systems) and certain other hardware to customers without requiring them to purchase the equipment or enter into a lease. The Company installed the instrumentation or equipment at the customer's site and recovered the cost of providing the instrumentation or equipment in the amount it charged for its diagnostic tests, assays and other disposables. Customers entered into a customer usage agreement and typically committed to purchasing minimum quantities of disposable products at a stated price over a defined contract term, which was typically between three and five years. Revenue was recognized over the term of the customer usage agreement as tests, assays and other disposable products are shipped or delivered, depending on the customer's arrangement.

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 is 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, is effective for public entities for annual periods beginning after December 15, 2018, including interim periods within those annual periods and 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. Prior periods are presented in accordance with the lease guidance under ASC Topic 840, Leases (ASC 840).

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. Under ASC 840, 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 includes 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 are 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 15 years, some of which may include options to extend the leases for up to 20 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 26, 2020. The Company's lease classified as a capital lease in fiscal 2019 is now classified as a finance lease on the balance sheet as of September 26, 2020.

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 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 26, 2020 was 2.62%.

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

		September 26, 2020	
	Balance Sheet Location	Operating Leases	Finance Lease
Assets			
Lease right-of-use assets	*Other assets*	$ 80.7	$ —
Liabilities			
Operating lease liabilities (current)	*Accrued expenses*	$ 23.5	$ —
Finance lease liabilities (current)	*Finance lease obligations - short term*	$ —	$ 1.9
Operating lease liabilities (non-current)	*Other long-term liabilities*	$ 65.6	$ —
Finance lease liabilities (non-current)	*Finance lease obligations - long term*	$ —	$ 17.4

The finance lease was previously recorded as a capital lease in the consolidated balance at September 28, 2019, and the short-term and long-term liabilities were $1.8 million and $19.2 million, respectively.

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 26, 2020	
	Operating Leases	Finance Lease
Weighted average remaining lease term	5.58	7.64
Weighted average discount rate	2.0 %	5.1 %

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

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

(a) Includes short-term lease expense and variable lease costs, which were immaterial for the year ended September 26, 2020.

Rent expense under FASB ASC Topic 840 was $ 23.1 million for fiscal 2019 and 2018.

The following table presents the future minimum lease payments under non-cancellable operating lease liabilities and finance lease as of September 26, 2020:

Fiscal Year	Operating Leases	Finance Lease
2021	25.0	2.8
2022	20.3	3.0
2023	13.8	3.0
2024	11.1	3.0
2025	8.5	3.1
Thereafter	16.0	8.4
Total future minimum lease payments	94.7	23.3
Less: imputed interest	(5.6)	(4.0)
Present value of lease liabilities	$ 89.1	$ 19.3

For comparative purposes, the Company's future minimum lease payments as of September 28, 2019 were as follows:

Fiscal Year	Operating Leases	Finance Lease
2020	20.5	5.8
2021	17.3	5.8
2022	13.3	6.1
2023	6.6	6.2
2024	5.9	5.5
Thereafter	14.6	19.5
Total future minimum lease payments	78.2	48.9

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 or sales-type lease as well as performance obligations for reagents and other consumables. These contractual arrangements are subject to termination provisions which are evaluated in determining the lease term for lease accounting purposes. Sales-type leases are not significant. 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. The allocation of revenue between the lease and non-lease components is based on stand-alone selling prices. Lease revenue represented approximately 4% of the Company's consolidated revenue for the twelve months ended September 26, 2020.

In connection with the disposition of the Medical Aesthetics business, 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, included in property, plant and equipment, and recorded a lease receivable, which was $19.3 million as of September 26, 2020.

The Company subleases a portion of a building it owns and some of its rented facilities and has received aggregate rental income of $2.0 million, $2.7 million and $2.6 million in fiscal 2020, 2019 and 2018, respectively, which has been recorded as an offset to operating lease costs. The future minimum annual rental income payments under these sublease agreements at September 26, 2020 are as follows:

Fiscal 2021	$	3.0
Fiscal 2022		3.0
Fiscal 2023		3.0
Fiscal 2024		2.9
Fiscal 2025		1.9
Thereafter		2.6
Total	$	16.4

5. Business Combinations

Acessa Health

On August 23, 2020, the Company completed the acquisition of Acessa Health, Inc. ("Acessa") for a purchase price of $161.3 million, which included a hold-back of $3.0 million payable five months from the date of acquisition, 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, 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 will be 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. 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.

The total purchase price was allocated to Acessa's preliminary 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
Identifiable intangible assets:		
Developed Technology		127.0
Trade names		1.2
Accounts payable and accrued expenses		(4.7)
Deferred income taxes, net		(20.2)
Goodwill		48.4
Purchase Price	$	161.3

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 Acessa's business. The allocation of the purchase price is preliminary as the Company continues to gather information supporting the acquired assets and liabilities, primarily taxes.

As part of the preliminary purchase price allocation, the Company has determined the identifiable intangible assets are developed technology and trade names. The preliminary fair value of the intangible assets has been estimated using the income approach, and the cash flow projections were discounted using a 18.0% rate. The cash flows are 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. The factors contributing to the recognition of the preliminary amount of goodwill are based on synergistic benefits of Acessa's products being complementary to the GYN Surgical portfolio of products and utilizing the GYN Surgical's 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 preliminary valuation, it has allocated $10.7 million of the purchase price to the preliminary value of developed technology and $6.2 million to goodwill. The remaining $2.8 million of the purchase price has been allocated to 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. 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 has estimated at $0.9 million. The contingent consideration is 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 products in the U.S. Based on the Company's preliminary valuation, the majority of the purchase price was allocated to a customer relationships intangible asset with a useful life of 5 years. Goodwill was immaterial. The allocation of the purchase price is preliminary as the Company continues to gather information supporting the acquired assets and liabilities.

SuperSonic Imagine

On August 1, 2019, the Company purchased 46% of the outstanding shares of SuperSonic Imagine ("SSI") for $ 18.2 million. SSI is 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, net.

On November 21, 2019, the Company acquired an additional 7.6 million common shares of SSI for $12.6 million. As a result, the Company's ownership interest increased to approximately 78% of the outstanding common shares of SSI at November 21, 2019, and it now 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 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, and as of September 26, 2020, the Company owned approximately 81% of the outstanding shares of SSI.

The total purchase price was allocated to SSI's preliminary 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 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 SSI's business. The Company has not yet obtained all of the information related to the fair value of the acquired assets and liabilities, primarily income taxes and recognition of uncertain tax positions, to finalize the purchase price allocation.

As part of the preliminary purchase price allocation, the Company determined the identifiable intangible assets are developed technology, 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 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 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. The factors contributing to the recognition of the preliminary amount of goodwill are based on 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 ("IPR&D"), 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.

Faxitron

On July 31, 2018, the Company completed the acquisition of Faxitron Bioptics, LLC ("Faxitron") for a purchase price of $ 89.5 million, which included hold-backs of $11.7 million payable up to one year from the date of acquisition, and contingent consideration, which the Company estimated at $2.9 million as of the measurement date. Faxitron, headquartered in Tucson, Arizona, develops, manufactures, and markets digital radiography systems. The contingent consideration is payable upon meeting certain revenue growth metrics. In the fourth quarter of fiscal 2019, the Company increased the contingent consideration liability by $1.7 million based on updated projections, and the Company paid $5.0 million in the second quarter of fiscal 2020. During fiscal 2019, the Company paid $ 6.5 million of the hold-backs and withheld the remainder of $5.2 million under the indemnification provisions of the purchase agreement, which the former shareholders had disputed. In the first quarter of fiscal 2020, the Company resolved this dispute and paid $4.1 million to the former shareholders. Faxitron'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 Faxitron's tangible and identifiable intangible assets and liabilities based on the estimated fair values of those assets as of July 31, 2018, as set forth below:

Cash	$	2.4
Accounts receivable		4.0
Inventory		5.8
Other assets		3.1
Accounts payable and accrued expenses		(8.8)
Deferred revenue		(1.9)
Long-term debt		(3.3)
Identifiable intangible assets:		
Developed technology		44.9
In-process research and development		5.5
Customer relationships		0.5
Trade names		2.3
Deferred income taxes, net		(10.6)
Goodwill		45.6
Purchase Price	$	89.5

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 Faxitron's business. As part of the purchase price allocation, the Company determined the identifiable intangible assets were developed technology, in-process research and development ("IPR&D"), 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 rates ranging from 17% to 19%. 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 both developed technology and customer relationships is 9 years and for trade names it is 7 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. The factors contributing to the recognition of the preliminary 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.

Emsor, S.A.

On December 11, 2017, the Company completed the acquisition of Emsor S.A. ("Emsor") for a purchase price of $ 16.3 million, and contingent consideration, which the Company estimated at $4.9 million as of the measurement date. The contingent consideration was payable upon Emsor achieving predefined amounts of cumulative revenue over a two-year period from the date of acquisition. The contingent consideration was paid in the second quarter of fiscal 2020. Emsor was a distributor of the Company's Breast and Skeletal Health products in Spain and Portugal. Based on the Company's valuation, it allocated $4.6 million of the purchase price to the value of customer relationship intangible assets and $5.7 million to goodwill. The remaining $6.0 million of purchase price was allocated to acquired tangible assets and liabilities.

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 2020, 2019 and 2018 and a rollforward of the charges to the accrued balances as of September 26, 2020:

	Fiscal 2020 Actions	Fiscal 2019 Actions	Fiscal 2018 Actions	Other	Total
Restructuring Charges					
Fiscal 2018 charges:					
Workforce reductions	$ —	$ —	$ 11.7	$ —	$ 11.7
Facility closure costs	—	—	0.9	1.6	2.5
Fiscal 2018 restructuring charges	$ —	$ —	$ 12.6	$ 1.6	$ 14.2
Fiscal 2019 charges:					
Workforce reductions	$ —	$ 4.0	$ 1.4	$ —	$ 5.4
Facility closure costs	—	—	(0.2)	1.4	1.2
Fiscal 2019 restructuring charges	$ —	$ 4.0	$ 1.2	$ 1.4	$ 6.6
Fiscal 2020 charges:					
Workforce reductions	$ 13.2	$ 0.3	$ (0.1)	$ —	$ 13.4
Divestiture charges	1.9	—	—	—	1.9
Fiscal 2020 restructuring charges	$ 15.1	$ 0.3	$ (0.1)	$ —	$ 15.3

	Fiscal 2020 Actions	Fiscal 2019 Actions	Fiscal 2018 Actions	Fiscal 2017 Actions	Previous Other Charges	Total
Rollforward of Accrued Restructuring						
Balance as of September 30, 2017	$ —	$ —	$ —	$ 7.5	$ 4.0	$ 11.5
Fiscal 2018 restructuring charges	$ —	$ —	$ 12.6	$ —	$ 1.6	$ 14.2
Stock-based compensation	—	—	(1.3)	—	—	(1.3)
Severance payments and adjustments	—	—	(6.8)	(6.7)	(0.2)	(13.7)
Other payments	—	—	(0.2)	—	(1.4)	(1.6)
Balance as of September 29, 2018	$ —	$ —	$ 4.3	$ 0.8	$ 4.0	$ 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

(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 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, *Compensation-Nonretirement Postemployment Benefits* (ASC 712) or ASC 420, *Exit or Disposal Cost Obligations* (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. The Company expects to record additional charges related to these actions totaling $1.7 million over the next twelve months, primarily related to the closure of its Sunnyvale, CA location as the Perinatal production line is being transferred to San Diego.

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 performs 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 24 personnel and implemented other employee termination actions. The charges for these actions are being 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.

Fiscal 2018 Actions

During the first, second and third quarters of fiscal 2018, the Company decided to terminate certain employees across the organization, including a corporate executive and primarily sales and marketing personnel in its Diagnostics and Medical Aesthetics reportable segments. The charges were recorded pursuant to ASC 712 or ASC 420 depending on the employee. As such, the Company recorded severance benefits charges of $9.0 million in fiscal 2018. Included within the charge was $ 1.3 million related to the modification of equity awards.

During fiscal 2018, the Company finalized its decision and plan to consolidate its legacy international accounting and customer service organizations into its Manchester, UK location and eliminated positions in Belgium, France, Italy, Spain and Germany. During fiscal 2018, the Company recorded $2.2 million for severance benefits pursuant to both ASC 712 and ASC 420 depending on the legal requirements on a country by country basis. The Company recorded an additional $1.0 million in fiscal 2019 for the remaining pro-rata charges. This transition was completed in the first quarter of fiscal 2019.

In the third quarter of fiscal 2018, the Company determined it would not use warehouse space located on Lyberty Way in Westford, Massachusetts. The Company met the cease use date criteria in the third quarter of fiscal 2018 and estimated the time period to sublet the space and related sublease rates resulting in a lease obligation charge of $0.9 million. During the first quarter of fiscal 2019, the Company executed a termination agreement with the landlord and agreed to pay a termination payment of $0.6 million resulting in a benefit of $0.3 million recorded in the first quarter of fiscal 2019.

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 26, 2020	September 28, 2019
Current debt obligations, net of debt discount and deferred issuance costs:		
Term Loan	$ 74.9	$ 37.4
Revolver	250.0	—
Securitization Program	—	234.0
Total current debt obligations	324.9	271.4
Long-term debt obligations, net of debt discount and issuance costs:		
Term Loan	1,379.9	1,452.4
2025 Senior Notes	939.4	937.3
2028 Senior Notes	394.6	393.9
Total long-term debt obligations	2,713.9	2,783.6
Total debt obligations	$ 3,038.8	$ 3,055.0

The debt maturity schedule for the Company's obligations as of September 26, 2020 was as follows:

	2021	2022	2023	2024	2025	2026 and Thereafter	Total
Term Loan	$ 75.0	$ 75.0	$ 112.5	$ 1,200.0	$ —	$ —	$ 1,462.5
Revolver	250.0	—	—	—	—	—	250.0
2025 Senior Notes	—	—	—	—	950.0	—	950.0
2028 Senior Notes	—	—	—	—	—	400.0	400.0
	$ 325.0	$ 75.0	$ 112.5	$ 1,200.0	$ 950.0	$ 400.0	$ 3,062.5

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 consist 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"; together with the 2018 Term Loan, the "Amended Credit Facilities") under which the Company may borrow up to $1.5 billion, subject to certain sublimits, with a maturity date of December 17, 2023.

The Company initially borrowed $350 million under the 2018 Revolver. This initial borrowing, together with the net proceeds of the 2018 Term Loan, were used to repay the amounts outstanding under the term loan and revolving credit facility under the 2017 Credit Agreement.

Borrowings under the 2018 Credit Agreement bear 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 26, 2020, the Company had $ 250.0 million outstanding under the 2018 Revolver and the interest rate under the Term loan was 1.40%.

The applicable margin to the Base Rate, Eurocurrency Rate, or LIBOR Daily Floating Rate is 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 bear interest at an annual rate equal to the Eurocurrency Rate (i.e., the LIBOR rate) plus an Applicable Rate equal to 1.25%. The borrowings of the 2018 Revolver initially bear interest at a rate equal to the LIBOR Daily Floating Rate plus an Applicable Rate equal to 1.25%. The Company is also required to pay a quarterly commitment fee calculated on the undrawn committed amount available under the 2018 Revolver.

The Company is 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 is $1.2 billion, and any amounts outstanding under the 2018 Revolver are due at maturity. In addition, subject to the terms and conditions set forth in the 2018 Credit Agreement, the Company 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). These mandatory prepayments are 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 may voluntarily prepay any of the 2018 Credit Facilities without premium or penalty.

The 2018 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 2018 Credit Agreement requires the Company to maintain certain financial ratios. The 2018 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.

Borrowings are 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. For example, borrowings under the 2018 Credit Agreement are not secured by those accounts receivable that are transferred to the special purpose entity under the Company's Accounts Receivable Securitization program. The 2018 Credit Agreement contains 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 remains as such until it decreases 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 remains as such for each quarter thereafter. The total net leverage ratio is 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 is 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 26, 2020.

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 are 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 26, 2020.

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%. We accounted for the amendments pursuant to ASC 470, subtopic 50-40, and third-party costs of $0.8 million related to this transaction were recorded as interest expense and $ 1.9 million was recorded as a reduction to debt representing deferred issuance costs and debt discount for fees paid directly to the lenders.

2017 Credit Agreement

On October 3, 2017, the Company and certain of its domestic subsidiaries entered into an Amended and Restated Credit and Guaranty Agreement (the "2017 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 from time to time party thereto. The 2017 Credit Agreement amended and restated the Company's prior credit and guaranty agreement, originally dated as of May 29, 2015 (the "Prior Credit Agreement"). The proceeds under the 2017 Credit Agreement of $1.8 billion were used, among other things, to pay off the Term Loan of $ 1.32 billion and the Revolver then outstanding under the Company's Prior Credit Agreement.

The credit facilities under the 2017 Credit Agreement consisted of:

- A $1.5 billion secured term loan to the Company with a maturity date of October 3, 2022; and
- A secured revolving credit facility under which the Company could borrow up to $ 1.5 billion, subject to certain sublimits, with a maturity date of October 3, 2022.

During the third quarter of fiscal 2018, the Company borrowed $ 250.0 million under the revolver to cash settle the conversions of its 2.00% Convertible Senior Notes due 2042.

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, the 2017 Credit Agreement and the Prior Credit Agreement was as follows:

	Years Ended		
	September 26, 2020	September 28, 2019	September 29, 2018
Interest expense (1)	$ 46.6	$ 67.0	$ 60.8
Non-cash interest expense	$ 2.5	$ 2.6	$ 2.6
Weighted average interest rate	2.25 %	3.79 %	3.23 %
Interest rate at end of period	1.40 %	3.43 %	3.74 %

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

Pursuant to ASC 470, the accounting for entering into the 2017 Credit Agreement and using the proceeds to pay off the Prior 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 Prior 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 $1.0 million in the first quarter of fiscal 2018. 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%. Pursuant to ASC 470, subtopic 50-40, third-party costs of $1.7 million related to this transaction were recorded as interest expense and $ 4.9 million was recorded as a reduction to debt representing deferred issuance costs and debt discount for fees paid directly to the lenders.

Senior Notes

2025 Senior Notes

On October 10, 2017, the Company completed a private placement of $ 350 million aggregate principal amount of its 4.375% Senior Notes due 2025 (the "2025 Senior Notes") at an offering price of 100% of the aggregate principal amount of the 2025 Senior Notes. On January 19, 2018, the Company completed a private placement and allocated an additional $600 million in aggregate principal amount to its 2025 Senior Notes pursuant to a supplement to the indenture governing the Company's existing 2025 Senior Notes at an offering price of 100% of the aggregate principal amount. As a result, the total aggregate principal balance of 2025 Senior Notes is $ 950 million. The 2025 Senior Notes were general senior unsecured obligations of the Company and were guaranteed on a senior unsecured basis by certain domestic subsidiaries. The 2025 Senior Notes were to mature on October 15, 2025 and bore interest at the rate of 4.375% per year, payable semi-annually on April 15 and October 15 of each year, commencing on April 15, 2018. On September 28, 2020 (in the first quarter of fiscal 2021), the Company completed a private placement of $950.0 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 proceeds from this offering and cash on hand were used to redeem the 2025 Senior Notes in full on October 15, 2020, at a redemption price of approximately $970.8 million (equal to 102.2% of the aggregate principal amount of the 2025 Senior Notes). In the first quarter of fiscal 2021, the Company will complete the accounting for this transaction under ASC 470 to determine modification versus extinguishment accounting on a creditor-by-creditor basis and record a debt extinguishment loss as applicable.

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 may also redeem up to 35% of the aggregate principal amount of the 2028 Senior Notes with the net cash proceeds of certain equity offerings at any time and from time to time before February 1, 2021, at a redemption price equal to 104.625% 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 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.

Interest expense for the 2028 Senior Notes, 2025 Senior Notes and 2022 Senior Notes is as follows:

		Years Ended					
		September 26, 2020		September 28, 2019		September 29, 2018	
	Interest Rate	Interest Expense (1)	Non-Cash Interest Expense	Interest Expense (1)	Non-Cash Interest Expense	Interest Expense (1)	Non-Cash Interest Expense
2028 Senior Notes	4.625 %	$ 19.2	$ 0.7	$ 19.2	$ 0.7	$ 13.3	$ 0.5
2025 Senior Notes	4.375 %	43.5	2.1	43.5	2.1	34.7	1.6
2022 Senior Notes	5.250 %	—	—	—	—	21.2	1.5
Total		$ 62.7	$ 2.8	$ 62.7	$ 2.8	$ 69.2	$ 3.6

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

2022 Senior Notes

The Company had 5.250% Senior Notes due 2022 (the "2022 Senior Notes") outstanding and bore interest at the rate of 5.250% per year, payable semi-annually on January 15 and July 15 of each year. The Company used the net proceeds of the 2025 Senior Notes and the 2028 Senior Notes offering in January 2018 to redeem in full the 2022 Senior Notes in the aggregate principal amount of $1.0 billion on February 15, 2018 at an aggregate redemption price of $1.04 billion, including a make-whole provision payment $ 37.7 million. Since the Company planned to use the proceeds from the 2025 Senior Notes and the 2028 Senior Notes offering to redeem the 2022 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 2022 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 second quarter of fiscal 2018 of $44.9 million, which comprised pro-rata amounts of the make-whole provision premium payment, debt discount and debt issuance costs. For the remaining 2022 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 $ 2.6 million to interest expense pursuant to ASC 470, subtopic 50-40. The remaining debt issuance costs of $1.5 million and debt discount of $1.5 million related to the modified debt were allocated between the 2025 Senior Notes and 2028 Senior Notes on a pro-rata basis, and are being amortized over the life of the debt using the effective interest method.

Convertible Notes

As of September 28, 2019 and September 29, 2018, the Company had no Convertible Notes outstanding. The following describes the Convertible Note transactions during fiscal 2018.

On December 10, 2007, the Company issued and sold $ 1.725 billion, at par, of 2.00% Convertible Senior Notes due December 15, 2037 ("2007 Notes"). On November 18, 2010, the Company entered into separate, privately-negotiated exchange agreements under which it retired $450.0 million in aggregate principal of its 2007 Notes for $ 450.0 million in aggregate principal of new 2.00% Convertible Exchange Senior Notes due December 15, 2037 ("2010 Notes"). On February 29, 2012, the Company entered into separate, privately-negotiated exchange agreements under which it retired $500.0 million in aggregate principal of the 2007 Notes for $ 500.0 million in aggregate principal of new 2.00% Convertible Senior Notes due March 1, 2042 ("2012 Notes"). On February 14, 2013, the Company entered into separate, privately-negotiated exchange agreements under which it retired $370.0 million in aggregate principal of the 2007 Notes for $370.0 million in aggregate principal of new 2.00% Convertible Senior Notes due December 15, 2043 ("2013 Notes"). The remaining 2007 Notes were redeemed in fiscal 2014. In fiscal 2017, all remaining 2010 Notes were either converted or surrendered for conversion. On various dates in fiscal 2017, the Company entered into privately negotiated repurchase transactions and extinguished $117.9 million and $168.0 million principal amount of the 2012 Notes and 2013 Notes, respectively.

On January 29, 2018, the Company announced that pursuant to the terms of the indenture for the 2012 Notes, holders of the 2012 Notes had the option of requiring the Company to repurchase their 2012 Notes on March 1, 2018 at a repurchase price payable in cash equal to 100% of the accreted principal amount of the 2012 Notes, plus accrued and unpaid interest. The Company also announced on January 29, 2018 that, it had elected to redeem, on March 6, 2018, all of the then outstanding 2012 Notes at a redemption price payable in cash equal to 100% of the accreted principal amount of the 2012 Notes, plus accrued and unpaid interest. Holders also had the right to convert their 2012 Notes. During the second quarter of fiscal 2018, 2012 Notes in aggregate original principal amount of $200.5 million were surrendered for conversion and the Company cash settled these conversions for $243.3 million during April 2018. As a result, on a gross basis, $42.8 million of the consideration paid was allocated to the reacquisition of the equity component of the original instrument, which was recorded net of deferred taxes of $12.0 million within additional paid-in-capital. The remaining $ 5.5 million in original principal amount of the 2012 Notes was redeemed by the Company on March 6, 2018.

On December 15, 2017, pursuant to the provisions of the indenture governing the Company's 2013 Notes, the Company redeemed or repurchased an aggregate of $201.7 million in original principal amount of the 2013 Notes then outstanding for an aggregate repurchase price of $244.1 million, representing the then accreted principal amount of the 2013 Notes. The remaining $ 0.3 million in original principal amount of the 2013 Notes were converted, and the Company settled these conversions in cash in the second quarter of fiscal 2018.

On various dates during the first quarter of fiscal 2018, the Company entered into privately negotiated repurchase transactions and extinguished $39.3 million principal amount of its 2012 Notes for total payments of $ 52.8 million. This amount includes the conversion premium resulting from the Company's stock price on the date of the transactions being in excess of the conversion prices of $31.175. As a result, on a gross basis, $13.4 million of the consideration paid was allocated

to the reacquisition of the equity component of the original instrument, which was recorded net of deferred taxes of $ 3.8 million within additional paid-in-capital.

Interest expense under the Convertible Notes was as follows:

	Year Ended September 29, 2018
Amortization of debt discount	$ 3.5
Amortization of deferred financing costs	0.2
Principal accretion	1.6
Non-cash interest expense	5.3
2.00% accrued interest (cash)	1.8
	$ 7.1

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 may 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. The entire amount available was borrowed in the third quarter of fiscal 2016. Borrowings outstanding under the Securitization Program bear interest at LIBOR plus the applicable margin of 0.7% 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 increase the borrowing capacity. The maximum borrowing amount increased to $250.0 million.

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. As of September 26, 2020, the Company did not have any borrowings under this program.

Interest expense under the Securitization Program was $3.1 million, $7.1 million and $5.4 million for fiscal 2020, 2019 and 2018, respectively.

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 26, 2020, the Company was not required to be in compliance with the Credit and Security Agreement covenants.

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.

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 interest rate caps, 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 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 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:				
Foreign 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

		Fair Value Measurements at September 28, 2019		
	Carrying Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Interest rate caps - derivative	$ 0.1	$ —	$ 0.1	$ —
Interest rate swaps - derivative	4.7	—	4.7	—
Forward currency option contracts	2.0	—	$ 2.0	—
Forward foreign currency contracts	0.9	—	$ 0.9	—
Total	$ 7.7	$ —	$ 7.7	$ —
Liabilities:				
Contingent consideration	$ 9.1	$ —	$ —	$ 9.1
Forward foreign currency contracts	0.1	—	0.1	—
Total	$ 9.2	$ —	$ 0.1	$ 9.1

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 26, 2020, September 28, 2019, and September 29, 2018 were as follows:

	Years Ended		
	2020	2019	2018
Balance at beginning of period	$ 9.1	$ 7.8	$ —
Contingent consideration recorded at acquisition	82.7	—	7.8
Fair value adjustments	0.3	1.7	—
Payments/Accruals	(10.3)	(0.4)	—
Balance at end of period	$ 81.8	$ 9.1	$ 7.8

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. There were no such remeasurements to equity investments in fiscal 2020, 2019 and 2018. 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 second quarter of fiscal 2018, the Company recorded a $685.7 million goodwill impairment charge in its Medical Aesthetics reportable segment Refer to Note 6 for disclosure of the nonrecurring fair value measurement related to the debt extinguishment losses recorded in fiscal 2019 and 2018.

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, interest rate caps, 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 caps, 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 $ 1.71 billion aggregate principal as of September 26, 2020 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 2025 Senior Notes and 2028 Senior Notes had fair values of approximately $971.5 million and $419.1 million, respectively, as of September 26, 2020 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 26, 2020	**September 28, 2019**	**September 29, 2018**
Domestic	$ 921.1	$ (174.3)	$ (581.9)
Foreign	80.8	(83.4)	163.3
	$ 1,001.9	$ (257.7)	$ (418.6)

The benefit for income taxes contained the following components:

	Years ended		
	September 26, 2020	September 28, 2019	September 29, 2018
Federal:			
Current	$ (62.1)	$ 142.9	$ 137.1
Deferred	(76.6)	(189.9)	(461.9)
	(138.7)	(47.0)	(324.8)
State:			
Current	33.9	22.1	11.0
Deferred	(12.5)	(41.0)	(11.3)
	21.4	(18.9)	(0.3)
Foreign:			
Current	14.0	16.5	21.9
Deferred	(5.3)	(4.7)	(4.1)
	8.7	11.8	17.8
	$ (108.6)	$ (54.1)	$ (307.3)

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

	Years ended		
	September 26, 2020	September 28, 2019	September 29, 2018
Income tax (benefit) provision at federal statutory rate	21.0 %	(21.0) %	(24.5) %
Increase (decrease) in tax resulting from:			
Loss on sale of Cynosure	(31.3)	—	—
Domestic production activities deduction	—	—	(3.1)
State income taxes, net of federal benefit	2.9	(0.7)	0.7
U.S. tax on foreign earnings	(2.6)	(2.1)	0.1
Internal restructuring	—	(3.8)	—
Non-deductible goodwill	—	—	39.4
Tax credits	(0.6)	(3.3)	(1.9)
Tax reform	—	2.0	(82.7)
Unrecognized tax benefits	—	(0.1)	1.8
Compensation	0.4	0.8	0.3
Foreign rate differential	(1.2)	(5.4)	(5.2)
Change in deferred tax rate	(0.6)	—	1.2
Change in valuation allowance	1.3	9.5	(0.5)
Other	(0.1)	3.1	1.0
	(10.8) %	(21.0) %	(73.4) %

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 is recorded in other assets net of unrecognized tax benefits noted below, 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.

The Company's effective tax rate for in fiscal 2019, applied to an overall pre-tax loss resulting in a benefit, was equal to the statutory tax rate primarily due to the offsetting impacts of a discrete benefit related to an internal restructuring, earnings in jurisdictions subject to lower tax rates, reserves for uncertain tax positions and 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 (the "Act") in the first quarter of fiscal 2019.

The Company's effective tax rate for fiscal 2018, applied to an overall pre-tax loss resulting in a benefit, differed from the statutory rate primarily due to the favorable impact of the Act, which required the Company to remeasure its U.S. net deferred tax liabilities at a lower rate, partially offset by the unfavorable impact of the Medical Aesthetics goodwill impairment charge, substantially all of which was non-deductible.

The Act, which was enacted on December 22, 2017, reduced the U.S. federal corporate tax rate from 35% to 21% effective January 1, 2018, required companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and created new taxes on certain foreign sourced earnings. The Company applied SAB 118 when accounting for the enactment effects of the Act. In accordance with SAB 118, the Company recorded an estimated tax benefit of $346.2 million related to the enactment of the Act during the fiscal year ended September 29, 2018. During the quarter ended December 29, 2018, the Company completed its accounting for the Act, and recorded a final net benefit amount of $341.2 million, based on its understanding and interpretation of the regulatory guidance issued.

The Company uses the asset and liability method to account for income taxes in accordance with ASC 740, *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 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 26, 2020	September 28, 2019
Deferred tax assets		
Net operating loss carryforwards	$ 81.1	$ 34.5
Capital losses	57.0	6.4
Non-deductible accruals	24.9	24.7
Non-deductible reserves	33.2	22.7
UK intangible assets	—	25.4
Stock-based compensation	18.6	20.9
Tax credits	10.2	14.8
Nonqualified deferred compensation plan	14.4	12.9
Lease liability	17.3	—
Other temporary differences	25.2	17.8
	281.9	180.1
Less: valuation allowance	(118.5)	(60.7)
	$ 163.4	$ 119.4
Deferred tax liabilities		
Depreciation and amortization	$ (333.9)	$ (373.0)
Right of use asset	(15.8)	—
Debt discounts and deferrals	—	(4.5)
	$ (349.7)	$ (377.5)
	$ (186.3)	$ (258.1)

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 $57.8 million in fiscal 2020 from fiscal 2019 primarily due to acquired foreign loss carryforwards and state loss carryforwards resulting from the sale of the Medical Aesthetics business, partially offset by attribute expiration and valuation allowance releases.

At September 26, 2020, the Company had $40.1 million, $44.5 million, and $207.1 million in gross federal, state, and foreign net operating losses, respectively, $5.0 million, $4.5 million, and $1.2 million in federal, state, and foreign credit carryforwards, respectively, and $0.0 million, and $32.2 million in gross state and foreign capital loss carryforwards

respectively. These losses, credits, and capital loss carryforwards expire between 2021 and 2040, except for $ 22.5 million in losses, $3.4 million in credits, and $32.2 million in capital loss carryforwards that have unlimited carryforward periods. The federal, state, and foreign net operating losses exclude $4.5 million, $74.6 million, and $47.2 million, respectively, and the state capital loss carryforwards exclude $26.1 million, that the Company expects will expire unutilized.

As of December 29, 2018, the Company recorded a final net reduction of its deferred tax liabilities of $ 341.2 million related to the Act, as compared to the Company's provisional net reduction of $346.4 million as of September 29, 2018. The Act resulted in a tax benefit relating to the re-measurement of certain U.S. deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%, partially offset by additional tax expense pertaining to credit utilization limitations and executive compensation deduction disallowances.

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 reduce the Company's effective tax rate. As of September 28, 2019, the Company had $101.6 million in gross unrecognized tax benefits excluding interest, of which $87.3 million, if recognized, would have reduced the Company's effective tax rate. The $95.5 million increase in gross unrecognized tax benefits from fiscal 2019 was primarily related to the divestiture of the Medical Aesthetics business, and to a lesser extent intercompany transfer pricing related to ordinary business operations and other current year positions, partially offset by reserve releases resulting from statute of limitations expirations and audit settlements. In the next twelve months it is reasonably possible that the Company will reduce its gross unrecognized tax benefits by up to $1.3 million due to expiring statutes of limitations.

The Company's unrecognized income tax benefits activity for fiscal 2020 and 2019 was as follows:

	2020	2019
Balance at beginning of fiscal year	$ 101.6	$ 89.5
Tax positions related to current year:		
Additions	109.6	22.7
Reductions	—	—
Tax positions related to prior years:		
Additions related to change in estimate	1.5	—
Reductions	(0.7)	(4.8)
Payments	—	—
Lapses in statutes of limitations	(15.6)	(5.8)
Acquired tax positions:		
Additions related to reserves acquired from acquisitions	0.7	—
Balance as of the end of the fiscal year	$ 197.1	$ 101.6

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 26, 2020, and September 28, 2019, gross accrued interest was $11.9 million and $ 11.1 million, respectively. As of September 26, 2020, no penalties have been accrued.

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

During fiscal year 2020, the Company determined that unremitted foreign earnings are no longer 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.

This ASU is effective for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The Company adopted ASU 2016-16 in the first quarter of fiscal 2019 on a modified retrospective basis through a cumulative-effect adjustment to decrease the opening balance of accumulated deficit within stockholders' equity as of September 30, 2018, the first day of fiscal 2019. This change in accounting principle resulted in an increase in deferred tax assets of $2.9 million, a decrease in accumulated deficit of $ 2.5 million, and a decrease in prepaid taxes of $0.4 million as of the beginning of the Company's fiscal year beginning September 30, 2018.

The Company was required to account for the internal restructuring discussed above 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.

The Company settled an ongoing state non-income tax audit during the fourth quarter of fiscal 2020, which was fully reserved. The settlement resulted in a net benefit of $2.9 million recorded to general and administrative expenses from the reserve release. The Company settled an ongoing state non-income tax audit during the second quarter of fiscal 2018. This settlement resulted in a net $4.0 million benefit recorded to general and administrative expenses from the reserve release.

10. Stockholders' Equity and Stock-Based Compensation

Stock Repurchase Program

On June 21, 2016, the Company's Board of Directors authorized the repurchase of up to $ 500.0 million of the Company's outstanding common stock over the next five years. During fiscal 2018, the Company repurchased 5.0 million shares of its common stock for a total consideration of $187.3 million under this authorization.

On June 13, 2018, the Board of Directors authorized another share repurchase plan to repurchase up to $ 500.0 million of the Company's outstanding common stock. This share repurchase plan, which replaced the prior plan, was effective August 1, 2018 and expired March 27, 2020. Under this authorization, during the fourth quarter of 2018, the Company repurchased 2.3 million shares of its common stock for total consideration of $88.5 million. 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. As of September 26, 2020, $ 262.4 million was available under this authorization. Subsequent to September 26, 2020, the Company repurchased 1.1 million shares of its common stock for $74.8 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 26, 2020, the Company had 5.7 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 2020, 2019 and 2018:

	2020	2019	2018
Cost of revenues	$ 6.7	$ 7.1	$ 8.3
Research and development	8.0	9.2	9.5
Selling and marketing	10.2	10.2	10.3
General and administrative	50.9	35.5	35.6
Restructuring	7.5	—	1.3
	$ 83.3	$ 62.0	$ 65.0

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 2020, 2019 and 2018 and related assumptions are noted in the following table:

	Years ended		
	September 26, 2020	September 28, 2019	September 29, 2018
Options granted (in millions)	1.0	1.0	1.7
Weighted-average exercise price	$ 45.96	$ 41.36	$ 40.76
Weighted-average grant date fair value	$ 13.92	$ 13.54	$ 12.98
Assumptions:			
Risk-free interest rates	1.7 %	3.0 %	2.1 %
Expected life (in years)	4.8	4.8	4.7
Expected volatility	33.6 %	34.3 %	35.3 %
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 or five years with annual vesting of 25% and 20% per year, respectively, 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 26, 2020 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 $ 15.5 million, $14.1 million, and $14.3 million in fiscal 2020, 2019 and 2018, 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 $63.3 million, $43.7 million, and $46.5 million in fiscal 2020, 2019 and 2018, respectively. The related tax benefit recorded in the Consolidated Statements of Operations was $9.5 million, $8.9 million and $11.7 million in fiscal 2020, 2019 and 2018, respectively. At September 26, 2020, there was $ 19.5 million and $50.0 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 1.7 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 26, 2020:

	Number of Shares (in millions)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value (in millions)
Options exercisable at September 28, 2019	5.5	$ 35.23	6.1	$ 78.4
Granted	1.0	45.96		
Canceled/ forfeited	(0.1)	42.26		
Exercised	(1.8)	27.51		44.8
Options outstanding at September 26, 2020	4.6	$ 40.37	7.0	$ 109.5
Options exercisable at September 26, 2020	2.2	$ 37.81	6.0	$ 57.2
Options vested and expected to vest at September 26, 2020 (1)	4.5	$ 40.35	7.0	$ 108.9

(1) This represents the number of vested stock options as of September 26, 2020 plus the unvested outstanding options at September 26, 2020 expected to vest in the future, adjusted for estimated forfeitures.

During fiscal 2019 and 2018, 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 $26.1 million and $15.2 million, respectively.

A summary of the Company's RSU, PSU, FCF and MSU activity during the year ended September 26, 2020 is presented below:

Non-vested Shares	Number of Shares (in millions)	Weighted-Average Grant-Date Fair Value
Non-vested at September 28, 2019	2.5	$ 42.17
Granted	0.9	45.65
Vested	(0.9)	38.54
Forfeited	(0.1)	42.69
Non-vested at September 26, 2020	2.4	$ 44.22

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 2020, 2019 and 2018 the total fair value of RSUs and PSUs vested was $34.9 million, $34.6 million and $38.9 million, respectively.

The Company granted 0.6 million, 0.9 million and 0.8 million RSUs during fiscal 2020, 2019 and 2018, respectively. In addition, included in the above chart, the Company also granted 0.1 million, 0.1 million and 0.6 million PSUs during fiscal

2020, 2019, and 2018 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 $45.38, $40.97 and $40.86 per share based on the ending stock price on the date of grant in fiscal 2020, 2019 and 2018, 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 of PSUs based on a one-year free cash flow measure (FCF) to its senior management team. 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 0.3 million MSUs during fiscal 2020, 2019 and 2018, 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 $43.54, $55.13 and $49.44 per share using the Monte Carlo simulation model in fiscal 2020, 2019 and 2018, 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 2020, 2019 and 2018 was $4.5 million, $4.2 million and $4.0 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 26, 2020	September 28, 2019	September 29, 2018
Assumptions:			
Risk-free interest rates	1.32 %	2.27 %	1.62 %
Expected life (in years)	0.5	0.5	0.5
Expected volatility	26.9 %	27.1 %	25.0 %
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 $19.6 million, $19.2 million and $18.6 million for fiscal 2020, 2019 and 2018, 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 $3.1 million, $2.7 million and $2.9 million in fiscal 2020, 2019 and 2018, respectively. The full amount of the discretionary contribution, net of forfeitures, along with employee deferrals is recorded within accrued expenses and totaled $57.7 million and $51.9 million at September 26, 2020 and September 28, 2019, 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 26, 2020 and September 28, 2019 was $49.3 million and $44.6 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 2020, 2019 and 2018, are recorded within other income, 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 26, 2020, non-cancelable purchase commitments are as follows:

Fiscal 2021	267.7
Fiscal 2022	10.2
Fiscal 2023	0.7
Fiscal 2024	0.7
Fiscal 2025	0.4
Thereafter	0.1
Total	$ 279.8

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. 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, which was filed on September 30, 2020. On November 5, 2020, the Company opposed Minerva’s petition and filed a counter petition for Supreme Court review.

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. 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. On March 9, 2020, Minerva elected to withdraw its claim for lost profits damages. The original trial date of July 20, 2020 was vacated due to circumstances surrounding the COVID-19 pandemic. On October 21, 2020, the Court entered an amended case schedule and set a new trial date of August 9, 2021. The parties submitted a joint status report on September 25, 2020. 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.

On July 8, 2020, the Company filed suit against Minerva in the United States District Court for the District of Delaware, alleging that Minerva’s redesigned endometrial ablation device infringes U.S. Patent 9,095,348 (the '348 patent). A trial is set to begin on August 23, 2021.

On February 3, 2017, bioMérieux, S.A. and bioMérieux, Inc. (collectively “bioMérieux”) filed suit against the Company in the United States District Court for the Middle District of North Carolina ("MDNC"), alleging that the Company’s HIV products, including blood screening products previously manufactured by the Company for its former blood screening

partner Grifols Diagnostic Solutions Inc. ("Grifols USA"), infringe U.S. Patent Nos. 8,697,352 and 9,074,262. On January 3, 2018, the MDNC Court granted the parties' consent motion to transfer the case to Delaware. On June 11, 2019, the Court issued a claim construction ruling regarding the disputed terms in the patents. Motions for summary judgment were filed by the parties on September 30, 2019, and a hearing on these motions was held on December 18, 2019. A six-day trial concluded on February 25, 2020, with the jury finding that all claims of U.S. Patent No. 8,697,352 are invalid (U.S. Patent No. 9,074,262 was dropped from the case by bioMérieux prior to trial). On March 18, 2020, the parties agreed to a settlement under which bioMérieux agreed to dismiss all claims with prejudice and to waive the filing of post-trial motions and pursuing an appeal in exchange for a de minimis payment from the Company and Grifols USA.

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 as of September 26, 2020, but this amount could become greater if some or all of the cases which it is indemnifying have an adverse result.

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, 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.

The assets and liabilities of the disposed business at the date of disposition were as follows:

Assets:		
Cash	$	10.7
Accounts Receivable		59.6
Inventory		90.6
Prepaid expenses and other current assets		7.7
Property, plant, and equipment		4.0
Intangible assets		28.2
Other assets		9.8
Total assets disposed of	$	210.6
Liabilities:		
Accounts payable	$	12.3
Accrued expenses		49.0
Deferred revenue		16.6
Total liabilities disposed of	$	77.9

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 is performing 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, which it will continue to report in the Medical Aesthetics reportable segment. Subsequent to the disposition, the Company recorded additional expenses of $6.2 million 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 the years ended September 26, 2020 and September 28, 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 the first quarter of fiscal 2020, and each of fiscal 2019 and 2018, 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, but has continued to incur operating expenses primarily related to indemnification provisions and other matters. 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 five reportable segments consist of inventories, intangible assets, goodwill, and property, plant and equipment. The Company fully allocates depreciation expense to its five reportable segments. The Company has presented all other identifiable assets as corporate assets. There were no intersegment revenues. Segment information for fiscal 2020, 2019, and 2018 was as follows:

	Years ended		
	September 26, 2020	September 28, 2019	September 29, 2018
Total revenues:			
Diagnostics	$ 2,102.1	$ 1,205.5	$ 1,147.4
Breast Health	1,151.9	1,314.2	1,218.2
GYN Surgical	376.1	$ 437.2	422.0
Skeletal Health	81.0	94.8	91.2
Medical Aesthetics	65.3	315.6	339.1
	$ 3,776.4	$ 3,367.3	$ 3,217.9
Operating income (loss):			
Diagnostics	$ 929.7	$ 163.1	$ 145.5
Breast Health	192.8	399.3	399.7
GYN Surgical	42.0	99.2	58.3
Skeletal Health	(2.4)	(4.2)	3.3
Medical Aesthetics	(57.1)	(781.2)	(844.7)
	$ 1,105.0	$ (123.8)	$ (237.9)
Depreciation and amortization:			
Diagnostics	$ 237.3	$ 246.6	$ 257.3
Breast Health	48.8	36.8	22.7
GYN Surgical	85.1	87.7	91.6
Skeletal Health	0.7	0.6	0.6
Medical Aesthetics	4.1	91.4	108.1
	$ 376.0	$ 463.1	$ 480.3
Capital expenditures:			
Diagnostics	$ 110.7	$ 59.2	$ 57.7
Breast Health	22.4	18.3	14.8
GYN Surgical	17.9	15.7	13.1
Skeletal Health	0.2	1.2	3.3
Medical Aesthetics	1.4	7.0	9.4
Corporate	3.8	7.7	7.3
	$ 156.4	$ 109.1	$ 105.6
Identifiable assets:			
Diagnostics	$ 2,161.4	$ 2,276.6	$ 2,442.9
Breast Health	1,200.9	1,127.8	972.4
GYN Surgical	1,438.7	1,328.6	1,414.9
Skeletal Health	38.9	27.3	30.3
Medical Aesthetics	—	159.3	913.3
Corporate	2,355.9	1,522.5	1,457.1
	$ 7,195.8	$ 6,442.1	$ 7,230.9

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 26, 2020	September 28, 2019	September 29, 2018
United States	75.8 %	75.3 %	75.1 %
Europe	15.1 %	11.8 %	11.7 %
Asia-Pacific	6.0 %	8.5 %	8.6 %
Rest of world	3.1 %	4.4 %	4.6 %
	100.0 %	100.0 %	100.0 %

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

	September 26, 2020	September 28, 2019	September 29, 2018
United States	$ 383.0	$ 355.5	$ 366.5
Europe	77.5	64.4	62.0
Costa Rica	20.8	33.0	30.9
Rest of world	10.2	18.0	18.8
	$ 491.5	$ 470.9	$ 478.2

17. Accrued Expenses and Other Long-Term Liabilities

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

	September 26, 2020	September 28, 2019
Accrued Expenses		
Compensation and employee benefits	$ 262.7	$ 223.4
Income and other taxes	125.3	56.1
Operating leases	23.5	—
Accrued interest	22.1	22.6
Other	114.0	128.8
	$ 547.6	$ 430.9

	September 26, 2020	September 28, 2019
Other Long-Term Liabilities		
Reserve for income tax uncertainties	$ 103.7	$ 106.8
Contingent consideration	81.8	—
Operating leases	65.6	—
Interest rate swap	23.0	—
Pension liabilities	11.1	10.2
Accrued lease obligation—long-term	—	33.7
Other	18.0	11.7
	$ 303.2	$ 162.4

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 26, 2020 and September 28, 2019, the Company's pension liability was $10.9 million and $10.0 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 26, 2020**	**September 28, 2019**	**September 29, 2018**
Benefit obligation at beginning of year	$ (10.0)	$ (9.7)	$ (9.9)
Service cost	—	—	—
Interest cost	(0.1)	(0.2)	(0.2)
Plan participants' contributions	—	—	—
Actuarial gain (loss)	(0.5)	(1.0)	(0.1)
Foreign exchange gain	(0.7)	0.6	0.2
Benefits paid	0.4	0.3	0.3
Benefit obligation at end of year	(10.9)	(10.0)	(9.7)
Plan assets	—	—	—
Benefit obligation at end of year	$ (10.9)	$ (10.0)	$ (9.7)

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 26, 2020**	**September 28, 2019**	**September 29, 2018**
Service cost	$ —	$ —	$ —
Interest cost	0.1	0.2	0.2
Expected return on plan assets	—	—	—
Amortization of prior service cost	—	—	—
Recognized net actuarial gain	0.2	0.1	0.1
Net periodic benefit cost	$ 0.3	$ 0.3	$ 0.3

Weighted-Average Net Periodic Benefit Cost Assumptions	**2020**	**2019**	**2018**
Discount rate	0.80 %	1.10 %	1.95 %
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 $10.9 million and $10.0 million at September 26, 2020 and September 28, 2019, respectively, and the accumulated benefit obligation for the German Pension Benefits was $10.9 million and $10.0 million at September 26, 2020 and September 28, 2019, 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 26, 2020 and September 28, 2019, respectively.

The table below reflects the total Pension Benefits expected to be paid for the German Pension Benefits each fiscal year as of September 26, 2020:

2021	$	0.4
2022	$	0.4
2023	$	0.4
2024	$	0.4
2025	$	0.4
2026 to 2030	$	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 2020, 2019 and 2018. Additionally, the Company has Swiss pension plans, which were insignificant in fiscal 2020, 2019, and 2018.

19. Quarterly Statement of Operations Information (Unaudited)

The following table presents a summary of quarterly results of operations for fiscal 2020 and 2019:

	2020			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenue	$ 850.5	$ 756.1	$ 822.9	$ 1,347.0
Gross profit	433.8	395.8	466.1	931.8
Net income attributable to Hologic (1)	386.1	96.3	137.9	495.0
Diluted net income per common share	$ 1.43	$ 0.36	$ 0.53	$ 1.88

	2019			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenue	$ 830.7	$ 818.4	$ 852.4	$ 865.8
Gross profit	$ 434.1	$ 42.4	$ 444.8	$ 249.5
Net income (loss) (2)	$ 98.6	$ (272.6)	$ 93.9	$ (123.5)
Diluted net income (loss) per common share	$ 0.36	$ (1.01)	$ 0.35	$ (0.46)

(1) Net income in the first quarter of fiscal 2020 included an intangible assets and equipment charge of $ 30.2 million due to classifying the Medical Aesthetics business as assets held-for-sale. Net income also included a discrete tax benefit related to the disposition of this business of $312.2 million related to its outside basis difference.

(2) Net loss in the second quarter of fiscal 2019 included intangible asset and equipment impairment charges of $ 443.8 million. Net loss in the fourth quarter of fiscal 2019 included intangible asset and equipment impairment charges of $241.6 million.