HOLOGIC INC
Form 10-K
November 19, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended: September 26, 2015

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	Name of Each Exchange on which Registered
Common Stock, $.01 par value	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ý 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 ý

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 ý No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ý No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements

incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See 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	ý	Accelerated filer	¨
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.) Yes ¨ No ý

The aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant as of March 28, 2015 was $9,098,955,240 based on the price of the last reported sale on Nasdaq Global Select Market on that date.

As of November 13, 2015, 282,905,150 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, 2015 are incorporated into Part III (Items 10, 11, 12, 13 and 14) of this Annual Report on Form 10-K where indicated.

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For the Fiscal Year Ended September 26, 2015

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this report are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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 include, but are not limited to, statements regarding:

- the effect of the continuing worldwide macroeconomic uncertainty on our business and results of operations;
- the coverage and reimbursement decisions of third-party payors and the guidelines, recommendations, and studies published by various organizations relating to the use of our products and treatments;
- the uncertainty of the impact of cost containment efforts and federal healthcare reform legislation on our business and results of operations;
- the ability to successfully manage ongoing organizational and strategic changes, including our ability to attract, motivate and retain key employees;
- the impact and anticipated benefits of completed acquisitions and acquisitions we may complete in the future;
- the ability to consolidate certain of our manufacturing and other operations on a timely basis and within budget, without disrupting our business and to achieve anticipated cost synergies related to such actions;
- our goal of expanding our market positions;
- the development of new competitive technologies and products;
- regulatory approval and clearances for our products;
- production schedules for our products;
- the anticipated development of our markets and the success of our products in these markets;
- the anticipated performance and benefits of our products;
- business strategies;
- estimated asset and liability values;
- the impact and costs and expenses of any litigation we may be subject to now or in the future;
- our compliance with covenants contained in the terms of our indebtedness;
- anticipated trends relating to our financial condition or results of operations, including the impact of interest rates and foreign currency exchange fluctuations; and
- our capital resources and the adequacy thereof.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expe "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this report. Except as otherwise required by law, we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statement contained in this report to reflect any change in our expectations or any change in events, conditions or circumstances on which any of our forward-looking statements are based. Factors that could cause or contribute to differences in our future financial results include the cautionary statements set forth herein and in our other filings with the Securities and Exchange Commission, or 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: 3D, 3D Mammography, Affirm, Aptima, Aptima Combo 2, ATEC, Celero, Cervista, Contura, C-View, Cytyc, Dimensions, DirectRay, Discovery, Eviva, Fluoroscan, Genius, Gen-Probe, Healthcome, Horizon, Interlace, Invader, MultiCare, MyoSure, NovaSure, Panther, PreservCyt, Progensa, SecurView, Selenia, StereoLoc, TCT, ThinPrep,

Tigris, TLI IQ, and TMA.

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PART I

Item 1. Business

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. The Company operates in four segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health. 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 offer a wide range of diagnostic products which are used primarily to aid in the diagnosis of human diseases and screen donated human blood and plasma. Our primary diagnostics products include our Aptima family of assays, which run on our advanced instrumentation systems (Panther and Tigris), our ThinPrep system, the Rapid Fetal Fibronectin Test and our Procleix blood screening assays. The Aptima family of assays is used to detect the infectious microorganisms that cause the common sexually transmitted diseases, or STDs, chlamydia and gonorrhea, certain high-risk strains of human papillomavirus, or HPV, and Trichomonas vaginalis, the parasite that causes trichomoniasis. 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 blood screening, we develop and manufacture the Procleix family of assays, which are used to detect various infectious diseases. These blood screening products are marketed worldwide by our blood screening collaborator, Grifols S.A., or Grifols, under Grifols' trademarks.

Our Breast Health products include a broad portfolio of breast imaging and related products and accessories, including digital mammography systems, computer-aided detection, or CAD, for mammography and minimally invasive breast biopsy devices, breast biopsy site markers, and breast biopsy guidance systems. Our most advanced breast imaging platform, Dimensions, utilizes 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.

Our GYN Surgical products include our NovaSure Endometrial Ablation System and our MyoSure Hysteroscopic Tissue Removal System. The NovaSure system involves a trans-cervical procedure for the treatment of abnormal uterine bleeding. The MyoSure system is a tissue removal device that is designed to provide incision-less removal of fibroids, polyps, and other pathology within the uterus.

Our Skeletal Health segment offers Discovery and Horizon X-ray bone densitometers that assess the bone density of fracture sites; and mini C-arm imaging systems that assist in performing minimally invasive surgical procedures on a patient's extremities, such as the hand, wrist, knee, foot, and ankle.

Available Information

Our Internet website address is http://www.hologic.com. Through our website, we make available, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as well as proxy statements, and, from time to time, other documents as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or 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 (http://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.

Further 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 and Compliance.” 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.

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You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also 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 http://www.sec.gov.

Products

We view our operations and manage our business in four principal reporting segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health. Financial information concerning these segments is provided in Note 14 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

Aptima Family of Assays

Our Aptima family of assays includes the Aptima Combo 2 assay for the simultaneous detection of Chlamydia trachomatis and Neisseria gonorrhoeae, the infectious microorganisms that cause chlamydia and gonorrhea, respectively, the standalone Aptima CT and Aptima GC assays for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae, respectively, the Aptima HPV assay for the detection of 14 sub-types of high-risk HPV associated with cervical cancer, the Aptima HPV 16 18/45 Genotype assay and the Aptima Trichomonas assay for the detection of Trichomonas vaginalis, the parasite that causes trichomoniasis. Our Aptima products integrate various proprietary 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 refined 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 the use of a "capture probe" that attaches 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 the sample tube, while the remainder of the sample is washed away and removed. When used in conjunction with our patented amplification methods, 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 produce millions of copies of the target nucleic acid sequences that are present in samples in small numbers. These copies can then be detected using DNA 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 patented 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-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.

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Procleix Family of Assays for Blood Screening

We develop and manufacture the Procleix family of assays, which are marketed and sold worldwide by Grifols, our blood screening collaborator, under Grifols' trademarks. The Procleix family of assays includes the Ultrio and Ultrio Plus assays which simultaneously detect HIV type-1, or HIV-1, the hepatitis C virus, or HCV, and the hepatitis B virus, or HBV, in donated blood, plasma, organs and tissues, the Ultrio Elite assay which simultaneously detects HIV-1, HIV type-2, or HIV-2, HBV and HCV in donated blood, plasma, organs and tissues, the HEV assay, which detects the hepatitis E Virus in donated blood, plasma, organs and tissues, the WNV assay, which detects West Nile Virus, or WNV, in donated blood, plasma, organs and tissues, and the Parvo/HAV assay, which detects the Parvovirus and hepatitis A virus, or HAV, in donated blood, plasma, organs and tissues.

Instrumentation. We have developed and continue to develop instrumentation and software designed specifically for use with certain of our diagnostic assays, including the Aptima family of assays and the Procleix family of assays. We also provide technical support and instrument 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 diagnostic 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 and Procleix assays, the Panther instrument system, an integrated, fully-automated testing instrument capable of serving both high- 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. In the fourth quarter of fiscal 2014, we also introduced our Tomcat instrument, a fully-automated general purpose instrument designed to ease the strain of pre-analytical sample processing by eliminating the inefficient and error-prone activities associated with manually aliquoting samples.

Invader Chemistry Platform

Our Invader chemistry platform is a DNA probe-based system for highly sensitive detection of specific nucleic acid sequences. It is an accurate and specific method for detecting single-base pair changes, insertions, deletions, gene copy number, infectious agents, and gene expression. Invader reactions can be performed using genomic DNA, amplified RNA, PCR, or real-time PCR products. Our products and clinical diagnostic offerings based upon our Invader chemistry include our Cervista HPV tests and products to assist in the diagnosis of cystic fibrosis, cardiovascular risk and other diseases.

ThinPrep System

The ThinPrep System is the most widely used method for cervical cancer screening in the U.S. If detected in the pre-cancerous stage, most cervical cancer cases are preventable. The ThinPrep System consists of any one or more of the following: the ThinPrep 2000 Processor, ThinPrep 3000 Processor, ThinPrep 5000 Processor, 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. In Europe, where laboratories tend to be smaller and process fewer tests, we also offer a lower throughput imaging device to assist in the detection of cervical cancer.

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).

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Rapid Fetal Fibronectin Test

The Rapid Fetal Fibronectin Test is a patented 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. This test is approved by the FDA for use in assessing the risk of pre-term birth. The test utilizes a single-use, disposable cassette and is analyzed on our patented instrument, the TLI IQ System.

Virology and Infectious Disease Products

In virology, NAT assays can be used to detect viral DNA or RNA in a patient sample. These tests can be qualitative, meaning that the tests simply provide a "yes-no" answer for the presence or absence of the virus, or quantitative, meaning that the test determines the quantity of virus in the patient sample. We currently offer Aptima assays for the qualitative detection of HIV-1 and HCV. We are developing quantitative viral load assays for the quantitation of HIV-1, HBV and HCV to run on our Panther instrument system. The first of these quantitative viral load assays, the Aptima HIV Dx Quant assay, was CE-marked in December 2014.

We offer a number of products in the infectious disease space, including a number of assays for the detection of certain respiratory and gastrointestinal diseases. Our infectious disease products include multiplex real-time PCR assays to detect and differentiate various influenza types and viruses, a rapid assay for the direct detection of Streptococcus pyogenes in one hour from a throat swab and an amplified TMA assay to detect the Tuberculosis pathogen.

Breast Health Products

Full Field Digital Mammography System

Our full field digital mammography systems are based on our proprietary DirectRay digital detector, which employs an amorphous selenium photoconductor to directly convert x-ray photons into an electrical signal. No intensifying screens or additional processes are required to capture and convert the x-ray energy, enabling high imaging resolution and contrast sensitivity. Other digital technologies employ an indirect two-step process by first converting x-ray energy into light and then converting the light energy into electrical signals. We believe that digital x-ray imaging technologies that require light conversion may compromise image resolution, lessening detection capability.

Dimensions: Breast Tomosynthesis

Our Dimensions platform includes a mammography gantry incorporating our DirectRay digital detector capable of performing both 2D and tomosynthesis image acquisition and display. When operating in tomosynthesis mode, the 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. We believe by revealing the internal structure of the breast, the more subtle architecture of various types of suspicious lesions may be able to be better interpreted, which may ultimately increase cancer detection and reduce unnecessary patient callbacks. 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.

C-View System

Our C-View product provides 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 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 C-View software is approved for sale throughout the European Economic Area and in other countries recognizing the CE-mark. In May 2013, the FDA approved the use of the C-View software with our Dimensions tomosynthesis system.

Selenia

The Selenia product family is our original full field digital mammography platform. The Selenia product family includes the Selenia base configuration, the Selenia Value (a lower cost alternative to the Selenia base configuration) and a remanufactured Selenia system, each of which offer customers varying performance capabilities.

SecurView Workstation

The images captured by digital mammography systems are typically transmitted electronically for review by a radiologist at a work station. To this end, we developed the SecurViewDX breast imaging softcopy workstation, approved for interpretation of digital mammograms from most vendors as well as images from other diagnostic breast modalities. To complement this product, we also developed the SecurViewRT workstation, a technologist workstation enabling bi-

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directional exchange of electronic communications between the reviewer and the technologist.

CAD (Computer Aided Detection) Systems

We have developed CAD software tools for our mammography products and visualization tools for magnetic resonance imaging, or MRI. 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. We also market an MRI visualization product, which manages the data set from an MRI procedure, designed to improve data workflow for the physician and provide analytical tools to aid in the identification and evaluation of the extent of disease.

Stereotactic Breast Biopsy Systems

We provide clinicians with the flexibility of choosing upright or prone systems for breast biopsy by offering three minimally invasive stereotactic breast biopsy guidance systems, the MultiCare Platinum dedicated, prone breast biopsy table, the StereoLoc II upright attachment, and the Affirm upright attachment. The StereoLoc II attachment is used in conjunction with our Selenia systems. The Affirm upright attachment is employed with our Dimensions 2D and tomosynthesis 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 Eviva and ATEC vacuum-assisted breast biopsy devices.

Breast Biopsy Products

We offer a wide range of minimally invasive products for breast biopsy and biopsy site marking. Our breast biopsy portfolio includes two types of tethered vacuum-assisted breast biopsy products, the Automated Tissue Excision Collection, or ATEC, and Eviva devices. Each tethered device is a disposable biopsy tool that is powered by a console and utilizes our patented 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 Eviva device is used exclusively under stereotactic x-ray guidance. In addition to our ATEC and Eviva products, we also offer the Celero device, a non-tethered (no separate console), vacuum-assisted, spring-loaded, disposable core biopsy device which is used exclusively under ultrasound-guidance. All of our breast biopsy devices have been designed to accommodate a broad spectrum of patients as well as hard-to-reach lesions in the axilla, near the chest wall, near implants or behind the nipple.

GYN Surgical Products

NovaSure

The NovaSure system involves a minimally-invasive procedure that allows physicians to treat women suffering from abnormal uterine bleeding. The system consists of a disposable device and a controller that delivers radio frequency, or RF, energy to ablate the endometrial lining of the uterus in order to eliminate or reduce the patient’s 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 during the NovaSure procedure. The NovaSure RF Controller generates and delivers the RF energy customized for each patient, monitors several critical treatment and safety parameters, and automatically controls other aspects of the procedure.

The NovaSure system is approved by the FDA to be performed without drug or surgical pre-treatment. Pre-treatment can be time-consuming, expensive and inconvenient for both patients and physicians and can result in uncomfortable or painful side effects and complications. In contrast, the NovaSure procedure is typically performed as an outpatient procedure in the hospital, ambulatory surgery center or physician’s office and often does not require the use of general anesthesia.

MyoSure

The MyoSure system is designed to provide efficient and effective hysteroscopic removal of fibroids located just below the lining of the uterus as well as uterine polyps and other pathology within the uterus. Removal of fibroids can provide effective relief of 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 designed to remove a 3 cm fibroid in less than 10 minutes. 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.

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Skeletal Health Products

Discovery and Horizon X-Ray Bone Densitometers

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 debilitating bone fractures. Osteoporosis is a disease that is most prevalent in post-menopausal women. Our proprietary Discovery x-ray bone densitometers incorporate dual-energy x-ray technology to precisely assess bone density of the most important fracture sites, the spine and hip. Since our commercial introduction of the first bone densitometer employing dual-energy x-ray technology in 1987, we have continually improved upon our technology, and the use of dual-energy x-ray technology has become and remains a leading bone densitometry assessment tool. We offer a range of bone densitometers with various features and options to address the requirements of our diverse customer base. In the fourth quarter of fiscal 2013, we launched our Horizon line of x-ray bone densitometers, which incorporates advanced features and performance characteristics.

Mini C-arm Imaging

We manufacture and distribute Fluoroscan mini C-arm imaging systems. Mini C-arms provide 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 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 2015, 2014, and 2013, no customer accounted for more than 10% of our consolidated revenues. In fiscal 2015, 2014, and 2013, revenues under our blood screening collaboration agreement, which is currently with Grifols, accounted for 20.9%, 18.8% and 16.6% of our Diagnostics segment revenue, respectively. No other customer accounted for more than 10% of our revenues in any other business segment in fiscal 2015, 2014, or 2013. In fiscal 2015, 2014, and 2013, international revenues accounted for 25.4%, 26.4% and 26.1% of our product sales, respectively. See Note 14 to our consolidated financial statements contained in Item 15 of this Annual Report for geographical information.

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. A critical element of our strategy in the U.S. 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 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 radiologists and breast surgeons. Our U.S. sales efforts 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 are marketed and sold through a combination of a direct sales force and a network of distributors. We maintain direct sales operations in Canada, Europe, Australia and China.

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 typically last for twelve months and cover only parts and components. We also offer service contracts that generally last one to five 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. Internationally, we primarily use distributors, sales representatives and third parties to provide maintenance service for our products.

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 new industry standards or changing technology. We can give no assurance that we will be able to compete successfully with existing or new competitors.

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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.

We believe that our Rapid Fetal Fibronectin Test is currently the only approved 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. 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 ultrasound to diagnose the likelihood of pre-term birth and may choose these techniques rather than use 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 diagnostic tests.

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 tests compete against BD and Roche Diagnostics Corporation, or Roche, and our Aptima HPV and Cervista HPV tests compete with tests marketed by Qiagen and Roche.

In the market for blood screening products, our primary competitor is Roche. We also compete with assays developed internally by blood screening centers and laboratories based on PCR technology. In the future, our blood screening products may compete with viral inactivation or reduction technologies and blood substitutes.

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, Agfa-Gevaert N.V., or Agfa, Carestream Health, Inc., FUJIFILM Holdings Corporation, or Fuji, I.M.S., and Toshiba Corporation. In the U.S., our full field 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 received FDA approval in September 2014 for its breast tomosynthesis system, and Siemens received FDA approval for its tomosynthesis system in April 2015. In addition, we believe that other competitors, including Fuji, 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 Johnson & Johnson, 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.

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Our MyoSure product competes directly with hysteroscopic loop resection, such as Smith & Nephew’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 of 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 high quality and reliable supply. We have established long-term supply contracts with many of our suppliers and in other instances, we have 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, pursuant to a fixed-price contract, is Roche Diagnostics Corporation. In addition, we have a supply and purchase agreement for oligonucleotides for HPV with Roche Molecular Systems, Inc. The parent company of both Roche Diagnostics Corporation and Roche Molecular Systems, Inc. is F. Hoffmann-La Roche Ltd, a direct competitor of our Diagnostics business. We also have a supply agreement with GE Healthcare Bio-Sciences Corp., an affiliate of GE, for membranes used in connection with our ThinPrep product line. GE is a director competitor with our Breast Health and Skeletal Health businesses.

We have sole-source third-party manufacturers for each of our molecular diagnostics instrument product lines. KMC Systems, Inc., or KMC Systems, is the only manufacturer of the Tigris instrument and Stratec Biomedical AG, or Stratec, is the only manufacturer of the Panther instrument. 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 or Stratec. If KMC Systems, Stratec, or any of our other third-party manufacturers 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 products in sufficient quantities, instrument shipments to our customers could be delayed, which would decrease our revenues and harm our competitive position and reputation. Further, because we place orders with our manufacturers based on forecasts of expected demand for our instruments, 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 United States 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” in Item 1A below.

We continually review our operations and facilities in an effort to reduce costs and increase efficiencies. During fiscal 2015, we decided to shut down our Bedford, Massachusetts facility and outsource the manufacturing of certain of our Skeletal Health products to a third party and transfer certain other manufacturing operations for our Breast Health segment to our Danbury, Connecticut and Marlborough, Massachusetts facilities. In addition, research and

development, sales and service support and administrative functions will be moved to Danbury and Marlborough. This full transition is expected to be completed by the end of fiscal 2016. During fiscal 2014, we completed the process of consolidating our Madison, Wisconsin molecular diagnostics operations into our Diagnostics facilities in San Diego, California. During fiscal 2013, we moved our selenium panel coating production line from Germany into our digital detector manufacturing facility in Newark, Delaware, and completed the consolidation of our breast biopsy operations, including manufacturing, research and development and sales support to our Costa Rica manufacturing facility and facilities in Massachusetts. We may experience unexpected problems and expenses associated with our consolidation of operations and facilities that could materially harm

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our business and prospects.

From time to time new regulations are enacted that can affect the content and manufacturing of our products. We continue to evaluate the necessary steps for compliance with regulations as they are enacted. In August 2012, the SEC adopted a new 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 diligence, 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 regulate the use of certain hazardous substances 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.

Backlog

Our backlog as of October 25, 2015 and October 26, 2014 totaled $408.9 million and $377.0 million, respectively. Backlog consists of customer orders for which a delivery schedule within the next twelve months has been specified. Orders included in backlog may be canceled or rescheduled by customers without significant penalty. Backlog as of any particular date should not be relied upon as indicative of our net revenues for any future period.

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 innovative medical technologies and regulatory compliance.

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. Our research and development expenses were $214.9 million, $203.2 million and $197.6 million in fiscal 2015, 2014, and 2013, respectively.

Patents and Proprietary Rights

We rely primarily on a combination of trade secrets, patents, copyrights 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 the enhancement of existing products, reliance upon trade secrets and unpatented proprietary know-how and the development of new 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.

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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 issue 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. Unauthorized third parties may infringe 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, 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 thus allowing third parties to utilize certain of our 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 12 to our consolidated financial statements entitled “Litigation and Related Matters,” and we may be notified in the future of claims that we may be infringing intellectual property rights possessed by third-parties. In connection with any such litigation or if any claims are asserted against us or our products, 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 by a third-party may require us to remove the infringing product from the market or to design around the patented technology, potentially resulting in a less acceptable product.

Regulatory and Reimbursement

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 3 classes based on risk. The FDA generally must clear the commercial sale of new medical devices in Classes II and III. Commercial sales of our Class II and 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 application, or PMA (Class III). Our Class I medical devices must follow Hologic’s internal Quality System processes prior to commercialization. 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. The PMA procedure involves a complex and lengthy testing and review process by the FDA and may require several years to obtain. We may need to first obtain an investigational device exemption, 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 grant a PMA only if after evaluating clinical data it finds that the safety and effectiveness of the product has been sufficiently demonstrated. This approval may require 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 and Cervista HPV tests 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.

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Our blood screening products are subject to extensive pre- and post-market regulation as biologics by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising and promotion of the products under the FD&C Act and the Public Health Service Act, and by comparable agencies in most foreign countries. The process required by the FDA before a biologic may be marketed in the U.S. generally involves the completion of pre-clinical testing; the submission of an investigational new drug application which must become effective before clinical trials may begin; and the performance of adequate and well controlled human clinical trials to establish the safety and effectiveness of the biologic's proposed intended use.

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 additional 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 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, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the Health Information Technology for Economic and Clinical Health Act, or HITECH Act; 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, 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, 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.

In 2012, the European Commission proposed two new regulations, one each for medical devices and In-vitro Diagnostics (IVD). The adoption of these regulations may impact our international operations through a broadened scope of medical device and IVD oversight and/or regulatory reach. Compliance with the new European Commission regulations, if and when adopted, may impose additional administrative and financial burdens on us.

Federal, state and foreign regulations regarding the manufacture and sale of medical devices and pharmaceuticals are subject to future change. We cannot predict what impact, if any, such changes might have on our business.

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 caption "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 demand for our products and procedures, and the 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

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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 and reimbursement for patients with private insurance is dependent on the individual private payor's decisions and may not follow the policies and rates established by CMS. 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 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 appropriate reimbursement for our products and services from private and governmental third-party payors is critical to the success of medical technology companies because it affects which products customers purchase and the prices they are willing to pay. Reimbursement and coverage varies 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 legislative or administrative reforms to the reimbursement system in the United States and other countries in a manner that significantly reduces reimbursement for procedures using our medical 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.

Employees

As of September 26, 2015, we had approximately 5,290 full-time employees, including 1,483 in manufacturing operations, 806 in research and development, 2,390 in marketing, sales and support services, and 611 in general administration. The non-management employees of our Hitec-Imaging subsidiary located in Germany are represented by a union. Hitec-Imaging's 66 non-management German employees were subject to collective bargaining agreements negotiated on a national and regional basis between Unternehmens-Verband Südôstliches Westfalen e.V., the Employers Association of North Rhine-Westphalia, and the German Metal Workers Union, IndustrieGewerkschaft Metall. 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. We expect continuing fluctuations in our manufacture and shipment of blood screening products and instruments to our blood screening collaborator, Grifols, which vary each period based on Grifols' inventory levels and supply chain needs. 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 fiscal fourth quarter, typically have had lower order rates internationally for most of our products.

Item 1A. Risk Factors

This report contains forward-looking information that involves risks and uncertainties, including statements regarding our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed herein. Other risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect us. Factors that could cause or contribute to such differences include those discussed below, as well as those discussed elsewhere in this report. The cautionary statements made under the heading "Special Note Regarding Forward-Looking Statements" and elsewhere in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report.

Risks Relating to our Business

Our long-term success will depend upon our ability to successfully develop and commercialize new products and treatments and enhance our existing products and treatments.

Our growth potential depends in large part on our ability to identify and develop new products or new indications for or enhancements of existing products that address unmet medical needs and receive reimbursement from payors, either through internal research and development or through collaborations, acquisitions, joint ventures or licensing or other arrangements with third parties. However, balancing current growth and investment for the future remains a challenge. The development of new products and enhancement of existing products requires significant investment in research and development, clinical trials

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and regulatory approvals. Our ongoing investments in new product introductions and in research and development for new products and existing product enhancements could exceed corresponding sales growth. This could produce higher costs without a proportional increase in revenues.

Additionally, 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 approvals and reimbursement in the United States and abroad, manufacture products in a cost-effective manner, obtain appropriate intellectual property protection for our products, gain and maintain market approval of our products and access capital. There can be no assurance 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. If we are unable to develop and launch new products and enhanced products, our ability to maintain or expand our market position in the markets in which we participate may be materially adversely impacted.

We will likely continue to incur significant research and development expenses, which may reduce our profitability.

Historically, we have incurred significant costs in connection with the development and improvement of our products and technologies. We expect that research and development expenditures will remain high as we seek to expand our product offerings and continue to develop and improve products and technologies. As a result, we will need to continue to generate significant revenues to maintain current levels of profitability. We may not be able to generate sufficient revenues to maintain current levels of profitability in the future.

International expansion is a key component of our growth strategy, although our international operations and foreign acquisitions expose us to additional operational challenges that we might not otherwise face.

We are focused on international expansion as a key component of our growth strategy and have identified specific areas of opportunity in various international markets. In fiscal 2015, 24.0% of our revenue came from outside of the U.S. If we fail to capitalize in the opportunities we have identified, our future growth may be materially adversely affected.

In addition, even if we do succeed in our plans to grow internationally, our future and existing international operations may subject us to a number of additional risks and expenses. Any of these risks or expenses could harm our operating results. These risks and expenses include:

- difficulties in developing staffing and simultaneously managing operations in multiple locations as a result of, among other things, distance, language and cultural differences;
- protectionist laws and business practices that favor local companies;
- difficulties in the collection of trade accounts receivable;
- difficulties and expenses related to implementing internal control 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 favorable third-party reimbursements;
- the inability to obtain required regulatory approvals;
- governmental currency controls;
- multiple, conflicting and changing government laws and regulations (including, among other things antitrust and tax requirements);
- operation in parts of the world where strict compliance with anti-bribery laws may conflict with local customs and practices;
- political and economic changes and disruptions, export/import controls and tariff regulations;
- the inability to effectively obtain or enforce intellectual property rights, reduced protection for intellectual property rights in some countries, and otherwise protect against clone or “knock off” products; and
- the lack of ability to enforce non-compete agreements with former owners of acquired businesses competing with us in China and other foreign countries.

Our global operations are required to comply with the FCPA, Chinese anti-corruption and similar anti-bribery laws in other jurisdictions and with U.S. and foreign export control, trade embargo and customs laws. If we fail to comply with any of these laws, we could suffer civil and criminal sanctions.

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Our China operations are subject to national, regional and local regulations. 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.

Our future success depends on the continued services of key personnel.

We constantly monitor the dynamics of the economy, the healthcare industry and the markets in which we compete; and we continue to assess our key personnel that we believe are essential to our long-term success. Over the last two years, we have effected a leadership change and have made significant organizational and strategic changes in connection therewith. 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.

Moreover, in our industry, there is substantial competition for key personnel in the regions in which we operate and we may face increased competition for such employees. 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. Our success also depends upon our ability to attract and retain other qualified managerial and technical personnel. Competition for such personnel is intense. We may not be able to attract and retain personnel necessary for the development of our business.

Security breaches and other disruptions could compromise our information, expose us to liability and harm our reputation and business.

In the ordinary course of our business we collect and store sensitive data, including intellectual property, personal information, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees in our data centers and on our networks. The secure maintenance and transmission of this information is critical to our operations and business strategy. We rely on commercially available systems, software, tools and monitoring to provide security for processing, transmission and storage of confidential information. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate personal or confidential business information. In addition, an associate, contractor, or other third-party with whom we do business may attempt to circumvent our security measures in order to obtain such information, and may purposefully or inadvertently cause a breach involving such information. Any such compromise of our data security and access, public disclosure, or loss of personal or confidential business information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations, damage our reputation and customers' willingness to transact business with us, and subject us to additional costs and liabilities any of which could adversely affect our business. Although we have experienced occasional, actual or attempted breaches of our computer systems, to date none of these breaches has had a material effect on our business, operations or reputation.

Our business could be harmed if our products contain undetected errors or defects or do not meet applicable specifications.

We are continuously developing new products and improving our existing products. Our existing and newly introduced products can contain undetected errors or defects. In addition, these products may not meet their performance specifications under all conditions or for all applications. If, despite internal testing and testing by customers, any of our products contain errors or defects or fail to meet applicable specifications, then we may be required to enhance or improve those products or technologies. We may not be able to do so on a timely basis, if at all, and may only be able to do so at considerable expense. In addition, any significant reliability problems could result in adverse customer reaction, negative publicity, mandatory or voluntary recalls or legal claims and could harm our business and prospects.

Our products may be subject to recalls even after receiving regulatory clearance or approval, which could harm our reputation, business and prospects.

The FDA and similar governmental bodies in other countries have the authority to require the recall of medical products in the event of material deficiencies or defects in design or manufacture. A government mandated or

voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. Any recall could divert managerial and financial resources, be difficult and costly to correct, result in the suspension of sales of certain of our products, harm our reputation and the reputation of our products and adversely affect our business and prospects.

Our inability to obtain, or any delay in obtaining, any necessary U.S. or foreign regulatory clearances or approvals for our newly developed products and treatments or product enhancements could harm our business and prospects.

Our products and treatments are subject to a high level of regulatory oversight. Our inability to obtain, or any delay in obtaining, any necessary U.S. or foreign regulatory clearances or approvals for our newly developed products or product

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enhancements could harm our business and prospects. 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 or modified.

Most medical devices cannot be marketed in the U.S. without 510(k) clearance or premarket 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.

Medical devices sold in the U.S. must also be manufactured in compliance with FDA Good Manufacturing Practices, which regulate the design, manufacture, packing, storage and installation of medical devices. Moreover, medical devices are required to comply with FDA regulations relating to investigational research and labeling. 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.

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. In 2012, the European Commission proposed two new regulations, one each for medical devices and In-vitro Diagnostics (IVD). The adoption of these regulations may impact our international operations through a broadened scope of medical device and IVD oversight and/or regulatory reach. Compliance with the new European Commission regulations, if and when adopted, may impose additional administrative and financial burdens on us.

The continuing worldwide macroeconomic uncertainty may adversely affect our business and prospects.

Market acceptance of our medical products in the U.S. and other countries is dependent upon the medical equipment purchasing and procurement practices of our customers, patient demand for our products and procedures and the reimbursement of patients' medical expenses by government healthcare programs and third-party payors. The continuing uncertainty surrounding world financial markets and continuing weak worldwide macroeconomic conditions have caused and may continue to cause the purchasers of medical equipment to decrease their medical equipment purchasing and procurement activities. Economic uncertainty as well as increasing health insurance premiums and co-payments may continue to result in cost-conscious consumers making fewer elective trips to their physicians and specialists, which in turn would adversely affect demand for our products and procedures. Job losses or slow improvement in the unemployment rate in the U.S. as a result of current macroeconomic conditions may result in a smaller percentage of our patients being covered by an employer health group and a larger percentage being covered by lower paying Medicare and Medicaid programs. Furthermore, 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 adversely affect sales of our products. If the current adverse macroeconomic conditions continue, our business and prospects may be negatively impacted.

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

Sales and market acceptance of our medical products and the treatments facilitated by our products is dependent upon the coverage decisions and reimbursement policies established by government healthcare programs and private health insurers. The ability of customers to obtain appropriate reimbursement for their products and services from private and governmental third-party payors is critical to the success of medical technology companies because it affects 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 reimbursement approval is obtained from private and governmental third-party payors. Further legislative or administrative reforms to the reimbursement systems in the United States and other countries in a manner that significantly reduces reimbursement for procedures using our medical 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.

Healthcare policy changes, including healthcare reform legislation and the uncertainty surrounding the implementation of any such legislation, could harm our business and prospects.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, "the Healthcare Reform Act") was enacted into law in the United States in March 2010. As a U.S. headquartered company with significant sales in the United States, the medical device tax included in this law has

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materially affected us. The law imposed on medical device manufacturers a 2.3 percent excise tax on U.S. sales of Class I, II and III medical devices beginning in January 2013. We expect that this excise tax will continue to apply to the majority, if not all, of our products sold in the U.S. In addition, the judgments we make regarding which of our products are subject to the excise tax based on our interpretations of the law, related Internal Revenue Service, or IRS, regulations and the underlying factors used to calculate the amount of tax due on the sale of such products could differ from the judgments made by the IRS, resulting in additional charges to our results of operations. Our U.S. product revenues represented 74.6% and 73.6% of our net product revenues for the years ended September 26, 2015 and September 27, 2014, respectively. The Company incurred $23.6 million and $21.9 million of excise tax expense related to the domestic sales of its medical device products for the years ended September 26, 2015 and September 27, 2014, respectively.

The law also includes regulatory mandates and other measures designed to constrain medical costs, as well as 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.

Compliance with this healthcare legislation, including with these reporting requirements and the excise tax, has imposed significant additional administrative and financial burdens on us. Various healthcare reform proposals have also emerged at the state level in the U.S. The Healthcare Reform Act and these proposals could reduce medical procedure volumes and impact the demand for our products or the prices at which we sell our products. These reforms include a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. In addition, the excise tax has increased our costs of doing business. The impact of this healthcare reform legislation, and practices including price regulation, competitive pricing, comparative effectiveness of therapies, technology assessments, and managed care arrangements could harm our business and prospects, results of operations and/or financial condition. Healthcare reform proposals and medical cost containment measures in the U.S. and in many foreign countries could:

- limit the use of our products and treatments;
- reduce reimbursement available for such use;
- further tax the sale or use of our products;
- adversely affect the use of new therapies for which our products may be targeted; and
- further increase the administrative and financial burden of compliance.

These reforms, cost containment measures and new taxes, including the uncertainty in the medical community regarding their nature and effect, could also have an adverse effect on our customers' purchasing decisions regarding our products and treatments and could harm our business, results of operations, financial condition and prospects. We cannot predict the specific healthcare programs and regulations that will be ultimately implemented by regional and national governments globally. However, any changes that lower reimbursements for our products and/or procedures using our products, reduce medical procedure volumes or increase cost containment pressures on us or others in the healthcare sector could adversely affect our business and results of operations.

We operate in a highly regulated industry, and changes in healthcare-related laws and regulations could adversely affect our revenues and profitability.

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 treatments 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 and treatments to market,

which could increase our costs of doing business, adversely affect the future permitted uses of approved products or treatments, or otherwise adversely affect the market for our products and treatments; and

- new laws, regulations and judicial decisions affecting pricing or marketing practices.

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We anticipate that governmental authorities will continue to scrutinize the healthcare industry closely and that additional regulation by governmental authorities may cause increased compliance costs, exposure to litigation and other adverse effects to our 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. Recommendations of government agencies or these other groups/organizations may relate to such matters as usage, cost-effectiveness, and use of related therapies. Organizations like these have in the past made recommendations about our products and those of our competitors. Recommendations, guidelines or studies that are followed by healthcare providers and insurers 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 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. 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.

Consolidation in the healthcare industry could lead to increased demands for price concessions or the exclusion of some suppliers from certain of our significant market segments, which could harm our business and prospects.

The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry, including with respect to hospitals and clinical laboratories. This consolidation has resulted in greater pricing pressures, decreased average selling prices, and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to consolidate purchasing decisions for some of our hospital customers. We expect that market demand, government regulation, third-party reimbursement policies, government contracting requirements, and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers and competitors, which may reduce competition and continue to exert further downward pressure on the prices of our products and adversely impact our business, financial condition or results of operations. In particular, we are dependent upon a relatively small number of large clinical laboratory customers in the U.S. for a significant portion of our sales of diagnostics products. Due in part to a trend toward consolidation of clinical laboratories in recent years and the relative size of the largest U.S. laboratories, it is likely that a significant portion of these sales will continue to be concentrated among a relatively small number of large clinical laboratories.

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. In particular, any failure by us to successfully maintain our blood screening collaboration could have a material adverse effect on our business.

With respect to certain of our products we have relied, to a significant extent, on corporate collaborators for funding development and marketing as well as distribution. For example, in our Diagnostics business we are dependent on Grifols to distribute the blood screening products we manufacture. Commercial blood screening product sales to Grifols accounted for 20.9% and 18.8% of our Diagnostics segment revenue in fiscal 2015 and 2014, respectively. If our blood screening relationship with Grifols is terminated and not replaced, our revenues could be adversely affected. In addition, we expect to rely on our corporate collaborators for the commercialization of certain products. If any of our corporate collaborators were to breach or terminate its agreement with us or otherwise fail to conduct its collaborative activities successfully and in a timely manner, the development or commercialization and subsequent marketing of the products contemplated by the collaboration could be delayed or terminated. We cannot control the amount and timing of resources our corporate collaborators devote to our programs or potential products.

The continuation of any of these collaboration agreements depends upon their periodic renewal by us and our collaborators. If any of our current collaboration agreements are terminated, or if we are unable to renew those

collaborations on acceptable terms, we may be required to devote additional internal resources to product development or marketing or to terminate some development programs or seek alternative corporate collaborations. In addition, in the event of a dispute under our current or any future collaboration agreements, a court or arbitrator may not rule in our favor and our rights or obligations under an agreement subject to a dispute may be adversely affected, which may have an adverse effect on our business or operating results. Any corporate collaboration may divert management time and resources. In some instances we have entered into corporate collaborations, including alliances and joint ventures, with certain partners or companies that could make it more difficult for us to enter into advantageous business transactions or relationships with others.

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Failing to manage a collaboration effectively, failing to comply with the obligations associated with a collaboration, or entering into a disadvantageous corporate collaboration, could harm our business and prospects.

If we or our contract manufacturers are unable to manufacture our products in sufficient quantities, on a timely basis, at acceptable costs and in compliance with regulatory and quality requirements, our ability to sell our products will be harmed.

The manufacture of many of our products is highly complex and requires precise high quality manufacturing that is difficult to achieve. We have in the past and may in the future experience difficulties in manufacturing our products on a timely basis and in sufficient quantities. These difficulties have primarily related to delays and difficulties associated with ramping up production of newly introduced products and may result in increased delivery lead-times and increased costs of manufacturing these products. In addition, production of these newer products may require the development of new manufacturing technologies and expertise, which we may be unable to develop. Our failure, including the failure of our contract manufacturers, to achieve and maintain the required high manufacturing standards could result in further delays or failures in product testing or delivery, cost overruns, product recalls or withdrawals, increased warranty costs or other problems that could harm our business and prospects.

In determining the required quantities of our products and the manufacturing schedule, we must make significant judgments and estimates based on historical experience, inventory levels, current market trends and other related factors. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amounts of products we and our distributors require, which could harm our business and results of operations.

Blood screening, medical diagnostic and surgical device products are regulated by the FDA as well as other foreign medical regulatory bodies. In some cases, such as in the U.S. and the EU, certain products may also require individual lot release testing. Maintaining compliance with multiple regulators, and multiple centers within the FDA, adds complexity and cost to our manufacturing processes. In addition, 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.

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

We and our contract manufacturers manufacture our products at a limited number of different facilities located in the United States 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. Our manufacturing facilities and those of our contract manufacturers 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.

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. Anti-kickback and false claims laws prescribe civil and criminal penalties (including fines) for noncompliance that can be substantial. Similarly, our international operations are subject to the provisions of the FCPA, which prohibits U.S. companies and their representatives from offering, promising, authorizing, or making payments to foreign officials for the purpose of influencing any act or decision of such official in his or her official capacity, inducing the official to do any act in violation of his or her lawful duty, or to secure any improper advantage in 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. In addition to the FCPA, our international operations are also subject to various other international anti-bribery laws such as the UK Anti-Bribery Act. Our policies

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mandate compliance with these anti-bribery laws. However, despite meaningful measures that we undertake to facilitate lawful conduct, which include training and compliance programs and internal control 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. It is possible that our practices might be challenged under federal or state anti-kickback, FCPA or similar laws due to the breadth of the statutory provisions and the absence of extensive guidance regarding compliance. 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.

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

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

- uncertainty of the development of a market for such product or treatment;
- trends relating to, or the introduction or existence of, competing products, technologies or alternative treatments or therapies that may be more effective, safer or easier to use than our products, technologies, treatments or therapies;
- the perception of our products or treatments as compared to other products and treatments;
- recommendation and support for the use of our products or treatments by influential customers, such as hospitals, radiological practices, breast surgeons and radiation oncologists 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 or treatment will depend upon the establishment of a reimbursement code or an advantageous reimbursement level for use of the product or treatment. Moreover, even if addressed, such reimbursement codes or levels frequently are not established until after a product or treatment is developed and commercially introduced, which can delay the successful commercialization of a product or treatment. If we are unable to successfully commercialize and create a significant market for our newly developed products and treatments and newly introduced enhancements to our existing products and treatments our business and prospects could be harmed.

Our business may be harmed by prior acquisitions or acquisitions we may complete in the future.

We have acquired a number of businesses, technologies, product lines and products, and may make additional acquisitions in the future. Promising acquisitions are difficult to identify and complete for a number of reasons, including competition among prospective buyers and the need for regulatory, including antitrust, approvals. We may not be able to identify and successfully complete acquisition transactions. Any acquisition we may complete may be made at a substantial premium over the fair value of the net assets of the acquired company. Further, the long-term success of our acquisitions and any additional acquisitions we may complete in the future will depend upon our ability to realize the anticipated benefits from combining the acquired businesses with our business. We may fail to realize anticipated benefits for a number of reasons, including the following:

- problems may arise with our ability to successfully integrate the acquired businesses, which may result in us not operating as effectively and efficiently as expected, and may include:
- diversion of management time, as well as a shift of focus from operating the businesses to issues related to integration and administration or inadequate management resources available for integration activity and oversight;
- failure to retain and motivate key employees;

- failure to successfully oversee international sales efforts and inability to prevent FCPA violations;

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- failure to successfully obtain appropriate regulatory approval or clearance for products under development;
- failure to successfully manage relationships with customers, distributors and suppliers;
- failure of customers to accept new products;
- failure to effectively coordinate sales and marketing efforts;
- failure to combine product offerings and product lines quickly and effectively;
- failure to effectively enhance acquired technology and products or develop new products relating to the acquired businesses;
- potential difficulties and inefficiencies in managing and operating businesses in multiple locations or operating businesses in which we have either limited or no direct experience;
- potential difficulties integrating financial reporting systems;
- potential difficulties in the timely filing of required reports with the SEC; and
- potential difficulties in implementing controls, procedures and policies, including disclosure controls and procedures and internal control over financial reporting, appropriate for a larger public company at companies that, prior to the acquisition of such companies, had lacked such controls, procedures and policies, which may result in ineffective disclosure controls and procedures or material weaknesses in internal control over financial reporting;
- we may not be able to achieve the expected synergies from an acquisition or it may take longer than expected to achieve those synergies;
- an acquisition may result in future impairment charges related to a decline in the fair value of the acquired business as compared to the price we paid for such acquisition;
- an acquisition may involve restructuring operations or reductions in workforce which may result in substantial charges to our operations;
- our current and prospective customers and suppliers may experience uncertainty associated with an acquisition, including with respect to current or future business relationships with us and may attempt to negotiate changes in existing business;
- an acquisition may involve unexpected costs or liabilities, including as a result of pending and future shareholder lawsuits relating to acquisitions or exercise by shareholders of their statutory appraisal rights, or the effects of purchase accounting may be different from our expectations;
- an acquisition may involve significant deferred or contingent payments that may adversely affect our future liquidity or capital resources; and
- the acquired businesses may be adversely affected by future legislative, regulatory, or tax decisions and/or changes as well as other economic, business and/or competitive factors.

Our failure to realize the anticipated benefits from combining acquired businesses could harm our business and prospects.

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 decline, and we may be more vulnerable to economic downturns and competitive pressures. We cannot guarantee that we will be able to finance additional acquisitions or that we will realize any anticipated benefits from acquisitions that we complete.

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 the technology. Similarly, we may lose competitive advantages if we fail to maintain exclusivity under an exclusive license.

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Additionally, the U.S. Supreme Court has issued several recent decisions, the full impact of which is not yet known. For example, in March 2012 in Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc., the Court held that several claims drawn to measuring drug metabolite levels from patient samples and correlating them to drug doses were not patentable subject matter. The decision appears to impact diagnostics patents that merely apply a law of nature via a series of routine steps and has created uncertainty around the patentability of certain biomarker-related method claims. Additionally, in June 2013 in Association for Molecular Pathology v. Myriad Genetics, Inc., the Court held that claims to isolated genomic DNA are not patentable, but claims to complementary DNA, or cDNA, molecules were held to be valid. The effect of the decision on patents for other isolated natural products is uncertain and we may lose competitive advantages should the subject matter of our patents or patents we exclusively license be deemed non-patentable subject matter and we therefore fail to maintain exclusivity to such subject matter as a result.

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 will require access to technologies and materials that may be subject to patents or other intellectual property rights held by third parties. We may need to obtain additional intellectual property rights in order to commercialize our products. We may be unable to obtain such rights on commercially reasonable terms or at all, which could adversely affect our ability to grow our business.

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 and confidentiality procedures to protect our products and technology. Despite these precautions, unauthorized third parties may infringe 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 subject to interference proceedings or similar disputes over the priority of the inventions, 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. In addition, the laws governing patentability and the scope of patent coverage continue to evolve, particularly in the field of biotechnology. As a result, patents might not issue from certain of our patent applications or from applications licensed to us.

We have obtained or applied for corresponding patents and patent applications in several foreign countries for some of our U.S. patents and patent applications. There is a risk that these patent applications will not be granted or that the patent or patent application will not provide significant protection for our products and 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 thus allowing third parties to utilize certain of our technologies.

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, applications may have been filed by third parties that relate to our technology. 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, the effect of the Prometheus Laboratories and Myriad Genetics decisions on patents for other isolated natural products is uncertain and these decisions could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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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 patented 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.

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. For example, in our Diagnostics business we are dependent on Grifols to distribute the blood screening products we manufacture. Commercial blood screening product sales to Grifols accounted for 20.9% and 18.8% of our Diagnostics segment revenue in fiscal 2015 and 2014, respectively. If our blood screening relationship or any of our other strategic relationships are terminated and not replaced, our revenues and/or ability to service our products in the territories serviced by these distributors could be adversely affected. If any of our distribution or marketing agreements are terminated, particularly our blood screening collaboration agreement, or 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. We may not be able to enter into new distribution or marketing agreements on satisfactory terms, or at all. If we fail to enter into acceptable distribution or marketing agreements or 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.

Fluctuations in the exchange rates of European currencies and the other foreign currencies in which we conduct our business, in relation to the U.S. dollar, could harm our business and prospects.

We maintain sales and service offices outside the U.S., have manufacturing facilities in Costa Rica and the United Kingdom, and conduct business worldwide. The expenses of our international offices are denominated in local currencies, except at our Costa Rica subsidiary, where the majority of business is conducted in U.S. dollars. Our foreign sales may be denominated in local currencies, or the U.S. dollar.

Fluctuations in foreign currency exchange rates could affect our revenues, cost of goods and operating margins and could result in exchange losses. In addition, currency devaluation can result in a loss if we hold deposits of that currency. In the last few years we have not hedged foreign currency exposures, however, we have begun to hedge a portion of foreign currency denominated sales in fiscal 2016 although there can be no assurance we will continue to hedge in the future. There is a risk that any hedging activities will not be successful in mitigating our foreign exchange risk exposure and may adversely impact our financial condition and results of operations.

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

Certain of our raw materials, components or subassemblies are purchased from a single-source due to cost, quality, expertise or other considerations. Obtaining alternative sources of supply of these raw materials, components or subassemblies could involve significant delays and other costs and regulatory challenges, and may not be available to us on reasonable terms, if at all. 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 harm our business and prospects. Any disruption of supplies of goods could delay or reduce shipments, which could result

in lost or deferred sales. For example, we have sole-source third-party manufacturers for each of our molecular diagnostics instruments. KMC Systems, Inc., or KMC Systems, is the only manufacturer of the Tigris instrument and Stratec Biomedical AG, or Stratec, is the only manufacturer of the Panther instrument. We have no firm long-term volume commitments with either KMC Systems or Stratec. If KMC Systems, Stratec or any of our other third-party manufacturers 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

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goods in sufficient quantities, then instrument shipments to our customers could be delayed, which would decrease our revenues and harm our competitive position and reputation. Further, because we place orders with our manufacturers based on forecasts of expected demand for our 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. Similarly, we rely on one or a limited number of suppliers for some key raw materials for our products. For example, our current supplier of certain key raw materials for certain of our amplified NAT diagnostic assays, pursuant to a fixed-price contract, is Roche Diagnostics Corporation and we have a supply and purchase agreement for oligonucleotides for HPV with Roche Molecular Systems, Inc. The parent company of both Roche Diagnostics Corporation and Roche Molecular Systems, Inc. is F. Hoffmann-LaRoche Ltd, a direct competitor of our Diagnostics business. We also have a supply agreement with GE Healthcare Bio-Sciences Corp., an affiliate of GE, for membranes used in connection with our ThinPrep product line. GE is a direct competitor with our Breast Health and Skeletal Health businesses.

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, and even if we do the process is expensive and time consuming. If we are required or elect to change contract manufacturers or suppliers, we may lose revenues and our customer relationships may suffer.

We may experience unexpected problems and expenses associated with our planned consolidation of operations and facilities that could materially harm our business and prospects.

We continually review our operations and facilities in an effort to reduce costs and increase efficiencies. To that end, during fiscal 2015, we decided to shut down our Bedford, Massachusetts facility and outsource the manufacturing of certain of our Skeletal Health products to a third party and transfer certain other manufacturing operations for our Breast Health segment to our Danbury, Connecticut and Marlborough, Massachusetts facilities. In addition, research and development, sales and service support and administrative functions will be moved to Danbury and Marlborough. This full transition is expected to be completed by the end of fiscal 2016. Uncertainty is inherent within the consolidation process, and unforeseen circumstances, costs and expenses could offset the anticipated benefits, disrupt operations, including the timely delivery of products and service to customers, and impact product quality, which could materially harm our business and prospects. In addition, we may fail to retain key employees who possess specific knowledge or expertise and who we depend upon for the timely and successful transition, we may not be able to attract a sufficient number of skilled workers at the new locations to handle the additional production and other demands, and the relocation may absorb significant management and key employee attention and resources. If any of these risks materialize, our business, results of operations, financial condition and prospects may be adversely affected.

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

A number of companies have developed, or are expected to develop, products that compete or will compete with our products. In addition, some companies may have significant competitive advantages over us, which may make them more attractive to hospitals, 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.

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 our gross margins. 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.

The current environment of managed care, economically-motivated buyers, consolidation among healthcare providers, increased competition and declining reimbursement rates, together with current global economic conditions and healthcare

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reform measures, may put additional competitive pressure on us, including on our average selling prices, overall procedure rates and market sizes.

If we are unable to compete effectively against existing and future competitors and existing and future alternative products and treatments, our business and prospects could be harmed.

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 a limited number of customers. We have long-term commitments with some of our Diagnostics' customers, but only our collaboration agreement with Grifols results in revenues of more than 10% of our Diagnostics segment's total revenues. Product sales from our blood screening collaboration with Grifols accounted for 20.9% and 18.8% of our Diagnostics segment revenue in fiscal 2015 and 2014, respectively. In fiscal 2015, our blood screening collaboration was largely dependent on three significant customers, The American Red Cross, The Japanese Red Cross and Creative Testing Solutions, although we did not receive any revenues directly from those entities. We anticipate that our operating results in our Diagnostics segment will continue to depend, to a significant extent, upon revenues from a small number of customers. 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.

Our success depends upon our ability to adapt to rapid changes in technology and customer requirements.

The markets for our products have been characterized by rapid technological change, frequent product introductions and evolving customer requirements. These trends will likely continue into the foreseeable future. Our success depends, in part, upon our ability to enhance our existing products, successfully develop new products that meet increasingly challenging customer requirements and gain market acceptance. If we fail to do so our products may be rendered obsolete or uncompetitive by new industry standards or changing technology.

Our results of operations are subject to significant quarterly variation.

Our results of operations have been and may continue to be subject to significant quarterly variation. Our results for a particular quarter may also vary due to a number of factors, including:

- the overall state of healthcare and cost containment efforts;
- the timing and level of reimbursement for our products domestically and internationally;
- the development status and demand for our products;
- the development status and demand for therapies to treat the health concerns addressed by our products and treatments;
- economic conditions in our markets;
- foreign exchange rates;
- the timing of orders;
- the timing of expenditures in anticipation of future sales;
- the mix of products we sell and markets we serve;
- regulatory approval of products;
- the introduction of new products and product enhancements by us or our competitors;
- pricing and other competitive conditions;
- unanticipated expenses;
- complex revenue recognition rules pursuant to U.S. generally accepted accounting principles, which we refer to as U.S. GAAP;
- asset impairments;
- contingent consideration charges;
- restructuring and consolidation charges;
- debt refinancing charges and expenses; and
- seasonality of sales of certain of our products.

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Customers may also cancel or reschedule shipments. Production difficulties could also delay shipments. Any of these factors also could harm our business and prospects.

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 to reflect these legal requirements, 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. In addition, under the federal Health Information Technology for Economic and Clinical Health Act, or HITECH Act, some of our businesses that were previously only indirectly subject to federal HIPAA privacy and security rules became directly subject to such rules because the businesses may be deemed to serve as “business associates” to certain of our customers. In January 2013, the Office for Civil Rights of the Department of Health and Human Services released a final rule implementing the HITECH Act and making certain other changes to HIPAA privacy and security requirements. Compliance with the rule will increase the requirements applicable to some of our businesses. 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.

New regulations related to “conflict minerals” may cause us to incur additional expenses and could limit the supply and increase the cost of certain metals used in manufacturing our products.

In August 2012, the SEC adopted a new 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 diligence, disclose and report whether or not such minerals originate from the Democratic Republic of Congo and other specified countries. The new 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.

We are subject to the risk of product liability claims relating to our products.

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 the filing of 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, which could result in a diversion of management's attention from our business and could adversely affect the perceived safety and efficacy of our products, and could harm our business and prospects.

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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 European Union 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.

We may incur losses in excess of our insurance coverage.

Our insurance coverage includes product liability, property, fire, terrorism and business interruption policies. Our insurance coverage contains policy limits, specifications and exclusions. We believe that our insurance coverage is consistent with general practices within our industry. Nonetheless, we may incur losses of a type for which we are not covered by insurance or which exceed the limits of liability of our insurance policies. In that event, we could experience a significant loss which could have a material adverse impact on our financial condition.

An adverse change in the projected cash flows from our business units or the business climate in which they operate, including the continuation of the current financial and economic uncertainty, could require us to record an impairment charge, which could have an adverse impact on our operating results.

At least annually, we review the carrying value of our goodwill, and for other long-lived assets when indicators of impairment are present, to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment of the value of these assets. Conditions that could indicate impairment and necessitate an evaluation of these assets include, but are not limited to, a significant adverse change in the business climate or the legal or regulatory environment within which we operate. In addition, the deterioration of a company’s market capitalization significantly below its net book value is an indicator of impairment. We assess goodwill for impairment at the reporting unit level and in evaluating the potential impairment of goodwill, we make assumptions regarding the amount and timing of future cash flows, terminal value growth rates and appropriate discount rates.

All of our reporting units passed Step 1 of the goodwill impairment test in fiscal 2015. 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 Step 1 of the goodwill impairment test. Although we believe that we use reasonable methodologies for developing assumptions and estimates underlying the fair value calculations used in our impairment tests, these estimates are uncertain by nature and can vary from actual results. It is possible that the continuation of the current global financial and economic uncertainty could negatively affect our anticipated future cash flows, or the discount rates used to value the cash flows for each reporting unit, to such an extent that we could be required to perform an interim impairment test during fiscal 2016.

Our effective tax rate may fluctuate and we may incur obligations in tax jurisdictions in excess of amounts that have been accrued.

We are subject to income taxes and non-income based taxes in both the U.S. and various foreign jurisdictions. In certain instances, we take certain income tax return positions and provide additional taxes if it is more-likely-than-not that the tax position will not withstand a tax authority's challenge. We are subject to ongoing tax audits in various jurisdictions, and tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly evaluate the likely outcomes of audits to determine the appropriateness of our tax provision and tax reserves. However, we can give no assurance

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that we will accurately predict the audits' outcomes, which could have a material impact on our operating results and financial condition.

Our effective tax rate may be lower or higher than prior years due to numerous factors, including a change in our geographic earnings mix and changes in tax laws or tax rulings. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have a material impact on our business and operating results. In addition, U.S. law makers are considering several U.S. corporate tax reform proposals, including, among others, proposals which could reduce or eliminate U.S. income tax deferrals on unrepatriated foreign earnings and eliminate tax incentives, such as the domestic manufacturing deduction and research credits, in exchange for a lower U.S. statutory tax rate.

Risks Relating to our Indebtedness

We incurred significant indebtedness in order to finance the acquisition of Gen-Probe in fiscal 2012, which may limit our operating flexibility, and could adversely affect our operations and financial results and prevent us from fulfilling our obligations.

As of September 26, 2015, we had approximately $3.72 billion aggregate principal of indebtedness. We also have other contractual obligations and deferred tax liabilities. 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 will reduce the availability of our cash flow to fund working capital, capital expenditures, expansion efforts 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, general corporate purposes or acquisitions.

In addition, the terms of our credit facilities require us to meet certain financial covenants that are customary with these types of credit facilities, which are described in Note 4 "Borrowings and Credit Agreements" in the accompanying notes to the consolidated financial statements included in Item 15 of this Annual Report. Our ability to comply with these covenants may be adversely affected by general economic conditions, industry conditions and other events beyond our control. If we are unable to comply with these covenants, we could default under the credit facilities, which could cause us to be unable to borrow additional amounts under the credit facilities and may result in the acceleration of the maturity of our outstanding indebtedness under the facilities. If the maturities were accelerated, we may not have sufficient funds available for repayment, and if we were unable to make additional borrowings under the facilities, we may not be able to make investments in our business to support our strategy or we may end up in bankruptcy proceedings, or other processes, in which our business would be negatively impacted. In addition, our shareholders could be adversely impacted as shareholder value could decrease to a point of limited return. Each scenario would result in significant negative implications to our liquidity and results of operations.

Further, the terms of our indebtedness contain 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

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- use the proceeds of permitted sales of our assets.

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 senior 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 can give no assurance 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, 2015, approximately $1.66 billion aggregate principal of our indebtedness, which represents the outstanding principal under our Term Loan and Revolver under our Credit Agreement, was subject to floating interest rates. We currently have limited hedging arrangements in place to mitigate the impact of higher interest rates.

Risks Relating to our Common Stock

Future issuances of common stock and hedging activities may depress the trading price of our common stock and our convertible notes.

Any future issuance of equity securities, including the issuance of shares upon conversion of our convertible notes, could dilute the interests of our existing stockholders, including holders who have received shares upon conversion of our convertible notes, and could substantially decrease the trading price of our common stock and our convertible notes. We may issue equity securities in the future for a number of reasons, including to finance our operations and business strategy (including in connection with acquisitions, strategic collaborations or other transactions), to adjust our ratio of debt to equity, to satisfy our obligations upon the exercise of outstanding warrants or options or for other reasons.

In addition, the price of our common stock could also be affected by possible sales of our common stock by investors who view our convertible notes as a more attractive means of equity participation in our company and by hedging or arbitrage trading activity that may develop involving our common stock. The hedging or arbitrage could, in turn, affect the trading price of our convertible notes, or any common stock that note holders receive upon conversion of their notes.

Future sales of our common stock in the public market or the issuance of securities senior to our common stock could adversely affect the trading price of our common stock and the value of our convertible notes and our ability to raise

funds in new securities offerings.

Future sales of our common stock, the perception that such sales could occur or the availability of shares of our common stock or securities convertible into or exercisable for our common stock for future sale could adversely affect the market price of our common stock and the value of our convertible notes prevailing from time to time and could impair our ability to raise capital through future offerings of equity or equity-related securities. In addition, we may issue common stock or equity

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securities senior to our common stock in the future for a number of reasons, including to finance our operations and business strategy, to adjust our ratio of debt to equity, to satisfy our obligations upon the exercise of options or for other reasons.

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 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.

The price of our common stock also may be adversely affected by the amount of common stock issuable upon conversion of our convertible notes. In addition, in recent years the stock market in general and the markets for shares of “high-tech” companies, have 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.

Our previously announced stock repurchase program could affect the price of our common stock and increase volatility and may be suspended or terminated at any time, which may result in a decrease in the trading price of our common stock.

In November 2013, we announced that our Board of Directors authorized the repurchase of up to $250 million of our outstanding common stock over the next three years. Under the stock repurchase program, we are authorized to repurchase, from time-to-time, shares of our outstanding common stock on the open market or in privately negotiated transactions in the U.S. The timing and amount of stock repurchases will be determined based upon our evaluation of market conditions and other factors. The stock repurchase program may be suspended, modified or discontinued at any time, and we have no obligation to repurchase any amount of our common stock under the program. Repurchases pursuant to our stock repurchase program could affect our stock price and increase the volatility of our common stock. The existence of a stock repurchase program could also cause our stock price to be higher than it would be in the absence of such a program and could potentially reduce the market liquidity for our stock. There can be no assurance that any stock repurchases will enhance stockholder value because the market price of our common stock may decline below the levels at which we repurchased shares of common stock. Although our stock repurchase program is intended to enhance long-term stockholder value, short-term stock price fluctuations could reduce the program’s effectiveness. Through September 26, 2015, we had not repurchased any shares of our common stock under this stock repurchase program.

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Our convertible notes may adversely affect our earnings per share.

Any conversion of the convertible notes could cause dilution to our stockholders and to our earnings per share in the event the Company decided to settle such conversion in shares. In addition, because of the type of instrument and our accounting policy for settling the principal in cash, for any period in which we have reported net income, if the average trading price of our common stock for that period exceeds the conversion price of any of our convertible notes, the convertible notes of that class will increase our diluted share count and may result in lower reported diluted earnings per share. Our outstanding convertible notes in the principal amount of $150 million, $500 million and $370 million, respectively, have conversion prices of $23.03, $31.175 and $38.59, respectively.

Item 1B. Unresolved Staff Comments

None.

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Item 2. Properties

We own and lease the real property identified below. 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.

Principal Properties Owned:	Primary Use	Floor Space
Newark, DE (a)	DirectRay digital detector research and development and plate manufacturing operations	164,000 sq. ft.
Warstein, Germany	Hitec-Imaging's manufacturing operations, research and development and administrative functions	201,000 sq. ft.
Londonderry, NH	Manufacturing operations	47,000 sq. ft.
San Diego, CA (b)	Diagnostics headquarters, including research and development, administrative and manufacturing operations	262,000 sq. ft.
San Diego, CA (b)(c)	Diagnostics headquarters, including research and development, administrative and manufacturing operations	290,000 sq. ft.
San Diego, CA (b)	Manufacturing operations for blood screening products	94,000 sq. ft.

Principal Properties Leased:	Primary Use	Floor Space	Lease Expiration (fiscal year)	Renewals
Bedford, MA (d)	Administrative, research and development, and manufacturing operations	207,000 sq. ft.	2022	4, five-yr. periods
Danbury, CT	Manufacturing facility	62,000 sq. ft.	2022	4, five-yr. periods
Danbury, CT	Manufacturing operations and research and development	60,000 sq. ft.	2018	1, five-yr. period
Marlborough, MA	Headquarters, including research and development, manufacturing and distribution operations	216,000 sq. ft.	2019	2, five-yr. periods
Marlborough, MA	Manufacturing operations	146,000 sq. ft.	2019	2, five-yr. periods
Alajuela, Costa Rica	Manufacturing facility	164,000 sq. ft.	2018	2, five-yr. periods
Manchester, England	Manufacturing operations and research and development	66,000 sq. ft.	2035	None

(a) We currently occupy approximately 59,000 square feet of this building, which houses our plate manufacturing facility, including both a Class 1 and a Class 2 clean room. We lease approximately 105,000 square feet of the facility to Siemens under a lease which expires in April 2020.

(b) Subject to a mortgage to secure obligations under our senior secured credit facilities.

(c) We currently occupy approximately 221,000 square feet of this building, with the remaining space available to accommodate future growth.

(d) During fiscal 2015, we decided to shut down our Bedford, Massachusetts facility and outsource the manufacturing of certain of our Skeletal Health products to a third party and transfer certain other manufacturing operations for our Breast Health segment to our Danbury, Connecticut and Marlborough, Massachusetts facilities. In addition, research and development, sales and service support and administrative functions will be moved to Danbury and Marlborough. This transition is expected to be completed by the end of fiscal 2016.

We lease other facilities utilized for office space and manufacturing and distribution operations across the United States, Europe, Canada and China. We also lease several sales and service offices throughout the world.

Item 3. Legal Proceedings

For a discussion of legal matters as of September 26, 2015, please see Note 12 to our consolidated financial statements entitled “Litigation and Related Matters,” which is incorporated by reference into this item.

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Item 4. Mine Safety Disclosures
Not Applicable.

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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.” The following table sets forth the high and low sales prices per share of our common stock, as reported by the Nasdaq Global Select Market.

Fiscal Year Ended September 26, 2015	High	Low
First Quarter	$27.35	$22.70
Second Quarter	33.33	25.60
Third Quarter	38.55	32.12
Fourth Quarter	43.00	35.80
Fiscal Year Ended September 27, 2014	High	Low
First Quarter	$23.07	$19.25
Second Quarter	22.72	19.91
Third Quarter	26.18	20.24
Fourth Quarter	26.75	24.07

Number of Holders. As of November 13, 2015, there were approximately 1,189 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 depositary, 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 our debt instruments also place limits on our ability to issue dividends and repurchase stock.

Recent Sales of Unregistered Securities. We did not sell unregistered equity securities during the fourth quarter of fiscal 2015.

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)	Maximum Number (or Approximate Dollar Value) of Shares That May Yet Be Purchased Under Our Programs (in millions)
June 28, 2015 – July 25, 2015	898	$38.21	—	$250.0
July 26, 2015 – August 22, 2015	1,661	40.95	—	250.0
August 23, 2015 – September 26, 2015	5,122	41.25	—	250.0
Total	7,681	$40.83	—	$250.0

(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 taxing authorities on behalf of our employees. These repurchases of our common stock were to cover employee income tax withholding obligations in connection with the vesting of restricted stock units under our equity incentive plans.

(2) On November 11, 2013, we announced that our Board of Directors authorized the repurchase of up to $250.0 million of our outstanding common stock over a three year period. Through September 26, 2015, we had not

repurchased any shares of our common stock under this program.

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Stock Performance Graph

The following graph compares cumulative total shareholder return on our common stock since September 25, 2010 with the cumulative total return of the Russell 1000 Index and the Standard & Poor's Health Care Supplies Index. This graph assumes the investment of $100 on September 25, 2010 in our common stock, the Russell 1000 Index and the S&P Health Care Supplies Index. Measurement points are the last trading day of each respective fiscal year.

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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 fourth quarter of fiscal 2012, we acquired Gen-Probe Incorporated. In fiscal 2011, we acquired Interlace Medical, Inc., TCT International Co. Ltd., and Beijing Healthcome Technology Company, Ltd. Results of operations for each of these businesses are included in our consolidated financial statements from the dates of acquisition.

	Fiscal Years Ended				
	September 26, 2015 (5)	September 27, 2014 (4)	September 28, 2013 (3)	September 29, 2012 (2)	September 24, 2011 (1)
	(In millions, except per share data)				
Consolidated Statement of Operations Data					
Total revenues	$2,705.0	$2,530.7	$2,492.3	$2,002.6	$1,789.3
Total operating costs and expenses	$2,249.9	$2,251.0	$3,398.5	$1,888.9	$1,414.9
Net income (loss)	$131.6	$17.3	$(1,172.8)	$(73.6)	$157.2
Basic net income (loss) per common share	$0.47	$0.06	$(4.36)	$(0.28)	$0.60
Diluted net income (loss) per common share	$0.45	$0.06	$(4.36)	$(0.28)	$0.59
Consolidated Balance Sheet Data					
Working capital	$322.4	$946.2	$535.8	$901.7	$833.5
Total assets	$7,670.1	$8,414.7	$9,000.8	$10,477.1	$6,008.8
Long-term debt obligations, less current portion (6)	$3,254.3	$4,162.6	$4,254.4	$4,986.3	$1,506.4
Total stockholders' equity	$2,079.2	$2,063.0	$1,941.5	$2,961.0	$2,936.9

(1) Fiscal 2011 total operating costs and expenses include a net gain on the sale of intellectual property of $84.5 million, and included in net income in fiscal 2011 was a debt extinguishment loss of $29.9 million.

(2) Fiscal 2012 total operating costs and expenses include charges for contingent consideration of $119.5 million related to certain of our acquisitions, aggregate restructuring and divestiture charges of $36.6 million and acquisition transaction costs related to the Gen-Probe acquisition of $34.3 million. Included in net loss was a debt extinguishment loss of $42.3 million.

(3) Fiscal 2013 total operating costs and expenses include a goodwill impairment charge of $1.1 billion, which related to our Molecular Diagnostics reporting unit within our Diagnostics reportable segment, contingent consideration of $91.3 million related to certain of our acquisitions, restructuring and divestiture charges of $32.8 million partially offset by a net gain on the sale of intellectual property of $53.9 million.

(4) Fiscal 2014 total operating costs and expenses include restructuring and divestiture charges of $51.7 million and intangible asset impairment charges of $32.2 million.

Fiscal 2015 total operating costs and expenses include restructuring and divestiture charges of $28.5 million.

(5) Included in net income was a debt extinguishment loss of $62.7 million and related transaction costs of $9.3 million.

(6) Long-term obligations are net of unamortized debt discounts of $68.7 million, $121.3 million, $157.1 million, $188.8 million and $236.4 million for fiscal years 2015, 2014, 2013, 2012 and 2011, respectively.

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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 and the information described under the caption “Risk Factors” in Part I, Item 1A 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. We operate in four segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health. 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 offer a wide range of diagnostic products which are used primarily to aid in the diagnosis of human diseases and screen donated human blood and plasma. Our primary diagnostics products include our Aptima family of assays, which run on our advanced instrumentation systems (Panther and Tigris), our ThinPrep system, the Rapid Fetal Fibronectin Test and Procleix blood screening assays. The Aptima family of assays is used to detect the infectious microorganisms that cause the common sexually transmitted diseases, or STDs, chlamydia and gonorrhea, certain high-risk strains of human papillomavirus, or HPV, and Trichomonas vaginalis, the parasite that causes trichomoniasis. 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 blood screening, we develop and manufacture the Procleix family of assays, which are used to detect various infectious diseases. These blood screening products are marketed worldwide by our blood screening collaborator, Grifols S.A., or Grifols, under Grifols' trademarks.

Our Breast Health products include a broad portfolio of breast imaging and related products and accessories, including digital and film-based mammography systems, computer-aided detection, or CAD, for mammography and minimally invasive breast biopsy devices, breast biopsy site markers, breast biopsy guidance systems and breast brachytherapy products. Our most advanced breast imaging platform, Dimensions, utilizes 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 GYN Surgical products include our NovaSure Endometrial Ablation System, or NovaSure, and our MyoSure Hysteroscopic Tissue Removal System, or MyoSure. The NovaSure system involves a trans-cervical procedure for the treatment of abnormal uterine bleeding. The MyoSure system is a tissue removal device that is designed to provide incision-less removal of fibroids, polyps, and other pathology within the uterus.

Our Skeletal Health segment offers Discovery and Horizon X-ray bone densitometers that assess the bone density of fracture sites; and mini C-arm imaging systems that assist in performing minimally invasive surgical procedures on a patient's extremities, such as the hand, wrist, knee, foot, and ankle.

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

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RECENT DEVELOPMENTS

The continuing uncertainty surrounding worldwide financial markets and macroeconomic conditions has caused and may continue to cause the purchasers of medical equipment to decrease or delay their medical equipment purchasing and procurement activities. Economic uncertainty as well as increasing health insurance premiums, deductibles and co-payments have resulted and may continue to result in cost-conscious consumers focusing on acute care rather than wellness, which has and may continue to adversely affect demand for our products and procedures. Furthermore, 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 adversely affect sales of our products. If the current adverse macroeconomic conditions continue, our business and prospects may be negatively impacted.

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 from time to time which could result in decreased reimbursement or use of our products. For instance, on October 20, 2015, the American Cancer Society issued new guidelines recommending that women start annual mammograms at age 45 instead of 40 and that women have a mammogram every two years instead of annually. This recommendation could result in a decrease in purchases of our mammography systems. In addition, 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, known as the USPSTF, and the American Cancer Society. However, the USPSTF recommendations now also include HPV co-testing for certain patient populations, an update from their draft guidelines in October 2011. Overall, we believe that these guidelines may have contributed to an increase in testing intervals in the U.S. for cervical cancer screening, resulting in fewer such tests being performed.

Over the last few years, there have been periodic significant fluctuations in foreign currencies relative to the U.S. dollar. In fiscal 2015, there was a significant strengthening of the U.S. dollar versus the Euro, UK Pound and other currencies we transact in, which resulted in lower reported revenues of over $50 million compared to fiscal 2014. The ongoing fluctuations of the value of the U.S. dollar may cause our products to be less competitive in international markets and may impact sales and profitability over time. A majority of our international sales are denominated in foreign currencies. Given the uncertainty in the worldwide financial markets, foreign currency fluctuations may be significant in the future and we may experience a material adverse effect on our international revenues and operating results.

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.

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	Fiscal Years Ended					
	September 26, 2015		September 27, 2014		September 28, 2013	
Revenues:						
Product	83.9	%	82.8	%	84.3	%
Service and other	16.1	%	17.2	%	15.7	%
	100.0	%	100.0	%	100.0	%
Costs of revenues:						
Product	27.9	%	28.9	%	32.8	%
Amortization of intangible assets	11.1	%	12.4	%	12.3	%
Impairment of intangible assets	—	%	1.1	%	0.1	%
Service and other	8.0	%	8.4	%	8.2	%
Gross Profit	53.0	%	49.2	%	46.6	%
Operating expenses:						
Research and development	7.9	%	8.0	%	7.9	%
Selling and marketing	13.4	%	13.1	%	13.7	%
General and administrative	9.7	%	10.3	%	9.1	%
Amortization of intangible assets	4.1	%	4.5	%	4.5	%
Impairment of intangible assets	—	%	0.2	%	—	%
Contingent consideration—compensation expense	—	%	—	%	3.2	%
Contingent consideration—fair value adjustments	—	%	—	%	0.5	%
Impairment of goodwill	—	%	—	%	44.8	%
Gain on sale of intellectual property	—	%	—	%	(2.2	)%
Restructuring and divestiture charges	1.1	%	2.0	%	1.3	%
	36.2	%	38.2	%	83.0	%
Income (loss) from operations	16.8	%	11.1	%	(36.4	)%
Interest income	—	%	0.1	%	0.1	%
Interest expense	(7.6	)%	(8.7	)%	(11.3	)%
Debt extinguishment loss	(2.3	)%	(0.3	)%	(0.4	)%
Other (expense) income, net	(0.4	)%	(0.2	)%	0.1	%
Income (loss) before income taxes	6.6	%	1.9	%	(47.9	)%
Provision (benefit) for income taxes	1.7	%	1.2	%	(0.8	)%
Net income (loss)	4.9	%	0.7	%	(47.1	)%

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Fiscal Year Ended September 26, 2015 Compared to Fiscal Year Ended September 27, 2014

Product Revenues.

	Years Ended September 26, 2015		September 27, 2014		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Product Revenues						
Diagnostics	$1,184.1	43.8 %	$1,136.9	44.9 %	$47.2	4.2 %
Breast Health	685.1	25.3 %	587.9	23.2 %	97.2	16.5 %
GYN Surgical	334.6	12.4 %	306.6	12.1 %	28.0	9.1 %
Skeletal Health	66.6	2.5 %	63.5	2.5 %	3.1	4.9 %
	$2,270.4	83.9 %	$2,094.9	82.7 %	$175.5	8.4 %

We generated an increase in product revenues in fiscal 2015 compared to fiscal 2014. The growth was across all four of our business segments on both a domestic and worldwide basis. Product revenues increased 8.4% in the current fiscal year compared to the prior fiscal year, as reported growth was partially offset by the negative foreign currency exchange impact of the strengthening U.S. dollar against a number of currencies, most notably the Euro, UK Pound and Renminbi.

Diagnostics product revenues increased 4.2% in fiscal 2015 compared to fiscal 2014 primarily due to increases in Molecular Diagnostics of $32.3 million and Blood Screening of $27.1 million. These increases were partially offset by a decrease of $12.1 million in our Cytology & PeriNatal business.

The increase in Molecular Diagnostics products, and in particular our Aptima family of assays was primarily due to increased volumes due to our increased installed base of Panther instruments, and increased sales volumes of our HPV screening assay, which was FDA approved for use on our Panther system in the fourth quarter of fiscal 2013. These increases were partially offset by a reduction in Cervista HPV revenues as customers transition to our Panther system and Aptima HPV assay and lower instrumentation sales due to the significant purchases made by Quest Diagnostics Incorporated, or Quest, in the first quarter of fiscal 2014. In addition, we have experienced slightly lower average selling prices. Our Blood Screening revenues increased in fiscal 2015 compared to fiscal 2014 primarily due to volume increases related to the agreement between Grifols, our blood screening partner, and the Japanese Red Cross, and restocking of certain assays for Grifols to normalize its inventory levels. The decrease in our Cytology & PeriNatal revenues in fiscal 2015 compared to fiscal 2014 was primarily related to the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies, lower instrument sales and slightly lower average selling prices in China. ThinPrep Pap Test volumes domestically increased slightly in the current fiscal year compared to the prior fiscal year, and have increased more modestly internationally. In the U.S., we believe the negative impact on ThinPrep Pap test volumes resulting from interval expansion for cervical cancer screening was largely negated by our increased market share gains.

Breast Health product revenues increased 16.5% in fiscal 2015 compared to fiscal 2014. Our digital mammography systems and related products revenue increased $116.1 million in fiscal 2015 compared to fiscal 2014 primarily due to the increase in 3D Dimensions units sold on a worldwide basis, which was principally driven by domestic sales. This increase was partially offset by slightly lower average selling prices and a product mix shift within the 3D offerings to systems with less features. In addition, we also had higher sales of 3D upgrades and related products primarily driven by our C-View product. As expected, we continue to experience a decline in the number of 2D systems sold as customers transition to the 3D Dimensions systems, which is occurring primarily in the United States. The increase in revenue was also partially offset by the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies, lower MRI breast coils product line revenue of $6.9 million as a result of the divestiture of this product line in the fourth quarter of fiscal 2014, and a decline of $10.2 million related to our Hitec-Imaging business primarily as a result of the completed shutdown of its organic photoconductor production line in fiscal 2014.

GYN Surgical product revenues increased 9.1% in fiscal 2015 compared to fiscal 2014 primarily due to an increase in MyoSure system sales of $29.1 million partially offset by lower NovaSure device sales of $1.3 million. The MyoSure system continues to gain strong market acceptance as unit sales increase globally, partially offset by a product mix shift and slightly lower average sales prices. NovaSure revenues were slightly lower in fiscal 2015 compared to fiscal 2014 primarily due to the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies and slightly lower domestic volume, partially offset by higher international volume.

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Skeletal Health product revenues increased 4.9% in fiscal 2015 compared to fiscal 2014 primarily due to volume increases in our Horizon osteoporosis assessment product sales on worldwide basis, which were partially offset by lower volumes of our older Discovery products, the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies, and lower average selling prices.

In fiscal 2015, 74.6% of product revenues were generated in the United States, 12.4% in Europe, 9.3% in Asia-Pacific, and 3.7% in other international markets. In fiscal 2014, 73.6% of product revenues were generated in the United States, 13.8% in Europe, 8.6% in Asia-Pacific, and 4.0% in other international markets. The increase in the percentage of U.S. revenues was primarily due to increased sales of our 3D Dimensions system and related products and the negative impact of the strengthening U.S. dollar against the Euro and UK Pound, which resulted in lower European revenues.

Service and Other Revenues.

	Years Ended September 26, 2015		September 27, 2014		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Service and Other Revenues	$434.6	16.1 %	$435.8	17.2 %	$(1.2)	(0.3)%

Service and other revenues are primarily comprised of revenue generated from our field service organization to provide ongoing service, installation and repair of our products. The majority of these revenues are generated within our Breast Health segment. Service and other revenues decreased 0.3% in fiscal 2015 compared to fiscal 2014 as fiscal 2014 service and other revenues included $20.1 million of non-recurring revenue related to executing a license amendment with Roka Bioscience, Inc. in the fourth quarter of fiscal 2014, which is included in our Diagnostics segment. Excluding this impact, service and other revenues increased by $18.9 million or 4.5% in fiscal 2015 due to a favorable shift in service contract pricing and higher installation and training revenues related to our increased sales of our 3D Dimensions systems. The increase was also driven to a lesser extent by an increase in the number of service contracts in our Breast Health business as our installed base of our digital mammography systems continues to grow.

Cost of Product Revenues.

	Years Ended September 26, 2015		September 27, 2014		Change	
	Amount	% of Product Sales	Amount	% of Product Sales	Amount	%
Cost of Product Revenues	$755.5	33.3 %	$731.3	34.9 %	$24.2	3.3 %
Amortization of Intangible Assets	299.7	13.2 %	314.6	15.0 %	(14.9)	(4.7)%
Impairment of Intangible Assets	—	— %	26.6	1.3 %	(26.6)	(100.0)%
	$1,055.2	46.5 %	$1,072.5	51.2 %	$(17.3)	(1.6)%

Product gross margin increased to 53.5% in fiscal 2015 compared to 48.8% in fiscal 2014.

Cost of Product Revenues. Cost of product revenues as a percentage of product revenues in the current fiscal year decreased in Diagnostics and Breast Health, and increased in GYN Surgical and Skeletal Health compared to the prior fiscal year, resulting in the overall improvement in gross margins.

Diagnostics' product costs as a percentage of revenue decreased in fiscal 2015 compared to fiscal 2014 primarily due to an increase in product revenue related to the increase in Aptima assay sales and related volumes resulting in favorable manufacturing variances, higher blood screening revenues, lower production costs at our manufacturing facilities, lower royalty expenses primarily for ThinPrep due to the expiration of a royalty obligation during fiscal 2014, lower Cervista HPV sales, and lower molecular diagnostics instrumentation sales, which have very low gross margins. Partially offsetting these improvements was the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies.

Breast Health’s product costs as a percentage of revenue decreased in fiscal 2015 compared to fiscal 2014 primarily due to the favorable product mix shift to our higher margin 3D Dimensions system. Our 3D Dimensions systems have higher average sales prices than our 2D systems and sales in the U.S. have higher average sales prices than those sold internationally, resulting in higher gross margins. In addition, we had higher software sales for 3D upgrades and our C-View product, which

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have higher gross margins than capital equipment sales, while we had lower revenues from our Hitec-Imaging business, which has lower gross margins than the majority of our Breast Health products. Partially offsetting these improvements was the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies.

GYN Surgical's product costs as a percentage of revenue increased in fiscal 2015 compared to fiscal 2014 primarily due to an increase in sales volumes for our MyoSure system and product mix shift. The MyoSure system has slightly lower gross margins than our NovaSure system. In addition, in the current fiscal year we recorded a $4.0 million charge to write-off certain inventory that will not be utilized.

Skeletal Health's product costs as a percentage of revenue increased in fiscal 2015 compared to fiscal 2014 primarily due to decreases in the average selling prices for both our Horizon and legacy Discovery products principally due to the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies.

Amortization of Intangible Assets. Amortization of intangible assets relates to acquired developed technology. These intangible assets are generally amortized over their estimated useful lives of between 8.5 and 20 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. The economic pattern is based on undiscounted future cash flows. The decrease in amortization expense in fiscal 2015 compared to fiscal 2014 was primarily due to lower amortization expense from intangible assets from the Cytyc Corporation acquisition, which are being amortized based on the pattern of economic use, and the write-down in the second quarter of fiscal 2014 and the eventual write-off of the MRI breast coils developed technology asset as a result of the divestiture of this product line in the fourth quarter of fiscal 2014. Amortization expense in fiscal 2014 from the MRI breast coil product line was $9.1 million. Partially offsetting these decreases was an increase due to certain in-process R&D projects from our Gen-Probe acquisition being completed in 2014 and reclassified to developed technology. The value assigned to these projects is now being amortized.

Impairment of Intangible Assets. There was no impairment of intangible assets in fiscal 2015. In the second quarter of fiscal 2014, we evaluated our MRI breast coils product line asset group, which is within our Breast Health segment, for impairment due to our expectation that it would be sold or disposed of significantly before the end of its previously estimated useful life. The undiscounted cash flows expected to be generated by this asset group over its estimated remaining life were not sufficient to recover its carrying value. At that time, we estimated the fair value of the asset group resulting in an aggregate impairment charge of $28.6 million, comprised of $27.1 million of intangible assets and $1.5 million of property and equipment. The impairment charge was allocated to the long-lived assets, resulting in $26.6 million being allocated to developed technology. The MRI breast coils product line was sold in the fourth quarter of fiscal 2014.

Cost of Service and Other Revenues.

	Years Ended								
	September 26, 2015			September 27, 2014			Change		
	Amount	% of Service and Other Revenues		Amount	% of Service and Other Revenues		Amount	%	
Cost of Service and Other Revenues	$217.1	50.0	%	$212.7	48.8	%	$4.4	2.1	%

Service and other revenues gross margin was 50.0% in fiscal 2015 compared to 51.2% in fiscal 2014. Gross margin in fiscal 2015 was lower than the previous year as fiscal 2014 service and other revenues included $20.1 million of revenue from the Roka Bioscience, Inc. license amendment transaction, which did not have any corresponding costs. Excluding this transaction, gross margin would have improved by 1.2% in fiscal 2015. Within our Breast Health segment, gross margin improved primarily due to a favorable shift in service contract pricing and higher installation and training revenues related to our increased sales of 3D Dimensions systems. The increase was also driven to a lesser extent by the continued conversion of a high percentage of our domestic installed base of digital mammography

systems to service contracts upon expiration of the warranty period improving leverage of our service infrastructure.

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Operating Expenses.

	Years Ended September 26, 2015		September 27, 2014		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Operating Expenses						
Research and development	$214.9	7.9 %	$203.2	8.0 %	$11.7	5.8 %
Selling and marketing	363.0	13.4 %	331.7	13.1 %	31.3	9.4 %
General and administrative	261.0	9.7 %	259.8	10.3 %	1.2	0.5 %
Amortization of intangible assets	110.2	4.1 %	113.8	4.5 %	(3.6)	(3.2)%
Impairment of intangible assets	—	— %	5.6	0.2 %	(5.6)	(100.0)%
Restructuring and divestiture charges	28.5	1.1 %	51.7	2.0 %	(23.2)	(44.9)%
	$977.6	36.2 %	$965.8	38.1 %	$11.8	1.2 %

Research and Development Expenses. Research and development expenses increased 5.8% in fiscal 2015 compared to fiscal 2014 primarily due to an increase in compensation from higher headcount and variable compensation due to improved operating results, primarily in our Diagnostics and GYN Surgical segments, and additional program spend for our virology product line within our molecular diagnostics business, including increased clinical spending and higher spend for prototype materials. Partially offsetting these increases was lower spend of $3.5 million from our MRI breast coils product line as a result of the divestiture of this business in the fourth quarter of fiscal 2014. At any point in time, we have a number of different research projects and clinical trials being conducted and the timing of these projects and related costs can vary from period to period.

Selling and Marketing Expenses. Selling and marketing expenses increased 9.4% in fiscal 2015 compared to fiscal 2014 primarily due to increased commissions as a result of higher sales, an increase in spending on marketing initiatives primarily for our breast cancer awareness, Genius 3D mammography and cervical cancer awareness campaigns and higher training costs. These increases were partially offset by lower spend of $4.4 million from our MRI breast coils product line as a result of the divestiture of this business in the fourth quarter of fiscal 2014, lower international headcount from restructuring actions, and lower travel expenses.

General and Administrative Expenses. General and administrative expenses increased 0.5% in fiscal 2015 compared to fiscal 2014 primarily due to higher variable compensation due to improved operating results and higher stock-based compensation, increased consulting expenses for a number of corporate initiatives and higher medical device excise taxes from increased U.S. product sales. These increases were partially offset by decreases in credit card fees related to customer sales, lower spend related to our MRI breast coils line as a result of the divestiture in the fourth quarter of fiscal 2014, decreases in certain non-income tax expenses, a reduction of bad debt expense, reduced legal and consulting fees related to shareholder activism, and lower headcount primarily internationally from restructuring actions.

Amortization of Intangible Assets. Amortization of intangible assets results from customer relationships, trade names, and business licenses from our acquisitions. These intangible assets are generally amortized over their estimated useful lives of between 2 and 30 years using a straight-line method or, if reliably determinable, based on the pattern in which the economic benefits of the assets are expected to be consumed utilizing expected undiscounted future cash flows. The decrease in fiscal 2015 compared to fiscal 2014 was primarily due to lower amortization from intangibles acquired in the Cytyc Corporation acquisition in fiscal 2008 as the pattern of economic benefits decreases, partially offset by the shortening the remaining life of certain corporate trade names in the second quarter of fiscal 2014 as we decided to phase out their use.

Impairment of Intangible Assets. There was no impairment of intangible assets in fiscal 2015. In fiscal 2014, we recorded a $5.1 million impairment charge for our existing in-process research and development, or IPR&D, projects from our Gen-Probe acquisition primarily due to a reduction in estimated future revenues from these products.

Additionally, in the second quarter of fiscal 2014, we recorded an impairment charge for a trade name intangible asset related to our MRI breast coils product line as previously discussed.

Restructuring and Divestiture Charges. In the fourth quarter of fiscal 2012, in connection with our acquisition of Gen-Probe, we implemented a restructuring action to consolidate our Diagnostics operations by decreasing headcount and

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transferring our legacy molecular diagnostics operations in Madison, Wisconsin. We also finalized our decision to transfer production of our interventional breast products from our Indianapolis facility to our Costa Rica facility. In fiscal 2013 and in the first quarter of fiscal 2014, we implemented cost containment measures that primarily resulted in headcount reductions. In the second, third and fourth quarters of fiscal 2014, we terminated certain personnel at our Hitec Imaging operation in Germany, and as part of ongoing management changes and structural refinement, we terminated certain executives and employees on a worldwide basis. Certain of these actions and related charges continued into fiscal 2015 and additional actions were taken in fiscal 2015 for executive management changes and to further consolidate operations. Pursuant to U.S. generally accepted accounting principles, the related severance and benefit charges are being recognized either ratably over the respective required employee service periods or when benefits become probable for contractual and statutory benefits, and other charges are being recognized as incurred. In fiscal 2015 and 2014, we recorded aggregate charges of $28.5 million and $51.7 million, respectively, from these actions, primarily for severance and benefits and to a lesser extent facility closure costs. Included in the fiscal 2015 charges was a $9.6 million charge to write-off the cumulative translation adjustment related to the divestiture of our MRI breast coils product line. This subsidiary was deemed to be substantially liquidated in the third quarter of fiscal 2015 as operations fully ceased. The charges recorded in fiscal 2014 primarily related to severance and benefits and include a $3.1 million impairment charge to record certain buildings at our Warstein, Germany location to their estimated fair value. In addition, the fiscal 2014 charges included a loss on divestiture of $5.3 million related to the sale of our MRI breast coils product line in the fourth quarter of fiscal 2014. For additional information, please refer to Note 3 contained in Item 15 of this Annual Report.

Interest Expense.

	Years Ended			
	September 26, 2015	September 27, 2014	Change	
	Amount	Amount	Amount	%
Interest Expense	$(205.5)	$(220.6)	$15.1	(6.8)%

Interest expense consists primarily of the cash interest costs and the related amortization of the debt discount and deferred issuance costs on our convertible notes, senior notes and amounts borrowed under our Credit Agreement and Prior Credit Agreement. The decrease in interest expense in fiscal 2015 compared to fiscal 2014 was primarily due to lower outstanding balances as a result of principal payments, prepayments and extinguishments and lower interest rates as a result of debt restructurings, partially offset by the increase in interest expense for transaction fees that were expensed related to executing the new Credit Agreement and our 5.250% Senior Notes due 2022. See below for additional discussion, including “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Liquidity and Capital Resources” for definitions of “Credit Agreement” and “Prior Credit Agreement".

Debt Extinguishment Loss.

	Years Ended			
	September 26, 2015	September 27, 2014	Change	
	Amount	Amount	Amount	%
Debt Extinguishment Loss	$(62.7)	$(7.4)	$(55.3)	747.3%

In the fourth quarter of fiscal 2015, we completed a private placement of $1.0 billion aggregate principal amount of our 5.250% Senior Notes due 2022 (the "2022 Senior Notes"). We used the net proceeds of the 2022 Senior Notes, plus available cash to discharge the outstanding 6.25% Senior Notes due 2020 at an aggregate redemption price of $1.03 billion, reflecting a redemption premium payment of $31.25 million. As a result of this transaction, we recorded a debt extinguishment loss of $22.3 million for the write-off of the pro-rata share of the redemption premium and debt issuance costs for extinguished lenders.

Also in the fourth quarter of fiscal 2015, on various dates, we entered into privately negotiated transactions and repurchased $300 million principal amount of our 2010 Notes for a total payment of $543.7 million, which includes the conversion premium resulting from our stock price on the date of transaction being in excess of the conversion

price of $23.03. In connection with these transactions, we recorded a debt extinguishment loss of $15.5 million related to the difference between the fair value of the liability component of the 2010 Notes and their respective carrying value at the redemption date. The remaining cash payments were allocated to the reacquisition of the equity component and recorded within additional paid-in-capital within stockholders' equity.

In the third quarter of fiscal 2015, we entered into a new Credit Agreement with Bank of America, N.A. The initial net proceeds under the new Credit Agreement were used to refinance our obligations under our Prior Credit Agreement with

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Goldman Sachs Bank USA. In connection with this transaction, we recorded a debt extinguishment loss of $18.2 million for the write-off of the pro-rata share of the debt discount and deferred issuance costs under the existing facility.

In the first quarter of fiscal 2015, we voluntarily pre-paid $300.0 million of our Term Loan B facility under the Prior Credit Agreement. In connection with this transaction, we recorded a debt extinguishment loss of $6.7 million to write-off the pro-rata amount of unamortized debt discount and deferred issuance costs related to this voluntary pre-payment.

In the second quarter of fiscal 2014, we refinanced the Term Loan B facility of our Prior Credit Agreement and voluntarily prepaid $25.0 million of principal. In connection with this transaction, we recorded a debt extinguishment loss of $4.5 million for the write-off of the pro-rata share of the debt discount and deferred issuance costs. In the first quarter of fiscal 2014, we made a $100.0 million voluntary pre-payment on our Term Loan B facility under the Prior Credit Agreement. As a result, the pro-rata share of the debt discount and deferred issuance costs aggregating $2.9 million related to this prepayment was recorded as a debt extinguishment loss.

Other Expense, net.

	Years Ended September 26, 2015	September 27, 2014	Change		
	Amount	Amount	Amount	%	
Other Expense, net	$(11.0)	$(4.9)	$(6.1)	124.5	%

In fiscal 2015, this account was primarily comprised of an other-than-temporary impairment charge of $7.8 million on a marketable security, net foreign currency exchange losses of $2.9 million, and $1.0 million of losses on cash surrender value of life insurance contracts and mutual funds related to our deferred compensation plan.

In fiscal 2014, this account was primarily comprised of other-than-temporary impairment charges on cost-method equity investments of $6.9 million and net foreign currency exchange losses of $1.8 million, partially offset by gains of $3.8 million on the cash surrender value of life insurance contracts and mutual funds related to our deferred compensation plan.

Provision for Income Taxes.

	Years Ended September 26, 2015	September 27, 2014	Change		
	Amount	Amount	Amount	%	
Provision for Income Taxes	$45.6	$30.8	$14.8	48.1	%

Our effective tax rate for fiscal 2015 was 25.8% compared to 63.9% in fiscal 2014. For fiscal 2015, the effective tax rate was lower than the statutory rate primarily due to the domestic production activities deduction benefit.

For fiscal 2014, the effective tax rate was higher than the statutory rate primarily due to unbenefited foreign losses partially offset by the domestic production activities deduction benefit.

Segment Results of Operations

We report our business as four segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health. 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 or loss. Revenues from product sales of each of these segments are described in further detail above. The discussion that follows is a summary analysis of total revenues and the primary changes in operating income or loss by segment.

Diagnostics.

	Years Ended September 26, 2015	September 27, 2014	Change		
	Amount	Amount	Amount	%	
Total Revenues	$1,211.8	$1,186.8	$25.0	2.1	%

Operating Income	$109.5	$48.7	$60.8	124.8	%
Operating Income as a % of Segment Revenue	9.0 %	4.1 %			

Diagnostics revenues increased in fiscal 2015 compared to fiscal 2014 primarily due to the increase in product revenues discussed above.

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Operating income for this business segment increased in fiscal 2015 compared to fiscal 2014 primarily due to increased gross profit in absolute dollars and lower operating expenses. Gross profit increased primarily due to increased Aptima sales, higher blood screening revenues as a result of a full year of revenue from the agreement between Grifols and the Japanese Red Cross, favorable manufacturing variances and lower royalty expense, partially offset by a decrease in Cervista HPV volume, lower instrumentation sales and the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies. In addition, also offsetting gross profit dollar and margin in fiscal 2015, fiscal 2014 included $20.1 million of non-recurring revenue related to executing a license amendment with Roka Bioscience, Inc. with no corresponding costs. Overall, the gross margin improved to 49.3% in fiscal 2015 from 46.8% in fiscal 2014.

Operating expenses decreased in fiscal 2015 compared to fiscal 2014 primarily due to a reduction in headcount in general and administrative functions and sales and marketing, lower restructuring charges, and a decrease in the amortization of intangible assets. There was also lower bad debt expense and a decrease in non-income tax expense. These decreases were partially offset by an increase in spending on research and development for additional headcount and project spending, primarily for our virology product line, higher spend for various marketing initiatives and increased variable compensation from improved operating results.

Breast Health.

	Years Ended September 26, 2015		September 27, 2014		Change		
	Amount		Amount		Amount	%	
Total Revenues	$1,063.4		$944.7		$118.7	12.6	%
Operating Income	$296.3		$187.6		$108.7	57.9	%
Operating Income as a % of Segment Revenue	27.9	%	19.9	%			

Breast Health revenues increased in fiscal 2015 compared to fiscal 2014 primarily due to the $97.1 million increase in product revenues discussed above and a $21.6 million increase in service revenues.

Operating income for this business segment increased in fiscal 2015 compared to fiscal 2014 primarily due to an increase in gross profit from higher revenue, partially offset by an increase in operating expenses. Gross profit in absolute dollars increased primarily due to the increase in 3D Dimensions sales, on both a unit basis and as a percentage of total digital mammography systems, compared to our 2D systems, an increase in software related sales, which have higher gross margins, and lower amortization expense primarily due to the divestiture of our MRI breast coils product in fiscal 2014, partially offset by the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies. In addition, fiscal 2014 included a $26.6 million impairment charge for developed technology assets related to our MRI breast coils product line discussed above. Service revenues also improved in fiscal 2015 compared to fiscal 2014 primarily due to an increase in service contracts from our higher installed base. As a result, overall gross margin increased to 56.4% in fiscal 2015 compared to 50.1% in fiscal 2014.

Operating expenses increased in fiscal 2015 compared to fiscal 2014 primarily due to an increase in commissions from higher revenues, higher marketing expenditures primarily for our breast cancer awareness and Genius 3D campaigns, the $9.6 million charge to write-off the cumulative translation adjustment related to the divestiture of our MRI breast coils product line discussed above, and increased variable compensation from improved operating results. These expense increases were partially offset by lower intangible asset amortization expense, lower restructuring expenses, and lower MRI breast coils product line expenses (excluding restructuring) of $11.9 million as a result of its divestiture.

GYN Surgical.

	Years Ended September 26, 2015	September 27, 2014	Change	
	Amount	Amount	Amount	%

Total Revenues	$335.8	$307.9	$27.9	9.1	%
Operating Income	$38.6	$30.3	$8.3	27.4	%
Operating Income as a % of Segment Revenue	11.5 %	9.9 %			

GYN Surgical revenues increased in fiscal 2015 compared to fiscal 2014 due to the increase in product revenues discussed above.

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Operating income for this business segment increased in fiscal 2015 compared to fiscal 2014 primarily due to an increase in gross profit in absolute dollars, partially offset by an increase in operating expenses. Gross margin increased to 57.3% in fiscal 2015 from 56.9% in fiscal 2014 primarily due to the benefit of higher sales volume partially offset by a $4.0 million charge to write-off inventory that will not be utilized, a product mix shift to higher sales volume of MyoSure systems and the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies.

Operating expenses increased in fiscal 2015 primarily due to an increase in sales force headcount, higher commissions, increased costs associated with international sales initiatives, and increased research and development expenses as we develop next generation devices. These increases were partially offset by lower litigation fees.

Skeletal Health.

	Years Ended September 26, 2015	September 27, 2014	Change	
	Amount	Amount	Amount	%
Total Revenues	$94.0	$91.3	$2.7	3.0 %
Operating Income	$10.7	$13.1	$(2.4)	(18.3)%
Operating Income as a % of Segment Revenue	11.4 %	14.3 %		

Skeletal Health revenues increased in fiscal 2015 compared to fiscal 2014 primarily due to the increase in product revenues of $3.1 million discussed above which was partially offset by a slight decrease in service and other revenue.

Operating income decreased in fiscal 2015 compared to the prior year primarily due to higher operating expenses.

Operating expenses increased in fiscal 2015 primarily due to higher compensation from improved operating results and additional investment in research and development projects.

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Fiscal Year Ended September 27, 2014 Compared to Fiscal Year Ended September 28, 2013

Product Revenues.

	Years Ended September 27, 2014		September 28, 2013		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Product Revenues						
Diagnostics	$1,136.9	44.9 %	$1,156.2	46.4 %	$(19.3)	(1.7)%
Breast Health	587.9	23.2 %	576.3	23.1 %	11.6	2.0 %
GYN Surgical	306.6	12.1 %	305.8	12.3 %	0.8	0.3 %
Skeletal Health	63.5	2.5 %	62.6	2.5 %	0.9	1.4 %
	$2,094.9	82.7 %	$2,100.9	84.3 %	$(6.0)	(0.3)%

Diagnostics product revenues decreased 1.7% in fiscal 2014 compared to fiscal 2013 primarily due to a reduction in ThinPrep revenues of $31.5 million and a decrease of $23.1 million in Lifecodes revenue as a result of the divestiture of this product line in the second quarter of fiscal 2013. These decreases were partially offset by an increase in our molecular diagnostics products of $12.4 million primarily due to an increase in revenues from our Aptima family of assays and an increase in blood screening revenues of $24.5 million, which were partially offset by lower sales of our Tigris and Panther instrumentation and lower Prodesse sales.

We attributed the reduction in ThinPrep revenues primarily to lower domestic sales volumes resulting from an increase in screening intervals based on guidelines released in 2012 by the American Congress of Obstetrics and Gynecologists and the U.S. Preventative Services Task Force and lower average sales prices internationally.

The increase in revenues in fiscal 2014 related to our Aptima family of assays was primarily due to increased volumes from our strategic alliance with Quest Diagnostics Incorporated, or Quest, entered into in the third quarter of fiscal 2013, our increased installed base of Panther instruments, and increased sales volumes of our HPV screening assay, which was FDA approved for use on our Panther system in the fourth quarter of fiscal 2013. These increases were partially offset by slightly lower average sales prices for our Aptima products due to increased competitive pressures, and a reduction in Cervista HPV revenues as our larger customers transition to our Panther system and Aptima HPV assay. The reduction in instruments sales was primarily due to the ramp up of unit sales to Quest in the fourth quarter of fiscal 2013. Prodesse revenues decreased in the fiscal 2014 primarily due to a milder flu season this year compared to the corresponding period in the prior year and the recent introduction of competitive products.

Our blood screening revenues increased in fiscal 2014 compared to fiscal 2013 primarily due to the inclusion of contingent revenue under our blood screening collaboration that was not recognized in the first quarter of fiscal 2013, and to a lesser extent the second quarter of fiscal 2013, due to unbilled accounts receivable being recorded as a fair value adjustment in purchase accounting. Under the collaboration, a portion of our blood screening revenue is contingent on donations testing revenue earned by our blood screening collaborator. As a result, amounts that were to be received for this contingent revenue related to inventory on hand and not yet utilized by Novartis' (our blood screening collaborator at the time) customers as of the date we acquired Gen-Probe were recorded as unbilled accounts receivable on the balance sheet in purchase accounting, and these amounts were not recorded as revenue in our results of operations in fiscal 2013. The amount of this contingent revenue not recorded as revenue in fiscal 2013 was $23.5 million. We also experienced increased volume due to the agreement between Grifols, our current blood screening partner, and the Japanese Red Cross. These increases were partially offset by lower West Nile Virus assay sales compared to the corresponding period in fiscal 2013 as 2013 had a higher incidence of the West Nile Virus resulting in higher donation testing.

Breast Health product revenues increased 2.0% in fiscal 2014 compared to fiscal 2013. Our digital mammography systems revenue increased $22.8 million in fiscal 2014 compared to fiscal 2013 primarily due to the increase in our 3D Dimensions units sold on a worldwide basis and higher workstations and workflow product revenue driven by our C-View product. We also experienced a decline in the number of 2D systems sold as customers transitioned to the 3D Dimensions systems, which occurred primarily in the United States. In addition, our breast biopsy products revenue increased $2.3 million in fiscal 2014 compared to fiscal 2013 primarily due to the increase in the number of Eviva

biopsy devices sold worldwide. These increases were partially offset by declines in our analog mammography systems and Hitec Imaging products.

GYN Surgical product revenues increased 0.3% in fiscal 2014 compared to fiscal 2013 primarily due to an increase in MyoSure system sales of $18.3 million partially offset by lower NovaSure device sales of $16.8 million. The MyoSure system continued to gain strong market acceptance as unit sales increased globally, partially offset by product mix. We experienced a

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decrease in the number of NovaSure devices sold in the United States, which we believed was primarily attributable to patients delaying surgery or opting for lower cost and generally less effective alternatives, partially offset by higher international volume.

Skeletal Health product revenues increased 1.4% in fiscal 2014 compared to fiscal 2013 primarily due to an increase in our osteoporosis assessment product sales, namely our Horizon product, which was introduced in late fiscal 2013, and to a lesser extent our mini C-arm systems, partially offset by lower volumes of our older Discovery products and pricing pressures.

In fiscal 2014, 73.6% of product sales were generated in the United States, 13.8% in Europe, 8.6% in Asia-Pacific, and 4.0% in other international markets. In fiscal 2013, 73.9% of product sales were generated in the United States, 13.6% in Europe, 8.9% in Asia-Pacific, and 3.6% in other international markets.

Service and Other Revenues.

	Years Ended September 27, 2014			September 28, 2013			Change		
	Amount	% of Total Revenue		Amount	% of Total Revenue		Amount	%	
Service and Other Revenues	$435.8	17.2	%	$391.4	15.7	%	$44.4	11.3	%

Service and other revenues increased 11.3% in fiscal 2014 compared to fiscal 2013 primarily due to an increase in the number of service contracts in our Breast Health business driven by an increase in the installed base of our digital mammography systems, an increase in services not covered by service contracts and higher installation and training revenues related to our 3D Dimensions systems. In addition, within our Diagnostics' segment, we executed a license amendment with Roka Bioscience, Inc. and received $20.1 million of non-recurring revenue in the fourth quarter of fiscal 2014.

Cost of Product Revenues.

	Years Ended September 27, 2014			September 28, 2013			Change		
	Amount	% of Product Revenue		Amount	% of Product Revenue		Amount	%	
Cost of Product Revenues	$731.3	34.9	%	$818.2	38.9	%	$(86.9)	(10.6)	)%
Amortization of Intangible Assets	314.6	15.0	%	307.9	14.7	%	6.7	2.2	%
Impairment of Intangible Assets	26.6	1.3	%	1.7	0.1	%	24.9	1,464.7	%
	$1,072.5	51.2	%	$1,127.8	53.7	%	$(55.3)	(4.9)	)%

Product gross margin increased to 48.8% in fiscal 2014 compared to 46.3% in fiscal 2013.

Cost of Product Revenues. Cost of product revenues as a percentage of product revenues in fiscal 2014 decreased in Diagnostics, Breast Health, and Skeletal Health and remained relatively consistent in GYN Surgical compared to fiscal 2013, resulting in an overall improved gross margin.

Diagnostics’ product costs as a percentage of revenue decreased in fiscal 2014 compared to fiscal 2013 primarily due to the inclusion of $52.4 million in fiscal 2013 of additional costs related to the sale of acquired inventory written up to fair value in purchase accounting for the Gen-Probe acquisition. In addition, we were able to recognize contingent revenue under our blood screening collaboration in fiscal 2014 that we were not able to recognize in fiscal 2013 due to a purchase accounting adjustment. We also had lower Tigris and Panther sales in fiscal 2014 and these instrument sales are typically low margin transactions. Furthermore, we experienced favorable manufacturing variances across many of our products and lower royalty costs for ThinPrep, partially offset by unfavorable pricing on ThinPrep and Aptima sales and increased service costs for placed instruments.

Breast Health’s product costs as a percentage of revenue decreased in fiscal 2014 compared to fiscal 2013 primarily due to the increase in 3D Dimensions sales on both a unit basis and as a percentage of total digital mammography

systems sales compared to our 2D systems. Our 3D Dimensions systems have higher average sales prices than our 2D systems resulting in higher gross margins. In addition, we had higher software related sales for 3D upgrades and our C-View product, which have higher gross margins than capital equipment sales.

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GYN Surgical's product costs as a percentage of revenue in fiscal 2014 was relatively consistent with fiscal 2013. While we experienced lower domestic NovaSure volumes and a change in MyoSure product mix, this trend was offset by the increased utilization at our Costa Rica facility in fiscal 2014 as a result of the transfer of our breast biopsy products from our Indianapolis, Indiana facility during the second half of fiscal 2013.

Skeletal Health's product costs as a percentage of revenue decreased in fiscal 2014 compared to fiscal 2013 primarily due to the increase in revenue for our Horizon product, which has a higher gross margin than our legacy Discovery products.

Amortization of Intangible Assets. The increase in amortization expense in fiscal 2014 compared to fiscal 2013 was primarily due to certain in-process research and development projects recorded in the Gen-Probe acquisition receiving FDA approval in fiscal 2013. As a result, these approved projects are being amortized. In addition, we adjusted the estimated life of the MRI breast coils developed technology assets in the third quarter of fiscal 2014 resulting in higher amortization expense.

Impairment of Intangible Assets. In the second quarter of fiscal 2014, we evaluated our MRI breast coils product line asset group, which was within our Breast Health segment, for impairment due to our expectation that it would be sold or disposed of significantly before the end of its previously estimated useful life. The undiscounted cash flows expected to be generated by this asset group over its estimated remaining life were not sufficient to recover its carrying value. At that time, we estimated the fair value of the asset group resulting in an aggregate impairment charge of $28.6 million, comprised of $27.1 million of intangible assets and $1.5 million of property and equipment. The impairment charge was allocated to the long-lived assets, resulting in $26.6 million being allocated to developed technology. The MRI breast coils product line was sold in the fourth quarter of fiscal 2014.

During the third quarter of fiscal 2013, we determined that a developed technology asset was impaired due to our decision to cease selling and providing support for such product. As a result, we recorded a $1.7 million charge to record the asset at its fair value.

Cost of Service and Other Revenues.

	Years Ended September 27, 2014		September 28, 2013		Change	
	Amount	% of Service and Other Revenues	Amount	% of Service and Other Revenues	Amount	%
Cost of Service and Other Revenues	$212.7	48.8 %	$203.1	51.9 %	$9.6	4.7 %

Service and other revenues gross margin was 51.2% in fiscal 2014 compared to 48.1% in fiscal 2013. Within our Breast Health segment, the continued conversion of a high percentage of our domestic installed base of digital mammography systems to service contracts upon expiration of the warranty period without a corresponding increase in costs to service such contracts resulted in higher gross margins. In addition, the $20.1 million of revenue from the Roka Bioscience, Inc. license amendment transaction, which did not have any corresponding costs, increased gross margin.

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Operating Expenses.

	Years Ended September 27, 2014		September 28, 2013		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Operating Expenses						
Research and development	$203.2	8.0 %	$197.6	7.9 %	$5.6	2.8 %
Selling and marketing	331.7	13.1 %	342.1	13.7 %	(10.4)	(3.0)%
General and administrative	259.8	10.3 %	227.7	9.1 %	32.1	14.1 %
Amortization of intangible assets	113.8	4.5 %	112.6	4.5 %	1.2	1.1 %
Impairment of intangible assets	5.6	0.2 %	—	— %	5.6	**
Contingent consideration—compensation expense	—	— %	80.0	3.2 %	(80.0)	(100.0)%
Contingent consideration—fair value adjustments	—	— %	11.3	0.5 %	(11.3)	(100.0)%
Impairment of goodwill	—	— %	1,117.4	44.8 %	(1,117.4)	(100.0)%
Gain on sale of intellectual property	—	— %	(53.9)	(2.2)%	53.9	(100.0)%
Restructuring and divestiture charges	51.7	2.0 %	32.8	1.3 %	18.9	57.6 %
	$965.8	38.1 %	$2,067.6	82.8 %	$(1,101.8)	(53.3)%

** Percentage not meaningful

Research and Development Expenses. Research and development expenses increased 2.8% in fiscal 2014 compared to fiscal 2013 primarily due to increased compensation, additional program spend for our virology product line and increased spending for our next generation breast biopsy products. These increases were partially offset by lower headcount, reductions to certain development programs, primarily in the GYN Surgical business as part of our cost containment measures implemented in fiscal 2013 and the beginning of the first quarter of fiscal 2014, lower integration costs related to the Gen-Probe acquisition, and the divestiture of Lifecodes (in the second quarter of fiscal 2013), which contributed $4.2 million of expense in the prior year. Research and development primarily reflects spending on new product development programs, regulatory compliance and clinical research and trials. 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 3.0% in fiscal 2014 compared to fiscal 2013 primarily due to lower compensation as a result of headcount reductions and lower spend on trade shows, seminars, consulting services, medical education and travel, primarily as a result of our cost containment measures, and lower integration costs related to the Gen-Probe acquisition. In addition, fiscal 2013 included $4.6 million of expense related to Lifecodes. These reductions were partially offset by an increase in spend for advertising initiatives and market research.

General and Administrative Expenses. General and administrative expenses increased 14.1% in fiscal 2014 compared to fiscal 2013 primarily due to an increase in the medical device excise tax of $6.2 million (primarily due to the inclusion of this expense for the entire fiscal year in 2014 compared to three quarters in fiscal 2013), legal and consulting fees of $4.7 million incurred in the first quarter of fiscal 2014 to assist us in our negotiations and response to shareholder activism, higher legal fees for litigation, an increase in certain non-income tax expenses, tax consulting fees and credit card fees related to customer payments, partially offset by lower compensation due to headcount reductions from our cost containment measures and lower integration costs related to the Gen-Probe acquisition. In addition, the first quarter of fiscal 2013 included legal settlement benefits of $8.9 million.

Amortization of Intangible Assets. The increase in amortization expense in fiscal 2014 compared to fiscal 2013 was primarily due to shortening the remaining life of certain corporate trade names as we decided to phase out their use during the second quarter of fiscal 2014 partially offset by lower amortization from intangibles acquired in the Cytyc Corporation acquisition in fiscal 2008 as the pattern of economic benefits decreased.

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Impairment of Intangible Assets. In the fourth quarter of fiscal 2014, we recorded a $5.1 million impairment charge for our existing in-process research and development, or IPR&D, projects from our Gen-Probe acquisition primarily due to a reduction in estimated future revenues from these products.

Contingent Consideration—Compensation Expense. In connection with our acquisition of TCT International Co., Ltd., or TCT, we were obligated to make contingent earn-out payments. The payments were contingent on future employment and based on achieving certain incremental revenue growth milestones. The measurement period ended in fiscal 2013, and as such, there were no charges in fiscal 2014.

Contingent Consideration—Fair Value Adjustments. In connection with our acquisition of Interlace Medical, Inc., or Interlace, we were required to pay future consideration that was contingent on achieving certain revenue based milestones. As of the acquisition date, we recorded a contingent consideration liability for the estimated fair value of the amount we expected to pay to the former shareholders of Interlace. This liability was based on future revenue projections. We recorded charges of $11.3 million in fiscal 2013 reflecting an increase in the fair value of the liability due to higher revenues from Interlace than originally estimated. The measurement period for this contingent consideration ended in the second quarter of fiscal 2013, and as such, there were no charges in fiscal 2014.

Impairment of Goodwill. During the fourth quarter of fiscal 2013, as a result of our company-wide annual budgeting and forecasting process and a full re-evaluation of our existing product development efforts and cost structure, we reduced our short term and long term revenue forecasts and determined that indicators of impairment existed in our Molecular Diagnostics reporting unit. The Molecular Diagnostics reporting unit is primarily comprised of our Aptima business acquired in the Gen-Probe acquisition and the molecular diagnostics business acquired in the acquisition of Third Wave Technologies, Inc. The updated forecast, which reflected pricing pressures, for revenue and profitability were lower than those expected at the time of the Gen-Probe acquisition. As such, the fair value of this reporting unit declined. As a result of performing Step 2 of the goodwill impairment test, which requires the completion of a hypothetical purchase price allocation to determine the fair value of the implied goodwill, we recorded a $1.1 billion goodwill impairment charge. For additional information, refer to Note 2— “Intangible Assets and Goodwill” to the consolidated financial statements contained in Item 15 of this Annual Report.

Gain on Sale of Intellectual Property. In the first quarter of fiscal 2013, we recorded a net gain of $53.9 million related to the sale of our Makena asset to K-V Pharmaceutical Company, or KV. On August 4, 2012, KV and certain of its subsidiaries filed voluntary petitions for reorganization under Chapter 11 of Title 11 of the United States Code in the United States Bankruptcy Court for the Southern District of New York. At that time, KV still owed us $95.0 million. In December 2012, we executed a settlement agreement with KV and released KV from all claims in consideration of a $60.0 million payment. We recorded this payment, net of certain costs, in the first quarter of fiscal 2013. For additional information, please refer to Note 6 contained in Item 15 of this Annual Report.

Restructuring and Divestiture Charges. In the fourth quarter of fiscal 2012, in connection with our acquisition of Gen-Probe, we implemented a restructuring action to consolidate our Diagnostics operations by decreasing headcount and transferring our legacy molecular diagnostics operations in Madison, Wisconsin. We also finalized our decision to transfer production of our interventional breast products from our Indianapolis facility to our Costa Rica facility. In fiscal 2013 and in the first quarter of fiscal 2014, we implemented cost containment measures that primarily resulted in headcount reductions. In the second, third and fourth quarters of fiscal 2014, we terminated certain personnel at our Hitec Imaging operation in Germany, and as part of ongoing management changes and structural refinement, we terminated certain executives and employees on a worldwide basis. Pursuant to U.S. generally accepted accounting principles, the related severance and benefit charges are being recognized either ratably over the respective required employee service periods or when benefits become probable for contractual and statutory benefits, and other charges are being recognized as incurred. In fiscal 2014 and 2013, we recorded aggregate charges of $51.7 million and $32.8 million, respectively, from these actions. The charges recorded in fiscal 2014 primarily related to severance and benefits and include a $3.1 million impairment charge to record certain buildings at our Warstein, Germany location to their estimated fair value. In addition, these charges include a loss on divestiture of $5.3 million related to the sale of our MRI breast coils product line in the fourth quarter of fiscal 2014. The charges in fiscal 2013 primarily related to severance and benefits. In addition, in fiscal 2013 we recorded a net gain of $0.6 million primarily related to the sale of our Lifecodes business in the second quarter of fiscal 2013. For additional information, please refer to Note 3

contained in Item 15 of this Annual Report.

Interest Expense.

	Years Ended				
	September 27, 2014	September 28, 2013	Change		
	Amount	Amount	Amount	%	
Interest Expense	$(220.6)	$(281.1)	$60.5	(21.5)	%

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The decrease in interest expense in fiscal 2014 compared to fiscal 2013 was primarily due to principal payments in fiscal 2013 and 2014, which included $325.0 million of voluntary pre-payments, of amounts borrowed under our Prior Credit Agreement, lower weighted-average interest rates due to refinancing both the Term Loan A and Term Loan B facilities under the Prior Credit Agreement, and the redemption of $405.0 million in principal amount of our 2007 Notes in December 2013. These decreases were partially offset by additional interest expense from the accretion of principal on our 2.00% Convertible Senior Notes due 2043, or the 2013 Notes, at 4.0% annually.

Debt Extinguishment Loss.

	Years Ended		Change	
	September 27, 2014	September 28, 2013		
	Amount	Amount	Amount	%
Debt Extinguishment Loss	$(7.4)	$(9.2)	$1.8	(19.6)%

In the second quarter of fiscal 2014, we refinanced the Term Loan B facility of our Prior Credit Agreement and voluntarily prepaid $25.0 million of principal. In connection with this transaction, we recorded a debt extinguishment loss of $4.5 million for the write-off of the pro-rata share of the debt discount and deferred issuance costs. In the first quarter of fiscal 2014, we made a $100.0 million voluntary pre-payment on the Term Loan B facility of our Prior Credit Agreement. As a result, the pro-rata share of the debt discount and deferred issuance costs aggregating $2.9 million related to this prepayment was recorded as a debt extinguishment loss.

In the fourth quarter of fiscal 2013, we refinanced the Term Loan B facility of the Prior Credit Agreement and made a voluntary prepayment of $200.0 million of principal. In connection with this transaction, we recorded a debt extinguishment loss of $6.0 million for the write-off of the pro-rata share of the debt discount and deferred issuance costs. In the second quarter of fiscal 2013, we refinanced the Term Loan A facility of the Prior Credit Agreement and certain existing creditors opted not to participate in such refinancing. In connection with this transaction, we recorded a debt extinguishment loss of $3.2 million for the write-off of the pro-rata share of the debt discount and deferred issuance costs.

Other (Expense) Income, net.

	Years Ended		Change	
	September 27, 2014	September 28, 2013		
	Amount	Amount	Amount	%
Other (Expense) Income, net	$(4.9)	$2.3	$(7.2)	(313.0)%

In fiscal 2014, this account was primarily comprised of other-than-temporary impairment charges on cost-method equity investments of $6.9 million and net foreign currency exchange losses of $1.8 million, partially offset by gains of $3.8 million on the cash surrender value of life insurance contracts and mutual funds related to our deferred compensation plan.

In fiscal 2013, this account was primarily comprised of gains on our investments for our deferred compensation plan of $4.7 million, a $2.0 million gain on the sale of a cost-method investment, $1.3 million from insurance and investment recoveries, and net foreign currency exchange gains of $0.5 million. Partially offsetting these gains were other-than-temporary impairment charges for cost-method equity investments of $6.4 million.

Provision (Benefit) for Income Taxes.

	Years Ended		Change	
	September 27, 2014	September 28, 2013		
	Amount	Amount	Amount	%
Provision (Benefit) for Income Taxes	$30.8	$(20.1)	$50.9	(253.2)%

Our effective tax rate for fiscal 2014 was 63.9% compared to a benefit of 1.7% on the pretax loss in fiscal 2013. For fiscal 2014, the effective tax rate was higher than the statutory rate primarily due to unbenefited foreign losses partially offset by the domestic production activities deduction benefit.

For fiscal 2013, the effective tax rate was lower than the statutory rate primarily due to the non-deductible goodwill impairment charge, non-deductible contingent consideration expense related to the TCT and Interlace acquisitions and unbenefited foreign losses, partially offset by the domestic production activities deduction benefit and the release of a $19.9 million valuation allowance related to capital losses utilized to offset capital gains generated during the year.

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Segment Results of Operations

Diagnostics.

	Years Ended September 27, 2014	September 28, 2013	Change	
	Amount	Amount	Amount	%
Total Revenues	$1,186.8	$1,189.8	$(3.0)	(0.3)%
Operating Income (Loss)	$48.7	$(1,149.1)	$1,197.8	104.2 %
Operating Income (Loss) as a % of Segment Revenue	4.1 %	(96.6)%		

Diagnostics revenues decreased in fiscal 2014 compared to fiscal 2013 primarily due to the decrease in product revenues discussed above.

Operating income for this business segment increased in fiscal 2014 compared to fiscal 2013, primarily due to the goodwill impairment charge of $1.1 billion recorded in the fourth quarter of fiscal 2013 related to our Molecular Diagnostics reporting unit discussed above.

Gross profit in absolute dollars increased primarily due to the inclusion in fiscal 2013 of fair value adjustments of $52.4 million for acquired Gen-Probe inventory that did not recur in fiscal 2014. In addition, we were able to record contingent revenue under our blood screening collaboration in fiscal 2014 that had previously been recorded as unbilled accounts receivable in purchase accounting as described above. Furthermore, we experienced favorable manufacturing variances across many of our products, lower royalty costs for ThinPrep, and lower instrumentation sales, partially offset by lower ThinPrep volumes and slightly lower pricing on ThinPrep and Aptima sales. As a result, the gross margin improved to 46.8% in fiscal 2014 from 41.4% in fiscal 2013.

Operating expenses, excluding the goodwill impairment charge noted above, decreased in fiscal 2014 compared to fiscal 2013 primarily due to a decrease of $80.0 million of contingent consideration charges related to TCT, the divestiture of Lifecodes, which contributed $9.4 million of operating expenses in fiscal 2013, and lower Gen-Probe integration costs, restructuring charges, and compensation from headcount reductions as part of our cost containment measures. These decreases were partially offset by the $5.1 million IPR&D charge, increases in spending on research and development for our virology products and market research, higher intangible asset amortization expense of $4.2 million due to changes in estimated useful lives, and an increase in the medical device excise tax of $2.8 million. As discussed above, fiscal 2013 included a $53.9 million gain related to the settlement with KV for the sale of our rights to Makena.

Breast Health.

	Years Ended September 27, 2014	September 28, 2013	Change	
	Amount	Amount	Amount	%
Total Revenues	$944.7	$905.1	$39.6	4.4 %
Operating Income	$187.6	$216.1	$(28.5)	(13.2)%
Operating Income as a % of Segment Revenue	19.9 %	23.9 %		

Breast Health revenues increased in fiscal 2014 compared to fiscal 2013 primarily due to the $28.0 million increase in service revenues and the $11.6 million increase in product revenues discussed above.

Operating income for this business segment decreased in fiscal 2014 compared to fiscal 2013 primarily due to higher operating expenses, partially offset by an increase in gross profit in absolute dollars. Gross profit in absolute dollars increased primarily due to the increase in product and service revenues and the favorable product mix between 3D Dimensions and our 2D systems partially offset by a $24.9 million increase in developed technology asset impairment charges related to our impairment assessment of the MRI breast coils product line in the second quarter of fiscal 2014 discussed above and higher intangible asset amortization expense. As a result, overall gross margin declined slightly to 50.1% in fiscal 2014 compared to 50.2% in fiscal 2013.

Operating expenses increased in fiscal 2014 compared to fiscal 2013 primarily due to higher restructuring and divestiture charges, which includes corporate allocated amounts and the loss on disposal of the MRI breast coils product line of $5.3 million, higher research and development expenditures primarily for next generation breast biopsy devices, higher

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compensation and an increase in the medical device excise tax of $2.6 million and intangible asset and property impairment charges related to the MRI breast coils product line aggregating $1.8 million.

GYN Surgical.

	Years Ended September 27, 2014		September 28, 2013		Change		
	Amount		Amount		Amount	%	
Total Revenues	$307.9		$307.1		$0.8	0.3	%
Operating Income	$30.3		$19.7		$10.6	53.8	%
Operating Income as a % of Segment Revenue	9.8	%	6.4	%			

GYN Surgical revenues remained relatively flat in fiscal 2014 compared to fiscal 2013 as discussed above.

Operating income for this business segment increased in fiscal 2014 compared to fiscal 2013 primarily due to a decrease in operating expenses while gross profit in absolute dollars was relatively flat as revenues were consistent year over year. Gross margin was 56.9% in both fiscal 2014 and 2013.

Operating expenses decreased in fiscal 2014 primarily due to the $11.3 million of contingent consideration charges related to the Interlace earn-out included in fiscal 2013. Additional reductions in operating expenses were primarily due to headcount reductions, lower research and development program expenditures and lower marketing related expenditures, all as a result of our cost containment measures, and lower intangible asset amortization expense. These decreases were offset by higher legal fees associated with our ongoing litigation, restructuring charges and an increase in the medical device excise tax.

Skeletal Health.

	Years Ended September 27, 2014		September 28, 2013		Change		
	Amount		Amount		Amount	%	
Total Revenues	$91.3		$90.3		$1.0	1.1	%
Operating Income	$13.1		$7.1		$6.0	84.5	%
Operating Income as a % of Segment Revenue	14.3	%	7.9	%			

Skeletal Health revenues increased in fiscal 2014 compared to fiscal 2013 primarily due to the increase in product revenues of $0.9 million discussed above and a slight increase in service and other revenue.

Operating income increased in fiscal 2014 compared to fiscal 2013 primarily due to the increase in gross profit in absolute dollars as a result of higher sales of our higher margin Horizon product and lower operating expenses. The decrease in operating expenses was primarily driven by a decrease in restructuring charges.

LIQUIDITY AND CAPITAL RESOURCES

At September 26, 2015, we had $322.4 million of working capital, and our cash and cash equivalents totaled $491.3 million. Our cash and cash equivalents balance decreased by $244.8 million during fiscal 2015 principally due to principal payments on our outstanding debt, repurchases of certain of our convertible notes and capital expenditures, partially offset by an increase in operating cash flows and proceeds from equity plans.

In fiscal 2015, our operating activities provided us with $786.1 million of cash, which included net income of $131.6 million, non-cash charges for depreciation and amortization aggregating $491.4 million, non-cash interest expense of $63.8 million related to our outstanding debt, stock-based compensation expense of $59.3 million, debt extinguishment losses of $62.7 million, and a $9.6 million charge related to writing off the cumulative translation adjustment of our MRI breast coils product line that was deemed to be substantially liquidated. These adjustments to net income were partially offset by a decrease in net deferred tax liabilities of $148.8 million, primarily from the amortization of intangible assets. Cash provided by operations included a net cash inflow of $98.5 million from changes in our operating assets and liabilities. Changes in our operating assets and liabilities were driven primarily by a decrease in inventory of $43.9 million as a result of increased sales in both the Diagnostics and Breast Health segments, an overall effort to reduce inventory levels and the divestiture of the MRI breast coils product line, an

increase in accrued expenses of $36.9 million primarily due to the accrual of higher annual bonuses, commissions and project spend, partially offset by payments for restructuring actions and litigation, an increase in accounts payable of $25.5 million due to the timing of payments, and an increase in deferred revenue of $16.1 million primarily

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due to an increase in our installed base of digital mammography systems. These cash flow increases were partially offset by an increase in accounts receivable of $30.3 million primarily driven by an increase in revenues.

In fiscal 2015, our investing activities utilized $86.1 million of cash primarily for capital expenditures of $89.4 million, which consisted primarily of the placement of equipment under customer usage agreements and purchases of manufacturing equipment and computer hardware, partially offset by net sales of mutual funds and insurance contracts of $3.6 million to pay participant withdrawals from our deferred compensation plan due to employee terminations.

In fiscal 2015, our financing activities used cash of $936.7 million, primarily due to net payments related to our Credit Agreement and Prior Credit Agreement (each as defined below) of $393.6 million in the aggregate, which included $300.0 million in voluntary prepayments under the Prior Credit Agreement, and $105.0 million of scheduled principal payments under our Credit Agreement and Prior Credit Agreement, partially offset by a $16.3 million increase in borrowing when we refinanced the Prior Credit Agreement with the new Credit Agreement. We also made a net payment of $31.25 million for the redemption premium related to refinancing our 6.25% Senior Notes due 2020 ("Prior Senior Notes") with our new 5.250% Senior Notes due 2022 ("2022 Senior Notes"). In addition, we repurchased $300 million principal amount of our 2.00% Convertible Exchange Senior Notes due 2037, or the 2010 Notes, for a total payment of $543.7 million, which includes the conversion premium resulting from our stock price on the date of transaction being in excess of the conversion price of $23.03. Other cash outflows included $22.7 million of debt issuance costs related to our various refinancing activities, $12.9 million for employee-related taxes withheld for the net share settlement of vested restricted stock units, and $13.2 million for the purchase of interest rate caps to hedge the variable interest rate on amounts outstanding under our Credit Agreement and Prior Credit Agreement. Partially offsetting these uses of cash were proceeds of $70.0 million from our equity plans, primarily from the exercise of stock options.

Debt

We had total recorded debt outstanding of $3.6 billion at September 26, 2015, which is comprised of amounts outstanding under our Credit Agreement of $1.65 billion (principal $1.66 billion), our 2022 Senior Notes of $1.0 billion and our convertible notes of $1.00 billion (principal $1.02 billion).

Credit Agreement

On May 29, 2015, we and certain of our domestic subsidiaries entered into a Credit and Guaranty Agreement, or the 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 party thereto (collectively, the "Lenders"). This Credit Agreement replaced our existing senior secured credit facility with Goldman Sachs Bank USA, in its capacity as administrative agent and collateral agent and the lenders party thereto ("Prior Credit Agreement") entered into on August 1, 2012, and the proceeds under the Credit Agreement of $1.68 billion were used to pay off the amounts outstanding under the Prior Credit Agreement.

The credit facilities under the Credit Agreement consist of:

- A $1.5 billion secured term loan to Hologic with a final maturity date of May 29, 2020 or the Term Loan; and
- A secured revolving credit facility under which the Borrowers (as defined below) may borrow up to $1 billion, subject to certain sublimits, with a final maturity date of May 29, 2020 or the Revolver.

Hologic and one of its subsidiaries, Hologic GGO 4 Ltd (“Hologic U.K.”) are the initial borrowers (the “Borrowers”) under the Credit Agreement. Hologic’s obligations under the Credit Agreement are guaranteed by certain of Hologic’s domestic subsidiaries (the “Subsidiary Guarantors”). Hologic U.K.’s obligations under the Credit Agreement are guaranteed by Hologic and the Subsidiary Guarantors.

In addition to the Term Loan, we borrowed $175.0 million under the Revolver. Borrowings under the Revolver may be made in certain alternative currencies pursuant to the terms of the Credit Agreement. We have the ability, subject to the terms of the Credit Agreement, to designate any additional wholly-owned foreign subsidiary as a Designated Borrower (as defined in the Credit Agreement) to receive loans up to a $100 million sublimit. The obligations of any Designated Borrower under such sublimit would be guaranteed by us and our Subsidiary Guarantors.

As of September 26, 2015, the interest rate under the Term Loan and Revolver was 1.95% on the outstanding amounts, which is reflective of the Eurocurrency Rate (i.e., Libor) plus the applicable margin of 1.75% per annum as set forth in the Credit Agreement. The applicable margin is subject to specified changes depending on the total net

leverage ratio as defined in the Credit Agreement.

We are required to make scheduled principal payments under the Term Loan in increasing amounts ranging from $18.75 million per three-month period commencing with the three-month period ending on September 25, 2015 to $37.5 million per three-month period commencing with the three-month period ending on September 28, 2018. The remaining balance of the

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Term Loan is due at maturity. Any amounts outstanding under the Revolver are due at maturity. In addition, subject to the terms and conditions set forth in the Credit Agreement, we are required to make certain mandatory prepayments from specified excess cash flows from operations (to the extent our net senior secured leverage ratio exceeds a certain ratio) and 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) (“Mandatory Prepayments”). Mandatory Prepayments are required to be applied by us, first, to the Term Loan, second, to any outstanding amount under the swing line sublimit, third, to the Revolver, and fourth to any outstanding amount under a letter of credit sublimit. Subject to certain limitations, we may voluntarily prepay any of the credit facilities under the Credit Agreement without premium or penalty.

The Credit Agreement contains affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants restricting our ability and that of the Subsidiary Guarantors, subject to negotiated exceptions, to incur additional indebtedness and additional liens on our assets, engage in mergers or acquisitions or dispose of assets, enter into sale-leaseback transactions, pay dividends or make other distributions, voluntarily prepay other indebtedness, enter into transactions with affiliated persons, make investments, and change the nature of our businesses. The 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 our assets, with certain exceptions. The 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 is 5.50:1.00 beginning on our fiscal quarter ended September 26, 2015, and then decreases over time to 4.00:1.00 for the quarter ending March 28, 2020. The interest coverage ratio is 3.75:1.00 beginning on our fiscal quarter ending September 26, 2015, and will remain as such for each quarter thereafter. The total net leverage ratio is defined as the ratio of our consolidated net debt as of the quarter end to our consolidated adjusted EBITDA (as defined in the Credit Agreement) for the four-fiscal quarter period ending on each measurement date. The interest coverage ratio is defined as the ratio of our consolidated adjusted EBITDA for the prior four-fiscal quarter period ending on each measurement date to adjusted consolidated cash interest expense for the same measurement period. These terms, and the calculation thereof, are defined in further detail in the Credit Agreement. As of September 26, 2015, we were in compliance with these covenants.

Senior Notes

On July 2, 2015, we completed a private placement of $1.0 billion aggregate principal amount of our 2022 Senior Notes. The 2022 Senior Notes are our general senior unsecured obligations and are guaranteed on a senior unsecured basis by certain of our domestic subsidiaries (the "Guarantors"). The 2022 Senior Notes mature on July 15, 2022 and bear interest at the rate of 5.250% per year, payable semi-annually on January 15 and July 15 of each year, commencing on January 15, 2016. We used the net proceeds of the 2022 Senior Notes, plus available cash to discharge our outstanding $1.0 billion aggregate principal amount of our Prior Senior Notes and we redeemed such Prior Senior Notes on August 1, 2015 at an aggregate redemption price of $1.03 billion, reflecting a premium payment of $31.25 million.

The 2022 Senior Notes indenture contains covenants which limit, among other things, our ability and the ability of the Guarantors to incur additional indebtedness and additional liens on our assets, to engage in mergers or acquisitions or dispose of assets, to pay dividends or make other distributions, to enter into certain transactions with affiliated persons and to make certain investments. These covenants are subject to a number of exceptions and qualifications, including the suspension of certain of these covenants upon the 2022 Senior Notes receiving an investment grade credit rating. We are not required to maintain any financial covenants with respect to the 2022 Senior Notes.

We may redeem the 2022 Senior Notes at any time prior to July 15, 2018 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 our 2022 Senior Notes with the net cash proceeds of certain equity offerings at any time and from time to time before July 15, 2018, at a redemption price equal to 105.250% 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 2022 Senior Notes on or after: July 15, 2018 through July 14, 2019 at 102.625% of par; July 15, 2019 through July 14, 2020 at 101.313% of par; and July 15, 2020 and thereafter at 100% of par. In addition, if we undergo a change of control, as provided in the indenture, we will be required to make an offer to purchase each holder's 2022 Senior Notes at a price equal to 101% of their principal amount, plus accrued and unpaid interest, if any, to the repurchase date.

Convertible Notes

At September 26, 2015, our convertible notes, in the aggregate principal amount of $1.02 billion, are recorded at $1.00 billion, which is net of the unamortized debt discount attributed to the embedded conversion feature of the convertible notes. These notes consist of:

- $150 million of our 2.00% Convertible Exchange Senior Notes due 2037 issued in November 2010 (2010 Notes);

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- $500 million of our 2.00% Convertible Senior Notes due 2042 issued in March 2012 (2012 Notes); and
- $370 million of our 2.00% Convertible Senior Notes due 2043 issued in February 2013 (2013 Notes).

The 2010 Notes, 2012 Notes and 2013 Notes are collectively referred to herein as the convertible notes. Interest on the 2013 Notes is currently being accreted to principal, from their date of issuance, at a rate of 4.00% per year until December 15, 2017, and 2.00% per year thereafter. All other notes bear interest at a rate of 2.00% per year on the original principal amount, payable semi-annually in arrears until their first put date and thereafter accrete principal at the rate of 2.00% per year. In addition, under certain circumstances contingent interest may be payable under the convertible notes after each of their first put date.

The 2010 Notes, 2012 Notes and 2013 Notes have conversion prices of approximately $23.03, $31.175 and $38.59, respectively, and are subject in each case to adjustment. Holders of the 2010 Notes, 2012 Notes and 2013 Notes may convert their convertible notes at the applicable conversion price under certain circumstances, including without limitation (x) if the last reported sale price of our common stock exceeds 130% of the applicable conversion price for at least 20 trading days in the 30 consecutive trading days ending on the last trading day of the preceding calendar quarter and (y) if the applicable series of convertible notes has been called for redemption. It is our current intent and policy to settle any conversion of the convertible notes as if we had elected to make either a net share settlement or all cash election, such that upon conversion, we intend to pay the holders in cash for the principal amount of the convertible notes and, if applicable shares of our common stock or cash to satisfy the premium based on a calculated daily conversion value.

During the fourth quarter of fiscal 2015, the closing price of our common stock exceeded 130% of the applicable conversion price of our 2010 Notes on at least 20 of the last 30 consecutive trading days of the quarter. Therefore holders of the 2010 Notes are able to convert their notes during the first quarter of fiscal 2016. As such, we classified the $142.2 million carrying value of our 2010 Notes (which have a principal value of $150.0 million) as a current debt obligation. In the event the closing price conditions are met in the first quarter of fiscal 2016 or a future fiscal quarter, the 2010 Notes will be convertible at a holder's option during the immediately following fiscal quarter. As of September 26, 2015, the if-converted value of the 2010 Notes exceeded the aggregate principal amount by approximately $114.1 million.

Holders may require us to repurchase the 2010 Notes on each of December 15, 2016, 2020, 2025, on December 13, 2030 and on December 14, 2035, or upon a fundamental change as provided in the indenture for the 2010 Notes, at a repurchase price equal to 100% of their accreted principal amount, plus accrued and unpaid interest.

Holders may require us to repurchase the 2012 Notes on each of March 1, 2018, 2022, 2027 and 2032, and on March 2, 2037, or upon a fundamental change as provided in the indenture for the 2012 Notes, at a repurchase price equal to 100% of their accreted principal amount, plus accrued and unpaid interest.

Holders may require us to repurchase the 2013 Notes on each of December 15, 2017, 2022, 2027, 2032 and 2037, or upon a fundamental change as provided in the indenture for the 2013 Notes, at a repurchase price equal to 100% of their accreted principal amount, plus accrued and unpaid interest.

We may redeem any of the 2010 Notes, 2012 Notes and 2013 Notes beginning December 19, 2016, March 6, 2018, and December 15, 2017, respectively. As discussed above, holders of the convertible notes may elect to convert their notes prior to redemption. We may redeem all or a portion of the 2010 Notes, 2012 Notes and 2013 Notes (i.e., in cash or a combination of cash and shares of our common stock) at a redemption price equal to 100% of their principal amount, plus accrued and unpaid interest to, but excluding, the applicable redemption date.

We have recorded deferred tax liabilities related to our convertible notes original issuance discount, representing the spread between the stated cash coupon rate and the higher interest rate that is deductible for tax purposes based on the type of security. When our convertible notes are extinguished, we are required to recapture the original issuance discount previously deducted for tax purposes. The tax recapture, however, decreases as the fair market value of the convertible notes and the amount paid on settlement increases.

Stock Repurchase Program

On November 11, 2013, we announced that our Board of Directors authorized the repurchase of up to $250.0 million of our outstanding common stock over the next three years. Under the stock repurchase program, we are authorized to repurchase, from time-to-time, shares of our outstanding common stock on the open market or in privately negotiated transactions in the United States. The timing and amount of stock repurchases will be determined based upon our evaluation of market conditions and other factors. The stock repurchase program may be suspended, modified or discontinued at any time, and we have no obligation to repurchase any amount of our common stock under the program. Through September 26, 2015 we had not repurchased any shares of our common stock under this program.

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Contractual Obligations

The following table summarizes our contractual obligations and commitments as of September 26, 2015:

	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 (1)	$400.0	$1,116.8	$1,200.0	$1,000.0	$3,716.8
Interest on Long-Term Debt Obligations	97.2	180.6	147.0	95.9	520.7
Operating Leases	16.3	27.0	13.9	21.8	79.0
Financing Leases (2)	3.1	6.0	0.3	—	9.4
Purchase Obligations (3)	34.6	7.0	0.8	—	42.4
Royalty and Collaborative Commitments (4)	1.3	1.3	1.2	3.3	7.1
Pension Obligations (5)	0.3	0.7	0.8	8.2	10.0
Total Contractual Obligations	$552.8	$1,339.4	$1,364.0	$1,129.2	$4,385.4

(1) Included within long-term debt obligations are our 2010 Notes which are convertible by their respective holders in the first quarter of fiscal 2016 as further discussed above. In addition, we have two other issuances (2012 Notes and 2013 Notes) of convertible notes which can first be put to us on March 1, 2018 ($500 million principal), and December 15, 2017 ($370 million principal) and we have assumed for purposes of the above table that the principal amounts for each issuance will be paid off when they first can be put to us, which is in fiscal 2017 and fiscal 2018. The 2013 Notes also have principal accretion of 4.00% annually, which is included in the principal amount in the 1-3 years column above. The amounts in the table do not include deferred tax liabilities for the recapture of the original issuance discount.

(2) The financing leases represent two leases for an office building and a manufacturing facility, which were required to be recorded on our balance sheet under U.S. GAAP. See Note 11 to our consolidated financial statements contained in Item 15 of this Annual Report.

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

(4) Represents minimum royalties due on net sales of products incorporating licensed technology and subject to a minimum annual royalty payment, and payments under collaborative agreements. In addition to the minimum payments due under our collaborative agreements included above, we may be required to pay up to $4.4 million in milestone payments, plus royalties on net sales of any products using specified technology.

(5) Pension obligations do not include our obligation under our deferred compensation plans of $29.4 million, 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 uncertain tax positions recorded under FIN 48 (codified primarily in ASC 740, Income Taxes) totaling $145.1 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 7 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 and alliances that we believe will complement our current or future business. 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 cash flow from operations and the cash available under our Revolver will provide us with sufficient funds in order to fund our expected normal operations, and debt payments, including interest 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 or other investments, or to repay our convertible notes and related deferred tax liabilities. As described above, we have significant indebtedness outstanding under our Credit Agreement, 2022 Senior Notes and convertible 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.

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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.

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, fair values of equity investments, 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. These factors include, but are not limited to, technological changes in our markets, our ability to meet changing customer requirements, competitive pressures on products and prices, and reliability and replacement of and the availability of key components from our suppliers. 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. We regularly evaluate our ability to realize the value of our inventory based on a combination of factors including the following: historical usage rates, forecasted sales or usage, product expiration or end of life dates, estimated current and future market values and new product introductions. Assumptions used in determining our estimates of future product demand may prove to be incorrect, in which case the provision required for excess and obsolete inventory would have to be adjusted in the future. If inventory is determined to be overvalued, excess or obsolete, we would be required to record impairment charges within cost of goods sold at the time of such determination. 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. When recorded, our reserves are intended to reduce the carrying value of our inventory to its net realizable value.

Accounts Receivable Reserves

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We regularly evaluate the collectability of our trade receivables based on a combination of factors, including discussions with the customer to determine the cause of non-payment, and evaluation of the

customer's current financial situation. In the event it is determined that the customer may not be able to meet its full obligation to us, we record a specific allowance to reduce the receivable to the amount that we expect to recover given all information present. We perform ongoing credit evaluations of our customers and adjust credit limits based upon payment history and our assessment of the customer's current credit worthiness. We continuously monitor collections from our customers and maintain a provision for estimated credit losses based upon our historical experience and any specific customer collection issues that we have identified. While such credit losses have historically been within our expectations and the provisions established, we cannot guarantee that

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we will continue to experience the same credit loss rates in the future. If the financial condition of our customers were to deteriorate, additional allowances may be required.

We also record a provision for estimated sales returns and allowances on product and service related sales in the same period as the related revenues are recorded. These estimates are based on the specific facts and circumstances of particular orders, analysis of credit memo data and other known factors. If the data we use to calculate these estimates do not properly reflect reserve requirements, then a change in the allowances would be made in the period in which such a determination is made and revenues in that period could be adversely affected.

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. The value recorded is based on estimates of future financial projections under various potential scenarios, which are generally probability weighted as to the outcome of each scenario. These cash flow projections are discounted with an appropriate risk adjusted rate. Quarterly until such contingent amounts are earned, the fair value of the liability is reassessed 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 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 also used the income approach, as described above, to determine the estimated fair value of certain other identifiable intangible assets including developed technology, customer relationships and contracts, and trade names. Developed technology represents patented and unpatented technology and know-how. 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.

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 approach as the primary method 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.

Intangible Assets and Goodwill

Intangible Assets

We amortize our 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 consumed. The economic pattern is based on undiscounted future cash flows. Amortization is recorded over the estimated useful lives ranging from 2 to 30 years. We review our intangible assets subject to amortization to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. If the carrying value of an asset exceeds its undiscounted cash flows, we will write-down the carrying value of the intangible asset to its fair value in the period identified. In assessing fair value, we must make assumptions regarding estimated future cash flows and discount rates. If these estimates or related assumptions change in the future, we may be required to record impairment charges. We generally determine fair value based on the present value of estimated future cash flows to be generated by the asset using a risk-adjusted discount rate. If the estimate of an intangible asset's remaining useful life is changed, we will amortize the remaining carrying value of the intangible asset prospectively over the revised remaining useful life.

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.

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In performing the test, we utilize the two-step approach prescribed under ASC 350. The first step requires 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 will perform the second step of the goodwill impairment test to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit's goodwill to its carrying value. The second step requires us to perform a hypothetical purchase price allocation as of the measurement date and estimate the fair value of net tangible and intangible assets. The fair value of intangible assets is determined as described above and is subject to significant judgment.

We conducted our fiscal 2015 annual impairment test on the first day of the fourth quarter. We utilized discounted cash flows, or DCF, and market approaches to estimate the fair value of our reporting units as of June 28, 2015 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 Step 1, all of the reporting units had fair values exceeding their carrying values, and as such, Step 2 of the impairment test was not required for those reporting units. 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 Step 1 of the goodwill impairment test.

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.

At September 26, 2015, we believe that all reporting units with goodwill aggregating $2.8 billion were not at risk of failing Step 1 of the goodwill impairment test based on our current forecasts.

We conducted our fiscal 2014 annual impairment test on the first day of the fourth quarter. We utilized discounted cash flows, or DCF, and market approaches to estimate the fair value of our reporting units as of June 29, 2014 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 Step 1, all of the reporting units had fair values exceeding their carrying values, and as such, Step 2 of the impairment test was not required for those reporting units.

We conducted our fiscal 2013 annual impairment test on the first day of the fourth quarter. We utilized discounted cash flows, or DCF, and market approaches to estimate the fair value of our reporting units as of June 30, 2013 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 Step 1, all of the reporting units, except for our Molecular Diagnostics reporting unit, which is within our Diagnostics reportable segment, had fair values exceeding their carrying values, and as such, Step 2 of the impairment test was not required for those reporting units.

In 2013, as a result of our company-wide annual budgeting and strategic planning process and a full re-evaluation of our existing product development efforts and cost structure performed in the fourth quarter, we reduced our short term and long term revenue forecasts and determined that indicators of impairment existed in our Molecular Diagnostics reporting unit. The Molecular Diagnostics reporting unit is primarily comprised of our Aptima business acquired in the Gen-Probe acquisition and the molecular diagnostics business acquired in the Third Wave acquisition. The updated forecast, which reflected pricing pressures, for revenue and profitability were lower than those expected at the time of the Gen-Probe acquisition.

In 2013, as a result, the fair value of this reporting unit was below its carrying value. We performed Step 2 of the impairment test, consistent with the procedures described above, and recorded a goodwill impairment charge of $1.1 billion. The basis of fair value for Molecular Diagnostics assumed the reporting unit would be purchased or sold in a taxable transaction, and the discount rate of 10% applied to the after-tax cash flows was relatively consistent with that used in our purchase accounting for the Gen-Probe acquisition. For illustrative purposes, had the fair value of Molecular Diagnostics been lower by 10%, the Company would have recorded an additional impairment charge of $195.4 million.

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Revenue Recognition

We generate revenue from the sale of 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.

We recognize product revenue upon shipment provided that there is persuasive evidence of an arrangement, there are no uncertainties regarding acceptance, the sales price is fixed or determinable, no right of return exists and collection of the resulting receivable is reasonably assured. Generally, our product arrangements for capital equipment sales, primarily in our Breast Health and Skeletal Health reporting segments, are multiple-element arrangements, including services, such as installation and training, and multiple products. In accordance with ASC 605-25, based on the terms and conditions of the product arrangements, we believe that these services and undelivered products can be accounted for separately from the delivered product element as our delivered products have value to our customers on a stand-alone basis. Accordingly, revenue for services not yet performed at the time of product shipment are deferred and recognized as such services are performed. The relative selling price of any undelivered products is also deferred at the time of shipment and recognized as revenue when these products are delivered. There is no customer right of return in our sales agreements.

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 are recognized ratably over the term of the contract. Other service revenues are recognized as the services are performed.

For revenue arrangements with multiple deliverables, we record revenue as separate units of accounting if the delivered items have value to the customer on a stand-alone basis, and if the arrangement includes a general right of return relative to the delivered items, the delivery or performance of the undelivered items is considered probable and substantially within our control. Some of our products have both software and non-software components that function together to deliver the product's essential functionality. We determined that except for our CAD products and C-View product, the software element in our other products is incidental and not within the scope of the software revenue recognition rules, ASC 985-605, Software—Revenue Recognition. We determined that given the significance of the software component's functionality to our CAD and C-View systems, which are sold by our Breast Health segment, these products are within the scope of the software revenue recognition rules. We evaluated the appropriate revenue recognition treatment of our other hardware products, including our Dimensions digital mammography systems, which have 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 are not within the scope of ASC 985-605.

We are required to allocate revenue to multiple element arrangements based on the relative fair value of each element's selling price. We typically determine the selling price of our products based on our best estimate of selling price, referred to as ESP, and services based on vendor-specific objective evidence of selling price, referred to as VSOE. We determine VSOE based on our normal pricing and discounting practices for the specific product or service when sold on a stand-alone basis. In determining VSOE, our policy requires a substantial majority of selling prices for a product or service to be within a reasonably narrow range. We also consider the class of customer, method of distribution, and the geographies into which our products and services are sold when determining VSOE. If VSOE cannot be established, which may occur in instances when a product or service has not been sold separately, stand-alone sales are too infrequent, or product pricing is not within a narrow range, we will generally establish the selling price using ESP to allocate arrangement consideration. The objective of ESP is to determine the price at which we would typically transact a stand-alone sale of the product or service. ESP is determined by considering a number of factors including our 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 requires revenue earned on software arrangements involving multiple elements to be allocated to each element based on their relative VSOE of fair value. If VSOE does not exist for a delivered element, the residual method is applied in which the arrangement consideration is 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, referred to as PCS, has been established, we recognize revenue using the residual method at the time all other revenue recognition criteria have been met.

As part of our Diagnostics reporting segment, we manufacture blood screening products according to demand schedules provided by our collaboration partner, Grifols. Our agreement provides that we share a portion of Grifols's revenue from screening blood donations. Upon shipment to Grifols, we recognize blood screening product sales at an agreed upon fixed transfer price, which is not refundable, and record the related cost of products sold. Based on the terms of our collaboration agreement with Grifols, our ultimate share of the net revenue from sales to the end user in excess of the transfer price revenues

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recognized is not known until it is reported to us by Grifols. On a monthly basis, Grifols reports net revenue generated during the prior month and remits an additional corresponding net payment to us which we record as revenue at that time. This payment combined with the transfer price revenues previously recognized represents our ultimate share of net revenue under the agreement.

While the majority of our instruments are placed at customer sites, in certain instances, we sell instruments to our clinical diagnostics customers and record sales of these instruments upon delivery and customer acceptance. Prior to delivery, each instrument is tested to meet the Company's specifications and the specifications of the FDA, and is shipped fully assembled. Customer acceptance of the Company's clinical diagnostic instrument systems requires installation and training by our technical service personnel. Installation is a standard process consisting principally of uncrating, calibrating and testing the instrumentation. We sell our instruments to Grifols for use in blood screening and record these instrument sales upon delivery since Grifols is responsible for the placement, maintenance and repair of the units with its customers.

Within our Diagnostics business and, to a lesser extent, our GYN Surgical business, we provide our instrumentation (for example, the ThinPrep Processor, ThinPrep Imaging System, Panther and Tigris) and certain other hardware to customers without requiring them to purchase the equipment or enter into a lease. Instead, we recover the cost of providing the instrumentation and equipment in the amount we charge for our diagnostic tests and assays and other disposables. Customers enter into a customer usage agreement, and we install the equipment at customer sites and customers commit to purchasing minimum quantities of disposable products at a stated price over a defined contract term, which is typically between three and five years. Revenue is recognized over the term of the customer usage agreement as tests, assays and other disposable products are shipped or delivered, depending on the customer arrangement.

Stock-Based Compensation

We recognize stock-based compensation expense associated with the granting of stock options, restricted stock units and performance stock units issued to our employees. Determining the amount of stock-based compensation to be recorded requires us to develop estimates to be used in calculating the grant-date fair value of stock options. We use a binomial lattice model to determine the fair value of our stock options. We consider a number of factors to determine the fair value of stock options including the advice of an outside valuation advisor and the advisor's model. The model requires us to make estimates of the following assumptions:

Expected volatility—We are responsible for estimating volatility and have considered a number of factors, including third-party estimates, when estimating volatility. We currently use a combination of historical and implied volatility, which is weighted based on a number of factors.

Expected term—We use historical employee exercise and option expiration data to estimate the expected term assumption. We believe that this historical data is currently the best estimate of the expected term of a new option, and that generally, all of our employees exhibit similar exercise behavior.

Risk-free interest rate—The yield on zero-coupon U.S. Treasury securities for a period that is commensurate with the expected term assumption is used as the risk-free interest rate.

The amount of stock-based compensation expense recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. ASC 718, Stock Compensation, requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Based on an analysis of historical forfeitures, we have determined a specific forfeiture rate for certain employee groups and have applied forfeiture rates ranging from 0% to 7.0% as of September 26, 2015 depending on the specific employee group. This analysis is re-evaluated periodically and the forfeiture rate is adjusted as necessary. Ultimately, the actual expense recognized over the vesting period will only be for those awards that vest.

We granted performance stock units to members of our senior management team during fiscal 2014 and 2015. Each recipient of a performance stock unit is eligible to receive between zero and 200% of the target number of shares of our common stock at the end of three years provided our defined Return on Invested Capital, or ROIC, metrics are achieved. We recognize compensation expense ratably over the required service period based on an estimate of the probability that the measurement criteria will be achieved for a targeted number of shares. Our estimate of the number of shares that are probable of vesting is based on our estimate of ROIC over the respective time periods using our

internal forecasts and projections. If there is a change in the estimate of the number of shares that are probable of vesting, we will cumulatively adjust compensation expense in the period that the change in estimate is made.
We recognized $59.3 million, $50.0 million and $52.3 million of stock-based compensation expense for employee equity awards in fiscal years 2015, 2014 and 2013, respectively. As of September 26, 2015, there was $22.8 million and $73.6 million

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of unrecognized compensation expense related to stock options and stock units, respectively, that we expect to recognize over a weighted-average period of 3.4 years and 2.5 years, respectively.

Income Taxes

We use the asset and liability method for accounting for income taxes. Under this method, we determine deferred tax assets and liabilities based on the difference between our assets and liabilities financial reporting and taxes bases. We measure deferred tax assets and liabilities using enacted tax rates and laws that will be in effect when we expect the differences to reverse.

We have recognized $1.16 billion in net deferred tax liabilities at September 26, 2015 and $1.34 billion at September 27, 2014. The liabilities primarily relate to deferred taxes associated with our acquisitions and debt. The tax assets relate primarily to net operating loss carryforwards, accruals and reserves, stock-based compensation, and research credits. We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we determine that we could realize our deferred tax assets in the future in excess of the net recorded amount, an adjustment to the deferred tax assets would increase income in the period such determination is made. Likewise, should we determine that we would not be able to realize all or part of our net deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to income in the period such determination is made.

We had $154.7 million in gross unrecognized tax benefits, excluding interest, at September 26, 2015 and $137.0 million at September 27, 2014. At September 26, 2015, $74.9 million represents the amount of unrecognized tax benefits that, if recognized, would result in a reduction of the Company’s effective tax rate. In the next twelve months, it is reasonably possible that we will reduce our unrecognized tax benefits by $2.0 to $4.0 million due to statute of limitations expiring and potentially favorably settling with taxing authorities.

In the ordinary course of global 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

In July 2015, the Financial Accounting Standards Board (FASB) issued guidance under Accounting Standards Codification (ASC) 330, Simplifying the Measurement of Inventory. The new guidance requires inventory to be measured at the lower of cost and net realizable value, which is defined as the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. This new guidance is effective for our first quarter of fiscal year 2018 and early adoption is permitted. The guidance must be applied prospectively. We are currently evaluating the impact of the adoption of this requirement on our consolidated financial statements.

In April 2015, the FASB issued Accounting Standards Update (ASU) No. 2015-03, Presentation of Debt Issuance Costs. This guidance intends to simplify the presentation of debt issuance costs and more closely align the presentation of debt issuance costs under U.S. GAAP to IFRS standards. This guidance is effective for annual periods beginning after December 15, 2015, and is applicable to us in fiscal 2017. Early adoption is permitted. We are currently evaluating this guidance, but do not anticipate that adoption of this guidance will have a material impact on our consolidated financial statements.

In February 2015, the FASB issued ASU No. 2015-02, Consolidation (Topic 810): Amendments to the Consolidation Analysis. This guidance focuses on a reporting company’s consolidation evaluation to determine whether certain legal entities should be consolidated. This guidance is effective for annual periods beginning after December 15, 2015, and is applicable to us in fiscal 2017. Early adoption is permitted, including adoption in an interim period. We are

currently evaluating this guidance, but do not anticipate that adoption of this guidance will have a material impact on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date the financial statements are issued and provide related disclosures. ASU 2014-15 is effective for annual

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periods ending after December 15, 2016 and is applicable to us in fiscal 2018. Earlier application is permitted. The adoption of ASU 2014-15 is not expected to have a material effect on our consolidated financial statements or disclosures.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 660), which provides guidance for revenue recognition. This ASU is applicable to any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets. ASU 2014-09 will supersede the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific guidance. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled to receive in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current U.S. GAAP. These judgments may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. On July 9, 2015, the FASB voted in favor of delaying the effective date of the new standard by one year, with early adoption permitted as of the original effective date. ASU 2014-09 is effective prospectively for fiscal years, and interim reporting periods within those years, beginning after December 15, 2017, which is our fiscal 2019. We are currently evaluating the impact of the adoption of ASU 2014-09 on our consolidated financial position and results of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Financial Instruments, Other Financial Instruments, and Derivative Commodity Instruments. Financial instruments consist of cash equivalents, accounts receivable, publicly-traded equity securities, cost-method equity investments, mutual funds, interest rate cap agreements, insurance contracts and related deferred compensation plan liabilities, accounts payable and debt obligations. Except for our outstanding convertible notes and 2022 Senior Notes, the fair value of these financial instruments approximates their carrying amount. As of September 26, 2015, we have $1.02 billion of principal of convertible notes outstanding, which are comprised of our 2010 Notes with a principal of $150.0 million, our 2012 Notes with a principal of $500.0 million, and our 2013 Notes with a principal of $370.0 million. The convertible notes are recorded net of the unamortized discount on our consolidated balance sheets. The fair value of our 2010 Notes, 2012 Notes and 2013 Notes as of September 26, 2015 was approximately $264.1 million, $688.2 million and $471.8 million, respectively. The fair value of our 2022 Senior Notes was approximately $1.03 billion. Amounts outstanding under our Credit Agreement aggregating $1.66 billion aggregate principal as of September 26, 2015 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 convertible notes, 2022 Senior Notes and Credit Agreement. The convertible notes and 2022 Senior Notes have fixed interest rates. Borrowings under our Credit Agreement currently bear interest at the Eurocurrency Rate (i.e., Libor) plus the applicable margin of 1.75% per annum.

As of September 26, 2015, there was $1.66 billion of aggregate principal outstanding under the Credit Agreement comprised of $1.49 billion under the Term Loan and $175.0 million under the Revolver. 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 less than $1 million due to the low current interest rate environment. During fiscal 2015, we entered into multiple interest rate cap agreements 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 were designed to mirror the terms of the Libor-based borrowings under the Credit Agreement and Prior Credit Agreement, and therefore the interest rate caps 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 over a 3-year period, which ends on December 31, 2017.

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 expenses of our international offices are denominated in local currencies, except at our Costa Rica subsidiary, where the majority of the business is conducted in U.S. dollars. Fluctuations in the foreign

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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 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 the Euro are affected by changes in the relative strength of the U.S. dollar against the Euro. Our expenses, denominated in Euros, are positively affected when the U.S. dollar strengthens against the Euro and adversely affected when the U.S. dollar weakens. However, we believe that the foreign currency exchange risk is not significant. We do not 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 2015, 2014 and 2013, we incurred net foreign exchange gains (losses) of $(3.0) million, $(1.8) million and $0.5 million, respectively.

Item 8. Financial Statements and Supplementary Data

Our Consolidated Financial Statements and Supplementary Data are listed under Part IV, Item 15, in this report.

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 Securities 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, 2015, 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 Securities Exchange Act of 1934. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective.

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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 Securities Exchange Act of 1934, 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 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, 2015. 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.

Subject to the foregoing, based on management’s assessment, we believe that, as of September 26, 2015, 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.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Hologic, Inc.:

We have audited Hologic, Inc.'s internal control over financial reporting as of September 26, 2015, 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). Hologic, Inc.'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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

In our opinion, Hologic, Inc. maintained, in all material respects, effective internal control over financial reporting as of September 26, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Hologic, Inc. as of September 26, 2015 and September 27, 2014 and 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, 2015 of Hologic, Inc. and our report dated November 19, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
November 19, 2015

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Changes in Internal Control over Financial Reporting
During the quarter ended September 26, 2015, 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.

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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 and principal financial officer, 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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, 2015 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)	10,952,419	$22.21	9,460,950
Equity compensation plans not approved by security holders	—	$—	—
Total	10,952,419	$22.21	9,460,950

(1) Includes 4,258,563 shares that are issuable upon restricted stock units (RSUs), and performance stock units (PSUs) 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 and PSUs, 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 Securities and Exchange Commission 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 Securities and Exchange Commission within 120 days after the close of our fiscal year.

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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 Securities and Exchange Commission within 120 days after the close of our fiscal year.

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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, 2015, September 27, 2014 and September 28, 2013

Consolidated Statements of Comprehensive Income (Loss) for the years ended September 26, 2015, September 27, 2014 and September 28, 2013

Consolidated Balance Sheets as of September 26, 2015 and September 27, 2014

Consolidated Statements of Stockholders' Equity for the years ended September 26, 2015, September 27, 2014 and September 28, 2013

Consolidated Statements of Cash Flows for the years ended September 26, 2015, September 27, 2014 and September 28, 2013

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

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
2.1	Agreement and Plan of Merger, dated April 29, 2012, by and among Hologic, Gold Acquisition Corp. and Gen-Probe Incorporated.	8-K	05/01/2012
3.1	Certificate of Incorporation of Hologic.	S-1	01/24/1990
3.2	Certificate of Amendment to Certificate of Incorporation of Hologic.	10-Q	03/30/1996
3.3	Certificate of Amendment to Certificate of Incorporation of Hologic.	10-K	09/24/2005
3.4	Certificate of Amendment to Certificate of Incorporation of Hologic.	8-K	10/22/2007
3.5	Certificate of Amendment to Certificate of Incorporation of Hologic.	8-K	03/11/2008
3.6	Certificate of Designation of Series A Junior Participating Preferred Stock of Hologic.	8-K	11/21/2013
3.7	Certificate of Elimination of Series A Junior Participating Preferred Stock of Hologic.	8-K	06/25/2014
3.8	Fourth Amended and Restated By-laws, as amended of Hologic.	10-Q	12/28/2013

4.1	Specimen Certificate for Shares of Hologic's Common Stock.	8-A	01/31/1990
4.2	Description of Capital Stock (Contained in Hologic's Certificate of Incorporation, as amended, filed as Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5 hereto).		
4.3	Indenture, dated December 10, 2007, by and between Wilmington Trust Company, as Trustee, and Hologic.	8-K	12/10/2007

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
4.4	Second Supplemental Indenture, dated November 23, 2010, by and between Wilmington Trust Company, as Trustee, and Hologic.	10-K	09/25/2010
4.5	Form of 2.00% Convertible Exchange Senior Note due 2037 (included in Exhibit 4.4).	10-K	09/25/2010
4.6	Third Supplemental Indenture, dated March 5, 2012, by and between Wilmington Trust Company, as Trustee, and Hologic.	8-K	03/08/2012
4.7	Form of 2.00% Convertible Senior Note due 2042 (included in Exhibit 4.6).	8-K	03/08/2012
4.8	Fourth Supplemental Indenture, dated February 21, 2013, by and between Wilmington Trust Company, as Trustee, and Hologic.	8-K	02/21/2013
4.9	Form of 2.00% Convertible Senior Note due 2043 (included in Exhibit 4.8).	8-K	02/21/2013
4.10	Indenture, dated July 2, 2015, by and among Hologic, the guarantors party thereto and Wells Fargo Bank, National Association, as Trustee.	8-K	07/02/2015
4.11	Form of 5.250% Senior Note due 2022 (included in Exhibit 4.10).	8-K	07/02/2015
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	03/11/2013
10.7*	Form of Stock Option Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2014).	8-K	11/12/2013
10.8*	Form of Stock Option Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2015).	8-K	11/05/2014

10.9*	Form of Stock Option Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2016).	8-K	10/14/2015
10.10*	Form of Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2014).	8-K	11/12/2013
10.11*	Form of Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2016).	8-K	10/14/2015
10.12*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2014).	8-K	11/12/2013
10.13*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2015).	8-K	11/05/2014
10.14*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2016).	8-K	11/06/2015
10.15*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan (annual grant, adopted fiscal 2014).	10-K	09/28/2013

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.16*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan (annual grant, adopted fiscal 2015).	10-K	09/27/2014
10.17*	Form of Independent Director Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (annual grant).	10-K	09/28/2013
10.18*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan (initial grant, adopted fiscal 2014).	10-K	09/28/2013
10.19*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan (initial grant, adopted fiscal 2015).	10-K	09/27/2014
10.20*	Form of Independent Director Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (initial grant).	10-K	09/28/2013
10.21*	Hologic 2012 Employee Stock Purchase Plan.	8-K	03/08/2012
10.22*	Hologic 2015 Short-Term Incentive Plan.	8-K	11/10/2014
10.23*	Hologic Short-Term Incentive Plan.	8-K	11/06/2015
10.24*	Hologic Amended and Restated Deferred Compensation Program.	8-K	09/21/2015
10.25*	Hologic Deferred Equity Plan.	8-K	09/21/2015
10.26*	Rabbi Trust Agreement.	10-K	09/28/2013
10.27*	Form of Indemnification Agreement (as executed with each director of Hologic).	8-K	03/06/2009
10.28*	Form of Senior Vice President Change of Control Agreement. (1)	10-Q	12/29/2012
10.29*	Form of Senior Executive Officer Change of Control Agreement. (1)	8-K	11/17/2009
10.30*	Form of Senior Vice President Severance Agreement. (1)	10-K	09/28/2013
10.31*	Separation Agreement and General Release of All Claims dated December 11, 2013 by and between John W. Cumming and Hologic.	10-Q	12/28/2013
10.32*	Separation Agreement and General Release of All Claims dated November 10, 2014 by and between Mark J. Casey and Hologic.	8-K	11/10/2014
10.33*	Employment Agreement dated December 6, 2013 by and between Stephen P. MacMillan and Hologic.	8-K	12/09/2013

10.34*	Amended and Restated Employment Agreement by and between the Company and Stephen P. MacMillan, dated September 18, 2015.	8-K	09/21/2015
10.35*	Form of Price Targets Performance Stock Unit Award Agreement.	8-K	12/09/2013
10.36*	Form of Matching Restricted Stock Unit Award Agreement.	8-K	12/09/2013
10.37*	Change of Control Agreement dated December 6, 2013 by and between Stephen P. MacMillan and Hologic.	8-K	12/09/2013
10.38*	Separation and Release Agreement dated September 2, 2014 by and between Rohan F. Hastie and Hologic.	8-K	09/08/2014
10.39*	Offer Letter dated March 9, 2014 by and between Eric B. Compton and Hologic.	8-K	03/14/2014
10.40*	Severance and Change of Control Agreement dated March 9, 2014 by and between Eric B. Compton and Hologic. (2)	Filed herewith	

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.41*	Transition Agreement dated March 13, 2014 by and between Glenn P. Muir and Hologic.	8-K	03/14/2014
10.42*	Transition and Severance Agreement dated May 1, 2014 by and between David P. Harding and Hologic.	10-Q	03/29/2014
10.43*	Settlement and Release Agreement dated May 1, 2014 by and between David P. Harding and Hologic.	10-Q	03/29/2014
10.44*	Offer Letter dated May 8, 2014 by and between Robert W. McMahon and Hologic.	8-K	05/13/2014
10.45*	Severance and Change of Control Agreement dated May 8, 2014 by and between Robert W. McMahon and Hologic. (2)	Filed herewith	
10.46*	Offer Letter dated May 4, 2014 by and between Peter J. Valenti and Hologic.	10-Q	06/28/2014
10.47*	Senior Vice President Severance Agreement dated May 26, 2014 by and between Peter J. Valenti and Hologic.	10-K	09/27/2014
10.48*	Offer Letter dated August 21, 2014 by and between Thomas A. West and Hologic.	10-K	09/27/2014
10.49*	Senior Vice President Severance Agreement dated October 3, 2014 by and between Thomas A. West and Hologic.	10-K	09/27/2014
10.50*	Letter of Intent dated February 27, 2014 and Terms and Conditions of Employment dated March 10, 2014 by and between Claus Egstrand and Hologic.	10-K	09/27/2014
10.51*	Severance and Change of Control Agreement dated September 18, 2014 by and between Claus Egstrand and Hologic.	10-K	09/27/2014
10.52*	Offer Letter dated January 6, 2015 by and between John M. Griffin and Hologic.	10-Q	03/28/2015
10.53*	Severance and Change of Control Agreement dated February 2, 2015 by and between John M. Griffin and Hologic.	10-Q	03/28/2015
10.54	Facility Lease (Danbury) dated December 30, 1995 by and among Melvin J. Powers and Mary P. Powers D/B/A M&N Realty and Lorad.	Trex Medical Corporation S-1	03/29/1996

10.55	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
10.56	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
10.57	Office Lease dated December 31, 2003 between Cytyc and Marlborough Campus Limited Partnership.	Cytyc Corporation 10-K	12/31/2003
10.58	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
10.59	Lease Agreement by and between 445 Simarano Drive, Marlborough LLC and Cytyc dated July 11, 2006.	10-K	09/29/2007
10.60	Lease Guaranty dated October 22, 2007 between Bel Marlborough I LLC and Hologic, as guarantor thereunder.	8-K	10/22/2007
10.61	Form of Exchange Agreement.	8-K	02/15/2013

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.62	Credit and Guaranty Agreement, dated May 29, 2015, 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	05/29/2015
10.63	Pledge and Security Agreement, dated May 29, 2015, among the grantors party thereto and Bank of America, N.A. as Collateral Agent	10-Q	06/27/2015
10.64	Restated Agreement dated July 24, 2009 by and between Gen-Probe Incorporated and Novartis Vaccines and Diagnostics, Inc. ‡	Gen-Probe 10-Q/A	09/30/2009
10.65	First Amendment to Restated Agreement dated November 8, 2013 by and between Gen-Probe Incorporated and Novartis Vaccines and Diagnostics, Inc.	10-K	09/28/2013
10.66	Second Amendment to Restated Agreement by and between Gen-Probe Incorporated and Grifols Diagnostic Solutions Inc.‡	10-Q	06/27/2015
10.67	Supply Agreement for Panther Instrument System effective November 22, 2006 between Gen-Probe Incorporated and STRATEC Biomedical Systems AG. ‡	Gen-Probe 10-Q	09/30/2007
10.68	Nomination and Standstill Agreement dated December 8, 2013 by and among Hologic, Icahn Partners Master Fund LP, Icahn Partners Master Fund II LP, Icahn Partners Master Fund III LP, Icahn Partners LP, Icahn Onshore LP, Icahn Offshore LP, Icahn Capital LP, IPH GP LLC, Icahn Enterprises Holdings LP, Icahn Enterprises G.P. Inc., Beckton Corp., High River Limited Partnership, Hopper Investments LLC, Barberry Corp., Carl C. Icahn, Jonathan Christodoro and Samuel Merksamer.	8-K	12/09/2013
10.69	Confidentiality Agreement dated December 8, 2013 by and among Hologic, Icahn Partners Master Fund LP, Icahn Partners Master Fund II LP, Icahn Partners Master Fund III LP, Icahn Partners LP, Icahn Onshore LP, Icahn Offshore LP, Icahn Capital LP, IPH GP LLC, Icahn Enterprises Holdings LP, Icahn Enterprises G.P. Inc., Beckton Corp., High River Limited Partnership, Hopper Investments LLC, Barberry Corp., Carl C. Icahn, Jonathan Christodoro and Samuel Merksamer.	8-K	12/09/2013
12.1	Ratio of Earnings to Fixed Charges.	Filed herewith	
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	XBRL Instance Document.	Filed herewith
101.SCH	XBRL Taxonomy Extension Schema Document.	Filed herewith

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith	

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

‡ 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 U.S. Securities and Exchange Commission.

(1) List of executive officers to whom provided filed herewith.

(2) Corrected version of a previously filed exhibit.

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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 19, 2015

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 19, 2015
/S/ ROBERT W. MCMAHON ROBERT W. MCMAHON	Chief Financial Officer (Principal Financial Officer)	November 19, 2015
/S/ KARLEEN M. OBERTON KARLEEN M. OBERTON	Corporate Vice President, Finance and Accounting, Chief Accounting Officer (Principal Accounting Officer)	November 19, 2015
/S/ ELAINE S. ULLIAN ELAINE S. ULLIAN	Lead Independent Director	November 19, 2015
/S/ JONATHAN CHRISTODORO JONATHAN CHRISTODORO	Director	November 19, 2015
/S/ SALLY W. CRAWFORD SALLY W. CRAWFORD	Director	November 19, 2015
/S/ SCOTT T. GARRETT SCOTT T. GARRETT	Director	November 19, 2015
/S/ DAVID R. LAVANCE, JR. DAVID R. LAVANCE, JR.	Director	November 19, 2015
/S/ NANCY L. LEAMING NANCY L. LEAMING	Director	November 19, 2015
/S/ LAWRENCE M. LEVY LAWRENCE M. LEVY	Director	November 19, 2015
/S/ SAMUEL MERKSAMER SAMUEL MERKSAMER	Director	November 19, 2015
/S/ CHRISTIANA STAMOULIS	Director	November 19, 2015

CHRISTIANA STAMOULIS		
/S/ WAYNE WILSON WAYNE WILSON	Director	November 19, 2015

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Hologic, Inc.
Consolidated Financial Statements
Years ended September 26, 2015, September 27, 2014 and September 28, 2013
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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Hologic, Inc.:

We have audited the accompanying consolidated balance sheets of Hologic, Inc. as of September 26, 2015 and September 27, 2014 and 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, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Hologic, Inc. at September 26, 2015 and September 27, 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended September 26, 2015, 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), Hologic, Inc.'s internal control over financial reporting as of September 26, 2015, 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 19, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
November 19, 2015

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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, 2015	September 27, 2014	September 28, 2013
Revenues:			
Product	$2,270.4	$2,094.9	$2,100.9
Service and other	434.6	435.8	391.4
	2,705.0	2,530.7	2,492.3
Costs of revenues:			
Product	755.5	731.3	818.2
Amortization of intangible assets	299.7	314.6	307.9
Impairment of intangible assets	—	26.6	1.7
Service and other	217.1	212.7	203.1
Gross Profit	1,432.7	1,245.5	1,161.4
Operating expenses:			
Research and development	214.9	203.2	197.6
Selling and marketing	363.0	331.7	342.1
General and administrative	261.0	259.8	227.7
Amortization of intangible assets	110.2	113.8	112.6
Impairment of intangible assets	—	5.6	—
Contingent consideration – compensation expense	—	—	80.0
Contingent consideration – fair value adjustments	—	—	11.3
Impairment of goodwill	—	—	1,117.4
Gain on sale of intellectual property	—	—	(53.9)
Restructuring and divestiture charges	28.5	51.7	32.8
	977.6	965.8	2,067.6
Income (loss) from operations	455.1	279.7	(906.2)
Interest income	1.3	1.3	1.3
Interest expense	(205.5)	(220.6)	(281.1)
Debt extinguishment loss	(62.7)	(7.4)	(9.2)
Other (expense) income, net	(11.0)	(4.9)	2.3
Income (loss) before income taxes	177.2	48.1	(1,192.9)
Provision (benefit) for income taxes	45.6	30.8	(20.1)
Net income (loss)	$131.6	$17.3	$(1,172.8)
Net income (loss) per common share:			
Basic	$0.47	$0.06	$(4.36)
Diluted	$0.45	$0.06	$(4.36)
Weighted average number of shares outstanding:			
Basic	280,566	275,499	268,704
Diluted	289,537	278,360	268,704

See accompanying notes.

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Hologic, Inc.
Consolidated Statements of Comprehensive Income (Loss)
(In millions)

	Years ended		
	September 26, 2015	September 27, 2014	September 28, 2013
Net income (loss)	$131.6	$17.3	$(1,172.8)
Changes in foreign currency translation adjustment	(11.0)	(13.3)	1.4
Changes in unrealized holding gains and losses on available-for-sale securities	(2.0)	(3.2)	12.1
Changes in pension plans, net of taxes of $0.3 in 2015, $0.2 in 2014, and $0.1 in 2013	(0.2)	(1.3)	0.1
Changes in value of hedged interest rate caps, net of tax of $2.5 in 2015	(3.9)	—	—
Other comprehensive (loss) income	(17.1)	(17.8)	13.6
Comprehensive income (loss)	$114.5	$(0.5)	$(1,159.2)

See accompanying notes.

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Hologic, Inc.
Consolidated Balance Sheets
(In millions, except number of shares, which are reflected in thousands, and par value)

	September 26, 2015	September 27, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$491.3	$736.1
Restricted cash	1.4	5.5
Accounts receivable, less reserves of $11.1 and $12.0, respectively	416.1	396.0
Inventories	283.1	330.6
Deferred income tax assets	19.0	39.4
Prepaid income taxes	21.7	22.4
Prepaid expenses and other current assets	33.8	35.8
Total current assets	1,266.4	1,565.8
Property, plant and equipment, net	457.1	461.9
Intangible assets, net	3,023.2	3,433.6
Goodwill	2,808.2	2,810.8
Other assets	115.2	142.6
Total assets	$7,670.1	$8,414.7
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$391.8	$114.5
Accounts payable	117.0	92.1
Accrued expenses	272.1	262.1
Deferred revenue	163.1	150.9
Total current liabilities	944.0	619.6
Long-term debt, net of current portion	3,248.0	4,153.2
Deferred income tax liabilities	1,178.4	1,375.4
Deferred revenue	19.6	20.1
Other long-term liabilities	200.9	183.4
Commitments and contingencies (Note 11)		
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; 282,495 and 277,972 shares issued, respectively	2.8	2.8
Additional paid-in-capital	5,559.9	5,658.2
Accumulated deficit	(3,469.0)	(3,600.6)
Accumulated other comprehensive income (loss)	(14.5)	2.6
Total stockholders' equity	2,079.2	2,063.0
Total liabilities and stockholders' equity	$7,670.1	$8,414.7

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		Additional Paid-in-Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock		Total Stockholders' Equity
	Number of Shares	Par Value				Number of Shares	Amount	
Balance at September 29, 2012	265,635	2.6	5,396.7	(2,443.6)	6.8	219	(1.5)	2,961.0
Exercise of stock options	4,786	0.1	65.6	—	—	—	—	65.7
Issuance of common stock to employees upon vesting of restricted stock units, net of shares withheld for employee taxes	1,117	—	(12.3)	—	—	—	—	(12.3)
Issuance of common stock under the employee stock purchase plan	498	—	8.0	—	—	—	—	8.0
Stock-based compensation expense	—	—	52.4	—	—	—	—	52.4
Excess tax benefit from employee equity awards	—	—	5.9	—	—	—	—	5.9
Equity component related to convertible notes, net of taxes	—	—	20.0	—	—	—	—	20.0
Net loss	—	—	—	(1,172.8)	—	—	—	(1,172.8)
Foreign currency translation adjustment	—	—	—	—	1.4	—	—	1.4
Adjustment to minimum pension liability, net	—	—	—	—	0.1	—	—	0.1
Unrealized gain on marketable securities	—	—	—	—	12.1	—	—	12.1
Balance at September 28, 2013	272,036	2.7	5,536.3	(3,616.4)	20.4	219	(1.5)	1,941.5
Exercise of stock options	4,697	0.1	70.5	—	—	—	—	70.6
Issuance of common stock to employees upon vesting of restricted stock units, net of shares	846	—	(9.8)	—	—	—	—	(9.8)

withheld for employee taxes								
Issuance of common stock under the employee stock purchase plan	612	—	10.9	—	—	—	—	10.9
Stock-based compensation expense	—	—	49.5	—	—	—	—	49.5
Excess tax benefit from employee equity awards	—	—	0.8	—	—	—	—	0.8
Net income	—	—	—	17.3	—	—	—	17.3
Foreign currency translation adjustment	—	—	—	—	(13.3)	—	—	(13.3)
Adjustment to minimum pension liability, net	—	—	—	—	(1.3)	—	—	(1.3)
Retirement of treasury shares	(219)	—	—	(1.5)	—	(219)	1.5	—
Unrealized losses on marketable securities	—	—	—	—	(3.2)	—	—	(3.2)
Balance at September 27, 2014	277,972	2.8	5,658.2	(3,600.6)	2.6	—	—	2,063.0
Exercise of stock options	3,036	—	57.3	—	—	—	—	57.3
Issuance of common stock to employees upon vesting of restricted stock units, net of shares withheld for employee taxes	949	—	(12.9)	—	—	—	—	(12.9)
Issuance of common stock under the employee stock purchase plan	538	—	12.0	—	—	—	—	12.0
Stock-based compensation expense	—	—	54.6	—	—	—	—	54.6
Excess tax benefit from employee equity awards	—	—	7.6	—	—	—	—	7.6
Reacquisition of equity component from convertible notes repurchase, net of taxes	—	—	(216.9)	—	—	—	—	(216.9)
Net income	—	—	—	131.6	—	—	—	131.6
	—	—	—	—	(20.6)	—	—	(20.6)

Foreign currency translation adjustment								
Amounts reclassified out of cumulative translation adjustment	—	—	—	—	9.6	—	—	9.6
Adjustment to minimum pension liability, net	—	—	—	—	(0.2)	—	—	(0.2)
Unrealized losses on derivatives, net of taxes	—	—	—	—	(3.9)	—	—	(3.9)
Other-than-temporary impairment of marketable security reclassified out of accumulated other comprehensive income (loss)	—	—	—	—	7.8	—	—	7.8
Unrealized losses on marketable securities	—	—	—	—	(9.8)	—	—	(9.8)
Balance at September 26, 2015	282,495	$2.8	$5,559.9	$ (3,469.0)	$ (14.5)	—	$—	$2,079.2

See accompanying notes.

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Hologic, Inc.
Consolidated Statements of Cash Flows
(In millions)

	Years ended		
	September 26, 2015	September 27, 2014	September 28, 2013
OPERATING ACTIVITIES			
Net income (loss)	$131.6	$17.3	$(1,172.8)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation	81.5	94.7	95.5
Amortization	409.9	428.5	420.5
Non-cash interest expense	63.8	68.7	81.2
Stock-based compensation expense	59.3	50.0	52.3
Excess tax benefit related to equity awards	(10.7)	(5.7)	(7.4)
Deferred income taxes	(148.8)	(243.1)	(198.0)
Gain on sale of intellectual property	—	—	(53.9)
Fair value adjustments to contingent consideration	—	—	11.3
Fair value write-up of inventory sold	—	—	52.4
Impairment of goodwill	—	—	1,117.4
Asset impairment charges	—	38.4	9.4
Debt extinguishment losses	62.7	7.4	9.2
Equity investment impairment charges	7.8	6.9	6.4
Loss on disposal of property and equipment	6.6	7.1	4.9
Loss on sale of businesses	9.6	5.5	—
Other adjustments and non-cash items	14.3	(11.8)	0.9
Changes in operating assets and liabilities:			
Accounts receivable	(30.3)	7.9	4.1
Inventories	43.9	(44.7)	25.2
Prepaid income taxes	0.7	22.4	25.1
Prepaid expenses and other assets	5.7	17.3	0.9
Accounts payable	25.5	11.8	(6.4)
Accrued expenses and other liabilities	36.9	14.7	2.3
Deferred revenue	16.1	15.1	13.3
Net cash provided by operating activities	786.1	508.4	493.8
INVESTING ACTIVITIES			
Acquisition of businesses, net of cash acquired	—	—	(6.3)
Payment of additional acquisition consideration	—	—	(16.8)
Net proceeds from sale of business	—	10.1	85.1
Purchase of property and equipment	(48.1)	(44.3)	(49.0)
Increase in equipment under customer usage agreements	(41.3)	(35.9)	(41.1)
Net (purchases) sales of insurance contracts	(6.4)	13.8	(4.0)
Purchases of mutual funds	—	(29.7)	—
Sales of mutual funds	10.0	22.4	—
Proceeds from sale of intellectual property	—	—	60.0
(Purchase) sale of a cost-method equity investment	—	—	(1.6)
Increase in other assets	(0.3)	(3.4)	(7.5)
Net cash (used in) provided by investing activities	(86.1)	(67.0)	18.8
FINANCING ACTIVITIES			

Proceeds from long-term debt	2,495.1	—	—
Repayment of long-term debt	(3,095.0)	(595.0)	(265.0)
Payments to extinguish convertible notes	(543.7)	—	—
Proceeds from revolving credit line	358.0	—	—
Repayment from revolving credit line	(183.0)	—	—
Payment of debt issuance costs	(22.7)	(2.4)	(9.4)
Purchase of interest rate caps	(13.2)	—	—
Payment of contingent consideration	—	—	(43.0)
Payment of deferred acquisition consideration	—	(5.0)	(1.6)
Net proceeds from issuance of common stock pursuant to employee stock plans	70.0	81.4	75.1
Excess tax benefit related to equity awards	10.7	5.7	7.4
Payment of minimum tax withholdings on net share settlements of equity awards	(12.9)	(9.8)	(12.3)
Net cash used in financing activities	(936.7)	(525.1)	(248.8)
Effect of exchange rate changes on cash and cash equivalents	(8.1)	(2.7)	(1.7)
Net (decrease) increase in cash and cash equivalents	(244.8)	(86.4)	262.1
Cash and cash equivalents, beginning of period	736.1	822.5	560.4
Cash and cash equivalents, end of period	$491.3	$736.1	$822.5

See accompanying notes.

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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. The Company operates in four segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation. The Company’s fiscal year ends on the last Saturday in September. Fiscal 2015, 2014 and 2013 ended on September 26, 2015, September 27, 2014 and September 28, 2013, respectively.

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 element arrangements, allowance for doubtful accounts, the net realizable value of inventory, estimated fair value of cost-method equity investments, 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, stock-based compensation, 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, future sales or issuances of its common stock, management of international activities, protection of proprietary rights, patent and other litigation 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.

Marketable Securities

The Company’s marketable securities are comprised of equity securities and mutual funds. The equity securities are investments in the common stock of publicly traded companies, and the mutual funds are used to fund a portion of the Company's deferred compensation plan. The equity securities are classified as available-for-sale and are recorded at fair value with the unrealized gains or losses, net of tax, within accumulated other comprehensive income (loss), which is a component of stockholders’ equity. The mutual funds are classified as trading and are recorded at fair value with unrealized gains and losses recorded in other income (expense), net in the Consolidated Statements of Operations.

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The Company periodically reviews its marketable equity securities classified as available-for-sale for other-than-temporary declines in fair value below carrying value, or whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. The determination that a decline is other-than-temporary is, in part, subjective and influenced by many factors. When assessing marketable equity securities for other-than-temporary declines in value, the Company considers factors including: the significance of the decline in value compared to the carrying value; the underlying factors contributing to a decline in the price of the security; how long the market value of the investment has been less than its carrying value; any market conditions that impact liquidity; the views of external investment analysts; the financial condition and near-term prospects of the investee; any news or financial information that has been released specific to the investee; and the outlook for the overall industry in which the investee operates. In the fourth quarter of fiscal 2015, the Company concluded that the decline in fair value of one of its marketable securities was other-than-temporary based on the length of time the security's market value was significantly below its carrying value and recorded an impairment charge of $7.8 million.

The following reconciles cost basis to fair market value.

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other Than Temporary Impairment	Fair Value
As of September 26, 2015	$16.1	$ 7.2	$ (0.3)	$(7.8)	$15.2
As of September 27, 2014	$15.5	$ 10.2	$ (1.3)	$—	$24.4
As of September 28, 2013	$5.9	$ 12.2	$ —	$—	$18.1

Concentrations of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents, cost-method equity 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, 2015. The Company generally has not experienced any material losses related to receivables from individual customers or groups of customers in the healthcare industry. The Company maintains an allowance for doubtful accounts based on accounts past due and historical collection experience.

There were no customers with balances greater than 10% of accounts receivable as of September 26, 2015 and September 27, 2014, or any customers that represented greater than 10% of consolidated revenues for fiscal years 2015, 2014 and 2013.

Supplemental Cash Flow Statement Information

	Years ended		
	September 26, 2015	September 27, 2014	September 28, 2013
Cash paid during the period for income taxes	$168.7	$231.8	$79.9
Cash paid during the period for interest	$143.0	$155.7	$192.8

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 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:

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	September 26, 2015	September 27, 2014
Raw materials	$98.3	$115.6
Work-in-process	58.7	57.1
Finished goods	126.1	157.9
	$283.1	$330.6

Property, Plant and Equipment

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

Property, plant and equipment consisted of the following:

	September 26, 2015	September 27, 2014
Equipment and software	$365.9	$342.5
Equipment under customer usage agreements	305.7	285.2
Buildings and improvements	182.1	176.9
Leasehold improvements	59.2	63.2
Land	51.4	51.6
Furniture and fixtures	17.3	16.3
	981.6	935.7
Less - accumulated depreciation and amortization	(524.5)	(473.8)
	$457.1	$461.9

Property, plant and equipment are depreciated over the following estimated useful lives:

Asset Classification	Estimated Useful Life
Building and improvements	35–40 years
Equipment and software	3–10 years
Equipment under customer usage agreements	3–8 years
Furniture and fixtures	5–7 years
Leasehold improvements	Shorter of the Original Term of Lease or Estimated Useful Life

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 it 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. 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.

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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.

In the second quarter of fiscal 2014, the Company evaluated its MRI breast coils product line asset group, which was within its Breast Health segment, for impairment due to the Company's expectation that it would be sold or disposed of significantly before the end of its previously estimated useful life. At this time, the undiscounted cash flows expected to be generated by this asset group over its estimated remaining useful life were not sufficient to recover its carrying value. The Company estimated the fair value of the asset group using market participant assumptions, which were based on underlying cash flow estimates, resulting in an impairment charge of $28.6 million. Pursuant to ASC 360 subtopic 10-35-28, the impairment charge was allocated to the long-lived assets with $27.1 million to intangible assets and $1.5 million to property and equipment. The property and equipment charge was recorded to cost of product revenues and general and administrative expenses in the amounts of $0.3 million and $1.2 million, respectively. The Company believes this adjustment falls within Level 3 of the fair value hierarchy. The Company completed the sale of this product line in the fourth quarter of fiscal 2014 (see Note 3).

In the first quarter of fiscal 2014, the Company recorded a $3.1 million impairment charge to record certain of its buildings at fair value related to the shutdown of its Hitec Imaging organic photoconductor manufacturing line (see Note 3).

At the end of the fourth quarter of fiscal 2013, the Company decided to transition certain of its placed equipment at customer sites to its Panther instrument, and as a result, the Company recorded a charge of $6.3 million to cost of product revenues of which $3.7 million related to recording certain equipment at its fair value.

Business Combinations and Acquisition of Intangible Assets

The Company records tangible and intangible assets acquired in business combinations under the purchase method of accounting. The Company accounts for acquisitions in accordance with ASC 805, Business Combinations (ASC 805). Amounts paid for each acquisition are allocated to the assets acquired and liabilities assumed based on their fair values at the dates of acquisition. The Company allocates the purchase price in excess of the fair value of the net tangible assets acquired to identifiable intangible assets, including purchased research and development, 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 use of alternative valuation assumptions, including estimated cash flows and discount rates, and alternative useful life assumptions could result in different purchase price allocations and intangible asset amortization expense in current and future periods.

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. Regarding the value of the in-process projects, the Company considers, among other factors, the in-process projects' 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 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.

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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 realizability 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.

During the fourth quarter of fiscal 2014, the Company recorded impairment charges of $5.1 million for a reduction in fair value of its remaining IPR&D assets. The reduction in fair value was primarily due to lower revenue projections of the respective products compared to those estimated at the time of the Gen-Probe acquisition.

During the second quarter of fiscal 2014, the Company recorded impairment charges of $26.6 million and $0.5 million to developed technology and trade names, respectively, related to its MRI breast coils product line discussed above. In addition, the Company periodically re-evaluates the lives of its definite-lived intangible assets, and in the second quarter of fiscal 2014 shortened the life of certain corporate trade names, which will be phased out.

During the fourth quarter of fiscal 2013, as a result of the Company's conclusion that its Molecular Diagnostics reporting unit was impaired (as discussed below), the Company performed an impairment test of this reporting unit's long-lived assets as of the first day of the fourth quarter. The 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 based upon future projected net cash flows derived from the Company-wide annual planning process, which were used for the annual goodwill impairment test discussed below. Based on this analysis, the Molecular Diagnostics long-lived assets were deemed to not be impaired. The Company believes its procedures for estimating future cash flows were reasonable and consistent with market conditions at the time of estimation.

Intangible assets consisted of the following:

	September 26, 2015		September 27, 2014	
Description	Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Developed technology	$3,979.1	$1,698.5	$3,965.6	$1,399.4
In-process research and development	3.7	—	17.9	—
Customer relationships and contracts	1,101.1	467.5	1,102.4	384.7
Trade names	236.4	131.5	236.5	105.3
Business licenses	2.5	2.1	2.6	2.0
	$5,322.8	$2,299.6	$5,325.0	$1,891.4

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

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The estimated amortization expense at September 26, 2015 for each of the five succeeding fiscal years was as follows:

Fiscal 2016	$377.0
Fiscal 2017	$365.6
Fiscal 2018	$355.1
Fiscal 2019	$343.5
Fiscal 2020	$332.3

Goodwill

In accordance with ASC 350, Intangibles—Goodwill and Other (ASC 350), the Company tests goodwill for impairment at the reporting unit level 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.

In performing the impairment test, the Company utilizes the two-step approach prescribed under ASC 350. The first step requires a comparison of the carrying value of each reporting unit to its estimated fair value. To estimate the fair value of its reporting units for Step 1, 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 a 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.

If the carrying value of a reporting unit exceeds its estimated fair value, the Company is required to perform the second step of the goodwill impairment test to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit’s goodwill to its carrying value. The implied fair value of goodwill is derived by performing a hypothetical purchase price allocation for each reporting unit as of the measurement date and allocating the reporting unit’s estimated fair value to its assets and liabilities. The residual amount from performing this allocation represents the implied fair value of goodwill. To the extent this amount is below the carrying value of goodwill, an impairment charge is recorded.

The Company conducted its fiscal 2015 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 June 28, 2015, 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 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. For illustrative purposes, had the fair value of each of the reporting units that passed Step 1 been lower than 10%, all of the reporting units would still have passed Step 1 of the goodwill impairment test.

At September 26, 2015, the Company believes that each reporting unit, with goodwill aggregating 2.81 billion, was not at risk of failing Step 1 of the goodwill impairment test based on the current forecasts.

The Company conducted its fiscal 2014 annual 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 June 29, 2014, 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

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of the measurement date. 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.

The Company conducted its fiscal 2013 annual impairment test on the first day of the fourth quarter, and as noted above used a DCF analysis to estimate the fair value of its reporting units as of June 30, 2013. 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 Step 1, all of the Company's reporting units, except for its Molecular Diagnostics reporting unit, which is within the Company's Diagnostics segment, had fair values exceeding their carrying values, and as such, Step 2 of the impairment test was not required for those reporting units. In connection with its company-wide annual budgeting and strategic planning process performed in the fourth quarter of fiscal 2013, the Company performed a full re-evaluation of its existing product development efforts and cost structure. As a result, the Company reduced its short term and long term revenue forecasts and determined that indicators of impairment existed in its Molecular Diagnostics reporting unit. The Molecular Diagnostics reporting unit is primarily comprised of the Company's Aptima business acquired in the Gen-Probe acquisition and the molecular diagnostics business acquired in the Third Wave acquisition. The updated forecast of revenue and profitability, which reflected recent pricing pressures at that time, was lower than those expected at the time of the Gen-Probe acquisition. As a result, the fair value of this reporting unit was below its carrying value. The Company performed Step 2 of the impairment test, consistent with the procedures described above, and recorded a goodwill impairment charge of $1.1 billion. The basis of fair value for Molecular Diagnostics assumed the reporting unit would be purchased or sold in a taxable transaction, and the discount rate of 10% applied to the after-tax cash flows was relatively consistent with that used in the Company's purchase accounting for the Gen-Probe acquisition.

A rollforward of goodwill activity by reportable segment from September 27, 2014 to September 26, 2015 is as follows:

	Diagnostics	Breast Health	GYN Surgical	Skeletal Health	Total
Balance at September 27, 2014	$1,154.1	$631.7	$1,016.8	$8.2	$2,810.8
Tax adjustments	0.6	0.7	—	—	1.3
Foreign currency and other	(2.4)	(0.6)	(0.8)	(0.1)	(3.9)
Balance at September 26, 2015	$1,152.3	$631.8	$1,016.0	$8.1	$2,808.2

Other Assets

Other assets consisted of the following:

	September 26, 2015	September 27, 2014
Other Assets		
Deferred financing costs	$27.0	$44.9
Life insurance contracts	27.5	22.4
Derivative asset	6.2	—
Mutual funds	5.6	15.4
Marketable securities	15.2	24.4
Manufacturing access fees	11.6	14.1
Cost-method equity investments	4.2	5.2
Other	17.9	16.2
	$115.2	$142.6

Deferred financing costs are related to the Company's Convertible Notes, Credit Agreement, Prior Credit Agreement and Senior Notes (see Note 4 for further discussion). The Company amortizes amounts related to each debt issuance using the effective interest rate method over the period of earliest redemption or the term of such debt. 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 10 for further discussion). The manufacturing access fees are related to a manufacturing supply and purchase agreement for our Aptima HPV products and are being amortized over the term of the agreement.

The Company’s cost-method equity investments are carried at cost as the Company owns less than 20% of the voting equity and does not have the ability to exercise significant influence over these companies. The Company regularly evaluates the carrying value of its cost-method equity investments for impairment and whether any events or circumstances are identified

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that would significantly harm the fair value of the investment. The primary indicators the Company utilizes to identify these events and circumstances are the investee's ability to remain in business, such as the investee's liquidity and rate of cash use, and the investee's ability to secure additional funding and the investee valuation as determined by that additional funding. In the event a decline in fair value is judged to be other-than-temporary, the Company will record an other-than-temporary impairment charge in other income (expense), net in the Consolidated Statements of Operations. During fiscal 2014 and fiscal 2013, the Company recorded other-than-temporary impairment charges of $6.9 million and $6.4 million, respectively, related to certain of its cost-method equity investments to adjust their carrying amounts to fair value. No such charges were recorded in fiscal 2015 for cost method investments. However, the Company recorded a $7.8 million other-than-temporary impairment charge related to one of its marketable securities in fiscal 2015. In the third quarter of fiscal 2013, the Company sold one of its investments and recorded a gain of $2.0 million.

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. Software development costs eligible for capitalization have not been significant to date.

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

Accumulated Other Comprehensive Income (Loss)

Other comprehensive income (loss) includes certain transactions that have generally been reported in the statement of stockholders' equity. The components of accumulated other comprehensive income (loss) consisted of the following:

	September 26, 2015	September 27, 2014
Foreign currency translation adjustment	$(15.7)	$(4.7)
Unrealized gains on available-for-sale securities	6.9	8.9
Minimum pension liability, net of tax of $0.3 and $0.2, respectively	(1.8)	(1.6)
Hedged Interest Rate Caps, net of tax of $2.5 in 2015	(3.9)	—
	$(14.5)	$2.6

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The following tables summarize the changes in accumulated balances of other comprehensive income for the periods presented:

	Year Ended September 26, 2015					Year Ended September 27, 2014			
	Foreign Currency Translation	Marketable Securities	Pension Plans	Hedged Interest Rate Caps	Total	Foreign Currency Translation	Marketable Securities	Pension Plans	Total
Beginning Balance	$(4.7)	$8.9	$(1.6)	$—	$2.6	$8.6	$12.1	$(0.3)	$20.4
Other comprehensive loss before reclassifications	(20.6)	(9.8)	(0.2)	(3.9)	(34.5)	(13.3)	(3.2)	(1.3)	(17.8)
Amounts reclassified to statement of operations	9.6	7.8	—	—	17.4	—	—	—	—
Ending Balance	$(15.7)	$6.9	$(1.8)	$(3.9)	$(14.5)	$(4.7)	$8.9	$(1.6)	$2.6

During fiscal 2015, the Company reclassified $9.6 million out of accumulated other comprehensive income to restructuring and divestiture charges related to writing off the cumulative translation adjustment in connection with its substantial liquidation of the MRI breast coils product line (see Note 3). In addition, during fiscal 2015 the Company reclassified $7.8 million out of accumulated other comprehensive income to other (expense) income, net for the other-than-temporary impairment of a marketable security.

Derivatives

Interest Rate Cap - Cash Flow Hedge

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

During fiscal 2015, the Company entered into separate interest rate cap agreements with multiple counter-parties to help mitigate the interest rate volatility associated with the variable rate interest on its credit facilities under its Prior Credit Agreement, which has been replaced by the new Credit Agreement (see Note 4). Interest rate cap agreements provide the right to receive cash if the reference interest rate rises above a contractual rate. The aggregate premium paid by the Company for the interest rate cap agreements was $6.1 million, and $7.1 million, respectively, 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 the Prior Credit Agreement. The terms in the new Credit Agreement are consistent with the Prior Credit Agreement, and therefore the interest rate caps continue to be 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 over a three-year period, which ends on December 30, 2017.

As of September 26, 2015, 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 in AOCI.

The aggregate fair value of these interest rate caps was $6.9 million at September 26, 2015 and is included in both Prepaid expenses and other current assets and Other assets on the Company's Consolidated Balance Sheet. Refer to Note 5 "Fair Value Measurements" below for related fair value disclosures.

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The tables below present the location of the Company's derivative financial instruments on the Consolidated Balance Sheets and the unrealized loss recognized in AOCI related to the interest rate caps for the following reporting periods (in millions):

	Balance Sheet Location	September 26, 2015
Assets:		
Derivative instruments designated as a cash flow hedge:		
Interest rate cap agreements	Prepaid expenses and other current assets	$0.7
Interest rate cap agreements	Other Assets	6.2
		$6.9

	Year Ended September 26, 2015	Year Ended September 27, 2014
Amount of loss recognized in other comprehensive income, net of taxes:		
Interest rate cap agreements	$(3.9)	$—

During fiscal 2015, an immaterial amount was reclassified from AOCI to the Company's Consolidated Statements of Operations related to the derivative financial instruments. The Company expects to similarly reclassify approximately $3.9 million from AOCI to the Consolidated Statements of Operations in the next twelve months.

Revenue Recognition

The Company generates revenue from the sale of its products, primarily medical imaging systems and diagnostic and surgical disposable products, and related services, which are primarily support and maintenance services on its medical imaging systems.

The Company recognizes product revenue upon shipment provided that there is persuasive evidence of an arrangement, there are no uncertainties regarding acceptance, the sales price is fixed or determinable, no right of return exists and collection of the resulting receivable is reasonably assured. Generally, the Company's product arrangements for capital equipment sales, primarily in its Breast Health and Skeletal Health reporting segments, are 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 believes that these services and undelivered products can 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, depending on shipment terms, are deferred and recognized as such services are performed. The relative selling price of any undelivered products is also deferred at the time of shipment and recognized as revenue when these products are delivered. There is no customer right of return in the Company's sales agreements.

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 are recognized ratably over the term of the contract. Other service revenues are recognized as the services are performed.

For revenue arrangements with multiple deliverables, the Company records revenue as separate units of accounting if the delivered items have value to the customer on a stand-alone basis, and if the arrangement includes a general right of return relative to the delivered items, the delivery or performance of the undelivered items is 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 product, the software element in its other products is incidental and 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 and C-View systems, which are sold by its Breast Health segment, these products are within the scope of the software revenue recognition rules. The Company evaluated the appropriate revenue recognition treatment of its other hardware products, including its Dimensions digital mammography systems, which have 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 are not within the scope of ASC 985-605.

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The Company is required to allocate revenue to its multiple element arrangements based on the relative fair value of each element's selling price. The Company typically determines 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 determines 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 requires a substantial majority of selling prices for a product or service to be within a reasonably narrow range. The Company also considers the class of customer, method of distribution, and the geographies into which its products and services are sold when determining VSOE. If VSOE cannot be established, which may occur in instances when a product or service has not been sold separately, stand-alone sales are too infrequent, or product pricing is not within a narrow range, the Company will generally establish the selling price using ESP to allocate arrangement consideration. The objective of ESP is to determine the price at which the Company would typically transact a stand-alone sale of the product or service. ESP is 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 requires revenue earned on software arrangements involving multiple elements to be allocated to each element based on their relative VSOE of fair value. If VSOE does not exist for a delivered element, the residual method is applied in which the arrangement consideration is 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") has been established, the Company recognizes revenue using the residual method at the time all other revenue recognition criteria have been met.

Within its Diagnostics segment, the Company manufactures blood screening products according to demand schedules provided by its collaboration partner, Grifols, S.A. ("Grifols"). The Company's agreement provides that it shares a portion of Grifols's revenue from screening blood donations. Upon shipment to Grifols, the Company recognizes product revenue at an agreed upon fixed transfer price, which is not refundable, and records the related cost of products sold. Based on the terms of the Company's collaboration agreement with Grifols, the Company's ultimate share of the net revenue from sales to the end user in excess of the transfer price is not known until it is reported to the Company by Grifols. On a monthly basis, Grifols reports net revenue generated during the prior month and remits an additional corresponding net payment to the Company, which is recorded as revenue at that time. This payment combined with the transfer price revenues previously recognized represents the Company's ultimate share of net revenue under the agreement.

While the majority of its instruments are placed at customer sites, in certain instances the Company sells instruments to its clinical diagnostics customers and records sales of these instruments upon delivery and customer acceptance. For certain customers with non-standard payment terms, instrument sales are recorded based upon expected cash collection. Prior to delivery, each instrument is tested to ensure it meets the Company's specifications and FDA regulations, and is shipped fully assembled. Customer acceptance of the Company's clinical diagnostic instrument systems requires installation and training by the Company's technical service personnel. Installation is a standard process consisting principally of uncrating, calibrating and testing the instrumentation. The Company sells its instruments to Grifols for use in blood screening and records these instrument sales upon delivery since Grifols is responsible for the placement, maintenance and repair of the units with its customers.

Within its Diagnostics business, and to a lesser extent, its GYN Surgical business, the Company provides 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 installs the instrumentation or equipment at the customer's site and recovers the cost of providing the instrumentation or equipment in the amount it charges for its diagnostic tests, assays and other disposables. Customers enter into a customer usage agreement and typically commit to purchasing minimum quantities of disposable products at a stated price over a defined contract term, which is typically between three and five years. Revenue is 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.

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.

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Accounts receivable reserve activity for fiscal 2015, 2014 and 2013 was as follows:

	Balance at Beginning of Period	Charged to Costs and Expenses	Write-offs and Payments	Balance at End of Period
Period Ended:				
September 26, 2015	$12.0	$1.6	$(2.5)	$11.1
September 27, 2014	$8.8	$4.4	$(1.2)	$12.0
September 28, 2013	$6.4	$4.3	$(1.9)	$8.8

Cost of Service and Other Revenues

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

Stock-Based Compensation

The Company accounts for share-based payments in accordance with ASC 718, Stock Compensation (ASC 718). As such, all share-based payments to employees, including grants of stock options, restricted stock units, performance stock units and market stock units and shares issued under the Company's employee stock purchase plan, are recognized in the Consolidated Statements of Operations based on their fair values on the date of grant.

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 (loss) per share is computed by dividing net income (loss) 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 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.

The Company applies the provisions of ASC 260, Earnings Per Share, Subsection 10-45-44, to determine the diluted weighted average shares outstanding as it relates to its convertible notes, and due to the type of debt instrument issued and its accounting policy, the Company applies the treasury stock method and not the if-converted method. The dilutive impact of the Company's convertible notes is based on the difference between the Company's current period average stock price and the conversion price of the convertible notes, provided there is a premium. As such, dilution related to the conversion premium on the 2010 Notes, 2012 Notes and 2013 Notes is included in the calculation of diluted weighted-average shares outstanding in fiscal 2015. In fiscal 2014, only the dilution of the conversion premium on the 2010 Notes is included in diluted weighted-average shares outstanding.

A reconciliation of basic and diluted share amounts for fiscal 2015, 2014, and 2013 was as follows:

	September 26, 2015	September 27, 2014	September 28, 2013
Basic weighted average common shares outstanding	280,566	275,499	268,704
Weighted average common stock equivalents from assumed exercise of stock options and restricted stock units	2,898	2,368	—
Incremental shares from Convertible Notes premium	6,073	493	—
Diluted weighted average common shares outstanding	289,537	278,360	268,704
Weighted-average anti-dilutive shares related to:			
Outstanding stock options	1,502	5,033	8,445
Restricted stock units	49	20	1,109

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, average unrecognized stock compensation expense and assumed tax benefits upon

exercise is greater

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than the average stock price for the period. In those reporting periods in which the Company has a net loss, anti-dilutive shares and common stock equivalents are comprised of the number of shares and common stock equivalents that would be anti-dilutive had the Company reported 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 2015 and 2014 was as follows:

	Balance at Beginning of Period	Provisions	Settlements/ Adjustments	Balance at End of Period
Period ended:				
September 26, 2015	$6.3	$6.1	$(7.0)	$5.4
September 27, 2014	$9.3	$7.1	$(10.1)	$6.3

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 $14.4 million, $14.1 million and $14.1 million for fiscal 2015, 2014 and 2013, respectively, and were included in selling and marketing expense in the Consolidated Statements of Operations.

Recently Issued Accounting Pronouncements

In July 2015, the Financial Accounting Standards Board (FASB) issued guidance under ASC 330, Simplifying the Measurement of Inventory. The new guidance requires inventory to be measured at the lower of cost and net realizable value, which is defined as the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. This new guidance is effective for the Company's first quarter of fiscal 2018 and early adoption is permitted. The guidance must be applied prospectively. The Company is currently evaluating the impact of the adoption of this requirement on its consolidated financial statements but does not anticipate that adoption of this guidance will have a material impact on its consolidated financial statements.

In April 2015, the FASB issued Accounting Standards Update (ASU) No. 2015-03, Presentation of Debt Issuance Costs. This guidance intends to simplify the presentation of debt issuance costs and more closely align the presentation of debt issuance costs under U.S. GAAP to IFRS standards. This guidance is effective for annual periods beginning after December 15, 2015, and is applicable to the Company in fiscal 2017. Early adoption is permitted. The Company is currently evaluating this guidance, but does not anticipate that adoption of this guidance will have a material impact on its consolidated financial statements.

In February 2015, the FASB issued ASU No. 2015-02, Consolidation (Topic 810): Amendments to the Consolidation Analysis. This guidance focuses on a reporting company's consolidation evaluation to determine whether certain legal entities should be consolidated. This guidance is effective for annual periods beginning after December 15, 2015, and is applicable to the Company in fiscal 2017. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating this guidance, but does not anticipate that adoption of this guidance will have a material impact on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist that raise substantial doubt about an entity's ability to continue as a

going concern within one year after the date the financial statements are issued and provide related disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and is applicable to us in fiscal 2018. Earlier application is permitted. The adoption of ASU 2014-15 is not expected to have a material effect on the Company's consolidated financial statements or disclosures.

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In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 660), which provides guidance for revenue recognition. This ASU is applicable to any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets. ASU 2014-09 will supersede the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific guidance. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled to receive in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current U.S. GAAP. These judgments may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. On July 9, 2015, the FASB voted in favor of delaying the effective date of the new standard by one year, with early adoption permitted as of the original effective date. ASU 2014-09 is effective prospectively for fiscal years, and interim reporting periods within those years, beginning after December 15, 2017, which is fiscal 2019 for the Company. The Company is currently evaluating the impact of the adoption of ASU 2014-09 on its consolidated financial position and results of operations.

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3. 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 2015, 2014 and 2013 and a rollforward of the charges to the accrued balances as of September 26, 2015:

	Consolidation of Diagnostics Operations	Closure of Indianapolis Facility	Fiscal 2015 Actions	Fiscal 2014 Actions	Fiscal 2013 Actions	Other Operating Cost Reductions	Total
Restructuring and Divestiture Charges							
Fiscal 2013 charges:							
Workforce reductions	$ 14.0	$4.8	$—	$—	$11.3	$1.1	$31.2
Facility closure costs	—	0.2	—	—	—	0.4	0.6
Other	—	0.7	—	—	—	0.2	0.9
Fiscal 2013 restructuring charges	$ 14.0	$5.7	$—	$—	$11.3	$1.7	$32.7
Divestiture net charges							0.1
Fiscal 2013 restructuring and divestiture charges							$32.8
Fiscal 2014 charges:							
Workforce reductions	$ 2.9	$0.2	$—	$29.5	$0.9	$8.7	$42.2
Non-cash impairment charge	—	—	—	—	—	3.1	3.1
Facility closure costs	—	0.5	—	—	—	0.1	0.6
Other	0.1	—	—	—	—	0.2	0.3
Fiscal 2014 restructuring charges	$ 3.0	$0.7	$—	$29.5	$0.9	$12.1	$46.2
Divestiture net charges							5.5
Fiscal 2014 restructuring and divestiture charges							$51.7
Fiscal 2015 charges:							
Workforce reductions	0.1	—	10.0	6.0	—	0.2	$16.3

Facility closure costs	0.5	—	—	2.0	—	0.1	2.6
Fiscal 2015 restructuring charges	$ 0.6	$—	$10.0	$8.0	$—	$0.3	$18.9
Divestiture net charges							9.6
Fiscal 2015 restructuring and divestiture charges							$28.5

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	Consolidation of Diagnostics Operations	Closure of Indianapolis Facility	Fiscal 2015 Actions	Fiscal 2014 Actions	Fiscal 2013 Actions	Other Operating Cost Reductions	Total
Rollforward of Accrued Restructuring							
Balance as of September 29, 2012	$ 8.4	$1.8	$—	$—	$—	$0.6	$10.8
Fiscal 2013 restructuring charges	$ 14.0	$5.7	$—	$—	$11.3	$1.7	$32.7
Stock-based compensation	(6.3)	—	—	—	(1.6)	—	(7.9)
Non-cash impairment charges	—	—	—	—	—	(0.1)	(0.1)
Severance payments	(13.1)	(3.1)	—	—	(4.4)	(0.9)	(21.5)
Other payments	—	(0.6)	—	—	—	(1.1)	(1.7)
Balance as of September 28, 2013	$ 3.0	$3.8	$—	$—	$5.3	$0.2	$12.3
Fiscal 2014 restructuring charges	$ 3.0	$0.7	$—	$29.5	$0.9	$12.1	$46.2
Stock-based compensation	—	—	—	(6.6)	—	—	(6.6)
Non-cash impairment charges	—	—	—	—	—	(3.1)	(3.1)
Severance payments	(3.0)	(4.0)	—	(10.9)	(6.1)	(7.0)	(31.0)
Other payments	—	(0.5)	—	—	—	(0.4)	(0.9)
Balance as of September 27, 2014	$ 3.0	$—	$—	$12.0	$0.1	$1.8	$16.9
Fiscal 2015 restructuring charges	$ 0.6	$—	$10.0	$8.0	$—	$0.3	$18.9
Stock-based compensation	—	—	(4.1)	—	—	—	(4.1)
Severance payments	(3.0)	—	(2.8)	(16.2)	(0.1)	(1.8)	(23.9)
Other payments	(0.5)	—	—	(1.3)	—	(0.3)	(2.1)

Balance as of September 26, 2015	$ 0.1	$—	$3.1	$2.5	$—	$—	$5.7

Consolidation of Diagnostics Operations

In connection with its acquisition of Gen-Probe in fiscal 2012, the Company implemented restructuring actions to consolidate its Diagnostics operations, including streamlining product development initiatives, reducing overlapping functional areas in sales, marketing and general and administrative functions, and consolidating manufacturing resources, field services and support. As a result, the Company terminated certain employees from Gen-Probe and its legacy diagnostics business in research and development, sales, marketing, and general and administrative functions. The Company recorded severance and benefit charges in fiscal 2012 of $13.3 million related to this action pursuant to ASC 420, Exit or Disposal Cost Obligations (ASC 420). The majority of these employees ceased working in the fourth quarter of fiscal 2012, and their full severance charge was recorded in the fourth quarter of fiscal 2012. In addition, certain of the terminated Gen-Probe employees had unvested stock options, which were accelerated at termination pursuant to the stock options' original terms. As such, the severance charges in fiscal 2012 include $3.5 million of stock-based compensation expense. In fiscal 2013, the Company recorded $10.8 million of severance charges, including $6.3 million for stock-based compensation. Included in these charges was $9.7 million recorded in the second quarter of fiscal 2013 related to the termination of certain Gen-Probe executives, including Carl Hull, Gen-Probe's former Chairman, President and Chief Executive Officer. The charge was for the acceleration of certain retention payments and equity awards pursuant to the original terms of the related agreements. No additional charges were recorded in fiscal 2014 or 2015 under this portion of the action.

In addition, under this plan, the Company completed moving its legacy molecular diagnostics operations from Madison, Wisconsin to Gen-Probe's facilities in San Diego, California. This transfer was completed at the end of fiscal 2014, and as a result, many of the employees in Madison were terminated. The Company recorded severance and benefit charges pursuant to ASC 420 beginning in fiscal 2012 through the third quarter of fiscal 2015 as charges were recorded over requisite service periods. The Company recorded $0.1 million, $3.0 million, $3.2 million and $0.9 million for severance and benefits in fiscal 2015, 2014, 2013 and 2012, respectively, and $0.5 million for facility closure costs in fiscal 2015. The Company also recorded

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non-cash charges of $0.6 million in the fourth quarter of fiscal 2012 as a result of exiting certain research projects. This action is complete and no additional charges will be recorded.

Closure of Indianapolis Facility

In the fourth quarter of fiscal 2012, the Company finalized its decision to transfer production of the majority of its interventional breast products, which are included within the Breast Health segment, from its Indianapolis, Indiana facility to its facility in Costa Rica. The transfer was completed in the first quarter of fiscal 2014, and all employees at the Indianapolis location were terminated. The Company recorded total severance and benefit charges under this action of $5.9 million pursuant to ASC 420. These charges were recorded ratably over the required service period of the affected employees. The Company recorded severance and benefits charges of $0.2 million, $4.8 million and $0.9 million in fiscal 2014, 2013 and 2012, respectively, related to this action. In addition, the Company recorded a charge of $0.4 million in the first quarter of fiscal 2014 related to the termination of its Indianapolis lease. The Company also recorded miscellaneous charges of $0.8 million in fiscal 2013 and $0.9 million in fiscal 2012 for amounts owed to the state of Indiana for employment credits. This action was completed in fiscal 2014 and no additional charges were recorded in fiscal 2015.

Fiscal 2015 Actions

During each quarter of fiscal 2015, the Company continued to make executive management changes resulting in the termination of certain executives and employees on a worldwide basis. In addition, the Company continued to consolidate and close certain international offices to improve operational efficiency and reduce costs. Severance and benefit charges under these actions have been recorded pursuant to ASC 712, Compensation-Nonretirement Postemployment Benefits (ASC 712), and ASC 420 depending on the employees terminated, and the Company recorded severance and benefit charges of $10.0 million in fiscal 2015. Included in the charge is $4.1 million of stock-based compensation in the twelve month period.

In connection with its review of operations, the Company decided to shut-down its manufacturing operation in China, which manufactured mammography systems for the Chinese market. As a result, the Company will terminate manufacturing and research and development personnel located in China, and the severance charge was insignificant.

Fiscal 2014 Actions

During the first quarter of fiscal 2014, the Company implemented a cost reduction initiative comprised of reducing headcount and evaluating research projects and operating costs. In connection with this plan, the Company terminated certain employees on a worldwide basis. The Company recorded the severance and benefit charges pursuant to ASC 420 and ASC 712, depending on the employee terminated. The Company recorded $6.3 million of severance and benefit charges in the first quarter of fiscal 2014, which included $0.4 million of stock-based compensation.

On December 6, 2013, Stephen P. MacMillan was appointed as President, Chief Executive Officer and a director of the Company. The employment of John W. Cumming, the Company’s prior President and Chief Executive Officer, terminated upon Mr. MacMillan’s appointment. The Company provided separation benefits to Mr. Cumming pursuant to his employment letter dated July 18, 2013 resulting in a charge of $6.6 million in the first quarter of fiscal 2014, which included $4.4 million of stock-based compensation related to the acceleration of all of Mr. Cumming’s outstanding equity awards in accordance with the existing terms of Mr. Cumming’s share based payment arrangements.

In the second, third, and fourth quarters of fiscal 2014, the Company continued to make executive management changes and implement additional cost reduction initiatives resulting in the termination of certain executives and employees on a worldwide basis. In addition, in the fourth quarter of fiscal 2014 the Company decided to consolidate and close certain international offices. Severance and benefit charges under these actions were recorded pursuant to ASC 420 and ASC 712 depending on the employees terminated, and the Company recorded severance and benefit charges of $16.6 million in fiscal 2014. Included in the charge was $1.8 million of stock-based compensation for the modification of the terms of equity awards to certain employees. For those employees who continued to be employed beyond the minimum retention period, charges were recorded ratably over the estimated service period of the affected employees.

During fiscal 2015, the Company recorded $6.0 million for severance and benefits costs and $2.0 million for facility closure costs related to this action. The facility closure costs primarily relate to lease obligation charges for three

office locations that were vacated and the Company had met the cease-use date criteria. This action was completed in fiscal 2015.

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Fiscal 2013 Actions

During the third quarter of fiscal 2013, the Company implemented a cost reduction initiative comprised of reducing headcount and evaluating research projects and operating costs. In connection with this plan, the Company terminated certain employees on a worldwide basis. The Company primarily recorded severance and benefit charges pursuant to ASC 420, and the total severance and benefits charge related to this plan was $5.4 million. For those employees who continued to be employed beyond the minimum retention period, charges were recorded ratably over the estimated service period of the affected employees. The Company recorded severance and benefit charges of $0.9 million and $4.6 million in fiscal 2014 and 2013, respectively, related to this action.

During the fourth quarter of fiscal 2013, Robert A. Cascella resigned as the Company's President and Chief Executive Officer and as a member of the Board of Directors of the Company, and effective at the same time, Mr. Cumming was appointed as the Company's President and Chief Executive Officer. In connection with this management change, additional headcount reductions were implemented. As a result of this action, the Company recorded $6.8 million in the fourth quarter of fiscal 2013 for severance and benefits charges. All employees were notified prior to September 28, 2013 and primarily ceased employment in the fourth quarter of fiscal 2013. The severance and benefit charges were recorded pursuant to ASC 712 for those employees with contractual arrangements and under ASC 420 for the remainder of the affected employees. In addition to the acceleration of stock options pursuant to the stock options' original terms for certain employees, the Company also modified the terms of equity awards to certain employees resulting in aggregate stock-based compensation charges of $1.4 million recorded in the fourth quarter of fiscal 2013.

Other Operating Cost Reductions:

Hitec-Imaging Organic Photoconductor Manufacturing Line Shut-down

In the fourth quarter of fiscal 2013, in connection with the Company's cost reduction initiatives, the Company decided to shut-down its Hitec-Imaging organic photoconductor manufacturing line located in Germany. This production line was included within the Breast Health segment. As a result, the Company terminated certain employees, primarily in manufacturing, in fiscal 2014. During the first quarter of fiscal 2014, the Company completed its negotiations with the local Works Council to determine severance benefits for the approximately 95 affected employees. The Company recorded severance and benefit charges pursuant to ASC 420 and began notifying the affected employees in the second quarter of fiscal 2014. The Company recorded charges of $0.3 million and $8.7 million in fiscal 2015 and 2014, respectively in connection with terminating these employees.

In the first quarter of fiscal 2014, the Company recorded an impairment charge of $3.1 million to record certain buildings at this location to their estimated fair value.

Divestitures

In the fourth quarter of fiscal 2014, the Company completed the sale of its MRI breast coils product line and recorded a loss on disposal of $5.3 million. The Company also provided certain transition services through April 2015, including the manufacturing and sale of inventory to the buyer. Since all operations had ceased during the third quarter of fiscal 2015, the Company concluded that this subsidiary had been substantially liquidated and recorded a $9.6 million charge in the third quarter of fiscal 2015 related to writing off the cumulative translation adjustment related to the subsidiary.

Subsequent Events - Fiscal 2016 Actions

During the third quarter of fiscal 2015, the Company decided to close its Bedford, Massachusetts facility where it manufactures its Skeletal Health products as well as certain support manufacturing services for its Breast Health segment. The manufacturing of the Skeletal Health products will be outsourced to a third-party and the Breast Health manufacturing services will be moved to the Company's Danbury, Connecticut and Marlborough, Massachusetts facilities. In addition, research and development, sales and services support and administrative functions will be moved to both Marlborough and Danbury. The transition is expected to be completed by the end of fiscal 2016. In connection with this plan, certain employees, primarily in manufacturing, will be terminated. The employees were notified of termination and related benefits in the first quarter of fiscal 2016, and the Company will account for these charges pursuant to ASC 420. Employees will be required to remain employed during this transition period and charges will be recorded ratably over the required service period. The Company estimates the severance benefits will

be approximately $3.0 million.

During the first quarter of fiscal 2016, the Company began implementing a second plan to consolidate and improve operational efficiency of its international sales and marketing and field services operations and certain support functions. As a

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result, the Company will terminate certain employees. Severance benefits will be recorded pursuant to ASC 420 and ASC 712, depending on the employees terminated. The Company is in process of finalizing the plan and estimating severance benefits that will commence in the first quarter of fiscal 2016.

4. Borrowings and Credit Agreements

The Company’s borrowings consisted of the following:

	September 26, 2015	September 27, 2014
Current debt obligations, net of debt discount:		
Term Loan	$74.6	$—
Revolver	175.0	—
Term Loan A	—	99.6
Term Loan B	—	14.9
Convertible Notes	142.2	—
Total current debt obligations	391.8	114.5
Long-term debt obligations, net of debt discount:		
Term Loan	1,399.8	—
Term Loan A	—	796.7
Term Loan B	—	1,120.9
Senior Notes	—	1,000.0
2022 Senior Notes	986.7	—
Convertible Notes	861.5	1,235.6
Total long-term debt obligations	3,248.0	4,153.2
Total debt obligations	$3,639.8	$4,267.7

The debt maturity schedule for the Company’s obligations as of September 26, 2015 is as follows:

	2016	2017	2018	2019	2020	2021 and Thereafter	Total
Term Loan	$75.0	$84.4	$121.9	$150.0	$1,050.0	—	$1,481.3
Revolver	175.0	—	—	—	—	—	$175.0
2022 Senior Notes	—	—	—	—	—	1,000.0	1,000.0
Convertible Notes (1)	150.0	—	910.5	—	—	—	1,060.5
	$400.0	$84.4	$1,032.4	$150.0	$1,050.0	$1,000.0	$3,716.8

(1) Classified based on the earliest date of redemption for each respective issuance with the exception of the 2010 Notes which are convertible by their respective holders as further discussed below. In addition, the balance in fiscal 2018 reflects accretion on the 2013 Notes through September 26, 2015.

Credit Agreement

On May 29, 2015, the Company and certain of its domestic subsidiaries entered into a Credit and Guaranty Agreement (the “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 party thereto (collectively, the "Lenders"). This Credit Agreement replaced the Company's existing senior secured credit facility with Goldman Sachs Bank USA, in its capacity as administrative agent and collateral agent and the lenders party thereto ("Prior Credit Agreement") entered into on August 1, 2012, and the proceeds under the Credit Agreement of $1.68 billion were used to pay off the amounts outstanding under the Prior Credit Agreement.

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The credit facilities ("Credit Facilities") under the Credit Agreement consist of:

- A $1.5 billion secured term loan to the Company with a final maturity date of May 29, 2020 (the “Term Loan”); and
- A secured revolving credit facility under which the Borrowers (as defined below) may borrow up to $1 billion, subject to certain sublimits, with a final maturity date of May 29, 2020 (the “Revolver”).

The Company and one of its subsidiaries, Hologic GGO 4 Ltd ("Hologic U.K.") are the initial borrowers (the “Borrowers”) under the Credit Agreement. The Company's obligations under the Credit Agreement are guaranteed by certain of its domestic subsidiaries (the "Subsidiary Guarantors"). Hologic U.K.’s obligations under the Credit Agreement are guaranteed by the Company and the Subsidiary Guarantors.

In addition to the Term Loan, the Company borrowed $175.0 million under the Revolver. Borrowings under the Revolver may be made in certain alternative currencies pursuant to the terms of the Credit Agreement. The Company has the ability, subject to the terms of the Credit Agreement, to designate any additional wholly-owned foreign subsidiary of the Company as a Designated Borrower (as defined in the Credit Agreement) to receive loans up to a $100 million sublimit. The obligations of any Designated Borrower under such sublimit would be guaranteed by the Company and the Subsidiary Guarantors.

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

- Term Loan: the Base Rate (as defined in the Credit Agreement) or the Eurocurrency Rate (i.e., the Libor rate); and
- Revolver: if funded in U.S. dollars, the Base Rate or the Eurocurrency Rate, and, if funded in an alternative currency, the Eurocurrency Rate; and if requested under the swing line sublimit, the Base Rate.

The applicable margin to the Base Rate and the Eurocurrency Rate is subject to specified changes depending on the total net leverage ratio as defined in the Credit Agreement. Current borrowings outstanding under the Credit Agreement bear interest at the Eurocurrency Rate plus the applicable margin of 1.75% per annum. The Company is also required to pay a quarterly commitment fee on the undrawn committed amount available under the Revolver.

The Company is required to make scheduled principal payments under the Term Loan in increasing amounts ranging from $18.75 million per three-month period commencing with the three-month period ending on September 25, 2015 to $37.5 million per three-month period commencing with the three-month period ending on September 28, 2018. The remaining balance of the Term Loan is due at maturity. Any amounts outstanding under the Revolver are due at maturity. In addition, subject to the terms and conditions set forth in the Credit Agreement, the Company is required to make certain mandatory prepayments from specified excess cash flows from operations (to the extent the Company’s net senior secured leverage ratio exceeds a certain ratio) and 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) (“Mandatory Prepayments”). Mandatory Prepayments are required to be applied by the Company, first, to the Term Loan, second, to any outstanding amount under the swing line sublimit, third, to the Revolver, and fourth to any outstanding amount under a letter of credit sublimit. Subject to certain limitations, the Company may voluntarily prepay any of the credit facilities under the Credit Agreement without premium or penalty.

Borrowings outstanding under either the Credit Agreement or the Prior Credit Agreement in fiscal 2015 had a weighted-average interest rate of 2.43%. The interest rate on the amounts outstanding at September 26, 2015 was 1.95%. Interest expense in fiscal 2015 under the Credit Agreement and the Prior Credit Agreement aggregated $54.7 million, which includes non-cash interest expense of $9.0 million, related to the amortization of the deferred issuance costs and accretion of the debt discount.

The Credit Agreement contains affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants restricting the ability of the Borrowers and the Subsidiary Guarantors, subject to negotiated exceptions, to incur additional indebtedness and additional liens on their 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. The 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.

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Borrowings are secured by first-priority liens on, and a first-priority security interest in, substantially all of the assets of the Company, with certain exceptions. The 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 is 5.50:1.00 beginning on the Company's fiscal quarter ended September 26, 2015, and then decreases over time to 4.00:1.00 for the quarter ending March 28, 2020. The interest coverage ratio is 3.75:1.00 beginning on the Company's fiscal quarter ended September 26, 2015, and will remain 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 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 for the same measurement period. These terms, and the calculation thereof, are defined in further detail in the Credit Agreement. The Company was in compliance with these covenants as of September 26, 2015.

The Company has evaluated the Credit Agreement for derivatives pursuant to ASC 815, Derivatives and Hedging, and identified embedded derivatives that require bifurcation as the features are not clearly and closely related to the host instrument. The embedded derivatives are 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 has determined that the fair value of these embedded derivatives was nominal as of September 26, 2015.

Pursuant to ASC 470, Debt (ASC 470), the accounting for the Credit Agreement was evaluated on a creditor-by-creditor basis with regard to the Prior Credit Agreement 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 $18.2 million in the third quarter of fiscal 2015 to write-off the pro-rata amount of unamortized debt discount and deferred issuance costs related to these creditors. For the remainder of the creditors, this transaction has been 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 $4.6 million related to this transaction were recorded as interest expense and $3.8 million were recorded as deferred issuance costs to be amortized over the term of the agreement. In addition, fees paid directly to the Lenders of $4.9 million were recorded as a debt discount.

Prior Credit Agreement

On August 1, 2012, the Company and certain domestic subsidiaries (the “Guarantors”) entered into the Prior Credit Agreement with Goldman Sachs Bank USA, in its capacity as administrative and collateral agent, and the lenders party thereto (collectively, the “Prior Lenders”).

The credit facilities under the Prior Credit Agreement initially consisted of:

- $1.0 billion senior secured tranche A term loan (“Term Loan A”) with a final maturity date of August 1, 2017;
- $1.5 billion secured tranche B term loan (“Term Loan B”) with a final maturity date of August 1, 2019; and
- $300.0 million secured revolving credit facility (“Revolving Facility”) with a final maturity date of August 1, 2017.

Pursuant to the terms and conditions of the Prior Credit Agreement, the Prior Lenders committed to provide senior secured financing in an aggregate amount of up to $2.8 billion. As of the closing of the Gen-Probe Incorporated acquisition on August 1, 2012, the Company borrowed $2.5 billion aggregate principal under the term loans of the Prior Credit Agreement. Net proceeds to the Company were $2.41 billion, after issuing the term loans at a discount and deducting associated fees and expenses, all of which will be amortized to interest expense over the respective maturity dates of the debt. The proceeds were used to fund a portion of the purchase price for the Gen-Probe acquisition.

On March 20, 2013, the Company, the Guarantors, Goldman Sachs, and the Prior Lenders entered into Refinancing Amendment No. 1 (the “Prior Credit Agreement Amendment”) to the Prior Credit Agreement. The Prior Credit Agreement Amendment (i) refinanced the Company’s original Term Loan A with a new senior secured tranche A term loan facility with the same principal amount, maturity date and amortization schedule but with an applicable margin 1.00% less than the original Term Loan A (at each margin level), (ii) refinanced the Company’s original Revolving Facility with a new senior secured revolving credit facility with the same principal amount and maturity date, but with

an applicable margin 1.00% less than the original Revolving Facility (at each margin level), and (iii) amended certain covenants and terms of the Prior Credit Agreement.

Effective as of the date of the Prior Credit Agreement Amendment, amounts outstanding under the new Term Loan A and the new Revolving Facility bore interest, at the Company's option: (i) at the Base Rate plus 1.00% per annum, or (ii) at the Adjusted Eurodollar Rate (i.e., the Libor rate) plus 2.00% per annum. The applicable margin with respect to the new Term Loan A and the new Revolving Facility were subject to specified changes depending on the Company's total net leverage ratio, as defined in the Prior Credit Agreement.

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Pursuant to ASC 470, the accounting for this refinancing 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 $3.2 million to write-off the pro-rata amount of unamortized debt discount and deferred issuance costs related to these creditors for the initial borrowings under the Term Loan A facility. For the remainder of the creditors, this transaction was accounted for as a modification because the present value of the cash flows on a creditor by creditor basis between the two debt instruments was less than 10%. Pursuant to ASC 470, subtopic 50-40, third-party costs incurred directly related to the exchange were expensed as incurred. As such, the Company recorded issuance costs related to the refinancing of $2.4 million to interest expense in the second quarter of fiscal 2013.

On August 2, 2013, the Company, the Guarantors, Goldman Sachs, and the Prior Lenders entered into Refinancing Amendment No. 2 (the "Prior Credit Agreement Amendment 2") to the Prior Credit Agreement. The Prior Credit Agreement Amendment 2 (i) refinanced the Company's original Term Loan B with a new senior secured tranche B term loan facility with the same principal amount (subject to the prepayment referenced below), maturity date and amortization schedule but with an applicable margin 0.75% less than the original Term Loan B, and (ii) amended certain covenants and terms of the Prior Credit Agreement. Effective as of the date of the Prior Credit Agreement Amendment 2, amounts outstanding under the new Term Loan B bore interest, at the Company's option: (A) at the Base Rate with a floor of 2.00%, plus 1.75% per annum, or (B) at the Adjusted Eurodollar Rate (i.e., the Libor rate) with a floor of 1.00%, plus 2.75% per annum. In connection with this refinancing, the Company voluntarily prepaid $200.0 million of principal of the Term Loan B facility.

Pursuant to ASC 470, the accounting for this refinancing was consistent with that described above for the Prior Credit Agreement Amendment. As a result, the Company recorded a debt extinguishment loss of $6.0 million to write-off the pro-rata amount of unamortized debt discount and deferred issuance costs related to the voluntary prepayment of the Term Loan B facility. The Company expensed direct third-party costs of $1.1 million to interest expense in the fourth quarter of fiscal 2013.

On October 31, 2013, the Company voluntarily prepaid $100.0 million of its Term Loan B facility. Pursuant to ASC 470, the Company recorded a debt extinguishment loss of $2.9 million in the first quarter of fiscal 2014 to write-off the pro-rata amount of unamortized debt discount and deferred issuance costs related to this voluntary prepayment.

On February 26, 2014, the Company, the Guarantors, Goldman Sachs, and the Prior Lenders entered into Refinancing Amendment No. 3 to the Prior Credit Agreement and reduced the applicable interest rates. In connection with this refinancing, the Company voluntarily prepaid $25.0 million of the new senior secured tranche B term loan facility. Pursuant to ASC 470, the accounting for this refinancing 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 $4.4 million in the second quarter of fiscal 2014 to write-off the pro-rata amount of unamortized debt discount and deferred issuance costs related to these creditors. 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 $1.0 million related to this transaction were recorded to interest expense.

On December 24, 2014, the Company voluntarily prepaid $300.0 million of its Term Loan B facility. Pursuant to ASC 470, the Company recorded a debt extinguishment loss of $6.7 million in the first quarter of fiscal 2015 to write-off the pro-rata amount of unamortized debt discount and deferred issuance costs related to this voluntary prepayment.

Borrowings outstanding under the Prior Credit Agreement in fiscal 2014 and 2013 had weighted-average interest rates of 2.89% and 3.70%, respectively. Interest expense under the Prior Credit Agreement totaled $75.3 million and $107.6 million for fiscal 2014 and 2013, respectively, which includes non-cash interest expense of $12.7 million and $14.5 million, respectively, related to the amortization of the deferred financing costs and accretion of the debt discount.

The Prior Credit Agreement contained affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants restricting the ability of the Company and the guarantors, subject to negotiated

exceptions, to: incur additional indebtedness and additional liens on their 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 business.

The Prior Credit Agreement also contained total net leverage ratio and interest coverage ratio financial covenants measured as of the last day of each fiscal quarter consistent with that described above under the Credit Agreement.

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Senior Notes

2022 Senior Notes

On July 2, 2015, the Company completed a private placement of $1.0 billion aggregate principal amount of its 5.250% Senior Notes due 2022 (the “2022 Senior Notes”) at an offering price of 100% of the aggregate principal amount of the 2022 Senior Notes. The 2022 Senior Notes mature on July 15, 2022 and bear interest at the rate of 5.250% per year, payable semi-annually on January 15 and July 15 of each year, commencing on January 15, 2016. The Company used the net proceeds of the 2022 Senior Notes, plus available cash to discharge the outstanding 6.25% Senior Notes due 2020 (the "Senior Notes") and redeemed such Senior Notes, in the aggregate principal amount of $1.0 billion on August 1, 2015 at an aggregate redemption price of $1.03 billion, reflecting a premium payment of $31.25 million. In addition, the Company made a final interest payment in the amount of $31.25 million for interest accrued to August 1, 2015, to holders of record of the Senior Notes as of July 15, 2015. As a result of this transaction, the Company recorded a debt extinguishment loss in the fourth quarter of fiscal 2015 of $22.3 million, which included the pro rata premium payment and pro-rata debt issuance costs. The Company evaluated the accounting under ASC 470 at the creditor-by-creditor level to determine modification versus extinguishment accounting.

The Company recorded interest expense related to the 2022 Senior Notes and Senior Notes of $67.2 million, $64.0 million and $63.9 million in fiscal 2015, 2014 and 2013, respectively, which includes non-cash interest expense of $2.1 million, $1.7 million and $1.6 million in fiscal 2015, 2014 and 2013, respectively, related to the amortization of the deferred financing costs.

The 2022 Senior Notes were not registered, and will be not registered, under the Securities Act of 1933, as amended (the “Securities Act”), or any state securities laws, and were offered only to qualified institutional buyers in reliance on Rule 144A under the Securities Act and outside the United States in accordance with Regulation S under the Securities Act. The 2022 Senior Notes are general senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain domestic subsidiaries of Hologic (the “Domestic Guarantors”).

The 2022 Senior Notes were issued pursuant to an indenture (the "Indenture"), dated as of July 2, 2015, among the Company, the Domestic Guarantors and Wells Fargo Bank, National Association, as trustee. The Indenture contains covenants which limit, among other things, the ability of the Company and the Domestic Guarantors to incur additional indebtedness and additional liens on their assets, engage in mergers or acquisitions or dispose of assets, pay dividends or make other distributions, enter into certain transactions with affiliated persons and to make certain investments. These covenants are subject to a number of exceptions and qualifications, including the suspension of certain of these covenants upon the 2022 Senior Notes receiving an investment grade credit rating. The Indenture does not require the Company to maintain any financial covenants.

The Company may redeem the 2022 Senior Notes at any time prior to July 15, 2018 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 2022 Senior Notes with the net cash proceeds of certain equity offerings at any time and from time to time before July 15, 2018, at a redemption price equal to 105.250% 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 2022 Senior Notes on or after: July 15, 2018 through July 14, 2019 at 102.625% of par; July 15, 2019 through July 14, 2020 at 101.313% of par; and July 15, 2020 and thereafter at 100% of par. In addition, if the Company undergoes a change of control, as provided in the Indenture, the Company will be required to make an offer to purchase each holder’s 2022 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 has evaluated the 2022 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.

Senior Notes

On August 1, 2012, the Company completed a private placement of $1.0 billion aggregate principal amount of its Senior Notes at an offering price of 100% of the aggregate principal amount of the Senior Notes. Net proceeds to the Company were $987.4 million after deducting underwriting fees and offering expenses, which were being amortized

to interest expense over the term of the Senior Notes. The Senior Notes bore interest at the rate of 6.25% per year, payable semi-annually on February 1 and August 1 of each year, commencing on February 1, 2013. The Senior Notes were registered under the Securities Act of 1933 in fiscal 2013. The Senior Notes were general senior unsecured obligations of the Company and were guaranteed on a senior unsecured basis by the Domestic Guarantors. The proceeds were used to fund a portion of the Gen-Probe acquisition.

The indenture contained customarily applicable affirmative and negative covenants, including covenants restricting the ability of the Company and certain of its subsidiaries', subject to negotiated exceptions and qualifications, to: incur additional

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indebtedness; pay dividends or repurchase or redeem capital stock; make certain investments; incur liens; enter into certain types of transactions with the Company's affiliates; and sell assets or consolidate or merge with or into other companies. The Company was not required to maintain any financial covenants with respect to the Senior Notes.

Convertible Notes

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"). Net proceeds from the offering were $1.69 billion, after deducting offering expenses. 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"). This exchange transaction was accounted for as a modification and no debt extinguishment loss or gain was recorded.

On November 14, 2013, the Company announced that it had issued a notice of redemption to the holders of its 2007 Notes to redeem any 2007 Notes outstanding on December 18, 2013 at a redemption price payable in cash equal to 100.00% of the principal amount of the 2007 Notes plus accrued and unpaid interest to, but not including, December 18, 2013. Holders of the 2007 Notes also had the option of putting the 2007 Notes to the Company as of December 13, 2013. The 2007 Notes were redeemed at their par value aggregating $405.0 million. Under ASC 470, the derecognition of the 2007 Notes did not result in a gain or loss as the fair value of the liability component of the 2007 Notes was determined to be equal to the consideration paid to redeem the 2007 Notes, and as a result, no value was allocated to the reacquisition of the conversion option.

The 2010 Notes, the 2012 Notes and the 2013 Notes are collectively referred to herein as the "Convertible Notes." Holders may require the Company to repurchase the Convertible Notes prior to maturity on the dates set forth below:

- the 2010 Notes on each of December 15, 2016, 2020 and 2025, December 13, 2030 and December 14, 2035;
- the 2012 Notes on each of March 1, 2018, 2022, 2027 and 2032 and March 2, 2037; and
- the 2013 Notes on each of December 15, 2017, 2022, 2027, 2032 and 2037.

Holders may also require the Company to repurchase the Convertible Notes upon a fundamental change, as defined in each of the applicable indentures. The Company may redeem all or a portion of the 2010 Notes at any time on or after December 19, 2016, all or a portion of the 2012 Notes at any time on or after March 6, 2018 and all or a portion of the 2013 Notes at any time on or after December 15, 2017. If, prior to maturity, a holder requires the Company to repurchase the Convertible Notes or the Company elects to redeem the Convertible Notes, the repurchase or redemption price of each Convertible Note will equal 100% of its principal amount, plus accrued and unpaid interest to, but excluding, the redemption or repurchase date, as applicable.

It is the Company's current intent and policy to settle any conversion of the Convertible Notes as if the Company had elected to make either a net share settlement or all cash election, such that upon conversion, the Company intends to pay the holders in cash for the principal amount of the Convertible Notes and, if applicable shares of its common stock or cash to satisfy the premium based on a calculated daily conversion value.

The 2010 Notes bear interest at a rate of 2.00% per year on the principal amount, payable semi-annually in arrears in cash on June 15 and December 15 of each year ending on December 15, 2016 and will accrete principal from December 15, 2016 at a rate that provides holders with an aggregate annual yield to maturity of 2.00% per year. Beginning with the six month interest period commencing December 15, 2016, the Company will pay contingent interest during any six month interest period to the holders of 2010 Notes if the "trading price", as defined, of the 2010 Notes for each of the five trading days ending on the second trading day immediately preceding the first day of the applicable six month interest period equals or exceeds 120% of the accreted principal amount of the 2010 Notes. The holders of the 2010 Notes may convert the 2010 Notes into shares of the Company's common stock at a conversion price of approximately $23.03 per share, subject to adjustment, prior to the close of business on September 15, 2037,

subject to prior redemption or repurchase of the 2010 Notes, under any of the following circumstances: (1) during any calendar quarter if the last reported sale price of the Company's common stock exceeds 130% of the conversion price for at least 20 trading days in the 30 consecutive trading days ending on the last trading day of the preceding calendar quarter; (2) during the five business day period after any five consecutive trading day period in which the trading price per note for each day of such period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such day; (3) if the 2010 Notes have been called for redemption; or

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(4) upon the occurrence of specified corporate events. At the option of the holder, regardless of the foregoing circumstances, holders may convert their respective 2010 Notes at any time on or after September 15, 2037 through the close of business on the second scheduled trading day immediately preceding the maturity date. The conversion rate will not be adjusted for accrued interest or accreted principal in excess of the original $1,000 principal amount, as accrued interest and accreted principal will not be convertible into common stock.

During the fourth quarter of fiscal 2015, the closing price of the Company's common stock exceeded 130% of the applicable conversion price of its 2010 Notes on at least 20 of the last 30 consecutive trading days of the quarter. Therefore holders of the 2010 Notes are able to convert their notes during the first quarter of fiscal 2016. As such, the Company classified the $142.2 million carrying value of its 2010 Notes (which have a principal value of $150.0 million) as a current debt obligation. In the event the closing price conditions are met in the first quarter of fiscal 2016 or a future fiscal quarter, the 2010 Notes will be convertible at a holder's option during the immediately following fiscal quarter. As of September 26, 2015, the if-converted value of the 2010 Notes exceeded the aggregate principal amount by approximately $114.1 million. It is the Company's current intent and policy to settle any conversion of the 2010 Notes as if the Company had elected to make either a net share settlement or all cash election, such that upon conversion, the Company intends to pay the holders in cash for the principal amount of the 2010 Notes and, if applicable shares of its common stock or cash to satisfy the premium based on a calculated daily conversion value.

On various dates during the fourth quarter of fiscal 2015, the Company entered into privately negotiated repurchase transactions and extinguished $300.0 million principal of the 2010 Notes for a total payment of $543.7 million, which includes the conversion premium resulting from the Company's stock price on the date of the transaction being in excess of the conversion price of $23.03. Under ASC 470, this transaction was accounted for as an extinguishment and derecognition of the 2010 Notes and resulted in a debt loss extinguishment of $15.5 million.

The 2012 Notes bear interest at a rate of 2.00% per year on the principal amount, payable semi-annually in arrears in cash on March 1 and September 1 of each year, beginning September 1, 2012 and ending on March 1, 2018 and will accrete principal from March 1, 2018 at a rate that provides holders with an aggregate annual yield to maturity of 2.00% per year. Beginning with the six month interest period commencing March 1, 2018, the Company will pay contingent interest during any six month interest period to the holders of 2012 Notes if the “trading price”, as defined, of the 2012 Notes for each of the five trading days ending on the second trading day immediately preceding the first day of the applicable six month interest period equals or exceeds 120% of the accreted principal amount of the 2012 Notes. The holders of the 2012 Notes may convert the 2012 Notes into shares of the Company’s common stock at a conversion price of $31.175 per share, subject to adjustment, prior to the close of business on December 1, 2041, subject to prior redemption or repurchase of the 2012 Notes, under any of the following circumstances: (1) during any calendar quarter if the last reported sale price of the Company’s common stock exceeds 130% of the conversion price for at least 20 trading days in the 30 consecutive trading days ending on the last trading day of the preceding calendar quarter; (2) during the five business day period after any five consecutive trading day period in which the trading price per note for each day of such period was less than 98% of the product of the last reported sale price of the Company’s common stock and the conversion rate on each such day; (3) if the 2012 Notes have been called for redemption; or (4) upon the occurrence of specified corporate events. None of these triggering events had occurred as of September 26, 2015. At the option of the holder, regardless of the foregoing circumstances, holders may convert their respective 2012 Notes at any time on or after December 1, 2041 through the close of business on the second scheduled trading day immediately preceding the maturity date. The conversion rate will not be adjusted for accrued interest or accreted principal in excess of the original $1,000 principal amount, as accrued interest and accreted principal will not be convertible into common stock. None of these triggering events has occurred as of September 26, 2015.

The 2013 Notes bear interest at a rate of 2.00% per year on the original principal amount, payable semi-annually in arrears in cash on June 15 and December 15 of each year, ending on December 15, 2013. The 2013 Notes accrete principal from their date of issuance at a rate of 4.00% per year until and including December 15, 2017, and 2.00% per year thereafter. Beginning with the six month interest period commencing December 15, 2017, the Company will pay contingent interest to the holders of 2013 Notes during any six month interest period if the “trading price,” as defined, of the 2013 Notes for each of the five trading days ending on the second trading day immediately preceding the first day of the applicable six month interest period equals or exceeds 120% of the accreted principal amount of the 2013

Notes. The holders of the 2013 Notes may convert the notes into shares of the Company's common stock at a conversion price of approximately $38.59 per share, subject to adjustment, prior to the close of business on September 15, 2043, subject to prior redemption or repurchase of the 2013 Notes, under any of the following circumstances: (1) during any calendar quarter if the last reported sale price of the Company's common stock exceeds 130% of the conversion price for at least 20 trading days in the 30 consecutive trading days ending on the last trading day of the preceding calendar quarter; (2) during the five business day period after any five consecutive trading day period in which the trading price per note for each day of such period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such day; (3) if the notes have been called for redemption; or (4) upon the occurrence of specified corporate events. At the option of the holder, regardless of the foregoing

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circumstances, holders may convert their respective 2013 Notes at any time on or after September 15, 2043 through the close of business on the second scheduled trading day immediately preceding the maturity date. The conversion rate will not be adjusted for accrued interest or accreted principal in excess of the original $1,000 principal amount, as accrued interest and accreted principal will not be convertible into common stock. None of these triggering events had occurred as of September 26, 2015.

In lieu of delivery of shares of the Company's common stock in satisfaction of the Company's obligation upon conversion of the Convertible Notes, the Company may elect to deliver cash or a combination of cash and shares of its common stock. If the Company elects to satisfy its conversion obligation in a combination of cash and shares of the Company's common stock, the Company is required to deliver up to a specified dollar amount of cash per $1,000 original principal amount of Convertible Notes, and will settle the remainder of its conversion obligation in shares of its common stock, in each case based on the daily conversion value calculated as provided in the respective indentures for the Convertible Notes. This net share settlement election is in the Company's sole discretion and does not require the consent of holders of the Convertible Notes. It is the Company's current intent and policy to settle any conversion of the Convertible Notes as if the Company had elected to make the net share settlement election.

The Convertible Notes are the Company's senior unsecured obligations and rank equally with all of its existing and future senior unsecured debt and prior to all future subordinated debt. The Convertible Notes are effectively subordinated to any future secured indebtedness to the extent of the collateral securing such indebtedness, and structurally subordinated to all indebtedness and other liabilities (including trade payables) of the Company's subsidiaries.

Accounting for the Convertible Notes

The Convertible Notes have been recorded pursuant to FASB Staff Position ("FSP") APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement) (FSP APB 14-1) (codified within ASC 470) since they can be settled in cash or partially in cash upon conversion. FSP APB 14-1 requires the liability and equity components of the convertible debt instrument to be separately accounted for in a manner that reflects the entity's nonconvertible debt borrowing rate when interest expense is subsequently recognized. The excess of the debt's principal amount over the amount allocated to the liability component is recognized as the value of the embedded conversion feature ("equity component") within additional-paid-in capital in stockholders' equity and amortized to interest expense over the expected life of the liability component (typically the date of the earliest redemption) using the effective interest method. The liability component is initially recorded at its fair value, which is calculated using a discounted cash flow technique. Key inputs used to estimate the fair value of the liability component included the Company's estimated nonconvertible debt borrowing rate as of the measurement date (i.e., the date the Convertible Notes are issued), the amount and timing of cash flows, and the expected life of the Convertible Notes. The effective interest rate is estimated by comparing other companies' debt issuances that had features similar to the Company's debt excluding the conversion feature and who had similar credit ratings during the same annual period as the Company. In addition, third-party transaction costs are required to be allocated to the liability and equity components based on their relative values. The original issuance of the 2007 Notes and both exchange transactions for the 2010 Notes and 2012 Notes, which each included a derecognition and re-recognition, were accounted for under this accounting guidance.

The 2013 Notes exchange transaction was accounted for as a modification pursuant to ASC 470-50 and not an extinguishment because the terms of the two debt instruments were not substantially different. This determination was based on the fact that the present value of the cash flows on a creditor by creditor basis between the two debt instruments was less than 10% and the change in the fair value of the conversion option before and after the exchange transaction was less than 10%. As a result, there is no gain or loss from this exchange. As required, the Company recorded the increase in the fair value of the conversion option of $32.5 million from this exchange to additional paid-in-capital, net of deferred taxes. The Company determined the fair value of the conversion option for each debt instrument on the date of modification by calculating the fair value of each debt instrument using the binomial model and subtracting the fair value of the respective debt instrument's liability component. The fair value of the liability component for each debt instrument was determined by using a discounted cash flow technique with an effective interest rate of 3.25% and 5.42% for the 2007 Notes and 2013 Notes, respectively. These rates represent the estimated

nonconvertible borrowing rate with a maturity as of the measurement date consistent with the first put dates of each debt instrument. The difference between the debt's fair value and the fair value of its liability component represents the value allocated to the debt's conversion option. In addition, direct costs incurred for this exchange of $4.1 million were expensed as incurred within interest expense.

The Company accounted for the 2010 Notes extinguishment in fiscal 2015, discussed above, under the derecognition provisions of subtopic ASC 470-20-40, which requires the allocation of the fair value of the consideration transferred and transaction costs incurred to the extinguishment of the liability component and the reacquisition of the equity component. In connection with this transaction, the Company recorded a debt extinguishment loss of $15.5 million in the fourth quarter fiscal 2015. This debt extinguishment loss was comprised of the loss on the debt itself of $14.4 million, the write-off of the pro-rata

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amount of debt issuance costs of $0.7 million allocated to the notes retired, and allocated third party costs of $0.4 million. The loss on the debt itself was calculated as the difference between the fair value of the liability component of the 2010 Notes amount retired immediately before the respective exchanges and its related carrying value immediately before the repurchases. The fair value of the liability component was calculated using a discounted cash flow technique as described above, and the Company used an effective interest rate of 2.71% representing the estimated rate for non-convertible debt (with similar features as the 2010 Notes excluding the conversion feature) issued by a company with a credit rating similar to the Company. In addition, under this accounting standard, a portion of the fair value of the consideration transferred is allocated to the reacquisition of the equity component, which is the difference between the fair value of the consideration transferred and the fair value of the liability component immediately before the extinguishment. As a result, on a gross basis, $246.1 million was allocated to the reacquisition of the equity component of the original instrument, which was recorded net of deferred taxes of $29.2 million within additional paid-in-capital.

As of September 26, 2015 and September 27, 2014, the Convertible Notes and related equity components (recorded in additional paid-in-capital, net of deferred taxes) consisted of the following:

	2015	2014
2010 Notes principal amount	$150.0	$450.0
Unamortized discount	(7.8)	(41.5)
Net carrying amount	$142.2	$408.5
Equity component, net of taxes	$20.0	$60.1
2012 Notes principal amount	$500.0	$500.0
Unamortized discount	(19.7)	(27.3)
Net carrying amount	$480.3	$472.7
Equity component, net of taxes	$49.2	$49.2
2013 Notes principal amount	$370.0	$370.0
Principal accretion	40.5	24.5
Unamortized discount	(29.3)	(40.1)
Net carrying amount	$381.2	$354.4
Equity component, net of taxes	$131.5	$131.5

Interest expense under the Convertible Notes is as follows:

	Years Ended		
	September 26, 2015	September 27, 2014	September 28, 2013
Amortization of debt discount	$34.9	$37.1	$52.7
Amortization of deferred financing costs	1.7	1.9	3.0
Principal accretion	15.9	15.3	9.2
Non-cash interest expense	52.5	54.3	64.9
2.00% accrued interest (cash)	18.2	22.3	34.4
	$70.7	$76.6	$99.3

If the Company fails to comply with the reporting obligations contained in the agreements for the Convertible Notes, the sole remedy of the holders of the Convertible Notes for the first 90 days following such event of default consists exclusively of the right to receive an extension fee in an amount equal to 0.25% of the accreted principal amount of the Convertible Notes. Based on its evaluation of the Convertible Notes in accordance with ASC 815, the Company determined that the Convertible Notes contain a single embedded derivative, comprising both the contingent interest feature and the filing failure penalty payment, requiring bifurcation as the features are not clearly and closely related to the host instrument. The Company has determined that the value of this embedded derivative was nominal as of September 26, 2015 and September 27, 2014.

As of September 26, 2015, upon conversion, including the potential premium that could be payable on a fundamental change (as defined), the Company would issue a maximum of approximately 44.3 million shares of common stock to the holders of the Convertible Notes.

5. Fair Value Measurements

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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 equity investments in publicly-traded companies and mutual funds, both of which are valued using quoted market prices, representing Level 1 assets, and investments in interest rate cap derivative instruments, 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 the Company's interest rate cap derivative instruments represent the estimated amounts the Company would receive to terminate the contracts. Refer to Note 2 for further discussion and information on both the equity investments and the interest rate cap derivative instruments.

The Company has a payment obligation to the participants under its Nonqualified Deferred Compensation Plan (“DCP”). This liability is recorded at fair value based on the underlying value of certain hypothetical investments under the DCP as designated by each participant for their benefit. Since the value of the DCP obligation is based on market prices, the liability is classified within Level 1. In addition, in fiscal 2013, the Company had a contingent consideration liability related to its acquisition of Interlace Medical, Inc. ("Interlace") that was recorded at fair value and based on Level 3 inputs.

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

		Fair Value Measurements at September 26, 2015		
	Carrying Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Marketable securities:				
Equity securities	$15.2	$15.2	$—	$—
Mutual funds	5.6	5.6	—	—
Interest rate cap - derivative	6.9	—	6.9	—
Total	$27.7	$20.8	$6.9	$—
Liabilities:				
Deferred compensation liabilities	$29.4	$29.4	$—	$—
Total	$29.4	$29.4	$—	$—

		Fair Value Measurements at September 27, 2014		
	Carrying Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Marketable securities:				
Equity securities	$24.4	$24.4	$—	$—
Mutual funds	15.4	15.4	—	—
Total	$39.8	$39.8	$—	$—
Liabilities:				
Deferred compensation liabilities	$35.8	$35.8	$—	$—
Total	$35.8	$35.8	$—	$—

There were no Level 3 assets or liabilities outstanding during fiscal 2015. 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 27, 2014, and September 28, 2013 were as follows:

	2014	2013
Balance at beginning of period	$3.8	$86.4
Contingent consideration recorded at acquisition	—	0.5
Fair value adjustments	—	11.3
Payments / Accruals	(3.8)	(94.4)
Balance at end of period	$—	$3.8

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 cost-method equity investments and long-lived assets, including property, plant and equipment, intangible assets and goodwill. During fiscal 2013, the Company recorded goodwill impairment charges of $1.1 billion related to its Molecular Diagnostics reporting unit. This adjustment falls within Level 3 of the fair value hierarchy due to the use of significant unobservable inputs to determine fair value. The fair value measurement was determined using a DCF analysis, and the amount and timing of future cash flows within the analysis were based on the Company's most recent operational budgets, long-range strategic plans and other estimates at the time such remeasurements were made.

In the fourth quarter of fiscal 2014, the Company recorded a $5.1 million impairment charge within its Diagnostics segment to record its remaining IPR&D assets at fair value. This adjustment falls within Level 3 of the fair value hierarchy.

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In the second quarter of fiscal 2014, the Company recorded an impairment charge of $28.6 million within its Breast Health segment, which was comprised of $27.1 million for intangible assets and $1.5 million for property and equipment. This adjustment falls within Level 3 of the fair value hierarchy.

In the first quarter of fiscal 2014, the Company recorded a $3.1 million impairment charge to record certain of its buildings at fair value related to the shutdown of its Hitec Imaging organic photoconductor manufacturing line. This adjustment falls within Level 3 of the fair value hierarchy.

The Company holds certain cost-method equity investments in non-publicly traded securities aggregating $4.2 million and $5.2 million at September 26, 2015 and September 27, 2014, respectively, which are included in other long-term assets on the Company's Consolidated Balance Sheets. These investments are generally carried at cost, less any write-downs for other-than-temporary impairment charges. To determine the fair value of these investments, the Company uses all available financial information related to the entities, including information based on recent or pending third-party equity investments in these entities. In certain instances, a cost method investment's fair value is not estimated as there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investment and to do so would be impractical. During fiscal 2014 and 2013, the Company recorded other-than-temporary impairment charges of $6.9 million and $6.4 million, respectively, related to its cost-method equity investments to adjust their carrying amounts to fair value.

The following chart depicts certain assets presented at fair value using level 3 inputs under the fair value hierarchy measured on a nonrecurring basis for which the Company has recorded impairment charges:

	Fair Value	Fair Value Measurements Using Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Losses
Fiscal 2014:					
Intangible assets	$36.2	—	—	$36.2	$(32.2)
Property and equipment	1.0	—	—	1.0	(1.5)
Buildings	1.4	—	—	1.4	(3.1)
Cost-method equity investments	0.8	—	—	0.8	(6.9)
					$(43.7)
Fiscal 2013:					
Goodwill	$277.8	—	—	$277.8	$(1,117.4)
Equipment	1.4	—	—	1.4	(5.0)
Cost-method equity investments	1.5	—	—	1.5	(6.4)
					$(1,128.8)

The above fair value amounts represent only those individual assets remeasured and not the consolidated balances. Refer to Note 4 for disclosure of the nonrecurring fair value measurement related to the debt extinguishment losses recorded in fiscal 2015, 2014 and 2013.

Disclosure of Fair Value of Financial Instruments

The Company's financial instruments mainly consist of cash, accounts receivable, marketable securities, cost-method equity investments, insurance contracts, interest rate cap agreements, DCP liability, accounts payable and debt obligations. The carrying amounts of the Company's cash, accounts receivable and accounts payable approximate their fair value due to the short-term nature of these instruments. The Company's marketable securities and interest rate cap agreements 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, and the related DCP liability is recorded at fair value. The Company believes the carrying amounts of its cost-method equity investments approximate fair value.

Amounts outstanding under the Company's Credit Agreement of $1.66 billion aggregate principal 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 Senior Notes had a fair value of approximately $1.03 billion

as of both September 26, 2015 and September 27, 2014 based on their trading price, representing a Level 1 measurement. The fair value of the

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Company's Convertible Notes is based on the trading prices of the respective notes and represents a Level 1 measurement. Refer to Note 4 for the carrying amounts of the various components of the Company's debt.
The estimated fair values of the Company's Convertible Notes at September 26, 2015 and September 27, 2014 are as follows:

	2015	2014
2010 Notes	264.1	536.6
2012 Notes	688.2	531.7
2013 Notes	471.8	401.1
	$1,424.1	$1,469.4

6. Sale of Makena
In fiscal 2008, the Company sold the rights of its Makena (formerly Gestiva) pharmaceutical product to K-V Pharmaceutical Company ("KV") upon FDA approval of the then pending Makena new drug application. The Company executed certain amendments to this agreement that resulted in an increase in the total sales price to $199.5 million and a change in the timing of when payments were due to the Company. On February 3, 2011, the Company received FDA approval of Makena, and all rights to Makena were transferred to KV. As a result in fiscal 2011, the Company recorded the up-front payments received prior to FDA approval under this agreement, which had been deferred, and a payment received at FDA approval as a gain on the sale of intellectual property of $84.5 million, which was net of certain asset write-offs and related expenses. In fiscal 2012, the Company received another scheduled payment and recorded a gain of $12.4 million, which was net of certain costs. In August 2012, KV and certain of its subsidiaries filed voluntary petitions for reorganization under Chapter 11 of Title 11 of the United States Code in the United States Bankruptcy Court. At that time, additional payments were still owed to the Company, and in December 2012 the Company and KV executed a settlement agreement, which released KV from all claims in consideration of a $60.0 million payment. The Company recorded this amount in the first quarter of fiscal 2013, net of certain costs, resulting in a gain of $53.9 million. The Company will receive no further payments from KV.
7. Income Taxes
The Company's income (loss) before income taxes consisted of the following:

	Years ended		
	September 26, 2015	September 27, 2014	September 28, 2013
Domestic	$158.3	$95.1	$(1,184.6)
Foreign	18.9	(47.0)	(8.3)
	$177.2	$48.1	$(1,192.9)

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

	Years ended		
	September 26, 2015	September 27, 2014	September 28, 2013
Federal:			
Current	$185.2	$242.2	$154.9
Deferred	(137.0)	(212.5)	(182.7)
	48.2	29.7	(27.8)
State:			
Current	3.5	22.1	15.3
Deferred	(11.0)	(24.7)	(16.7)
	(7.5)	(2.6)	(1.4)
Foreign:			
Current	5.7	9.6	7.7
Deferred	(0.8)	(5.9)	1.4
	4.9	3.7	9.1
	$45.6	$30.8	$(20.1)

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

	Years ended		
	September 26, 2015	September 27, 2014	September 28, 2013
Income tax provision (benefit) at federal statutory rate	35.0%	35.0%	(35.0)%
Increase (decrease) in tax resulting from:			
Goodwill impairment	—	—	32.8
Domestic production activities deduction	(10.1)	(30.6)	(1.2)
State income taxes, net of federal benefit	1.2	4.3	(0.2)
Tax credits	(3.8)	(5.2)	(1.2)
Unrecognized tax benefits	(1.8)	2.5	0.3
Contingent consideration	—	—	2.6
Cumulative translation adjustment write-off	1.9	—	—
Non-deductible compensation	1.9	5.5	0.2
Foreign rate differential	(1.6)	10.7	0.1
Change in valuation allowance	1.0	35.4	(0.8)
Other	2.1	6.3	0.7
	25.8%	63.9%	(1.7)%

The Company's effective tax rate in fiscal 2015 was lower than the statutory rate primarily due to the domestic production activities deduction benefit. The Company’s effective tax rate in fiscal 2014 was higher than the statutory rate primarily due to unbenefited foreign losses partially offset by the domestic production activities deduction benefit.

The Company’s effective tax rate in fiscal 2013 was lower than the statutory rate primarily due to the non-deductible goodwill impairment charge, non-deductible contingent consideration expense related to the TCT International Co., Ltd. ("TCT") and Interlace acquisitions, and unbenefited foreign losses, partially offset by the domestic production activities deduction benefit and the release of a $19.9 million valuation allowance related to capital losses which were utilized to offset capital gains generated during the year.

The Company uses the liability method to account for income taxes in accordance with ASC 740, Income Taxes. Under this method, deferred income taxes are recognized for the future tax consequences of differences between the tax and financial accounting bases of assets and liabilities at each reporting period. Deferred income taxes are based on enacted tax laws and statutory tax rates applicable to the period in which these differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts

expected to be realized.

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

	September 26, 2015	September 27, 2014
Deferred tax assets		
Net operating loss carryforwards	$45.4	$54.2
Capital losses	25.7	22.3
Non-deductible accruals	16.3	16.8
Non-deductible reserves	26.8	27.1
Stock-based compensation	24.3	25.0
Research and other credits	14.5	12.3
Nonqualified deferred compensation plan	11.3	13.7
Other temporary differences	10.2	11.6
	174.5	183.0
Less: valuation allowance	(60.9)	(62.8)
	$113.6	$120.2
Deferred tax liabilities		
Depreciation and amortization	$(1,171.5)	$(1,314.6)
Debt discounts and deferrals	(100.1)	(120.9)
Debt issuance costs	(1.4)	(6.8)
Investment in subsidiary	—	(13.9)
	$(1,273.0)	$(1,456.2)
	$(1,159.4)	$(1,336.0)

Under ASC 740, the Company can only recognize a deferred tax asset for the future benefit 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 will not be realized. In determining these assets realizability, the Company considered numerous factors including historical profitability, the character and estimated future taxable income, prudent and feasible tax planning strategies, and the industry in which it operates. The valuation allowance decreased $1.9 million in fiscal 2015 from fiscal 2014 primarily due to foreign exchange rate fluctuations offset by unrealized capital losses from investment write-downs.

At September 26, 2015, the Company had $17.3 million, $91.5 million and $56.6 million in gross federal, state, and foreign net operating losses, respectively, and $4.7 million, $13.0 million and $1.5 million in federal, state, and foreign credit carryforwards, respectively. These losses and credits expire between 2016 and 2035, except for $54.9 million in losses and $9.0 million in credits that have unlimited carryforward periods. The federal, state, and foreign net operating losses exclude $4.5 million, $180.5 million and $49.0 million, respectively, in net operating losses, that the Company expects will expire unutilized.

The Company had $154.7 million in gross unrecognized tax benefits, excluding interest, at September 26, 2015 and $137.0 million at September 27, 2014. At September 26, 2015, $74.9 million represents the unrecognized tax benefits that, if recognized, would reduce the Company's effective tax rate. In the next twelve months it is reasonably possible that the Company will reduce its gross unrecognized tax benefits by $2.0 to $4.0 million due to statutes of limitations expiring and potential favorable settlements with taxing authorities.

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The Company's unrecognized income tax benefits activity for fiscal 2015 and 2014 was as follows:

	2015	2014
Balance at beginning of fiscal year	$137.0	$121.8
Tax positions related to current year:		
Additions	11.0	10.8
Reductions	—	—
Tax positions related to prior years:		
Additions related to change in estimate	21.1	10.9
Reductions	(10.3)	(2.7)
Payments	(0.8)	—
Lapses in statutes of limitations and settlements	(3.7)	(3.8)
Acquired tax positions:		
Additions related to reserves acquired from acquisitions	0.4	—
Balance as of the end of the fiscal year	$154.7	$137.0

The Company's policy is to include accrued interest and penalties related to unrecognized tax benefits and income tax liabilities, when applicable, in income tax expense. As of September 26, 2015 and September 27, 2014, gross accrued interest was $9.9 million and $8.3 million, respectively. At September 26, 2015, no significant penalties have been accrued.

The Company and its subsidiaries are subject to various federal, state, and foreign income taxes. The Company's U.S. Federal income tax returns are no longer subject to examination prior to fiscal 2011. State income tax returns are generally no longer subject to examination prior to fiscal year 2011. The Internal Revenue Service commenced its fiscal 2011 federal income tax return examination in July 2013. The Company is also undergoing tax examinations in China and Germany for calendar 2004 through 2013, and fiscal 2008 through 2010, respectively. Massachusetts is scheduled to begin a state tax examination for fiscal 2012 through 2013 in fiscal 2016.

The Company intends to reinvest, indefinitely, approximately $60.9 million in unremitted foreign earnings. It is not practicable to estimate the additional taxes that may be payable upon repatriation.

8. Stockholders' Equity and Stock-Based Compensation

Stock Repurchase Program

On November 11, 2013, the Company announced that its Board of Directors authorized the repurchase of up to $250 million of the Company's outstanding common stock over a three-year period. Under the stock repurchase program, the Company is authorized to repurchase, from time-to-time, shares of its outstanding common stock on the open market or in privately negotiated transactions in the United States. As of September 26, 2015, the Company had not repurchased any shares under this program.

Stock-Based Compensation

Equity Compensation Plans

The Company has one share-based compensation plan pursuant to which awards are currently being made—the 2008 amended and restated Equity Incentive Plan ("2008 Equity Plan"). The Company has two share-based compensation plans pursuant to which outstanding awards have been made, but from which no further awards can or will be made—i) the 1995 Combination Stock Option Plan and ii) the 1999 Equity Incentive 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, 2015, the Company had 9.5 million shares available for future grant under the 2008 Equity Plan.

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The following presents stock-based compensation expense in the Company's Consolidated Statements of Operations in fiscal 2015, 2014 and 2013:

	2015	2014	2013
Cost of revenues	$8.7	$7.3	$7.0
Research and development	8.6	8.4	7.2
Selling and marketing	8.8	8.2	8.9
General and administrative	29.1	19.5	20.2
Restructuring and divestiture	4.1	6.6	9.0
	$59.3	$50.0	$52.3

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 2015, 2014 and 2013 and related assumptions are noted in the following table:

	Years ended		
	September 26, 2015	September 27, 2014	September 28, 2013
Options granted (in millions)	1.3	2.4	2.6
Weighted-average exercise price	$27.68	$22.01	$20.29
Weighted-average grant date fair value	$9.95	$7.67	$7.03
Assumptions:			
Risk-free interest rates	1.7 %	1.2 %	0.5 %
Expected life (in years)	5.3	4.4	4.4
Expected volatility	38.6 %	41.4 %	43.7 %
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.

In connection with appointing Stephen P. MacMillan as its new President and Chief Executive Officer in December 2013, the Company granted approximately 0.1 million market stock units ("MSUs"). The MSUs vest in three separate tranches in an amount of 1/3rd of the total amount of the award based on the Company's stock price meeting certain defined average stock prices for 30 consecutive trading days. These MSUs were valued at an average of $18.65 per share using the Monte Carlo simulation model and each tranche has its own derived service period. The Company recognized compensation expense under the accelerated method as prescribed by ASC 718, and all tranches have vested due to the defined average stock prices being met for the required period. In addition, per the terms of his employment agreement, the Company granted 0.2 million restricted stock units ("RSUs") to match Mr. MacMillan's purchase of 0.2 million shares of the Company's common stock on the open market in the second quarter of fiscal 2014. The RSUs cliff vest three years from the date of grant, and the Company is accounting for this grant as a liability award pursuant to ASC 718 because this RSU award contains an additional vesting condition (the requirement that Mr. MacMillan retain the matching shares during the vesting period) that is not service, performance or market based. As such, this award is marked-to-market at each reporting period, and at September 26, 2015, $4.6 million has been recorded as a liability for this award.

Stock-Based Compensation Expense Attribution

The Company uses the straight-line attribution method to recognize stock-based compensation expense for stock options and RSUs. The vesting term of stock options is generally five years with annual vesting of 20% per year on the anniversary of the grant date, and RSUs generally vest over four years with annual vesting at 25% 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. ASC 718 requires forfeitures to be estimated at

the time granted and revised, 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 7.0% as of September 26, 2015 depending on the specific employee group. This analysis is re-evaluated annually and the

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forfeiture rate will be 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 $12.2 million, $16.3 million, and $23.7 million in fiscal 2015, 2014 and 2013, respectively. Stock compensation expense related to stock units, including RSUs, performance stock units ("PSUs") and MSUs, was $43.7 million, $30.6 million, and $26.0 million in fiscal 2015, 2014 and 2013, respectively. The related tax benefit recorded in the Consolidated Statements of Operations was $17.7 million, $15.3 million and $17.2 million in fiscal 2015, 2014 and 2013, respectively. Included within stock-based compensation expense in fiscal 2015, 2014 and 2013 is $4.1 million, $6.6 million and $7.9 million, respectively, related to modification accounting, the acceleration of vesting of certain retention RSUs provided under their original terms upon termination, and the acceleration of vesting for certain options assumed in the Gen-Probe acquisition related to employees who were terminated in connection with the Company’s restructuring action to consolidate its Diagnostics operations. The original terms of the stock options assumed in the Gen-Probe acquisition provided for acceleration upon a change-in-control and termination within 18 months of the change-in-control. At September 26, 2015, there was $22.8 million and $73.6 million of unrecognized compensation expense related to stock options and RSUs, respectively, to be recognized over a weighted average period of 3.4 years and 2.5 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, 2015:

	Number of Shares (in millions)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value (in millions)
Options outstanding at September 27, 2014	9.8	$20.59	4.1	$46.4
Granted	1.3	27.68		
Canceled/ forfeited	(1.4)	23.36		
Exercised	(3.0)	18.89		$42.0
Options outstanding at September 26, 2015	6.7	$22.21	4.9	$119.1
Options exercisable at September 26, 2015	3.0	$21.05	3.2	$56.6
Options vested and expected to vest at September 26, 2015 (1)	6.6	$22.18	4.8	$118.1

(1) This represents the number of vested stock options as of September 26, 2015 plus the unvested outstanding options at September 26, 2015 expected to vest in the future, adjusted for estimated forfeitures.

During fiscal 2014 and 2013, 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 $34.7 million and $37.6 million, respectively.

A summary of the Company’s RSU activity during the year ended September 26, 2015 is presented below:

Non-vested Shares	Number of Shares (in millions)	Weighted-Average Grant-Date Fair Value
Non-vested at September 27, 2014	4.1	$20.67
Granted	1.6	27.19
Vested	(1.3)	20.40
Forfeited	(0.7)	21.37
Non-vested at September 26, 2015	3.7	$24.54

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 2015, 2014 and 2013 the total fair value of RSUs vested was $27.2 million, $22.6 million and $27.3 million, respectively.

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The Company also granted approximately 0.3 million and 0.5 million PSUs during fiscal 2015 and 2014, respectively, to members of its senior management team, which have a weighted-average grant date fair value of $26.58 and $21.69, 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 years provided the Company's defined Return on Invested Capital metrics are achieved. The Company is recognizing compensation expense ratably over the required service period based on its estimate that it is probable that the measurement criteria will be achieved and the targeted number of shares will vest. 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.

Employee Stock Purchase Plan

In March 2012, the Company's stockholders approved the Hologic, Inc. 2012 Employee Stock Purchase Plan ("2012 ESPP"), which 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. The first plan period began on July 1, 2012. Stock-based compensation expense in fiscal 2015, 2014 and 2013 was $3.4 million, $3.1 million and $2.7 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, 2015	September 27, 2014	September 28, 2013
Assumptions:			
Risk-free interest rates	0.10 %	0.08 %	0.11 %
Expected life (in years)	0.5	0.5	0.5
Expected volatility	27.4 %	30.0 %	32.0 %
Dividend yield	—	—	—

9. Profit Sharing 401(k) Plan

The Company has a qualified profit sharing plan covering substantially all of its employees. The Company made contributions of $14.4 million, $13.3 million and $13.4 million for fiscal 2015, 2014 and 2013, respectively.

10. Deferred Compensation Plans

Nonqualified Deferred Compensation Plan

Effective March 15, 2006, the Company adopted its 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 is recording compensation expense for the DCP discretionary contributions ratably over the three-year vesting period of each annual contribution, which totaled $1.8 million, $3.7 million and $2.7 million in fiscal 2015, 2014 and 2013, respectively. The full amount of the discretionary contribution, net of forfeitures, along with employee deferrals is recorded within accrued expenses and totaled $29.4 million and $35.8 million at September 26, 2015 and September 27, 2014, 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, 2015 and September 27, 2014 was $27.5 million and $22.4 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 2015, 2014 and 2013, are recorded within other income (expense), net.

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In addition, the Company had an additional $5.6 million and $15.4 million of investments in mutual funds to fund the DCP at September 26, 2015 and September 27, 2014, respectively. The mutual funds are classified as trading and the gains and losses in these investments are recorded in other income (expense), net.

Deferred Equity Plan

Effective September 17, 2015, the Company adopted the Hologic, Inc. Deferred Equity Plan (the "DEP"). The DEP is designed to allow executives and non-employee Directors to accumulate Company stock in a tax-efficient manner to meet their long-term equity accumulation goals and shareholder ownership guidelines. Under the DEP, eligible participants may elect to defer the settlement of RSUs and PSUs granted under the 2008 Equity Plan until separation from service or separation from service plus a fixed number of years. Participants may defer settlement by vesting tranche. Although the equity will vest on schedule, if deferral of settlement is elected, no shares will be issued until the settlement date. The settlement date will be 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.

11. Commitments and Contingencies

Contingent Earn-Out Payments

In connection with certain of its acquisitions, the Company incurred obligations to make contingent earn-out payments tied to performance criteria, principally revenue growth of the acquired businesses over a specified period.

These 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 the Company expects 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 changes in fair value recorded through a separate line item within the Company's Consolidated Statements of Operations. Increases or decreases in the fair value of contingent consideration liabilities can result from accretion of the liability for the passage of time, changes in discount rates, and changes in the timing, probabilities and amount of revenue estimates.

In connection with the Company's acquisition of Interlace in fiscal 2011, the Company had an obligation to the former Interlace stockholders to make contingent payments over a two-year period. Pursuant to ASC 805, the Company recorded its estimate of the fair value of the contingent consideration liability based on future revenue projections of the Interlace business. The fair value of the contingent consideration for the first and second measurement periods was $51.8 million and $93.8 million, respectively. Payments were disbursed in the second quarter of fiscal 2013 and 2012, respectively, of which $39.0 million and $47.6 million, respectively, was reflected in the Consolidated Statements of Cash Flows as cash used in financing activities, representing the liability recognized at fair value for the first measurement period as of the acquisition date. The remainder, which is related to changes in the fair value of the liability, is reflected within cash provided by operating activities. The second and final measurement period ended during the second quarter of fiscal 2013, resulting in a contingent consideration liability of $93.8 million. Of this amount, $86.9 million was paid to the former Interlace stockholders in the second quarter of fiscal 2013. The remainder was withheld for legal indemnification provisions and is being used to pay qualifying legal expenses. On October 29, 2013, the Interlace stockholder representatives filed a complaint in the Delaware Court of Chancery alleging breach of contract for issues related to the payment of contingent consideration under the Interlace acquisition agreement, and sought $14.7 million in additional payments. On October 20, 2014, a trial was held in Delaware. The parties executed a settlement agreement in January 2015 for an amount less than that sought. The effect of this settlement was not material to the Company's financial statements.

In connection with the Company's acquisition of TCT International Co. Ltd. in June 2011, the Company had an obligation to certain of the former TCT shareholders, based on future employment, to make contingent payments over a two year period provided certain revenue milestones were met. These earnouts were recorded as compensation expense ratably over the required service periods. The second and final earn-out period was completed in the third quarter of fiscal 2013, and the Company paid $87.4 million of this earn-out in the fourth quarter of fiscal 2013. The remaining $31.1 million of this earn-out was paid in the first quarter of fiscal 2014.

The Company also had an obligation to the former shareholders of Beijing Healthcome Technology Company, Ltd. for contingent payments that were accounted for as compensation expense. The remaining $0.7 million was paid out in the second quarter of fiscal 2015.

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There was no contingent consideration expense recorded in fiscal 2015 or fiscal 2014. A summary of amounts recorded to the Consolidated Statements of Operations is as follows:

Statement of Operations Line Item – Fiscal 2013	Interlace	TCT	Total
Contingent consideration—compensation expense	$—	$80.0	$80.0
Contingent consideration—fair value adjustments	11.3	—	11.3
	$11.3	$80.0	$91.3

Finance Lease Obligations

The Company has two non-cancelable lease agreements for buildings that are primarily used for manufacturing. The Company was responsible for a significant portion of the construction costs, and in accordance with ASC 840, Leases, Subsection 40-15-5, the Company was deemed to be the owner of the respective buildings during the construction period. The Company recorded the fair market value of the buildings and land aggregating $28.3 million within property and equipment on its Consolidated Balance Sheets. At September 26, 2015, the Company has recorded $3.1 million in accrued expenses and $33.8 million in other long-term liabilities related to these obligations. The term of the leases is for a period of approximately 10 and 12 years, respectively, with the option to extend for two consecutive 5-year terms. At the completion of the construction period, the Company reviewed the lease for potential sale-leaseback treatment in accordance with ASC 840, Subsection 40, Sale-Leaseback Transactions. Based on its analysis, the Company determined that the lease did not qualify for sale-leaseback treatment. Therefore, the building, leasehold improvements and associated liabilities remain on the Company's financial statements throughout the lease term, and the building and leasehold improvements are being depreciated on a straight line basis over their estimated useful lives of 35 years.

Future minimum lease payments, including principal and interest, under these leases were as follows at September 26, 2015:

Fiscal 2016	$3.1
Fiscal 2017	3.1
Fiscal 2018	2.9
Fiscal 2019	0.3
Total minimum payments	9.4
Less-amount representing interest	(1.4)
Total	$8.0

Non-cancelable Purchase and Royalty Commitments

The Company has certain non-cancelable purchase obligations primarily related to inventory purchases and diagnostics instruments, primarily the Tigris and 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, 2015, purchase commitments are as follows:

Fiscal 2016	$34.6
Fiscal 2017	4.0
Fiscal 2018	3.0
Fiscal 2019	0.8
Total	$42.4

In connection with its R&D efforts, the Company has various license agreements with unrelated parties that provide the Company with rights to develop and market products using certain technology and patent rights. Terms of the various license agreements require the Company to pay royalties ranging from less than 1% up to 35% of future sales on products using the specified technology. Such agreements generally provide for a term that commences upon execution and continues until expiration of the last patent covering the licensed technology. Under certain of these agreements, the Company is required to pay minimum annual royalty payments regardless of the level of sales. In

addition, the Company has commitments for

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minimum payments under certain collaboration agreements. At September 26, 2015, minimum commitments for these agreements are as follows:

Fiscal 2016	$1.3
Fiscal 2017	0.7
Fiscal 2018	0.6
Fiscal 2019	0.6
Fiscal 2020	0.6
Thereafter	3.3
Total	$7.1

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.

Operating Leases

The Company conducts its operations in leased facilities under operating lease agreements that expire through fiscal 2035. Substantially all of the Company's lease agreements require the Company to maintain the facilities during the term of the lease and to pay all taxes, insurance, utilities and other costs associated with those facilities. The Company makes customary representations and warranties and agrees to certain financial covenants and indemnities. In the event the Company defaults on a lease, typically the landlord may terminate the lease, accelerate payments and collect liquidated damages. As of September 26, 2015, the Company was not in default of any covenants contained in its lease agreements. Certain of the Company's lease agreements provide for renewal options. Such renewal options are at rates similar to the current rates under the agreements.

Future minimum lease payments under all of the Company's operating leases at September 26, 2015 are as follows:

Fiscal 2016	$16.3
Fiscal 2017	14.5
Fiscal 2018	12.5
Fiscal 2019	7.9
Fiscal 2020	6.0
Thereafter	21.8
Total	$79.0

Rent expense, net of sublease income from these locations, was $19.2 million, $21.1 million, and $19.9 million for fiscal 2015, 2014 and 2013, respectively.

The Company subleases a portion of a building it owns and some of its facilities and has received aggregate rental income of $2.0 million, $1.8 million and $1.9 million in fiscal 2015, 2014 and 2013, respectively, which has been recorded as an offset to rent expense. The future minimum annual rental income payments under these sublease agreements at September 26, 2015 are as follows:

Fiscal 2016	$2.0
Fiscal 2017	2.0
Fiscal 2018	1.9
Fiscal 2019	1.9
Fiscal 2020	1.3
Thereafter	1.2
Total	$10.3

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12. Litigation and Related Matters

On June 9, 2010, Smith & Nephew, Inc. ("Smith & Nephew") filed suit against Interlace, which the Company acquired on January 6, 2011, in the United States District Court for the District of Massachusetts. The complaint alleged that the Interlace MyoSure hysteroscopic tissue removal device infringed U.S. patent 7,226,459. On November 22, 2011, Smith & Nephew filed suit against the Company in the United States District Court for the District of Massachusetts. The complaint alleged that use of the MyoSure hysteroscopic tissue removal system infringed U.S. patent 8,061,359. Both complaints sought permanent injunctive relief and unspecified damages. On September 4, 2012, following a two week trial, the jury returned a verdict of infringement of both the ‘459 and ‘359 patents and assessed damages of $4.0 million. A bench trial regarding the Company’s assertion of inequitable conduct on the part of Smith & Nephew with regard to the ‘359 patent was held on December 9, 2012 and oral arguments on the issue of inequitable conduct were presented on February 27, 2013. On June 27, 2013, the Court denied the Company’s motions related to inequitable conduct and allowed Smith & Nephew’s request for injunction, but ordered that enforcement of the injunction be stayed until final resolution, including appeal, of the current re-examinations of both patents at the United States Patent and Trademark Office (“USPTO”). The Court also rejected the jury’s damage award and ordered the parties to identify a mechanism for resolving the damages issue. The Company intends to file post-trial motions seeking to reverse the jury’s verdict. The USPTO has issued final decisions that the claims of the ‘459 and the '359 patents asserted as part of the litigation are not patentable. Smith & Nephew has appealed these decisions to the U.S. Patent Trial and Appeal Board. 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.

In January 2012 , Enzo filed suit against Gen-Probe in the United States District Court for the District of Delaware. The Gen-Probe complaint alleged that certain of Gen-Probe’s diagnostics products, including products that incorporate Gen-Probe’s patented hybridization protection assay technology, such as the Aptima Combo 2 and Aptima HPV assays, infringe Enzo’s U.S. patent 6,992,180. On March 6, 2012, Enzo Life Sciences, Inc. (“Enzo”) filed suit against the Company in the United States District Court for the District of Delaware. The complaint alleged that certain of the Company’s molecular diagnostics products, including without limitation products based on its proprietary Invader chemistry, such as Cervista HPV HR and Cervista HPV 16/18, infringe Enzo’s U.S. patent 6,992,180. The complaint seeks permanent injunctive relief and unspecified damages. On September 30, 2013, Enzo amended its list of accused products to include Prodesse, MilliPROBE, PACE and Procleix assays. The complaint seeks permanent injunctive relief and unspecified damages. Enzo has asserted the ‘180 patent claims against six other companies. The court issued a Markman order on July 7, 2015 construing the claims, and it is expected that summary judgment motions will be heard in the fall of 2016. 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 March 27, 2015, Enzo filed an additional suit against the Company in the United States District Court for the District of Delaware, The complaint alleged that certain additional Company molecular diagnostic products, including, inter alia, the Procleix Parvo/HAV assays and coagulation products, including the Invader Factor II test and the Invader Factor V test, also infringe U.S. Patent 6,992,180. The complaint further alleged that certain of the Company’s molecular diagnostic products, including Hologic’s Progensa PCA3 products, all Aptima products and all Procleix products infringe Enzo’s U. S. Patent 7,064,197. On June 11, 2015, this matter was stayed pending the resolution of summary judgment motions in the 2012 case referenced above. 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 October 29, 2013, the Interlace stockholder representatives filed a complaint in the Delaware Court of Chancery alleging breach of contract for issues related to the payment of contingent consideration under the Interlace acquisition agreement, and sought $14.7 million in additional payments. On October 20, 2014, a trial was held in Delaware. The

parties executed a settlement agreement in January 2015 for an amount less than that sought. The effect of this settlement was not material to the Company's financial statements.

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 of which the ultimate resolution would 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.

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13. Grifols Collaboration Agreement

Under its collaboration agreement with Grifols, the Company manufactures blood screening products, while Grifols is responsible for marketing, sales and service of those products, which Grifols sells under its trademarks. The Company is entitled to recover 50% of its manufacturing costs incurred in connection with the collaboration and will receive a percentage of the blood screening assay revenue generated under the collaboration. The Company's share of revenue from any assay that includes a test for HCV is as follows: 2012-2013, 47%; 2014, 48%; and 2015 through the remainder of the term of the collaboration, 50%. The Company's share of blood screening assay revenue from any assay that does not test for HCV is 50%. Grifols is obligated to purchase all of the quantities of assays specified on a 90-day demand forecast, due 90 days prior to the date Grifols intends to take delivery, and certain quantities specified on a rolling 12-month forecast.

The Company recognizes product revenue, and collaborative research and license revenue, which is included within services and other revenues, under this collaboration agreement. The Company recognized $253.1 million, $223.3 million and $197.9 million under this collaboration agreement in fiscal 2015, 2014, and 2013 respectively.

14. 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. The Company has four reportable segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health. Certain reportable segments represent an aggregation of operating units within each segment. The Company measures and evaluates its reportable segments based on segment revenues and operating income (loss) adjusted to exclude the effect of non-cash charges, such as intangible asset amortization expense, intangible asset impairment charges, contingent consideration charges, restructuring and divestiture charges, and other one-time or unusual items, and related tax effects.

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Identifiable assets for the four principal reportable segments consist of inventories, intangible assets, goodwill, and property, plant and equipment. The Company fully allocates depreciation expense to its four reportable segments. The Company has presented all other identifiable assets as corporate assets. There were no intersegment revenues. Segment information for fiscal 2015, 2014, and 2013 was as follows:

	Years ended		
	September 26, 2015	September 27, 2014	September 28, 2013
Total revenues:			
Diagnostics	$1,211.8	$1,186.8	$1,189.8
Breast Health	1,063.4	944.7	905.1
GYN Surgical	335.8	307.9	307.1
Skeletal Health	94.0	91.3	90.3
	$2,705.0	$2,530.7	$2,492.3
Operating income (loss):			
Diagnostics	$109.5	$48.7	$(1,149.1)
Breast Health	296.3	187.6	216.1
GYN Surgical	38.6	30.3	19.7
Skeletal Health	10.7	13.1	7.1
	$455.1	$279.7	$(906.2)
Depreciation and amortization:			
Diagnostics	$358.7	$376.0	$369.8
Breast Health	28.6	41.7	40.1
GYN Surgical	102.7	104.6	105.2
Skeletal Health	1.4	0.9	0.9
	$491.4	$523.2	$516.0
Capital expenditures:			
Diagnostics	$55.6	$52.2	$51.6
Breast Health	12.8	10.0	16.4
GYN Surgical	9.5	8.0	9.1
Skeletal Health	0.4	0.4	0.6
Corporate	11.1	9.6	12.4
	$89.4	$80.2	$90.1

	September 26, 2015	September 27, 2014	September 28, 2013
Identifiable assets:			
Diagnostics	$4,055.8	$4,383.5	$4,667.9
Breast Health	815.4	859.8	932.2
GYN Surgical	1,658.1	1,748.2	1,849.5
Skeletal Health	25.3	26.1	33.5
Corporate	1,115.5	1,397.1	1,517.7
	$7,670.1	$8,414.7	$9,000.8

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, Germany and the United Kingdom. The Company’s sales in Asia-Pacific are predominantly derived from China, Australia and Japan. The “All others” designation includes Canada, Latin America and the Middle East.

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

	Years ended					
	September 26, 2015		September 27, 2014		September 28, 2013	
United States	76.0	%	75.1	%	74.9	%
Europe	11.8	%	13.3	%	13.2	%
Asia-Pacific	8.5	%	7.7	%	8.1	%
All others	3.7	%	3.9	%	3.8	%
	100.0	%	100.0	%	100.0	%

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

	September 26, 2015	September 27, 2014	September 28, 2013
United States	$369.1	$366.8	$386.0
Costa Rica	27.7	27.9	29.3
Europe	50.8	56.0	61.5
All other countries	9.5	11.2	14.7
	$457.1	$461.9	$491.5

15. Accrued Expenses and Other Long-Term Liabilities

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

	September 26, 2015	September 27, 2014
Accrued Expenses		
Compensation and employee benefits	$173.2	$157.6
Interest	14.6	18.0
Income and other taxes	13.3	9.8
Other	71.0	76.7
	$272.1	$262.1
	September 26, 2015	September 27, 2014
Other Long-Term Liabilities		
Reserve for income tax uncertainties	$145.1	$131.4
Accrued lease obligation—long-term	34.0	34.1
Pension liabilities	10.1	10.8
Other	11.7	7.1
	$200.9	$183.4

16. 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, 2015 and September 27, 2014, the Company's pension liability was $10.0 million and $10.3 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.

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Change in Benefit Obligation	Years ended September 26, 2015	September 27, 2014	September 28, 2013
Benefit obligation at beginning of year	$(10.3)	$(10.1)	$(9.7)
Service cost	—	—	—
Interest cost	(0.3)	(0.3)	(0.4)
Plan participants' contributions	—	—	—
Actuarial (loss) gain	(0.9)	(0.8)	0.2
Foreign exchange gain (loss)	1.2	0.6	(0.5)
Benefits paid	0.3	0.3	0.3
Benefit obligation at end of year	(10.0)	(10.3)	(10.1)
Plan assets	—	—	—
Benefit obligation at end of year	$(10.0)	$(10.3)	$(10.1)

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

Components of Net Periodic Benefit Cost	Years ended September 26, 2015	September 27, 2014	September 28, 2013
Service cost	$—	$—	$—
Interest cost	0.3	0.3	0.4
Expected return on plan assets	—	—	—
Amortization of prior service cost	—	—	—
Recognized net actuarial gain	—	—	—
Net periodic benefit cost	$0.3	$0.3	$0.4

Weighted-Average Net Periodic Benefit Cost Assumptions	2015	2014	2013
Discount rate	2.05%	2.95%	3.60%
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 $10.0 million and $10.3 million at September 26, 2015 and September 27, 2014, respectively, and the accumulated benefit obligation for the German Pension Benefits was $10.0 million and $10.3 million at September 26, 2015 and September 27, 2014, 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 and $0.2 million at September 26, 2015 and September 27, 2014, respectively.

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The table below reflects the total Pension Benefits expected to be paid for the German Pension Benefits each fiscal year as of September 26, 2015:

2016	$0.3
2017	$0.3
2018	$0.4
2019	$0.4
2020	$0.4
2021 to 2025	$2.0

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 2015, 2014 and 2013. Additionally, the Company has Swiss pension plans, which were insignificant in fiscal 2015, 2014, and 2013.

17. Quarterly Statement of Operations Information (Unaudited)

The following table presents a summary of quarterly results of operations for fiscal 2015 and 2014:

	2015			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenue	$652.8	$655.5	$693.9	$702.8
Gross profit	338.6	336.0	378.7	379.4
Net income (1)	29.2	47.8	29.4	25.2
Diluted net income per common share	$0.10	$0.17	$0.10	$0.09

	2014			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenue	$612.4	$625.0	$632.6	$660.6
Gross profit	305.6	282.1	312.8	345.0
Net income (loss) (2)	(5.4)	(16.8)	11.3	28.2
Diluted net income (loss) per common share	$(0.02)	$(0.06)	$0.04	$0.10

(1) Net income in the first quarter of fiscal 2015 included restructuring charges of $8.0 million and a debt extinguishment loss of $6.7 million. Net income in the third quarter of fiscal 2015 included restructuring and divestiture charges of $11.9 million and a debt extinguishment loss of $18.2 million. Net income in the fourth quarter of fiscal 2015 included restructuring charges of $6.5 million, a debt extinguishment loss of $37.8 million, and an other-than-temporary impairment charge of $7.8 million related to a marketable security.

(2) Net loss in the first quarter of fiscal 2014 included restructuring charges of $18.4 million and a debt extinguishment loss of $2.9 million. Net loss in the second quarter of fiscal 2014 included an impairment charge related to the MRI breast coils product line of $28.6 million, restructuring charges of $11.6 million and a debt extinguishment loss of $4.4 million. Net income in the third quarter of fiscal 2014 included restructuring charges of $6.7 million. Net income in the fourth quarter of fiscal 2014 included restructuring and divestiture charges of $15.1 million and a $5.1 million IPR&D charge.

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Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
2.1	Agreement and Plan of Merger, dated April 29, 2012, by and among Hologic, Gold Acquisition Corp. and Gen-Probe Incorporated.	8-K	05/01/2012
3.1	Certificate of Incorporation of Hologic.	S-1	01/24/1990
3.2	Certificate of Amendment to Certificate of Incorporation of Hologic.	10-Q	03/30/1996
3.3	Certificate of Amendment to Certificate of Incorporation of Hologic.	10-K	09/24/2005
3.4	Certificate of Amendment to Certificate of Incorporation of Hologic.	8-K	10/22/2007
3.5	Certificate of Amendment to Certificate of Incorporation of Hologic.	8-K	03/11/2008
3.6	Certificate of Designation of Series A Junior Participating Preferred Stock of Hologic.	8-K	11/21/2013
3.7	Certificate of Elimination of Series A Junior Participating Preferred Stock of Hologic.	8-K	06/25/2014
3.8	Fourth Amended and Restated By-laws, as amended of Hologic.	10-Q	12/28/2013
4.1	Specimen Certificate for Shares of Hologic’s Common Stock.	8-A	01/31/1990
4.2	Description of Capital Stock (Contained in Hologic’s Certificate of Incorporation, as amended, filed as Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5 hereto).		
4.3	Indenture, dated December 10, 2007, by and between Wilmington Trust Company, as Trustee, and Hologic.	8-K	12/10/2007
4.4	Second Supplemental Indenture, dated November 23, 2010, by and between Wilmington Trust Company, as Trustee, and Hologic.	10-K	09/25/2010
4.5	Form of 2.00% Convertible Exchange Senior Note due 2037 (included in Exhibit 4.4).	10-K	09/25/2010
4.6	Third Supplemental Indenture, dated March 5, 2012, by and between Wilmington Trust Company, as Trustee, and Hologic.	8-K	03/08/2012
4.7		8-K	03/08/2012

	Form of 2.00% Convertible Senior Note due 2042 (included in Exhibit 4.6).		
4.8	Fourth Supplemental Indenture, dated February 21, 2013, by and between Wilmington Trust Company, as Trustee, and Hologic.	8-K	02/21/2013
4.9	Form of 2.00% Convertible Senior Note due 2043 (included in Exhibit 4.8).	8-K	02/21/2013
4.10	Indenture, dated July 2, 2015, by and among Hologic, the guarantors party thereto and Wells Fargo Bank, National Association, as Trustee.	8-K	07/02/2015
4.11	Form of 5.250% Senior Note due 2022 (included in Exhibit 4.10).	8-K	07/02/2015
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

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Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
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	03/11/2013
10.7*	Form of Stock Option Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2014).	8-K	11/12/2013
10.8*	Form of Stock Option Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2015).	8-K	11/05/2014
10.9*	Form of Stock Option Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2016).	8-K	10/14/2015
10.10*	Form of Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2014).	8-K	11/12/2013
10.11*	Form of Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2016).	8-K	10/14/2015
10.12*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2014).	8-K	11/12/2013
10.13*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2015).	8-K	11/05/2014
10.14*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2016).	8-K	11/06/2015
10.15*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan (annual grant, adopted fiscal 2014).	10-K	09/28/2013
10.16*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan (annual grant, adopted fiscal 2015).	10-K	09/27/2014
10.17*	Form of Independent Director Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (annual grant).	10-K	09/28/2013
10.18*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan (initial grant, adopted fiscal 2014).	10-K	09/28/2013
10.19*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan (initial grant, adopted fiscal 2015).	10-K	09/27/2014

10.20*	Form of Independent Director Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (initial grant).	10-K	09/28/2013
10.21*	Hologic 2012 Employee Stock Purchase Plan.	8-K	03/08/2012
10.22*	Hologic 2015 Short-Term Incentive Plan.	8-K	11/10/2014
10.23*	Hologic Short-Term Incentive Plan.	8-K	11/06/2015
10.24*	Hologic Amended and Restated Deferred Compensation Program.	8-K	09/21/2015
10.25*	Hologic Deferred Equity Plan.	8-K	09/21/2015
10.26*	Rabbi Trust Agreement.	10-K	09/28/2013
10.27*	Form of Indemnification Agreement (as executed with each director of Hologic).	8-K	03/06/2009
10.28*	Form of Senior Vice President Change of Control Agreement. (1)	10-Q	12/29/2012
10.29*	Form of Senior Executive Officer Change of Control Agreement. (1)	8-K	11/17/2009

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Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.30*	Form of Senior Vice President Severance Agreement. (1)	10-K	09/28/2013
10.31*	Separation Agreement and General Release of All Claims dated December 11, 2013 by and between John W. Cumming and Hologic.	10-Q	12/28/2013
10.32*	Separation Agreement and General Release of All Claims dated November 10, 2014 by and between Mark J. Casey and Hologic.	8-K	11/10/2014
10.33*	Employment Agreement dated December 6, 2013 by and between Stephen P. MacMillan and Hologic.	8-K	12/09/2013
10.34*	Amended and Restated Employment Agreement by and between the Company and Stephen P. MacMillan, dated September 18, 2015.	8-K	09/21/2015
10.35*	Form of Price Targets Performance Stock Unit Award Agreement.	8-K	12/09/2013
10.36*	Form of Matching Restricted Stock Unit Award Agreement.	8-K	12/09/2013
10.37*	Change of Control Agreement dated December 6, 2013 by and between Stephen P. MacMillan and Hologic.	8-K	12/09/2013
10.38*	Separation and Release Agreement dated September 2, 2014 by and between Rohan F. Hastie and Hologic.	8-K	09/08/2014
10.39*	Offer Letter dated March 9, 2014 by and between Eric B. Compton and Hologic.	8-K	03/14/2014
10.40*	Severance and Change of Control Agreement dated March 9, 2014 by and between Eric B. Compton and Hologic. (2)	Filed herewith	
10.41*	Transition Agreement dated March 13, 2014 by and between Glenn P. Muir and Hologic.	8-K	03/14/2014
10.42*	Transition and Severance Agreement dated May 1, 2014 by and between David P. Harding and Hologic.	10-Q	03/29/2014
10.43*	Settlement and Release Agreement dated May 1, 2014 by and between David P. Harding and Hologic.	10-Q	03/29/2014
10.44*	Offer Letter dated May 8, 2014 by and between Robert W. McMahon and Hologic.	8-K	05/13/2014
10.45*			

	Severance and Change of Control Agreement dated May 8, 2014 by and between Robert W. McMahon and Hologic. (2)	Filed herewith	
10.46*	Offer Letter dated May 4, 2014 by and between Peter J. Valenti and Hologic.	10-Q	06/28/2014
10.47*	Senior Vice President Severance Agreement dated May 26, 2014 by and between Peter J. Valenti and Hologic.	10-K	09/27/2014
10.48*	Offer Letter dated August 21, 2014 by and between Thomas A. West and Hologic.	10-K	09/27/2014
10.49*	Senior Vice President Severance Agreement dated October 3, 2014 by and between Thomas A. West and Hologic.	10-K	09/27/2014
10.50*	Letter of Intent dated February 27, 2014 and Terms and Conditions of Employment dated March 10, 2014 by and between Claus Egstrand and Hologic.	10-K	09/27/2014
10.51*	Severance and Change of Control Agreement dated September 18, 2014 by and between Claus Egstrand and Hologic.	10-K	09/27/2014

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Exhibit Number	Exhibit Description	Incorporated by Reference Form	Filing Date/ Period End Date
10.52*	Offer Letter dated January 6, 2015 by and between John M. Griffin and Hologic.	10-Q	03/28/2015
10.53*	Severance and Change of Control Agreement dated February 2, 2015 by and between John M. Griffin and Hologic.	10-Q	03/28/2015
10.54	Facility Lease (Danbury) dated December 30, 1995 by and among Melvin J. Powers and Mary P. Powers D/B/A M&N Realty and Lorad.	Trex Medical Corporation S-1	03/29/1996
10.55	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
10.56	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
10.57	Office Lease dated December 31, 2003 between Cytyc and Marlborough Campus Limited Partnership.	Cytyc Corporation 10-K	12/31/2003
10.58	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
10.59	Lease Agreement by and between 445 Simarano Drive, Marlborough LLC and Cytyc dated July 11, 2006.	10-K	09/29/2007
10.60	Lease Guaranty dated October 22, 2007 between Bel Marlborough I LLC and Hologic, as guarantor thereunder.	8-K	10/22/2007
10.61	Form of Exchange Agreement.	8-K	02/15/2013
10.62	Credit and Guaranty Agreement, dated May 29, 2015, 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	05/29/2015
10.63	Pledge and Security Agreement, dated May 29, 2015, among the grantors party thereto and Bank of America, N.A. as Collateral Agent	10-Q	06/27/2015
10.64	Restated Agreement dated July 24, 2009 by and between Gen-Probe Incorporated and Novartis Vaccines and Diagnostics, Inc. ‡	Gen-Probe 10-Q/A	09/30/2009

10.65	First Amendment to Restated Agreement dated November 8, 2013 by and between Gen-Probe Incorporated and Novartis Vaccines and Diagnostics, Inc.	10-K	09/28/2013
10.66	Second Amendment to Restated Agreement by and between Gen-Probe Incorporated and Grifols Diagnostic Solutions Inc.‡	10-Q	06/27/2015
10.67	Supply Agreement for Panther Instrument System effective November 22, 2006 between Gen-Probe Incorporated and STRATEC Biomedical Systems AG. ‡	Gen-Probe 10-Q	09/30/2007
10.68	Nomination and Standstill Agreement dated December 8, 2013 by and among Hologic, Icahn Partners Master Fund LP, Icahn Partners Master Fund II LP, Icahn Partners Master Fund III LP, Icahn Partners LP, Icahn Onshore LP, Icahn Offshore LP, Icahn Capital LP, IPH GP LLC, Icahn Enterprises Holdings LP, Icahn Enterprises G.P. Inc., Beckton Corp., High River Limited Partnership, Hopper Investments LLC, Barberry Corp., Carl C. Icahn, Jonathan Christodoro and Samuel Merksamer.	8-K	12/09/2013

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Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.69	Confidentiality Agreement dated December 8, 2013 by and among Hologic, Icahn Partners Master Fund LP, Icahn Partners Master Fund II LP, Icahn Partners Master Fund III LP, Icahn Partners LP, Icahn Onshore LP, Icahn Offshore LP, Icahn Capital LP, IPH GP LLC, Icahn Enterprises Holdings LP, Icahn Enterprises G.P. Inc., Beckton Corp., High River Limited Partnership, Hopper Investments LLC, Barberry Corp., Carl C. Icahn, Jonathan Christodoro and Samuel Merksamer.	8-K	12/09/2013
12.1	Ratio of Earnings to Fixed Charges.	Filed herewith	
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	XBRL Instance Document.	Filed herewith	
101.SCH	XBRL Taxonomy Extension Schema Document.	Filed herewith	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith	

101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith

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

‡ 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 U.S. Securities and Exchange Commission.

(1) List of executive officers to whom provided filed herewith.

(2) Corrected version of a previously filed exhibit.