HOLOGIC INC
Form 10-K
November 21, 2017
Table of Contents

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 30, 2017
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

---

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, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act (Check one).

Large accelerated filer ý	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨
	Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

Indicate by check mark whether the registrant 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 April 1, 2017 was $11,852,439,894 based on the price of the last reported sale on Nasdaq Global Select Market on that date.

As of November 14, 2017, 275,683,548 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 30, 2017 are incorporated into Part III (Items 10, 11, 12, 13 and 14) of this Annual Report on Form 10-K where indicated.

Table of Contents

HOLOGIC, INC.
ANNUAL REPORT ON FORM 10-K
For the Fiscal Year Ended September 30, 2017

TABLE OF CONTENTS

Table of Contents

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, including the United Kingdom's decision to leave the European Union, 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 impact to our results of operations from the disposal of our blood screening business to Grifols S.A., or Grifols, and the operational challenges of separating this business unit from our molecular diagnostics business;
- 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, including our acquisition of Cynosure, Inc., or Cynosure, in the second quarter of fiscal 2017, 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 approvals and clearances for our products;
- production schedules for our products;
- the anticipated development of markets into which we sell our products 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 the agreements governing our indebtedness;
- anticipated trends relating to our financial condition or results of operations, including the impact of interest rate and foreign currency exchange fluctuations; and
- our anticipated use of proceeds, and 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.

3

Table of Contents

TRADEMARK NOTICE

Hologic is a trademark of Hologic, Inc. Other trademarks, logos, and slogans registered or used by Hologic and its divisions and subsidiaries in the United States and other countries include, but are not limited to, the following: 3Dimensions, 3D Mammography, Accolade, Accuprobe, Affirm, Affirm Prone, Apogee, Aptima, Aptima Combo 2, ATEC, Brevera, C-View, Celero, Cellulaze, Cervista, Cynergy, Cynosure, Dimensions, Discovery, DTS, Elite, Eviva, Fluoroscan, Gen-Probe, Genius, Genius 3D, Genius 3D Mammography, Horizon, Invader, Medicor, MedLite, MonaLisa Touch, MultiCare, MyoSure, NovaSure, Panther, PicoSure, PrecisionTx, PreservCyt, Prodesse, Progensa, RevLite, SculpSure, SecurView, Selenia, Sertera, SmartLipo Triplex, StereoLoc, Synthesized 2D, ThinPrep, Tigris, TLI IQ, Tomcat, TMA, and Vectus.

Procleix, Ultrio, and Ultrio Plus are trademarks of Grifols Worldwide Operations Limited.

Table of Contents

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. On March 22, 2017, we acquired Cynosure, Inc., or Cynosure. Cynosure is a developer, manufacturer and supplier of a broad array of light-based aesthetic and medical treatment systems. The products are used to provide a diverse range of treatment applications such as non-invasive body contouring, hair removal, tattoo removal, skin revitalization and scar reduction, as well as the treatment of vascular lesions. The Cynosure business is referred to as Medical Aesthetics and operates as a separate business segment. As a result of our acquisition of Cynosure, we operate in five segments: Diagnostics, Breast Health, Medical Aesthetics, 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 through January 31, 2017, we offered products that 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, through January 31, 2017, the Procleix blood screening assays. The Aptima family of assays is used to detect, among other things, 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 developed and manufactured the Procleix family of assays, which are used to detect various infectious diseases. The Procleix blood screening assays also run on our Panther and Tigris systems. These blood screening products were marketed worldwide by our former blood screening collaborator, Grifols S.A., or Grifols, to whom we sold the blood screening business on January 31, 2017. Following the closing of this disposition, we no longer operate our blood screening business, except to the limited extent we have agreed to support Grifols.

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 Medical Aesthetics segment offers a portfolio of aesthetic treatment systems, including SculpSure, PicoSure and MonaLisa Touch that enable plastic surgeons, dermatologists and other medical practitioners to perform non-invasive and minimally invasive procedures to remove hair, treat vascular and benign pigmented lesions, remove multi-colored tattoos, revitalize the skin, reduce fat through laser lipolysis, reduce cellulite, clear nails infected by toe fungus, ablate sweat glands and improve gynecologic health. This segment also markets radio frequency, or RF, energy sourced medical devices for precision surgical applications such as facial plastic and general surgery, gynecology, ear, nose, and throat procedures, back and thigh procedures, ophthalmology, oral and maxillofacial surgery, podiatry and proctology.

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.

Table of Contents

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.” 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.

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 five principal reporting segments: Diagnostics, Breast Health, Medical Aesthetics, 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

The Aptima family of assays is used to detect, among other things, 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. In addition, we also offer viral load assays for the quantitation of hepatitis B virus, or HBV, hepatitis C virus, or HCV, and human immunodeficiency virus, or HIV-1 for use on our Panther instrument system. All three of these viral load assays are CE-marked and are currently marketed in Europe. In addition, our HCV and HIV-1 viral load assays are approved for sale and marketing in the U.S., and we are seeking FDA approval of our HBV viral load assay. Our Aptima products integrate a proprietary number of core technologies, including our target capture technology, our Transcription Mediated Amplification, or TMA, technology, and our hybridization protection assay, or HPA, and dual kinetic assay, or DKA, technologies, to produce highly sensitive amplification assays that increase assay performance, improve laboratory efficiency and reduce laboratory costs. Each of these technologies is described in greater detail below.

Target Capture/Nucleic Acid Extraction Technology. The detection of target organisms that are present in small numbers in a large-volume clinical sample requires that target organisms be concentrated to a detectable level. One way to accomplish this is to isolate the particular nucleic acid of interest by binding it to a solid support. This support, with the target bound to it, can then be separated from the original sample. We refer to such techniques as “target capture.” We have developed target capture techniques to immobilize nucleic acids on magnetic beads by the use of a “capture probe” that binds to the bead and to the target nucleic acid. We use magnetic separation to concentrate the

target by drawing the magnetic beads to the sides of a sample tube, while the remainder of the sample is removed from the tube. When used in conjunction with our amplification procedures, target capture techniques concentrate the nucleic acid target(s) and also remove materials in the sample that might otherwise interfere with amplification.

Table of Contents

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

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

Instrumentation

We have developed and continue to develop instrumentation and software designed specifically for use with certain of our assays, including the Aptima 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 assays.

Our instrumentation includes the Tigris system, an integrated, fully-automated testing instrument for high-volume laboratories which is approved for use with a number of our Aptima assays, the Panther instrument system, an integrated, fully-automated testing instrument capable of serving both high- 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 improve pre-analytical sample processing by eliminating the inefficient and error-prone activities associated with manually transferring samples from one tube to another. In the third quarter of fiscal 2017, we received a CE-mark for our new Panther Fusion system and related Fusion assays for flu and respiratory testing, all of which are currently available in Europe. The Panther Fusion system extends the capabilities of the existing Panther system by adding the flexibility of polymerase chain reaction, or PCR, functionality to our existing TMA-based technology, all as a modular in-lab upgrade to the existing Panther system. We also received clearance from the FDA in October 2017 to market and sell the Panther Fusion system and related Fusion assays in the U.S.

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 cardiovascular risk and other diseases.

ThinPrep System

The ThinPrep System is the most widely used method for cervical cancer screening in the U.S. The ThinPrep System consists of any one or more of the following: the ThinPrep 2000 Processor, ThinPrep 5000 Processor, ThinPrep5000

Processor with Autoloader, ThinPrep Imaging System, and related reagents, filters and other supplies, such as the ThinPrep Pap Test and our ThinPrep PreservCyt Solution.

Table of Contents

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

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

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

Rapid Fetal Fibronectin Test

The Rapid Fetal Fibronectin Test is a 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. The test utilizes a single-use, disposable cassette and is analyzed on our patented instrument, the TLI IQ System.

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 the Selenia Dimensions gantry and the 3Dimensions gantry incorporating our DirectRay digital detector capable of performing both 2D and tomosynthesis image acquisition and display. When operating in tomosynthesis mode, each system acquires a series of low dose x-ray images taken in a scanning motion at various angles. The images are mathematically processed into a series of small slices, allowing for visualization of the breast in multiple contiguous slices. 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. The new 3Dimensions system, which was released for commercial shipment in Europe during the fourth quarter of fiscal 2017, is designed to be our most advanced 3D mammography system. In the U.S., the 3Dimensions system has been approved by the FDA, although we are awaiting FDA approval of certain hardware and software features.

Synthesized 2D System

Our Synthesized 2D product has two offerings: C-View and Intelligent 2D. These software products provide a 2D image that is mathematically synthesized from the data within a tomosynthesis exam. Our current recommended clinical practice involves what we refer to as a "combo" exam involving a tomosynthesis exam and a conventional digital 2D exam, but performed under the same breast compression. The C-View product allows for the mathematical

construction of a 2D image in standard resolution format from the tomosynthesis data, without the need for an actual 2D exposure. Elimination of the 2D exposure reduces the breast compression time and patient dose compared to the current combo exam. The new Intelligent 2D product, which was released in Europe during the fourth quarter of fiscal 2017, allows for the mathematical construction of a 2D image in high resolution format.

Table of Contents

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. We discontinued the Selenia system in fiscal 2016.

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-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 and Affirm Prone 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 systems. These breast biopsy systems provide an alternative to open surgical biopsy and can be performed as an outpatient procedure under local anesthesia, allowing shorter recovery times. The Affirm tomosynthesis option provides faster lesion targeting and reduced patient procedure time compared to traditional stereotactic biopsy procedures. The Affirm system is pre-programmed for use with our Brevera, Eviva and ATEC vacuum-assisted breast biopsy devices.

Breast Biopsy Products

We offer a wide range of minimally invasive products for breast biopsy and biopsy site marking. Our breast biopsy portfolio includes three types of tethered vacuum-assisted breast biopsy products, the Brevera, ATEC, and Eviva devices. Each tethered device is powered by a console and utilizes our 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 Brevera and Eviva devices are used exclusively under stereotactic x-ray guidance. We also offer the Celero and Sertera biopsy devices, both of which are non-tethered (no separate console), spring-loaded, disposable core biopsy devices, which are used exclusively under ultrasound-guidance.

Medical Aesthetics

SculpSure

Our SculpSure laser system is a hyperthermic laser treatment for non-invasive body contouring. Utilizing a 1060 nanometer (nm) diode laser, SculpSure is designed to reduce fat non-invasively by eliminating subcutaneous fat cells. Over time, the body naturally eliminates the fat cells that were disrupted by the SculpSure treatment. The hands-free device features a flexible applicator system to treat multiple anatomical areas of the body. SculpSure is currently approved for treatment on flanks, abdomen and back as well as inner and outer thighs. We recently received FDA 510(k) clearance for use of SculpSure in the submental, or below the chin, area. The SculpSure system requires the use of a Patented Applicator for Contouring, or PAC, to activate each applicator handpiece used in a treatment cycle.

PicoSure, MedLite and RevLite

Our PicoSure system uses a 755 nm wavelength laser for the removal of tattoos and benign pigmented lesions, as well as the reduction of wrinkles. PicoSure uses short bursts of energy which are measured in picoseconds (trillionths of a second) in contrast to nanosecond technology, used in our MedLite and RevLite products, which delivers pulses in billionths of a

Table of Contents

second. The bursts of energy cause the tattoo ink or other damage to break apart into tiny particles which are eliminated by the body. MedLite and RevLite are used for the removal of benign pigmented lesions and multi-colored tattoos. We also offer PicoSure 532 nm wavelength and the PicoSure 1064 nm wavelength to more effectively treat certain colors in tattoos.

MonaLisa Touch

The MonaLisa Touch is a CO_2 laser for vaginal rejuvenation for postmenopausal women, breast cancer survivors and women who have undergone hysterectomies and who may suffer from changes to their gynecologic health, including vaginal dryness, soreness and itching as well as painful urination and intercourse. Delivering short CO_2 ablative laser pulses to the vaginal wall, the MonaLisa Touch is designed to stimulate and promote the regeneration of collagen fibers and the restoration of hydration and elasticity within the vaginal mucosa. We distribute and market the MonaLisa Touch in North America pursuant to an exclusive distribution agreement with El.En. S.p.A., or El.En. We and El.En. have agreed to market and distribute the MonaLisa Touch under separate distribution agreements with our respective wholly-owned subsidiaries in the United Kingdom, Germany and Spain.

Other Products.

Other product offerings in our Medical Aesthetics business include, among others:

- the Icon aesthetic system for hair removal, wrinkle reduction and scar and stretch mark treatment;
- the Vectus diode laser for high volume hair removal;
- the Cellulaze laser device for the treatment of cellulite;
- the Cynergy product line for the treatment of vascular lesions;
- the Elite product line for hair removal and treatment of facial and leg veins and pigmentations; and
- the SmartLipo product line for Laser Body Sculpting for the minimally invasive removal of unwanted fat.

System Components.

Each of our Medical Aesthetics systems consists of a control console and one or more handpieces. Some of our systems consist of RF-based control consoles where energy is transferred through a handpiece or electrode. Our control consoles are each comprised of a graphical user interface, control system software and high voltage electronics. Depending on the system, the laser or other light source may be within the control console or the handpiece. The graphical user interface allows the practitioner to set the appropriate laser or flashlamp parameters, such as energy and pulse duration, to meet the requirements of a particular application for each particular patient. The control system software communicates the operator’s instructions from the graphical user interface to the system’s components and manages system performance and calibration.

For many applications, practitioners use cooling to protect the skin. The cooling system may be a separate system or integrated into the laser or intense pulsed light system itself. When not integrated, we offer our customers the SmartCool treatment cooling system, which we purchase from a third-party supplier and sell as a private label product under the SmartCool brand. The SmartCool handpiece, which is specially designed for use with our laser systems, interlocks with the laser handpiece.

GYN Surgical Products

NovaSure

The NovaSure endometrial ablation system 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 abnormal bleeding. The NovaSure disposable device is a hand-held, single-use device that incorporates a flexible gold-plated mesh electrode used to deliver the RF energy to the endometrial tissue. The NovaSure RF Controller generates and delivers the RF energy customized for each patient, monitors several critical treatment and safety parameters, and automatically controls the endpoint of the procedure. In the second quarter of fiscal 2017, we released a new NovaSure ADVANCED device with slimmer diameter designed to improve patient comfort and physician ease-of-use while maintaining the clinical efficacy of the NovaSure system.

MyoSure

The MyoSure system is designed to provide efficient and effective hysteroscopic removal of 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.

Table of Contents

The MyoSure system consists of a tissue removal device, control unit, and hysteroscope. The MyoSure tissue removal device is single-use and features simultaneous tissue cutting and removal. The device incorporates a rapidly rotating cutting blade. During the procedure, the tissue removal device is inserted through the MyoSure hysteroscope. This tissue removal device is powered by a control unit, which features a simple user interface and is foot pedal activated.

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. Our Horizon line of x-ray bone densitometers incorporates advanced features and performance characteristics. We offer a range of bone densitometers with various features and options to address the requirements of our diverse customer base.

Mini C-arm Imaging

Our Fluoroscan mini C-arm imaging systems 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 2017, 2016, and 2015, no customer accounted for more than 10% of our consolidated revenues. In fiscal 2017, 2016, and 2015, revenues generated from Grifols, to whom we sold our blood screening business, accounted for 11.7%, 18.8%, and 20.9% of our Diagnostics segment revenue, respectively. In addition, in fiscal 2017, revenues from another customer accounted for 12.8% of our Diagnostics segment revenue. No other customer accounted for more than 10% of our revenues in any other business segment in fiscal 2017, 2016, or 2015. In fiscal 2017, 2016, and 2015, international revenues accounted for 22.4%, 21.1%, and 24.0% of our consolidated revenues, 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, Medical Aesthetics, GYN Surgical, and Skeletal Health markets. Our end customers include clinical laboratories, hospitals, healthcare providers and surgeons in both hospital and office settings, and we target various specialists at healthcare entities who use our products, such as ob-gyns, dermatologists, radiologists and breast surgeons.

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

In our Medical Aesthetics division, we target potential customers through office visits, trade shows and trade journals. We also conduct clinical workshops and webinars featuring recognized expert panelists and opinion leaders to promote existing and new treatment techniques using our products. We believe that these workshops and webinars enhance customer loyalty and provide us with new sales opportunities. We also use direct mail programs to target specific segments of the market that we seek to access, such as members of medical societies and attendees at meetings sponsored by medical societies or associations. We actively maintain a public relations program to promote coverage of our products on daytime television shows in the U.S. and Europe and we are active on popular social media outlets.

Our service organization is responsible for installing our products and providing warranty and repair services, applications training and biomedical training. In our Medical Aesthetics business, we also provide business and practice development consulting. 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

Table of Contents

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.

El.En. Commercial Relationship

We have several distribution agreements with El.En. S.p.A. Under one of these agreements, we purchase from El.En. its SmartLipo MPX system and its proprietary SLT II laser system. The SLT II laser system is an essential component of our SmartLipo Triplex, Cellulaze, and PrecisionTx systems, which also incorporate our proprietary software and delivery systems. We have exclusive worldwide rights under this agreement to sell the SmartLipo MPX system and our products containing the SLT II laser system. Under another distribution agreement with El.En. and under separate distribution agreements with certain of our wholly-owned subsidiaries in the United Kingdom, Germany and Spain, we purchase from El.En. its MonaLisa Touch laser system.

The prices at which we purchase these laser systems from El.En. are specified in the agreements; however, they may be changed by El.En. at its discretion upon 30 days' notice. El.En. is required to provide us with training for the products we distribute under these agreements, as well as marketing and other sales support for such products as we and El.En. may agree. We are required to use commercially reasonable efforts to sell and promote our systems containing these laser systems, and we are responsible for obtaining and maintaining regulatory approvals for such products. We or El.En. may terminate these agreements at any time based upon material uncured breaches by, or the insolvency of, the other party. In addition, El.En. may terminate each agreement if we do not meet annual minimum purchase obligations specified in the agreement and we may terminate if El.En. rejects a purchase order that is in line with our forecast.

Competition

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

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

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

Diagnostics. Our ThinPrep liquid-based cytology product faces direct competition in the U.S. primarily from Becton, Dickinson and Company, or BD, which manufactures a competitive offering. We also compete with the conventional Pap smear and other alternative methods for detecting cervical cancer and/or its precursors. Internationally, our ThinPrep product competes with a variety of companies and other non-FDA approved tests, since fewer regulatory barriers exist in most international markets as compared to the U.S.

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.

Table of Contents

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

Breast Health. Our mammography and related products and subsystems compete on a worldwide basis with products offered by a number of competitors, including General Electric Company, or GE, Siemens, Koninklijke Philips NV, or Philips, Planmed Oy, or Planmed, Carestream Health, Inc., FUJIFILM Holdings Corporation, or Fuji, I.M.S., and Toshiba Corporation. In the U.S., our 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, Siemens and Fuji have received FDA approval for their breast tomosynthesis systems, and we believe that other competitors are developing tomosynthesis systems for commercial use in the U.S. Our Dimensions tomosynthesis systems also compete in certain countries outside of the U.S. with tomosynthesis systems developed by GE, Siemens, Fuji, and I.M.S.

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

Medical Aesthetics. Our Medical Aesthetics products compete against laser and other energy-based products offered by companies such as Cutera, Inc., Syneron Medical Ltd. and ZELTIQ Aesthetics, Inc. (acquired by Allergan plc in April 2017), as well as several smaller specialized companies, such as Alma Lasers Inc. (acquired in May 2013 by Shanghai Fosun Pharmaceutical) and Lumenis Inc. Some of these competitors have strong financial and human resources and have established reputations, as well as established worldwide distribution channels and sales and marketing capabilities. Additional competitors may enter the Medical Aesthetics market, and we are likely to compete with new Medical Aesthetics companies in the future. Our Medical Aesthetics products also compete against non-laser and non-light-based medical products, such as BOTOX and collagen injections, and surgical and non-surgical aesthetic procedures, such as face lifts, chemical peels, abdominoplasty, liposuction, microdermabrasion, sclerotherapy and electrolysis.

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

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

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

Manufacturing

We purchase many of the components, subassemblies, and raw materials used in our products from numerous suppliers worldwide. For reasons of quality assurance, scarcity and/or cost effectiveness, certain components, subassemblies, and raw materials used in our products are available only from one or a limited number of suppliers. We work closely with our suppliers to develop contingency plans to ensure continuity of quality and reliable supply. We established long-term supply contracts with many of our suppliers and in other instances, we developed in-house

capability to offset potential shortages caused by sole source suppliers. Due to the high standards and FDA requirements applicable to manufacturing our products, such as the FDA's Quality System Regulation and Good Manufacturing Practices, we may not be able to quickly establish additional or replacement sources for certain components or materials. In the event that we are unable to obtain sufficient quantities of raw materials or components or subassemblies on commercially reasonable terms or in a timely manner, our ability to manufacture our products on a timely and cost-competitive basis may be compromised, which may have a material adverse effect on our business, financial condition and results of operations.

Table of Contents

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

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

In our Medical Aesthetics business, we use Alexandrite rods in the lasers for our Elite+, Apogee+, and PicoSure systems and our sole source supplier is Northrop Grumman SYNOPTICS. We are aware of no alternative supplier of Alexandrite rods meeting our quality standards. We also offer our SmartCool cooling systems for use with our laser aesthetic treatment systems, and our sole source supplier is Zimmer Elektromedizin GmbH. We use diode laser bars from Coherent, Inc. to manufacture our Vectus diode laser, and we use diode laser modules from Dilas Diode Laser Inc. to manufacture our SculpSure laser system. Although alternative suppliers exist for the diode laser bars, they could take months to qualify and implement. We also have El.En. as our sole source supplier for the MonaLisa Touch, as well as the SLT II laser system that we integrate with our own proprietary software and delivery systems for our SmartLipo Triplex, Cellulaze and PrecisionTx systems. We use one third-party to assemble and test many of the components and subassemblies for our Cynergy, Accolade, MedLite, RevLite, and PicoSure product families. We also utilize one third-party to assemble and test Elite+, Apogee+, Icon, Vectus, and the SculpSure finished devices.

We, and our contract manufacturers, manufacture our products at a limited number of different facilities located in the U.S. and throughout the world. In most cases, the manufacturing of each of our products is concentrated in one or a few locations. An interruption in manufacturing capabilities at any of these facilities, as a result of equipment failure or other reasons, could reduce, delay or prevent the production of our products. Some of our manufacturing operations are located outside of the U.S., including in Costa Rica and the United Kingdom. Those manufacturing operations are also subject to additional challenges and risks associated with international operations described under the caption “Risk Factors” set forth in Part I, Item 1A of this annual report on Form 10-K.

From time to time new regulations are enacted that can affect the content and manufacturing of our products. We continue to evaluate the necessary steps for compliance with regulations as they are enacted. In August 2012, the SEC adopted a rule requiring disclosures of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured by public companies. The conflict minerals rule requires companies annually to disclose and report whether or not such minerals originate from the Democratic Republic of Congo or an adjoining country. The conflict minerals rule could affect sourcing at competitive prices and availability in sufficient quantities of certain minerals used in the manufacture of our products, including tantalum, tin, gold and tungsten. The number of suppliers who provide conflict-free minerals may be limited. In addition, there may be material costs associated with complying with the disclosure requirements, such as costs related to determining the source of certain minerals used in our products, as well as costs of possible changes to

products, processes, or sources of supply as a consequence of such verification activities. Since our supply chain is complex, we may not be able to sufficiently verify the origins of the relevant minerals used in our products through the due diligence procedures that we implement, which may harm our reputation. In addition, we may encounter challenges to satisfy those customers who require that all of the components of our products be certified as conflict-free, which could place us at a competitive disadvantage if we are unable to do so.

Other regulations which affect the content and manufacturing of our products include, for example, the Registration, Evaluation, Authorization and Restriction of Chemical substances, or REACH, the Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Directive, or RoHS, and the Waste Electrical and Electronic

Table of Contents

Equipment Directive, or WEEE, enacted in the European Union which require the registration of and regulate the use of certain hazardous substances and chemicals in, and require the collection, reuse and recycling of waste from, certain products we manufacture. Similar legislation that has been or is in the process of being enacted in Japan and China and various states of the U.S. may require us to re-design our products to ensure compliance with the applicable standards, for example by requiring the use of different types of materials. These redesigns or alternative materials may detrimentally impact the performance of our products, add greater testing lead-times for product introductions, result in additional costs or have other similar effects.

Backlog

Our backlog as of October 28, 2017 and October 23, 2016 totaled $294.1 million and $345.5 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 $232.8 million, $232.1 million and $214.9 million in fiscal 2017, 2016, and 2015, respectively.

Patents and Proprietary Rights

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

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

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

We are engaged in intellectual property litigation as described in Note 12 to our consolidated financial statements entitled "Litigation and Related Matters" , and as may also be described herein, and we may be notified in the future of claims that we may be infringing, misappropriating or otherwise violating the intellectual property rights of third-parties. In connection with any such claims, we may seek to enter into settlement and/or licensing arrangements.

There is a risk in these situations that no license will be available or that a license will not be available on reasonable terms. Alternatively, we may decide or be required to litigate such claims. A successful claim by a third-party may require us to remove the alleged

Table of Contents

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

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

The laboratories that purchase certain of our products, including the ThinPrep System, ThinPrep Imaging System, Rapid Fetal Fibronectin Test, Aptima Combo 2, Aptima HPV 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.

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

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

- anti-kickback and anti-bribery laws, such as the Foreign Corrupt Practices Act, or 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,

Table of Contents

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, Quality System certification, complying with European directives and in some cases receiving specific marketing authorization from the appropriate foreign regulatory authorities. Foreign registration is an ongoing process as we register additional products and/or product modifications.

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

In 2012, the European Commission proposed two new regulations, one each for medical devices and In-vitro Diagnostics (IVD). The European regulators have now reached consensus on the texts for both new regulations and they became official in May of 2017. There will be a three-year transition period for medical devices and a five-year transition period for IVDs. 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 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, other than for our Medical Aesthetics products, 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 performed using our products. Coverage policies for Medicare patients may vary by regional Medicare contractor in the absence of a national coverage determination and payment rates for procedures will vary based on the geographic price index. Coverage policies and reimbursement rates for Medicaid patients are dependent on each State Medicaid plan and will vary. Coverage policies and reimbursement rates for patients with private insurance is dependent on the individual private payor's decisions 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 policy and payment reform proposals and medical cost containment measures are being adopted in the U.S. and in many foreign countries. The ability of our customers to obtain 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 U.S. 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 30, 2017, we had 6,233 full-time employees, including 1,552 in manufacturing operations, 761 in research and development, 3,205 in marketing, sales and support services, and 715 in general administration. The 60 non-

Table of Contents

management employees of our Hitec-Imaging subsidiary located in Germany are represented by a union and are subject to collective bargaining agreements. In addition, Hitec-Imaging's German employees are represented by a works council, a Betriebsrat, with respect to various shop agreements for social matters and working conditions. We believe that our relationship with our employees is good. Except as described herein, none of our other employees are represented by a union.

Seasonality

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

Item 1A. Risk Factors

In evaluating our business, the risks described below, as well as other information contained in this Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission should be considered carefully. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business. The occurrence of any of these events or circumstances could individually or in the aggregate have a material adverse effect on our business, financial condition, cash flow or results of operations. This report contains forward-looking statements; please refer to the cautionary statements made under the heading "Special Note Regarding Forward-Looking Statements" for more information on the qualifications and limitations on forward-looking statements.

Risks Relating to our Business

Successful execution of the revenue growth plan for all of our divisions, but particularly for our newly-acquired Medical Aesthetics division, is essential to achieving our growth objectives and involves risk.

Our successful execution of the growth plan for our Medical Aesthetics business, which is essential to achieving our growth objectives, involves a number of risks. Among other things:

- we may not be able to successfully commercialize our Medical Aesthetics product pipeline on a timely basis or at all;
- we may be unable to drive increased disposable utilization of our SculpSure or other future products; and
- we face competition from well-established companies operating in the Medical Aesthetics field, some of whom are much larger than we are and have more resources to devote to promoting the business.

Competition in the Medical Aesthetics device industry is intense. Our Medical Aesthetics products compete against products offered by companies such as Cutera, Syneron Medical, and ZELTIQ Aesthetics (which was acquired by Allergan in 2017), as well as several smaller specialized companies, such as Alma Lasers (acquired in 2013 by Shanghai Fosun Pharmaceutical) and Lumenis. We also face competition against non-laser and non-light-based medical products, such as BOTOX and collagen injections, and surgical and non-surgical aesthetic procedures, such as face lifts, chemical peels, abdominoplasty, liposuction, microdermabrasion, sclerotherapy and electrolysis. We may also face competition from manufacturers of pharmaceutical and other products that have not yet been developed. Additional competitors may enter the market, and we are likely to compete with new companies in the future.

In addition, Medical Aesthetics is a new type of business for the Company, requiring understanding of a new market as well as new products and procedures that are not subject to reimbursement. As noted in a subsequent risk factor, the elective nature of the Medical Aesthetics procedures subjects our business to increased volatility due to macroeconomic conditions. We market our aesthetic treatment systems to physicians and other practitioners as well as to end-users directly. We believe, and our growth expectations assume, that we and other companies selling lasers and other aesthetic treatment systems have not fully penetrated these markets and that we will receive a significant percentage of our revenues from selling to these markets. In addition, the commercial success of the Medical Aesthetics products and technology we develop will depend upon the acceptance of these products by providers of aesthetic procedures and their patients and clients. It is difficult for us to predict how successful recently introduced products, or products we are currently developing, will be over the long term. If our expectations as to the size of

these markets and our ability to sell our products to participants in these markets are not correct, our revenues will suffer and our business will be harmed.

Additionally, as our Medical Aesthetics business is newly-acquired, we face risks relating to integration, including, among others:

- sales force and other employee turnover (including rebuilding the sales force of our Medical Aesthetics business);
- unforeseen internal control, regulatory or compliance issues;
- diversion of management's attention from day-to-day operations;
- difficulties or delays establishing, integrating or combining operations and systems (including accounting systems); and
- adverse effects on existing business relationships with suppliers or customers.

Finally, the aesthetic laser and light-based treatment system industry is subject to continuous technological development and product innovation. If we do not continue to innovate and develop new products and applications within our Medical Aesthetics business, our competitive position will likely deteriorate as other companies successfully design and commercialize

Table of Contents

new products and applications. Accordingly, the success of our Medical Aesthetics business depends in part on developing or acquiring new and innovative applications of laser and other light-based technology and identifying new markets for and applications of existing products and technology.

Any or all of these factors could impact our ability to successfully execute our Medical Aesthetics revenue growth plan, which could have a material adverse effect on our business and financial results.

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; the internal research and development and external business development activities necessary to do so involve risk.

The markets for our products have been characterized by rapid technological change, frequent product introductions and evolving customer requirements. 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, either through internal research and development or through collaborations, acquisitions, joint ventures or licensing or other arrangements with third parties. The development of new products and enhancement of existing products requires significant investment in research and development, clinical trials and regulatory approvals.

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

Additionally, as part of our long-term strategy, we are engaged in business development activities including evaluating acquisitions, joint development opportunities, technology licensing arrangements and other opportunities to further expand our presence in or diversify into priority growth areas by accessing new products and technologies. We may not be able to identify appropriate acquisition candidates, consummate transactions or obtain agreements with favorable terms. Further, once we acquire a business, such as Cynosure, for example, any inability to successfully integrate the business, decreases in customer loyalty or product orders, failure to retain and develop the acquired workforce, failure to establish and maintain appropriate controls or unknown or contingent liabilities could adversely affect our ability to realize the anticipated benefits of any acquisition. The integration of an acquired business such as Cynosure or any other acquired business, whether or not successful, requires significant efforts which may result in additional expenses and divert the attention of our management and technical personnel from other projects. These transactions are inherently risky, and there can be no assurance that any past or future transaction will be successful.

If we are successful in pursuing future acquisitions, we may be required to expend significant funds, incur additional debt or other obligations, or issue additional securities, which may negatively affect our operating results and financial condition. If we spend significant funds or incur additional debt or other obligations, our ability to obtain financing for working capital or other purposes could be adversely affected, and we may be more vulnerable to economic downturns and competitive pressures. 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.

If we fail to develop and successfully manufacture and launch new products, enhance existing products and identify, acquire and integrate complementary businesses, technologies and products, our business, results of operations and/or financial condition could be adversely affected.

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 2017, 22.4% of our revenue came from outside of the U.S. If we fail to capitalize on 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;

Table of Contents

- 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 required regulatory approvals or favorable third-party reimbursement;
- 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, maintain, protect or enforce intellectual property rights, reduced protection for intellectual property rights in some countries, and the inability to otherwise protect against clone or “knock off” products; 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 U.S. Foreign Corrupt Practices Act of 1977, as amended ("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.

Additionally, 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.

Further, the June 2016 referendum in the United Kingdom ("UK") in which voters approved a withdrawal from the European Union, commonly referred to as “Brexit,” has created uncertainty. Subsequent to the referendum, in March 2017, the UK formally initiated its withdrawal from the European Union by triggering Article 50 of the Treaty of Lisbon. As a result of the triggering of Article 50, the process of negotiating the terms of the UK’s exit from the European Union, which is expected to take two years, has commenced. Although it is unknown what those terms will be, it is possible that there will be greater restrictions on imports and exports between the UK and the European Union and increased regulatory complexities. We have a manufacturing facility in the UK. As a result of Brexit, we may face new regulatory costs and challenges that may have a material adverse effect on us and our operations. For example, depending on the terms of Brexit, we could become subject to export tariffs and regulatory restrictions that could increase the costs and time related to doing business in Europe. Additionally, Brexit could result in the UK or the European Union significantly altering its regulations affecting the clearance or approval of our products that are developed or manufactured in the UK. Any new regulations could add time and expense to the conduct of our business, as well as the process by which our products receive regulatory approval in the UK, the European Union and elsewhere. Given the lack of comparable precedent, it is unclear what economic, financial, trade and legal implications the withdrawal of the UK from the European Union would have and how such withdrawal may affect us.

Changes in currency exchange rates may reduce the reported value of our revenues outside the U.S., net of expenses, and cash flows. We cannot predict changes in currency exchange rates, the impact of exchange rate changes, nor the degree to which we will be able to manage the impact of currency exchange rate changes. We currently have limited hedging arrangements in place to mitigate some of the impact of lower exchange rates.

Our success depends on our ability to attract and retain 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 the key personnel that we believe are essential to our long-term success. Over the last four 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. Additionally, facilitating seamless leadership transitions for key positions is a critical factor in sustaining the success of an organization. If our succession planning efforts are not effective, it could adversely impact our business.

Table of Contents

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.

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 and our business 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.

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.

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.

Additionally, 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 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

Table of Contents

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.

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.

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, the reimbursement of patients' medical expenses by government healthcare programs and third-party payors and, for our Medical Aesthetics business, individual economic health. 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. 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.

Additionally, the aesthetic laser and energy-based treatment system industry in which our Medical Aesthetics business operates is particularly vulnerable to economic trends. Most procedures performed using our aesthetic treatment systems are elective procedures that are not reimbursable through government or private health insurance. The cost of these elective procedures must be borne by the patient. As a result, the decision to undergo a procedure that uses our products may be influenced by the cost. Consumer demand, and therefore our Medical Aesthetics business, is sensitive to a number of factors that affect consumer spending, including political and macroeconomic conditions, health of credit markets, disposable consumer income levels, consumer debt levels, interest rates, consumer confidence and other factors. If there is not sufficient consumer demand for the procedures performed with our Medical Aesthetics products, practitioner demand for our Medical Aesthetics products would decline, and our Medical

Aesthetics business would suffer.

In the event of deterioration of general business conditions or the availability of credit, the financial strength and stability of our Medical Aesthetics customers and potential customers may deteriorate over time, which may cause them to cancel or delay their purchase of our products. In addition, we may be subject to increased risk of non-payment of our accounts receivables for our Medical Aesthetics business. We may also be adversely affected by bankruptcies or other business failures of our customers and potential customers. A significant delay in the collection of funds or a reduction of funds collected may impact our liquidity or result in bad debts. If the current adverse macroeconomic conditions continue, our business and prospects may be negatively impacted.

Table of Contents

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

Sales and market acceptance of our diagnostics, breast and skeletal health and surgical products and the treatments facilitated by these products 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 the products and services they use 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 appropriate reimbursement approval is obtained from private and governmental third-party payors. Further legislative or administrative reforms to the reimbursement systems in the U.S. and other countries in a manner that significantly reduces reimbursement for procedures using our diagnostics, breast and skeletal health and surgical products or denies coverage for those procedures facilitated by our products, including price regulation, competitive bidding and tendering, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements, could have a material adverse effect on our business, financial condition or results of operations.

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 U.S. in March 2010. As a U.S. headquartered company with significant sales in the U.S., the medical device tax included in this law has 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. As such, this excise tax applied to the majority, if not all of our products sold in the U.S. Effective January 1, 2016, the implementation of the medical device tax was suspended for calendar years 2016 and 2017. The status of the tax for sales after December 31, 2017 will be reinstated unless there is legislative efforts to temporarily suspend or permanently repeal.

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, 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, while the excise tax was in effect, it 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

Table of Contents

adversely affect our business and results of operations. In addition, the draft Clinical Laboratory Fee Schedule (CLFS) published by CMS under the Protecting Access to Medicare Act of 2014 (PAMA), may impact our diagnostic laboratory customers. This impact could in turn, over time, put pressure on the prices at which we sell our diagnostic assays and instruments to these customers.

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.

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, or the USPSTF, and the American Cancer Society. We believe that these recommendations and guidelines may have contributed to increased screening intervals for cervical cancer, which we believe has and may continue to adversely affect our ThinPrep revenues. Further, in September 2017, the USPSTF released draft recommendations that excluded HPV and Pap co-testing for women, which could also adversely affect our HPV test and ThinPrep revenues if these guidelines were to become final. 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 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.

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

Table of Contents

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.

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, one of whom accounted for more than 12.8% of our Diagnostics segment revenue in fiscal 2017. Blood screening product sales to Grifols accounted for 11.5% of our Diagnostics segment product revenue in fiscal 2017. 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. Contracts with two of our key Diagnostics customers are up for renewal in the next two years. 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.

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.

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. We also 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.

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.

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

Table of Contents

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 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 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 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.

26

Table of Contents

Additionally, the U.S. Supreme Court has issued several 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, trademarks and confidentiality procedures to protect our products and technology. Despite these precautions, unauthorized third parties may infringe, misappropriate or otherwise violate our intellectual property, or copy or reverse engineer portions of our technology. The pursuit and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology, involve complex determinations and, therefore, are characterized by substantial uncertainty. We do not know if current or future patent applications will be issued with the full scope of the claims sought, if at all, or whether any patents that do issue will be challenged or invalidated. The patents that we own or license could also be subjected to invalidation proceedings or similar disputes, and an unfavorable outcome could require us to cease using the related technology or to attempt to license rights to the technology from the prevailing party. 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.

Table of Contents

Finally, within our Medical Aesthetics business, we jointly own certain patents and patent applications with third parties. In the absence of an agreement with each co-owner of jointly owned patent rights, we will be subject to default rules pertaining to joint ownership. Some countries require the consent of all joint owners to exploit, license or assign jointly owned patents, and if we are unable to obtain that consent from the joint owners, we may be unable to exploit the invention or to license or assign our rights under these patents and patent applications in those countries.

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. If any of our strategic relationships are terminated and not replaced or if our strategic partners fail to perform their contractual obligations, our revenues and/or ability to service our products in the territories serviced by these distributors could be adversely affected. If any of our distribution or marketing agreements are terminated 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. In addition, we cannot be sure that our distributors will agree with our interpretation of the terms of the agreements or that we will receive payments under the agreements. The third-party distributors with which we do not have written distributor agreements may also disagree with the terms of our relationship. 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. We do not control our distributors, and these parties may not be successful in marketing our products. These parties may fail to commit the necessary resources to market and sell our products to the level of our expectations. Currently, we have written distributor agreements in place with most of our third-party distributors.

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 and for our Skeletal Health products. KMC Systems, Inc., or KMC Systems, is the only manufacturer of the Tigris instrument, Stratec Biomedical AG, or Stratec, is the only manufacturer of the Panther instrument and Flextronics International LTD, or Flextronics, is the only manufacturer of our Skeletal Health finished goods products. We have no firm

long-term volume commitments with either KMC Systems or Stratec. If KMC Systems, Stratec, Flextronics or any of our other third-party manufacturers experiences delays, disruptions, capacity constraints or quality control problems in its development or manufacturing operations or becomes insolvent or otherwise fails to supply us with 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.

Table of Contents

Similarly, we rely on one or a limited number of suppliers for some key raw materials for our products and some of these suppliers are competitors. 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. In our Medical Aesthetics business, we use Alexandrite rods in the lasers for our Elite and PicoSure systems. We depend exclusively on Northrop Grumman SYNOPTICS to supply the Alexandrite rods to us, and we are aware of no alternative supplier of Alexandrite rods meeting our quality standards. We offer our SmartCool cooling systems for use with our laser aesthetic treatment systems, and we depend exclusively on Zimmer Elektromedizin GmbH to supply SmartCool systems to us. We use diode laser bars from Coherent, Inc. to manufacture our Vectus diode laser, and we use diode laser modules from Dilas Diodenlaser GmbH to manufacture our SculpSure laser system. Although alternative suppliers exist for the diode laser bars, they could take months to qualify and implement. We also depend on El.En. for the SLT II laser system that we integrate with our own proprietary software and delivery systems into our SmartLipo Triplex, Cellulaze and PrecisionTx systems. El.En. markets, sells, promotes and licenses other products that compete with our products.

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 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 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 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;

Table of Contents

- 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.

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 increases 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.

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.

Table of Contents

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.

Because we do not require training for users of our non-invasive Medical Aesthetics products, and we sell these products to non-physicians, there exists an increased potential for misuse of these products, which could harm our reputation and our business.

Federal regulations allow us to sell our Medical Aesthetics products to or on the order of practitioners licensed by law to use or order the use of a prescription device. The definition of "licensed practitioners" varies from state to state. As a result, our products may be purchased or operated by physicians with varying levels of training and, in many states, by non-physicians, including nurse practitioners, chiropractors and technicians. Outside the U.S., many jurisdictions do not require specific qualifications or training for purchasers or operators of our products. We do not supervise the procedures performed with our products, nor can we require that direct medical supervision occur. We and our distributors offer product training sessions, but neither we nor our distributors require purchasers or operators of our non-invasive products to attend training sessions. The lack of required training and the purchase and use of our non-invasive products by non-physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

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 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 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 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.

Table of Contents

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.

Charges to earnings resulting from the application of the purchase method of accounting may adversely affect our operating results following the acquisition of Cynosure.

We have accounted for the acquisition of Cynosure using the purchase method of accounting, resulting in charges to our earnings that adversely affect our results of operations as determined in accordance with U.S. GAAP. Under the purchase method of accounting, we allocated the total purchase price to the assets acquired and liabilities assumed from Cynosure based on their estimated fair values as of the acquisition date, and recorded the excess of the purchase price over those fair values as goodwill. For certain intangible assets, recording their fair values as of the acquisition date results in incurring significant additional amortization expense that exceeds the amounts recorded by Cynosure prior to the acquisition. This increased expense is recorded over the estimated useful lives of the underlying assets. In addition, to the extent the carrying value of goodwill, acquired in-process research and development, or other intangible assets post-acquisition were to become impaired, including without limitation as a result of a change in our anticipated future cash flows, terminal value growth rates and discount rates of those assets or related reporting unit, we may be required to record charges relating to the impairment of those assets.

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.

Based on performing a quantitative analysis, all of our reporting units passed Step 1 of the annual goodwill impairment test in fiscal 2017. 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, except our Medical Aesthetics reporting unit. This reporting unit had a fair value as of the measurement date that exceeded its carrying value by 2% with goodwill of $683.5 million. We acquired Cynosure, which is the sole business in Medical Aesthetics, on March 22, 2017. In connection with our annual strategic planning process and annual goodwill impairment test, we have lowered our estimated financial projections for this business as a result of its current operating performance being below expectations, which we primarily attribute to the significant turnover in the U.S. sales force in 2017. In the event, future operating performance is below our forecasted projections, or there are negative changes to long-term growth rates or if discount rates increase, these factors could result in a decline in the fair value of the reporting unit and we may be required to record a goodwill impairment charge.

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. Any significant adverse change regarding the amount and timing of future cash flows, terminal value growth rates and discount rates used in valuing our reporting units could require us to record an impairment charge, which could have an adverse effect on our operating results. In addition to the higher risk of impairment for our Medical Aesthetics reporting unit, 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 of our reporting units to such an extent that we could be required to perform an interim impairment test during fiscal

2018.

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

As a global company, we are subject to taxation in numerous countries, states and other jurisdictions. In preparing our financial statements, we record the amount of tax payable in each of the countries, states and other jurisdictions in which we operate. Our future effective tax rate, however, may be lower or higher than prior years due to numerous factors, including a

Table of Contents

change in our geographic earnings mix, changes in the measurement of our deferred taxes, and recently enacted and future tax law changes in jurisdictions in which we operate. We are also subject to ongoing tax audits in various jurisdictions, and tax authorities may disagree with certain positions we have taken and assess additional taxes. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could adversely affect our business, results of operations, and cash flows. U.S. lawmakers are evaluating proposals for substantial changes to U.S. fiscal and tax policies, which could include comprehensive tax reform. A variety of tax reform proposals that would significantly impact U.S. taxation of corporations are under consideration, including elimination of the interest deduction, taxation of previously unrepatriated foreign earnings and reductions in the U.S. corporate tax rate. We cannot predict which, if any, of these proposals will be enacted into law or the resulting impact any such enactment will have on our financial results. However, if new legislation were enacted, it could have a material adverse effect on our financial condition and results of operations.

Risks Relating to our Indebtedness

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

As of September 30, 2017, we had approximately $3.36 billion aggregate principal of indebtedness outstanding. 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 would reduce the availability of our cash flow to fund working capital, capital expenditures, expansion efforts, strategic transactions and other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and the markets in which we participate;
- place us at a competitive disadvantage compared to our competitors that have less debt; and
- limit our ability to borrow additional funds for working capital, capital expenditures, expansion efforts, strategic transactions or other general corporate purposes.

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

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

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

If there were an event of default under one of our debt instruments or a change of control, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately and may be cross-defaulted to other debt, including our 2022 and 2025 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.”

Table of Contents

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 30, 2017, approximately $1.87 billion aggregate principal of our indebtedness, which represented the outstanding principal under our Term Loan and Revolver under our Credit Agreement and amounts outstanding under our Accounts Receivable Securitization Program, was subject to floating interest rates. The term loan and revolver under our Amended and Restated Credit Agreement entered into on October 3, 2017 similarly provide for variable interest rates. We currently have certain hedging arrangements in the form of interest rate cap agreements in place to mitigate the impact of higher interest rates. The interest rate cap agreements hedge $1.0 billion of principal under our Credit Agreement and have a December 2018 termination date.

Risks Relating to our Common Stock
Future issuances of common stock and hedging activities may depress the trading price of our common stock.
Any future issuance of equity securities 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.
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;

Table of Contents

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

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

Item 1B. Unresolved Staff Comments

None.

Table of Contents

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	Diagnostics headquarters, including administrative and manufacturing operations	262,000 sq. ft.
San Diego, CA (b)	Diagnostics research and development, administrative and manufacturing operations	290,000 sq. ft.

Principal Properties Leased:	Primary Use	Floor Space	Lease Expiration (fiscal year)	Renewals
Bedford, MA (c)	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.	2021	1, five-yr. period
Marlborough, MA	Headquarters, including research and development, manufacturing and distribution operations	216,000 sq. ft.	2025	2, five-yr. periods
Marlborough, MA	Manufacturing operations	146,000 sq. ft.	2024	1, five-yr. period
Methuen, MA	Main Distribution facility	38,000 sq. ft.	2023	1, five-yr. period
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
Westford, MA	Administrative, research and development, and manufacturing operations	150,000 sq. ft.	2028	None
Westford, MA	Manufacturing operations	19,000 sq. ft.	2024	1, five-yr. period
Hicksville, NY	Manufacturing operations	44,000 sq. ft.	2020	4, five-yr. periods

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

(c) 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 were moved to Danbury and Marlborough. This transition is primarily completed. We are actively attempting to sublease this space.

We lease other facilities utilized for office space and distribution operations across the U.S. and a number of countries worldwide.

Item 3. Legal Proceedings

For a discussion of legal matters as of September 30, 2017, please see Note 12 to our consolidated financial statements entitled “Litigation and Related Matters,” which is incorporated by reference into this item.

Item 4. Mine Safety Disclosures

Not Applicable.

Table of Contents

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 30, 2017	High	Low
First Quarter	$41.01	$35.15
Second Quarter	42.97	37.76
Third Quarter	46.80	42.12
Fourth Quarter	45.61	36.20
Fiscal Year Ended September 24, 2016	High	Low
First Quarter	$41.66	$36.29
Second Quarter	39.94	31.84
Third Quarter	38.09	32.64
Fourth Quarter	39.35	32.81

Number of Holders. As of November 14, 2017, there were approximately 1,077 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 certain of 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 2017.

Issuer's Purchases of Equity Securities

Period of Repurchase	Total Number of Shares Purchased (#) (1)	Average Price Paid Per Share ($) (1)	Total Number of Shares Purchased As Part of Publicly Announced Plans or Programs (#) (2)	Average Price Paid Per Share As Part of Publicly Announced Plans or Programs ($) (2)	Maximum Number (or Approximate Dollar Value) of Shares That May Yet Be Purchased Under Our Programs (in millions) ($) (2)
July 2, 2017 – July 29, 2017	725	$ 45.26	—	$ —	$ 500.0
July 30, 2017– August 26, 2017	2,589	41.32	2,195,623	37.87	416.9
August 27, 2017 – September 30, 2017	5,479	37.89	3,075,170	38.00	300.0
Total	8,793	$ 39.51	5,270,793	$ 37.94	$ 300.0

(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 June 21, 2016, the Board of Directors authorized the repurchase of up to $500.0 million of our outstanding common stock over the next five years.

Table of Contents

Stock Performance Graph

The following information shall not be deemed to be "filed" with the SEC nor shall the information be incorporated by reference into any future filings under the Securities Act of 1934, as amended, except to the extent that we specifically incorporate it by reference into a document filed under the Securities Act of 1933 or the Securities Exchange Act of 1934.

The following graph compares cumulative total shareholder return on our common stock since September 29, 2012 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 29, 2012 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.

Table of Contents

Item 6. Selected Financial Data

The following selected financial data should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K, beginning on page F-1. In the second quarter of fiscal 2017, we acquired Cynosure and in the third quarter of fiscal 2017 we acquired Medicor. Results of operations for these businesses are included in our consolidated financial statements from the date of acquisition.

	Fiscal Years Ended				
	September 30, 2017 (5)	September 24, 2016 (4)	September 26, 2015 (3)	September 27, 2014 (2)	September 28, 2013 (1)
	(In millions, except per share data)				
Consolidated Statement of Operations Data					
Total revenues	$3,058.8	$ 2,832.7	$ 2,705.0	$ 2,530.7	$ 2,492.3
Total operating costs and expenses	$1,688.6	$ 2,284.1	$ 2,249.9	$ 2,251.0	$ 3,398.5
Net income (loss)	$755.5	$ 330.8	$ 131.6	$ 17.3	$ (1,172.8)
Basic net income (loss) per common share	$2.70	$ 1.18	$ 0.47	$ 0.06	$ (4.36)
Diluted net income (loss) per common share	$2.64	$ 1.16	$ 0.45	$ 0.06	$ (4.36)
Consolidated Balance Sheet Data					
Working capital	$(386.9)	$ 424.7	$ 322.4	$ 946.2	$ 535.8
Total assets	$7,979.6	$ 7,317.0	$ 7,642.5	$ 8,368.7	$ 8,936.9
Long-term debt obligations, less current portion (6)	$2,198.9	$ 3,058.7	$ 3,227.3	$ 4,117.7	$ 4,193.8
Total stockholders' equity	$2,784.7	$ 2,142.7	$ 2,079.2	$ 2,063.0	$ 1,941.5

(1) 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.

(2) 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.

(3) Fiscal 2015 total operating costs and expenses include restructuring and divestiture charges of $28.5 million. Included in net income was a debt extinguishment loss of $62.7 million and related transaction costs of $9.3 million.

(4) Fiscal 2016 total operating costs and expenses include restructuring and divestiture charges of $10.5 million. Included in net income was a gain on the sale of a marketable security of $25.1 million partially offset by a debt extinguishment loss of $5.3 million.

(5) Fiscal 2017 total operating costs and expenses include a gain on sale of the blood screening business of $899.7 million, inventory step-up costs of $39.7 million, transaction expenses for acquisitions of $23.2 million, restructuring charges of $13.3 million.

(6) Long-term obligations are net of unamortized debt discounts and deferred issuance costs aggregating $27.9 million, $62.9 million, $95.7 million, $166.2 million, and $217.7 million for fiscal years 2017, 2016, 2015, 2014, and 2013, respectively.

Table of Contents

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

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

OVERVIEW

We are a developer, manufacturer and supplier of premium diagnostics products, medical imaging systems and surgical products with an emphasis on women's health. On March 22, 2017, we acquired Cynosure, Inc., a developer, manufacturer and supplier of a broad array of light-based aesthetic and medical treatment systems. The products are used to provide a diverse range of treatment applications such as non-invasive body contouring, hair removal, skin revitalization and scar reduction, as well as the treatment of vascular lesions. The Cynosure business is referred to as Medical Aesthetics and operates as a separate business segment. As a result of our acquisition of Cynosure, we operate in five segments: Diagnostics, Breast Health, Medical Aesthetics, 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 through January 31, 2017, we offered products that screened 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, through January 31, 2017, the Procleix blood screening assays. The Aptima family of assays is used to detect, among other things, 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 developed and manufactured the Procleix family of assays, which are used to detect various infectious diseases. These blood screening products were marketed worldwide by our former blood screening collaborator, Grifols, to whom we sold the blood screening business.

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, 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 Medical Aesthetics segment offers a portfolio of aesthetic treatment systems, including SculpSure, PicoSure and MonaLisa Touch that enable plastic surgeons, dermatologists and other medical practitioners to perform non-invasive and minimally invasive procedures to remove hair, treat vascular and benign pigmented lesions, remove multi-colored tattoos, revitalize the skin, reduce fat through laser lipolysis, reduce cellulite, clear nails infected by toe fungus, ablate sweat glands and improve gynecologic health. This segment also markets radio frequency, or RF, energy sourced medical devices for precision surgical applications such as facial plastic and general surgery, gynecology, ear, nose, and throat procedures, back and thigh procedures, ophthalmology, oral and maxillofacial surgery, podiatry and proctology.

Our GYN Surgical products include our NovaSure endometrial ablation system and our MyoSure hysteroscopic tissue removal system. NovaSure endometrial ablation is a one-time procedure for the treatment of abnormal uterine bleeding. MyoSure tissue removal is a minimally invasive procedure that targets and removes 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.

Table of Contents

Acquisitions and Dispositions

Cynosure, Inc.

On March 22, 2017, we completed the acquisition of Cynosure pursuant to which we acquired all of the outstanding shares of Cynosure. The acquisition was funded through available cash, and the total purchase price was $1.66 billion. The preliminary allocation of the purchase price is based on estimates of the fair value of assets acquired and liabilities assumed as of March 22, 2017. The Company has not yet obtained all of the information related to the fair value of the acquired assets and liabilities, primarily taxes, to finalize the purchase price allocation.The purchase price has been allocated to the acquired assets and assumed liabilities based on management's estimate of their fair values. As part of the preliminary purchase price allocation, the Company has determined the identifiable intangible assets are developed technology of $736.0 million, in-process research and development of $107.0 million, trade names of $74.0 million, a distribution agreement of $42.0 million and customer relationships of $35.0 million. The preliminary fair value of the intangible assets has been estimated using the income approach, specifically the excess earning method and relief from royalty method, and the cash flow projections were discounted using rates ranging from 11% to 12%. The cash flows are based on estimates used to price the transaction, and the discount rates applied were benchmarked with reference to the implied rate of return from the transaction model and the weighted average cost of capital.

The developed technology assets comprise know-how, patents and technologies embedded in Cynosure's products and relate to currently marketed products. In-process research and development projects relate to in-process projects that have not reached technological feasibility as of the acquisition date and have no alternative future use. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval to market the underlying product or expected commercial release depending on the project. We recorded $107.0 million of in-process research and development assets related to three projects, which were expected to be completed during fiscal 2018 and 2019 with a preliminary cost to complete of approximately $18.0 million. During the fourth quarter of fiscal 2017, we obtained regulatory approval for two projects with an aggregate fair value of $61.0 million and these assets were reclassified to developed technology The remaining project is expected to be completed during fiscal 2019 with an estimated cost to complete of approximately $4.0 million. Given the uncertainties inherent with product development and introduction, we cannot assure that any of our product development efforts will be successful, completed on a timely basis or within budget, if at all. All of the in-process research and development assets were valued using the multiple-period excess earnings method approach using discount rates ranging from 14% to 22%. The excess of the purchase price over the preliminary estimated fair value of the tangible net assets and intangible assets acquired of $683.5 million was recorded to goodwill. The factors contributing to the recognition of the amount of goodwill are based on several strategic and synergistic benefits that are expected to be realized from the Cynosure acquisition. These benefits include the expectation that the Company's entry into the aesthetics market will significantly broaden our offering in women's health. The Company is expected to benefit from a broader global presence, synergistic utilization of Hologic's direct sales force, primarily its GYN Surgical sales force, with certain Cynosure products and entry into an adjacent, cash-pay segment. For additional information, please refer to Note 3 to our consolidated financial statements contained in Item 15 of this Annual Report.

Medicor Medical Supply

On April 7, 2017, we completed the acquisition of MMS Medicor Medical Supplies GmbH, or Medicor, for a purchase price of approximately $19.0 million, which includes a working capital adjustment of $2.0 million that was paid in the fourth quarter of fiscal 2017, and a holdback of $1.9 million that is payable two years from the date of acquisition. Medicor was a long-standing distributor of our Breast and Skeletal Health products in Germany, Austria and Switzerland. Based on the preliminary valuation, we have allocated $5.4 million of the purchase price to the preliminary value of intangible assets and $9.5 million to goodwill. The allocation of the purchase price is preliminary as we are continuing to gather information supporting the acquired assets and liabilities.

Blood Screening Business

In the first quarter of fiscal 2017, we entered into a definitive agreement to sell our blood screening business to Grifols for a sales price of $1.85 billion in cash, subject to adjustment based on the closing amount of inventory. The transaction closed on January 31, 2017 and we received $1.865 billion. The sales price is subject to adjustment based

on a finalization of inventory provided to Grifols. The sale resulted in a gain of $899.7 million recorded in the second quarter of fiscal 2017. As a result of this disposition and proceeds received, we recorded a tax obligation of $649.5 million, which was paid in fiscal 2017. Upon the closing of the transaction, our existing collaboration agreement with Grifols terminated, and a new collaboration

Table of Contents

agreement was executed as part of this transaction for us to provide certain research and development services to Grifols. In addition, we have agreed to provide transition services to Grifols over the next two to three years depending on the nature of the respective service, including the manufacture of inventory, and we are in effect serving as a contract manufacturer of assays for Grifols for a two to three year period. We have also agreed to sell Panther instrumentation and certain supplies to Grifols as part of a long term supply agreement. Revenue, gross profit and operating income of the disposed business presented below represents the financial impact of the business as it was operated prior to the date of disposition. The operating expenses include only those that were incurred directly by and were retained by the disposed business and are now incurred by Grifols. As noted above, we are performing a number of transition services and the financial impact from these services is not included in the amounts presented below for the disposed business. For the disposed blood screening business, in fiscal 2017, revenue was $96.5 million, gross profit was $64.8 million, and operating income was $45.8 million. For the disposed blood screening business, in fiscal 2016, revenue was $235.4 million, gross profit was $163.3 million, and operating income was $99.1 million. Following the closing of this disposition, we no longer operate our blood screening business, except to the limited extent we have agreed to support Grifols. Under the long term supply agreement, transition services agreement to manufacture assays and new collaboration agreement, subsequent to disposing the blood screening business, we recognized revenues of $44.0 million in fiscal 2017.

Table of Contents

RESULTS OF OPERATIONS

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

	Fiscal Years Ended		
	September 30, 2017	September 24, 2016	September 26, 2015
Revenues:			
Product	83.0 %	84.0 %	83.9 %
Service and other	17.0 %	16.0 %	16.1 %
	100.0 %	100.0 %	100.0 %
Costs of revenues:			
Product	28.8 %	26.7 %	27.9 %
Amortization of intangible assets	9.7 %	10.4 %	11.1 %
Impairment of intangible assets	— %	— %	— %
Service and other	8.5 %	7.7 %	8.0 %
Gross Profit	53.0 %	55.2 %	53.0 %
Operating expenses:			
Research and development	7.6 %	8.2 %	7.9 %
Selling and marketing	16.3 %	14.7 %	13.4 %
General and administrative	11.2 %	9.4 %	9.7 %
Amortization of intangible assets	2.0 %	3.2 %	4.1 %
Gain on sale of business	(29.4)%	— %	— %
Restructuring and divestiture charges	0.4 %	0.4 %	1.1 %
	8.1 %	35.9 %	36.1 %
Income from operations	44.8 %	19.4 %	16.8 %
Interest income	0.1 %	— %	— %
Interest expense	(5.0)%	(5.5)%	(7.6)%
Debt extinguishment loss	(0.1)%	(0.2)%	(2.3)%
Other income (expense), net	0.4 %	0.9 %	(0.4)%
Income before income taxes	40.2 %	14.7 %	6.6 %
Provision for income taxes	15.5 %	3.0 %	1.7 %
Net income	24.7 %	11.7 %	4.9 %

Table of Contents

Fiscal Year Ended September 30, 2017 Compared to Fiscal Year Ended September 24, 2016

Product Revenues.

	Years Ended September 30, 2017		September 24, 2016		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Product Revenues						
Diagnostics	$1,165.1	38.1 %	$1,204.7	42.5 %	$(39.6)	(3.3)%
Breast Health	708.1	23.2 %	719.7	25.4 %	(11.6)	(1.6)%
Medical Aesthetics	178.3	5.8 %	—	— %	178.3	— %
GYN Surgical	426.1	13.9 %	392.0	13.9 %	34.1	8.7 %
Skeletal Health	60.4	2.0 %	62.6	2.2 %	(2.2)	(3.5)%
	$2,538.0	83.0 %	$2,379.0	84.0 %	$159.0	6.7 %

We generated a 6.7% increase in product revenues in fiscal 2017 compared to fiscal 2016 primarily due to our acquisition of Cynosure on March 22, 2017 and an increase in GYN Surgical sales. Cynosure's results (after the date of the acquisition) are reported in our new Medical Aesthetics segment. Cynosure is the sole business in this segment. We had decreases in our Diagnostics business as a result of the sale of our blood screening business effective January 31, 2017. We also experienced decreases in our Breast Health and Skeletal Health segments. Our Diagnostics revenues, excluding blood screening, increased in the current year. The increase in overall product revenues was reduced partially by the negative foreign currency exchange impact of the strengthening U.S. dollar against a number of currencies, most notably the Euro and UK Pound. The current year included an extra week as fiscal 2017 is a 53-week year.

Diagnostics product revenues decreased 3.3% in fiscal 2017 compared to fiscal 2016 primarily due to the decrease in blood screening revenues of $94.6 million in the current year as a result of the divestiture of the business during the second quarter of FY17. In connection with the divestiture agreement, we have committed to providing Grifols manufacturing support through the defined transition services period and long term access to Panther instrumentation and certain supplies. As such, we will continue to generate a level of revenues, but much lower than historical trends. For the current year, product revenue under the new long term supply agreement and transition services agreement to manufacture assays for Grifols was $37.1 million. Excluding the divestiture of the blood screening business, diagnostic product revenues grew driven by increases in Molecular Diagnostics of $57.5 million in the current year, respectively, while Cytology and Perinatal revenues were slightly lower by $2.4 million year over year primarily due to lower Perinatal sales volume.

The increase in Molecular Diagnostics product revenues was primarily due to our increased installed base of Panther instruments, which is driving higher volumes of assay testing, in particular our Aptima family of assays, an increase in the number of our virology products, as we have recently received regulatory approval for certain of these products, and an additional week in the current year compared to prior year. These increases were partially offset by a slight decline in average selling prices, a reduction in Cervista HPV revenues as our larger customers transition to our Panther system, a reduction in Cystic Fibrosis revenues as we discontinued the product at the end of the second quarter of fiscal 2016, and the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies.

Breast Health product revenues decreased 1.6% in fiscal 2017 compared to fiscal 2016 primarily due to lower sales volume of our 3D Dimensions systems and related components in the U.S., partially offset by an increase in international sales volume and 3D upgrades. The increase in international sales was partially due to our acquisition of Medicor in the third quarter of fiscal 2017. In addition, the lower revenue reflected a decline in 2D systems primarily due to discontinuing the Selenia system in fiscal 2016. These decreases were partially offset by the sales volume increase in our recently launched Affirm Prone table, an increase in C-view sales and higher volumes of our Eviva and ATEC products, partially offset by slightly lower average selling prices for ATEC.

Our Medical Aesthetics business was formed in fiscal 2017 by the acquisition of Cynosure effective March 22, 2017. Accordingly, we did not have any Medical Aesthetics revenues in the prior year period.

Table of Contents

GYN Surgical product revenues increased 8.7% in fiscal 2017 compared to fiscal 2016 primarily due to increases in MyoSure system sales of $33.0 million as MyoSure continues to gain strong market acceptance with new devices being released, such as the MyoSure REACH, partially offset by a slight decrease in average selling prices primarily due to product mix. NovaSure revenues were lower by $2.9 million in fiscal 2017 compared to fiscal 2016 primarily due to slight decrease in average selling prices. Our GYN Surgical revenues were also adversely affected by the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies.

Skeletal Health product revenues decreased 3.5% in fiscal 2017 compared to fiscal 2016 primarily due to a decrease in our mini C-arm sales in the U.S. due to competitive pressures, which was partially offset by increases in Horizon osteoporosis assessment product revenues primarily attributable to higher sales volume on a worldwide basis.

In fiscal 2017, 76.7% of product revenues were generated in the United States, 10.3% in Europe, 8.5% in Asia-Pacific, and 4.5% in other international markets. In fiscal 2016, 77.8% of product revenues were generated in the United States, 10.6% in Europe, 8.3% in Asia-Pacific, and 3.3% in other international markets. The slight decrease in the percentage of U.S. revenues was primarily due to lower sales volumes of 3D Dimensions systems and related components in the U.S. and higher revenues in other international markets as a result of our Cynosure acquisition.

Service and Other Revenues.

	Years Ended September 30, 2017		September 24, 2016		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Service and Other Revenues	$520.8	17.0 %	$453.7	16.0 %	$67.1	14.8%

Service and other revenues are primarily comprised of revenue generated from our field service organization to provide ongoing service, installation and repair of our products. The majority of these revenues are generated within our Breast Health segment. Service and other revenues increased 14.8% in fiscal 2017 compared to fiscal 2016 primarily due to higher service contract conversion and renewal rates, an additional week in the current year, higher spare parts sales, and the Cynosure acquisition, which contributed $29.2 million in the current year.

Cost of Product Revenues.

	Years Ended September 30, 2017			September 24, 2016			Change	
	Amount	% of Product Sales		Amount	% of Product Sales		Amount	%
Cost of Product Revenues	$881.8	34.7	%	$756.8	31.8	%	$125.0	16.5%
Amortization of Intangible Assets	297.1	11.7	%	293.4	12.3	%	3.7	1.3 %
	$1,178.9	46.4	%	$1,050.2	44.1	%	$128.7	12.3%

Product gross margin decreased to 53.6% in fiscal 2017 compared to 55.9% in fiscal 2016.

Cost of Product Revenues. The cost of product revenues as a percentage of product revenues was 34.7% in the current year, compared to 31.8% in the prior year. Cost of product revenues as a percentage of product revenues in the current year were higher in Diagnostics and Skeletal Health, relatively consistent in GYN Surgical, and decreased in Breast Health compared to the prior year, resulting in the decrease in overall product margins. In addition, the cost of product revenues was higher due the inclusion of Cynosure results partially due to the impact of the step-up in inventory from purchase accounting, which was $39.3 million in the current year, and the Cynosure products have a lower gross margin than our legacy products.

Diagnostics' product costs as a percentage of revenue increased in fiscal 2017 compared to fiscal 2016 primarily due to the divestiture of the higher margin blood screening business that occurred during the second quarter of fiscal 2017. The products that we supply to Grifols under the new supply and collaboration agreements are at significantly lower gross margins than we earned in the disposed business, and we expect this to continue. The cost as a percentage of

revenue also increased due to a shift in sales to lower margin international molecular diagnostic products, a slight decline in Aptima average selling prices, lower Perinatal sales and the negative impact of the strengthening U.S. dollar on our sales denominated in foreign currencies, partially offset by the increase in Aptima assay volumes.

Table of Contents

Breast Health's product costs as a percentage of revenue decreased in fiscal 2017 compared to fiscal 2016 primarily due to higher software revenues for our C-View product and 3D upgrades, which have higher gross margins than capital equipment sales, as well as manufacturing efficiencies, increase in average sales prices for breast biopsy systems due to increased volume in our Affirm Prone table, and an increase in Eviva and ATEC volumes. These decreases in product costs as a percentage of revenue were partially offset by the volume impact of the decreases in 3D Dimensions systems and related component revenue.

GYN Surgical's product costs as a percentage of revenue were relatively consistent in fiscal 2017 compared to fiscal 2016.

Skeletal Health's product costs as a percentage of revenue increased in fiscal 2017 compared to fiscal 2016 primarily due to lower volumes and an increase in obsolescence charges.

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 and 15 years using a straight-line method or, if reliably determinable, based on the pattern in which the economic benefits of the assets are expected to be consumed. The decrease in amortization expense as a percentage of revenue in fiscal 2017 compared to fiscal 2016 was primarily due to the divestiture of the blood screening business resulting in lower amortization expense of $17.9 million, and the $6.2 million acceleration of the discontinued Cystic Fibrosis developed technology asset in the prior year. The decrease was also driven, to a lesser extent, from lower amortization expense related to the Cytyc acquisition intangibles, which are being amortized based on the pattern of economic benefits. These decreases were partially offset by amortization expense of $33.5 million from intangible assets acquired from Cynosure.

Cost of Service and Other Revenues.

	Years Ended					
	September 30, 2017		September 24, 2016		Change	
	Amount	% of Service and Other Revenues	Amount	% of Service and Other Revenues	Amount	%
Cost of Service and Other Revenues	$258.9	49.7 %	$219.2	48.3 %	$39.7	18.1%

Service and other revenues gross margin was 50.3% in fiscal 2017 compared to 51.7% in fiscal 2016. Slight decrease in gross margin is related to lower margin Cynosure service business offset by the strength of the Breast Health service margins. The Breast Health business continues to convert a high percentage of our installed base of digital mammography systems to service contracts upon expiration of the warranty period leveraging our service infrastructure.

Operating Expenses.

	Years Ended					
	September 30, 2017		September 24, 2016		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Operating Expenses						
Research and development	$232.8	7.6 %	$232.1	8.2 %	$0.7	0.3 %
Selling and marketing	498.6	16.3 %	415.1	14.7 %	83.5	20.1 %
General and administrative	343.3	11.2 %	267.3	9.4 %	76.0	28.4 %
Amortization of intangible assets	62.5	2.0 %	89.7	3.2 %	(27.2)	(30.3)%
Gain on sale of business	(899.7)	(29.4)%	—	— %	(899.7)	(100.0)%
Restructuring and divestiture charges	13.3	0.4 %	10.5	0.4 %	2.8	26.7 %
	$250.8	8.1 %	$1,014.7	35.9 %	$(763.9)	(75.3)%

Research and Development Expenses. Research and development expenses increased 0.3% in fiscal 2017 compared to fiscal 2016 primarily due to the inclusion of Cynosure research and development expenses of $15.3 million and

increased consulting expenses, partially offset by the divestiture of the blood screening business, lower project spend, and a reduction in headcount primarily in Diagnostics. In addition, for fiscal 2017 there was an additional week of expenses. At any point in time,

Table of Contents

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 20.1% in fiscal 2017 compared to fiscal 2016 primarily due to the inclusion of Cynosure, which contributed $81.0 million. Excluding the impact of Cynosure, expenses related to Hologic's legacy business increased in the current year compared to the prior year primarily due to increased headcount in GYN Surgical and Breast Health, increased training, meeting and consulting expenses and higher spend internationally as we invest to expand our presence in targeted geographic markets, partially offset by lower commissions, trade shows and marketing initiatives. In addition, there was an extra week of spend in the current year.

General and Administrative Expenses. General and administrative expenses increased 28.4% in fiscal 2017 compared to fiscal 2016 primarily due to the inclusion of Cynosure, which contributed $30.4 million, which includes retention and integration related expenses including legal and consulting professional fees. Excluding the impact of Cynosure, expenses related to Hologic's legacy business increased in the current year compared to the prior year primarily due to acquisition and divestiture transaction fees of $23.2 million, charges of $35.6 million for non-income tax matters, increased compensation and benefits partially due to higher stock compensation, increased information systems infrastructure and project costs, integration and consolidation charges, and an additional week of expenses. These increases were partially offset by $12.4 million refund received in fiscal 2017 related to amended medical device excise tax filings, overall lower legal fees as the prior year period included a $6.0 million charge to settle a legal fee dispute, lower consulting and tax fees related to organizational structure changes and improvements and decrease in facilities costs.

Amortization of Intangible Assets. Amortization of intangible assets results from customer relationships, trade names, distributor relationships and business licenses related to our acquisitions. These intangible assets are generally amortized over their estimated useful lives of between 2 and 30 years using a straight-line method or, if reliably determinable, based on the pattern in which the economic benefits of the assets are expected to be consumed utilizing expected undiscounted future cash flows. Amortization expense decreased 30.3% in fiscal 2017 compared to fiscal 2016 primarily due to lower amortization expense from intangible assets related to the blood screening business of $34.5 million that was disposed of during the second quarter of fiscal 2017. This decrease was partially offset by intangible asset amortization expense of $10.1 million as a result of the Cynosure acquisition and an additional week of expense in fiscal 2017.

Gain on Sale of Business. In the second quarter of fiscal 2017, we completed the sale of our blood screening business to Grifols and recorded a gain of $899.7 million.

Restructuring and Divestiture Charges. In fiscal 2015, we decided to shut down our Bedford, Massachusetts facility and transfer production of our Skeletal Health products to a third-party contract manufacturer and other activities to our Marlborough, Massachusetts and Danbury, Connecticut facilities. We also implemented additional organizational changes to our international operations in fiscal 2016. In fiscal 2017, in connection with our acquisition of Cynosure, we have and will implement certain organizational changes, and we also eliminated certain research and development positions in Breast Health and manufacturing positions primarily in our Diagnostics division. Pursuant to U.S. generally accepted accounting principles, the related severance and benefit charges are recognized either ratably over the respective required employee service periods or up-front for contractual benefits, and other charges are being recognized as incurred. In fiscal 2017 and 2016, we recorded aggregate charges of $13.3 million and $10.5 million, respectively, from these actions, primarily for severance and benefits and to a lesser extent facility closure costs. The current year charges are for severance benefits primarily related to the termination of Cynosure executives and employees and lease obligation charges for a vacated section of our Bedford facility. For additional information, please refer to Note 3 to our consolidated financial statements contained in Item 15 of this Annual Report.

Interest Expense.

	Years Ended			
	September 30, 2017	September 24, 2016	Change	
	Amount	Amount	Amount	%

Interest Expense	$(153.2)	$(155.3)	$2.1 (1.4)%

Interest expense in fiscal 2016 and 2017 consists primarily of the cash interest costs and the related amortization of the debt discount and deferred issuance costs on our Convertible Notes, 2022 Senior Notes, and amounts borrowed under our Credit Agreement, and Accounts Receivable Securitization Program. Interest expense in fiscal 2017 compared to fiscal 2016 was relatively consistent but had offsetting factors. While we lowered outstanding debt balances as a result of scheduled principal payments, and Convertible Note repurchases in fiscal 2017, this effect on interest was offset by an additional week in the current year, higher expense from interest rate cap agreements and an increase in the LIBOR rate compared to the prior year period.

Table of Contents

Debt Extinguishment Loss.

	Years Ended September 30, 2017	September 24, 2016	Change	
	Amount	Amount	Amount	%
Debt Extinguishment Loss	$(3.2)	$ (5.3)	$2.1	(39.6)%

On various dates during the third and fourth quarters of fiscal 2017, we entered into privately negotiated repurchase transactions and extinguished $117.9 million and $168.0 million principal amount of our 2012 and 2013 Notes, respectively, for an aggregate payment of $375.1 million, which includes a premium conversion resulting from our stock price on the date of the transactions being in excess of the conversion prices. In connection with these transactions, we recorded a debt extinguishment loss of $0.9 million and $2.3 million on the 2012 and 2013 Notes, respectively, related to the difference between the fair value of their respective liability components and carrying values at the repurchase dates. The remaining cash payments were allocated to the reacquisition of the equity component and recorded within additional paid-in capital, a component of stockholders' equity.

On various dates during the second and fourth quarters of fiscal 2016, we entered into privately negotiated repurchase transactions and extinguished $137.6 million and $136.6 million principal amount of our 2010 and 2012 Notes, respectively, for an aggregate payment of $392.8 million, which includes a premium conversion resulting from our stock price on the date of the transactions being in excess of the conversion prices. In connection with these transactions, we recorded a debt extinguishment loss of $4.6 million and $0.7 million on the 2010 Notes and 2012 Notes, respectively, related to the difference between the fair value of their respective liability components and carrying values at the repurchase dates. The remaining cash payments were allocated to the reacquisition of the equity component and recorded within additional paid-in capital, a component of stockholders' equity.

Other Income (Expense), net.

	Years Ended September 30, 2017	September 24, 2016	Change	
	Amount	Amount	Amount	%
Other Income (Expense), net	$12.9	$ 26.6	$(13.7)	(51.5)%

In fiscal 2017, this account primarily consisted of a gain of $4.9 million on the cash surrender value of life insurance contracts related to our deferred compensation plan, $2.3 million in net foreign currency exchange gains partially due to hedging activities and $5.6 million of net realized gains on the sale of investments.

In fiscal 2016, this account was primarily comprised of a $25.1 million realized gain on the sale of a marketable security, and a gain of $3.3 million on the cash surrender value of life insurance contracts related to our deferred compensation plan. These gains were partially offset by an other-than-temporary impairment charge of $1.1 million on a marketable security and net foreign currency exchange losses of $1.0 million.

Provision for Income Taxes.

	Years Ended September 30, 2017	September 24, 2016	Change	
	Amount	Amount	Amount	%
Provision for Income Taxes	$475.0	$ 84.5	$390.5	462.1%

Our effective tax rate for fiscal 2017 was 38.6% compared to 20.3% in fiscal 2016. Our effective tax rate in fiscal 2017 was higher than the statutory rate primarily due to non-deductible goodwill related to the sale of the Blood Screening business, partially offset by the release of valuation allowances for capital losses utilized against the capital gain generated on the sale of the Blood Screening business, earnings in jurisdictions subject to lower tax rates, the domestic production activities deduction benefit, the release of uncertain tax positions due to statutes of limitations

expirations and audit settlements, stock compensation benefits, and federal and state tax credits.
For fiscal 2016, the effective tax rate was lower than the statutory tax rate primarily due to earnings in jurisdictions subject to lower tax rates, the domestic production activities deduction benefit, and a change in the valuation allowance related to the sale of a marketable security with a higher tax than book basis.

Table of Contents

Segment Results of Operations

We report our business as five segments: Diagnostics, Breast Health, Medical Aesthetics, 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. 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 30, 2017	September 24, 2016	Change	
	Amount	Amount	Amount	%
Total Revenues	$1,197.1	$1,236.9	$(39.8)	(3.2)%
Operating Income	$1,054.2	$126.0	$928.2	736.7 %
Operating Income as a % of Segment Revenue	88.1 %	10.2 %		

Diagnostics revenues decreased in fiscal 2017 compared to fiscal 2016 primarily due to the decrease in product revenues discussed above. The primary driver of the reduction in revenues was the divestiture of the blood screening business in the second quarter of fiscal 2017.

Operating income for this business segment increased in fiscal 2017 compared to fiscal 2016 primarily due to the gain on the disposition of the blood screening business of $899.7 million partially offset by a decrease in gross profit primarily due to the blood screening divestiture. Excluding the impact of the gain, operating income increased $28.7 million in the current year compared to the prior year. Gross margin was 47.8% in the current year compared with 49.5% in the prior year. The decrease in gross margin was primarily due to lower revenues as a result of the disposition of the higher-margin blood screening business and the lower margins generated under the new supply and collaboration arrangement, the slight decline in Aptima average selling prices, a shift in sales to lower margin international molecular diagnostic products and the negative impact of the strengthening U.S. dollar on our sales denominated in foreign currencies, partially offset by the increase in Aptima assay volumes and lower amortization expense primarily attributable to the divestiture of the blood screening business.

Exclusive of the impact of the gain on the sale of the blood screening business, operating expenses decreased in fiscal 2017 compared to fiscal 2016 primarily due to lower amortization expense primarily as a result of the blood screening divestiture, lower research and development expenses related to a reduction in project spending as well as the divestiture of blood screening, and the refund received related to amended medical device excise tax filings, $5.5 million of which related to Diagnostics. In addition, the current year expenses were lower primarily due to a reduction of legal fees and charges as the prior year period included a $6.0 million settlement of a legal fee dispute, and the prior year period included $2.8 million for the medical device excise tax. These decreases in operating expenses were partially offset by an increase in non-income taxes of $3.7 million recorded in fiscal 2017 and increased compensation from higher sales and marketing headcount.

Breast Health.

	Years Ended			
	September 30, 2017	September 24, 2016	Change	
	Amount	Amount	Amount	%
Total Revenues	$1,138.3	$1,112.8	$25.5	2.3%
Operating Income	$373.4	$350.5	$22.9	6.5%
Operating Income as a % of Segment Revenue	32.8 %	31.5 %		

Breast Health revenues increased in fiscal 2017 compared to fiscal 2016 primarily due primarily due to an increase of $37.2 million in service revenue, partially offset by a $11.7 million decrease in product revenue discussed above.

Operating income for this business segment increased in fiscal 2017 compared to fiscal 2016 primarily due to an increase in gross profit from higher revenue partially offset by an increase in operating expenses in the current year.

The overall gross margin increased to 60.9% in the current year compared to 59.9% in the prior year primarily due to the increase in service revenue and software product sales, which have higher gross margins than capital equipment sales. The gross margin increases

Table of Contents

were partially offset by the volume impact of the decreases in 3D Dimensions systems and related component revenue in the US.

Operating expenses increased in fiscal 2017 compared to fiscal 2016. We experienced an increase in non-income tax charges of $5.8 million recorded in fiscal 2017, an increase in compensation and commissions from increased head count, higher marketing expenditures internationally, increased legal fees, and operating expenses from Medicor. These increases were partially offset by lower marketing initiatives and program spend on Genius 3D, lower meeting and related expenses, lower restructuring costs, and a $4.5 million refund received in the third quarter of fiscal 2017 relating to this business segment from amending the Company's medical device excise tax filings. In addition, the prior year period included medical device excise taxes of $2.5 million.

Medical Aesthetics.

	Years Ended			
	September 30, 2017	September 24, 2016	Change	
	Amount	Amount	Amount	%
Total Revenues	$207.5	$ —	$207.5	100.0%
Operating Income	$(115.9)	$ —	$(115.9)	100.0%
Operating Income as a % of Segment Revenue	(55.9)%	— %		

Medical Aesthetics revenues increased in fiscal 2017 related to the acquisition of Cynosure on March 22, 2017.

The operating loss of $115.9 million in the fiscal 2017 was primarily due to amortization of intangible assets of $43.7 million, the step-up to fair value of inventory sold of $39.3 million, and restructuring, retention and integration expenses, including legal and professional consulting fees and accelerated depreciation expense, aggregating $25.7 million partially offset by gross profit. Fiscal 2017 also includes acquisition transaction fees of $18.8 million.

GYN Surgical.

	Years Ended			
	September 30, 2017	September 24, 2016	Change	
	Amount	Amount	Amount	%
Total Revenues	$427.1	$393.1	$34.0	8.6 %
Operating Income	$65.0	$69.1	$(4.1)	(5.9)%
Operating Income as a % of Segment Revenue	15.2 %	17.6 %		

GYN Surgical revenues increased in fiscal 2017 compared to fiscal 2016 due to the increase in product revenues discussed above.

Operating income for this business segment decreased in fiscal 2017 compared to fiscal 2016 primarily due to increase in operating expense related to charges recorded for non-income tax matters of $26.1 million. Excluding the impact of the non-income tax matter, operating income in fiscal 2017 compared to fiscal 2016 would have increased due to an increase in gross profit as a result of higher revenues. Gross margin increased to 63.6% in fiscal 2017 period from 62.0% in fiscal 2016 primarily due to higher revenues with improved manufacturing efficiencies, a decrease in amortization expense, and the inclusion in the prior year period of a write-off of inventory that would not be utilized.

Operating expenses increased in fiscal 2017 primarily due to charges recorded for non-income tax matters of $26.1 million, increases in compensation from additional headcount, higher commissions due to increased sales, increased spend on marketing initiatives and increased product development spend, partially offset by lower amortization expenses.

Table of Contents

Skeletal Health.

	Years Ended			
	September 30, 2017	September 24, 2016	Change	
	Amount	Amount	Amount	%
Total Revenues	$88.8	$ 89.9	$(1.1)	(1.2)%
Operating Income	$(6.5)	$ 3.0	$(9.5)	(316.7)%
Operating Income as a % of Segment Revenue	(7.3)%	3.3 %		

Skeletal Health revenues decreased in fiscal 2017 compared to fiscal 2016 primarily due to the decrease in product revenues discussed above.

Operating income decreased in fiscal 2017 compared to the prior year primarily due to a decrease in gross profit from lower revenues and increased obsolescence charges. Gross margin rate was 42.2% in fiscal 2017 compared to 46.3% in fiscal 2016. This business also had higher operating expenses in fiscal 2017 primarily related to the facility closure costs incurred for the Bedford facility of $4.8 million.

Table of Contents

Fiscal Year Ended September 24, 2016 Compared to Fiscal Year Ended September 26, 2015

Product Revenues.

	Years Ended September 24, 2016		September 26, 2015		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Product Revenues						
Diagnostics	$1,204.7	42.5 %	$1,184.1	43.8 %	$20.6	1.7 %
Breast Health	719.7	25.4 %	685.1	25.3 %	34.6	5.1 %
GYN Surgical	392.0	13.9 %	334.6	12.4 %	57.4	17.2 %
Skeletal Health	62.6	2.2 %	66.6	2.5 %	(4.0)	(6.0)%
	$2,379.0	84.0 %	$2,270.4	84.0 %	$108.6	4.8 %

We generated an increase in product revenues in fiscal 2016 compared to fiscal 2015. The growth was across our three primary business segments on both a domestic and worldwide basis, while Skeletal Health experienced a decline domestically and internationally. Product revenues increased 4.8% in fiscal 2016 compared to fiscal 2015, 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, Australian dollar and UK Pound.

Diagnostics product revenues increased 1.7% in fiscal 2016 compared to fiscal 2015 primarily due to increases in Molecular Diagnostics of $28.6 million and Cytology & PeriNatal of $8.1 million. These increases were partially offset by a decrease of $16.2 million in our Blood Screening business.

The increase in Molecular Diagnostics products, and in particular our Aptima family of assays, was primarily due to our increased installed base of Panther instruments, which is driving higher volumes of assay testing. These increases were partially offset by a slight decline in average selling prices, a reduction in Cervista HPV revenues as our larger customers transition to our Panther system, a reduction in Cystic Fibrosis revenues as we discontinued the product at the end of the second quarter of fiscal 2016, and a slight negative foreign currency exchange impact from the strengthening U.S. dollar on our sales denominated in foreign currencies. Overall, we experienced revenue growth both domestically and internationally in our Molecular Diagnostics business. The increase in our Cytology & PeriNatal products was primarily related to increases in instrument sales and Perinatal volumes partially offset by a decrease in our ThinPrep products, where ThinPrep volumes increased slightly domestically and increased more modestly internationally, but international sales were negatively impacted by the strengthening U.S. dollar on our sales denominated in foreign currencies. As a result, this business experienced an increase in domestic revenues but a decline in international revenues. Blood Screening revenues decreased in fiscal 2016 compared to fiscal 2015 primarily due to a reduction in volumes related to the agreement between Grifols, our blood screening partner, and the Japanese Red Cross and lower instrument and ancillary volumes as well as the trend of lower blood donations in the U.S. The revenue decrease was partially offset by fluctuations in Grifols' domestic inventory levels, including increased fulfillment of the West Nile Virus assay. As a result, this business experienced an increase in domestic revenues but a decline in international revenues.

Breast Health product revenues increased 5.1% in fiscal 2016 compared to fiscal 2015. Our digital mammography systems and related products revenue increased $56.8 million in fiscal 2016 compared to fiscal 2015 primarily due to higher sales volume of our 3D Dimensions systems on a worldwide basis, principally driven by domestic sales. This resulted in our domestic 3D Dimension systems sales, which have higher average selling prices than international sales, increasing as a percentage of our total 3D Dimension system sales. In addition, we also had higher software sales primarily driven by our C-View product. These increases were partially offset by negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies and decreases in the sales volume of our 2D Selenia product. In addition, we had lower sales of our interventional breast solutions products of $4.7 million and had no sales from our MRI breast coils product line in fiscal 2016, which was fully disposed during fiscal 2015 and contributed $8.4 million in fiscal 2015. Overall, we experienced growth domestically in this business segment but had a decline internationally in our primary product lines.

GYN Surgical product revenues increased 17.2% in fiscal 2016 compared to fiscal 2015 primarily due to increases in MyoSure system sales of $38.8 million and NovaSure system sales of $19.1 million compared to fiscal 2015 as volumes increased both domestically and internationally for each product. We believe the increase in domestic NovaSure volumes is partially attributable to a competitor's recent withdrawal from the market. The MyoSure system continued to gain strong market acceptance as unit sales increased globally. These increases were partially offset by the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies.

Table of Contents

Skeletal Health product revenues decreased 6.0% in fiscal 2016 compared to fiscal 2015 primarily due to decreases in the sales volume of our older Discovery products, lower sales of our mini C-arm product and the negative foreign currency exchange impact of the strengthening U.S. dollar on our sales denominated in foreign currencies. These decreases were partially offset by an increase in our Horizon osteoporosis assessment product sales volume.

In fiscal 2016, 77.8% of product revenues were generated in the United States, 10.6% in Europe, 8.3% in Asia-Pacific, and 3.3% in other international markets. 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. The increase in the percentage of U.S. revenues was primarily due to higher total product revenue in the U.S. in our Surgical, Breast Health and Molecular Diagnostic product lines. The impact of the U.S. revenue increases, lower overall international revenues, and the negative impact of the strengthening U.S. dollar, primarily against the Euro, Australian dollar and the UK Pound, resulted in a reduction in the European and Asia-Pacific revenues as a percentage of consolidated revenues.

Service and Other Revenues.

	Years Ended September 24, 2016		September 26, 2015		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Service and Other Revenues	$453.7	16.0 %	$434.6	16.1 %	$19.1	4.4%

Service and other revenues are primarily comprised of revenue generated from our field service organization to provide ongoing service, installation and repair of our products. The majority of these revenues are generated within our Breast Health segment. Service and other revenues increased 4.4% in fiscal 2016 compared to fiscal 2015 primarily due to higher service contract conversion and renewal rates and higher installation and training revenues related to increased sales of our 3D Dimensions systems. In addition, other revenue in our Diagnostics segment increased in fiscal 2016 primarily due to $9 million of payments received under an agreement to license certain technology.

Cost of Product Revenues.

	Years Ended September 24, 2016		September 26, 2015		Change	
	Amount	% of Product Revenue	Amount	% of Product Revenue	Amount	%
Cost of Product Revenues	$756.8	31.8 %	$755.5	33.3 %	$1.3	0.2 %
Amortization of Intangible Assets	293.4	12.3 %	299.7	13.2 %	(6.3)	(2.1)%
	$1,050.2	44.1 %	$1,055.2	46.5 %	$(5.0)	(0.5)%

Product gross margin increased to 55.9% in fiscal 2016 compared to 53.5% in fiscal 2015.

Cost of Product Revenues. Cost of product revenues as a percentage of product revenues in fiscal 2016 decreased in our Breast Health and GYN Surgical business segments and increased in Diagnostics and Skeletal Health compared to fiscal 2015, resulting in the overall improvement in gross margins.

Diagnostics' product costs as a percentage of revenue increased slightly in fiscal 2016 compared to fiscal 2015 primarily due to unfavorable absorption variances, a mix shift in international sales to a higher percentage of lower margin molecular diagnostic products, inventory related charges for discontinuing the Cystic Fibrosis product, and the negative impact of the strengthening U.S. dollar on our sales denominated in foreign currencies. These increases were partially offset by an increase in product revenue related to the increase in Aptima assay sales and related volumes resulting in favorable manufacturing variances, and lower production costs at our manufacturing facilities as we improve our operational efficiency and renegotiate pricing with certain of our vendors. In addition, we generated an increase in domestic sales, which have higher average selling prices, while international sales declined in fiscal 2016 compared to fiscal 2015.

Breast Health's product costs as a percentage of revenue decreased in fiscal 2016 compared to fiscal 2015 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. In addition, we had higher software sales primarily due to our C-View product, which have higher gross margins than capital equipment sales, and we experienced favorable manufacturing variances. Further, we

Table of Contents

generated an increase in domestic sales, which have higher average selling prices, while international sales declined in fiscal 2016 compared to fiscal 2015 resulting in an improved gross margin. We also had lower sales of our interventional breast solutions disposables and no sales from our MRI breast coils product line, which was fully disposed during fiscal 2015. Both of these product lines have lower gross margins than our digital mammography systems.

GYN Surgical's product costs as a percentage of revenue decreased in fiscal 2016 compared to fiscal 2015 primarily due to an increase in sales volumes for both our MyoSure and NovaSure products resulting in favorable manufacturing variances, partially offset by product mix shift to our lower margin MyoSure products. In addition, the prior fiscal year included a $4.0 million charge to write-off certain inventory that would not be utilized.

Skeletal Health's product costs as a percentage of revenue increased in fiscal 2016 compared to fiscal 2015 primarily due to an overall decrease in revenues, partially offset by favorable manufacturing variances as we built additional inventory in anticipation of outsourcing the manufacturing of a majority of the division's products to a third party.

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 15 years using a straight-line method or, if reliably determinable, based on the pattern in which the economic benefits of the assets are expected to be consumed. The economic pattern is based on undiscounted future cash flows. The decrease in amortization expense in fiscal 2016 compared to fiscal 2015 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 full amortization of assets acquired in our Suros acquisition. These decreases were partially offset due to the acceleration of amortization of the Cystic Fibrosis developed technology asset of $6.2 million in fiscal 2016 as a result of discontinuing this product.

Cost of Service and Other Revenues.

	Years Ended							
	September 24, 2016			September 26, 2015			Change	
	Amount	% of Service and Other Revenues		Amount	% of Service and Other Revenues		Amount	%
Cost of Service and Other Revenues	$219.2	48.3	%	$217.1	50.0	%	$2.1	1.0%

Service and other revenues gross margin was 51.7% in fiscal 2016 compared to 50.0% in fiscal 2015. Within our Breast Health segment, the increase in gross margin is related to higher service contract conversion and renewal rates and higher installation and training revenues related to our increased sales of 3D Dimensions systems. In addition, we had an increase in other revenue in our Diagnostics segment primarily due to $9 million of royalty payments from licensing certain technology, which had no corresponding service costs.

Operating Expenses.

	Years Ended								
	September 24, 2016			September 26, 2015			Change		
	Amount	% of Total Revenue		Amount	% of Total Revenue		Amount	%	
Operating Expenses									
Research and development	$232.1	8.2	%	$214.9	7.9	%	$17.2	8.0	%
Selling and marketing	415.1	14.7	%	363.0	13.4	%	52.1	14.4	%
General and administrative	267.3	9.4	%	261.0	9.7	%	6.3	2.4	%
Amortization of intangible assets	89.7	3.2	%	110.2	4.1	%	(20.5)	(18.6)%	
Restructuring and divestiture charges	10.5	0.4	%	28.5	1.1	%	(18.0)	(63.2)%	
	$1,014.7	35.9	%	$977.6	36.2	%	$37.1	3.8	%

Research and Development Expenses. Research and development expenses increased 8.0% in fiscal 2016 compared to fiscal 2015 primarily due to higher compensation, primarily in our Breast Health segment from additional headcount. There was also an increase in new product development spend in Breast Health, GYN Surgical and Skeletal Health for prototype

Table of Contents

materials and consulting. 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 14.4% in fiscal 2016 compared to fiscal 2015 primarily due to higher compensation from an increase in headcount in Diagnostics, GYN Surgical and Breast Health, increased commissions as a result of higher sales, an increase in spending on a number of marketing initiatives primarily in our Breast Health and Diagnostics businesses, higher medical education spend in GYN Surgical and higher travel, trade show and meeting expenses.

General and Administrative Expenses. General and administrative expenses increased 2.4% in fiscal 2016 compared to fiscal 2015 primarily due to a $6.0 million charge for settling a legal fee dispute in the first quarter of fiscal 2016, and to a lesser extent, due to higher salary and compensation from increased headcount, increased consulting and legal expenses for a number of corporate initiatives including organizational structure changes and finance operational improvements, an increase in information systems infrastructure and project costs, and an increase in stock-based compensation from implementing a retirement plan provision in our equity compensation plan in the fourth quarter. Partially offsetting these increases was a decrease in the medical device excise tax of $16.9 million as a result of the Protecting Americans from Tax Hikes Act of 2015 ("PATH"), which went into effect December 15, 2015, and provides for a two-year moratorium on the 2.3% excise tax imposed on the sale of medical devices in the United States on or after January 1, 2016 through December 31, 2017, and lower tax fees.

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. Amortization expense decreased 18.6% in fiscal 2016 compared to fiscal 2015 primarily due to lower amortization expense from intangible assets from the Gen-Probe Incorporated acquisition and the Cytyc acquisition, which are being amortized based on the pattern of economic use.

Restructuring and Divestiture Charges. In fiscal 2014, we implemented cost containment measures that primarily resulted in headcount reductions and also started the process of reorganizing our senior management team and international structure, which led to additional headcount actions in fiscal 2015. In addition, in fiscal 2015, we decided to shut down our Bedford, Massachusetts facility and transfer production of our Skeletal Health products to a third-party contract manufacturer and other activities to our Marlborough, Massachusetts and Danbury, Connecticut facilities. We also implemented additional organizational changes to our international operations throughout fiscal 2016 which resulted in additional charges. Pursuant to U.S. generally accepted accounting principles, the related severance and benefit charges are recognized either ratably over the respective required employee service periods or up-front for contractual benefits, and other charges are being recognized as incurred. In fiscal 2016 and 2015, we recorded aggregate charges of $10.5 million and $28.5 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. For additional information, please refer to Note 3 to our consolidated financial statements contained in Item 15 of this Annual Report.

Interest Expense.

	Years Ended			
	September 24, 2016	September 26, 2015	Change	
	Amount	Amount	Amount	%
Interest Expense	$(155.3)	$(205.5)	$50.2	(24.4)%

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, 2022 Senior Notes, 6.25% Senior Notes due 2020, and amounts borrowed under our Credit Agreement, our prior senior secured credit facility with Goldman Sachs Bank USA, in its capacity as administrative and collateral agent, referred to as the Prior Credit Agreement and our Accounts Receivable

Securitization Program. The decrease in interest expense in fiscal 2016 compared to fiscal 2015 was primarily due to lower outstanding balances as a result of scheduled principal payments, a term loan prepayment and extinguishments in fiscal 2015 and, to a lesser extent, Convertible Note repurchases in fiscal 2016 of $274.2 million principal amount, and lower interest rates in fiscal 2016 as a result of debt refinancings in fiscal 2015.

Table of Contents

Debt Extinguishment Loss.

	Years Ended			
	September 24, 2016	September 26, 2015	Change	
	Amount	Amount	Amount	%
Debt Extinguishment Loss	$(5.3)	$ (62.7)	$57.4	(91.5)%

On various dates during the second and fourth quarters of fiscal 2016, we entered into privately negotiated repurchase transactions and extinguished $137.6 million and $136.6 million principal amount of our 2010 and 2012 Notes, respectively, for an aggregate payment of $392.8 million, which includes a premium conversion resulting from our stock price on the date of the transactions being in excess of the conversion prices. In connection with these transactions, we recorded a debt extinguishment loss of $4.6 million and $0.7 million on the 2010 and 2012 Notes, respectively, related to the difference between the fair value of their respective liability components and carrying values at the repurchase dates. The remaining cash payments were allocated to the reacquisition of the equity component and recorded within additional paid-in capital, a component of stockholders' equity.

In the fourth quarter of fiscal 2015, we completed a private placement of $1.0 billion aggregate principal amount of our 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 included the conversion premium resulting from our stock price on the date of transaction being in excess of the conversion price. 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 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.

Other Income (Expense), net.

	Years Ended			
	September 24, 2016	September 26, 2015	Change	
	Amount	Amount	Amount	%
Other Income (Expense), net	$26.6	$ (11.0)	$37.6	**

** Percentage not meaningful

In fiscal 2016, this account was primarily comprised of a $25.1 million realized gain on the sale of a marketable security, and a gain of $3.3 million on the cash surrender value of life insurance contracts related to our deferred compensation plan. These gains were partially offset by an other-than-temporary impairment charge of $1.1 million

on a marketable security and net foreign currency exchange losses of $1.0 million.
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.

Table of Contents

Provision for Income Taxes.

	Years Ended			
	September 24, 2016	September 26, 2015	Change	
	Amount	Amount	Amount	%
Provision for Income Taxes	$84.5	$ 45.6	$38.9	85.3%

Our effective tax rate for fiscal 2016 was 20.3% compared to 25.8% in fiscal 2015. For fiscal 2016, the effective tax rate was lower than the statutory tax rate primarily due to earnings in jurisdictions subject to lower tax rates, the domestic production activities deduction benefit, and a change in the valuation allowance related to the sale of a marketable security with a higher tax than book basis. For fiscal 2015, the effective tax rate was lower than the statutory rate primarily due to the domestic production activities deduction benefit.

Segment Results of Operations

Diagnostics.

	Years Ended			
	September 24, 2016	September 26, 2015	Change	
	Amount	Amount	Amount	%
Total Revenues	$1,236.9	$1,211.8	$25.1	2.1 %
Operating Income	$126.0	$109.5	$16.5	15.1%
Operating Income as a % of Segment Revenue	10.2 %	9.0 %		

Diagnostics revenues increased in fiscal 2016 compared to fiscal 2015 primarily due to the increase in product revenues discussed above.

Operating income for this business segment increased in fiscal 2016 compared to fiscal 2015 primarily due to increased gross profit and lower operating expenses. Gross profit increased primarily due to increased Aptima and Cytology & Perinatal product sales, partially offset by lower blood screening revenues, as discussed above, and an increase in other revenue primarily due to $9.0 million in payments received in fiscal 2016 under an agreement to license certain technology for which there were no corresponding costs. In addition, we had favorable manufacturing variances and lower production costs at our manufacturing facilities as we improve our operational effectiveness and renegotiate pricing with certain of our vendors. Partially offsetting these improvements were unfavorable absorption variances, a mix shift in international sales to lower margin molecular diagnostic products, inventory related charges for discontinuing the Cystic Fibrosis product, the negative impact of the strengthening U.S. dollar on our sales denominated in foreign currencies, and the acceleration of amortization of the Cystic Fibrosis developed technology asset of $6.2 million. Overall, the gross margin improved slightly to 49.5% in fiscal 2016 from 49.3% in fiscal 2015.

Operating expenses decreased in fiscal 2016 compared to fiscal 2015 primarily due to lower amortization expense of $16.9 million, lower medical device excise taxes of $7.5 million, and lower restructuring charges. These decreases were partially offset by higher sales and marketing expenses related to increased compensation for additional headcount and commissions, increased marketing initiatives and trade shows and an increase in legal fees related to the settlement of a fee dispute for $6.0 million.

Breast Health.

	Years Ended			
	September 24, 2016	September 26, 2015	Change	
	Amount	Amount	Amount	%
Total Revenues	$1,112.8	$1,063.4	$49.4	4.6 %
Operating Income	$350.5	$296.3	$54.2	18.3%
Operating Income as a % of Segment Revenue	31.5 %	27.9 %		

Breast Health revenues increased in fiscal 2016 compared to fiscal 2015 primarily due to the $34.6 million increase in product revenues discussed above and a $14.7 million increase in service revenues.

Operating income for this business segment increased in fiscal 2016 compared to fiscal 2015 primarily due to an increase in gross profit from higher revenue, partially offset by an increase in operating expenses. Gross profit increased primarily due

Table of Contents

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, and an increase in software related sales, each of which have higher gross margins. We also generated an increase in domestic sales, which have higher average selling prices, while international sales declined in fiscal 2016 compared to fiscal 2015 resulting in an improved gross margin. In addition, this business experienced favorable manufacturing variances. These increases were partially offset by the negative foreign currency impact of the strengthening U.S. dollar on our sales denominated in foreign currencies. As a result, overall gross margin increased to 59.9% in fiscal 2016 compared to 56.4% in fiscal 2015.

Operating expenses increased in fiscal 2016 compared to fiscal 2015 primarily due to an increase in compensation and commissions from increased headcount and improved operating results, higher marketing expenditures for a number of marketing programs, and increased trade show and meeting expenses, higher clinical trial and prototype materials expenses, and increased information systems infrastructure costs. These expense increases were partially offset by lower medical device excise taxes of $5.8 million, lower intangible asset amortization expense of $2.5 million, and lower restructuring expenses in which the prior year included a $9.6 million charge to write-off the cumulative translation adjustment related to the divestiture of our MRI breast coils product line.

GYN Surgical.

	Years Ended			
	September 24, 2016	September 26, 2015	Change	
	Amount	Amount	Amount	%
Total Revenues	$393.1	$335.8	$57.3	17.1%
Operating Income	$69.1	$38.6	$30.5	79.0%
Operating Income as a % of Segment Revenue	17.6 %	11.5 %		

GYN Surgical revenues increased in fiscal 2016 compared to fiscal 2015 due to the increase in product revenues discussed above.

Operating income for this business segment increased in fiscal 2016 compared to fiscal 2015 primarily due to an increase in revenues and gross profit, partially offset by an increase in operating expenses. Gross margin increased to 62.0% in fiscal 2016 from 57.3% in fiscal 2015 primarily due to increased sales volumes for both our MyoSure and NovaSure products resulting in favorable manufacturing variances, partially offset by product mix shift to our lower margin MyoSure products. In addition, intangible asset amortization expense was lower in the current year. Gross margin was also higher in the current year as the prior year included a $4.0 million charge to write-off inventory that would not be utilized.

Operating expenses increased in fiscal 2016 primarily due to an increase in compensation from additional headcount, higher commissions due to increased sales, increased spend on marketing initiatives, trade shows and medical education, increased research and development expenses and higher legal expenses.

Skeletal Health.

	Years Ended			
	September 24, 2016	September 26, 2015	Change	
	Amount	Amount	Amount	%
Total Revenues	$89.9	$ 94.0	$(4.1)	(4.4)%
Operating Income	$3.0	$ 10.7	$(7.7)	(72.0)%
Operating Income as a % of Segment Revenue	3.3 %	11.4 %		

Skeletal Health revenues decreased in fiscal 2016 compared to fiscal 2015 primarily due to the decrease in product revenues of $4.0 million discussed above.

Operating income decreased in fiscal 2016 compared to fiscal 2015 primarily due to higher operating expenses for compensation and additional investment in research and development projects, while gross profit increased slightly as a result of higher sales of our higher margin Horizon product and favorable manufacturing variances as we built up inventory in advance of transitioning production of these products to a third-party manufacturer.

58

Table of Contents

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2017, we had a negative $(386.9) million of working capital, and our cash and cash equivalents totaled $540.6 million. Our cash and cash equivalents balance decreased by $7.8 million during fiscal 2017 principally due to the purchase of Cynosure, tax payments on the gain on the sale of the blood screening business, payments to extinguish certain of our Convertible Notes and repurchase of our common stock, partially offset by cash generated through investing activities as a result of the sale of our blood screening business, sales of marketable securities, cash flows from our core operating activities and borrowings under our revolving line of credit.

In fiscal 2017, our operating activities provided us with $8.3 million of cash, which included tax payments of $649.5 million related to the gain on the sale of our blood screening business. The cash received from the sale of the business is separately classified within cash from investing activities. Cash flow from operations, excluding this tax payment, was $657.8 million. Adjustments to net income of $755.5 million included non-cash charges for depreciation and amortization aggregating $449.2 million, stock-based compensation expense of $68.2 million and non-cash interest expense of $49.4 million related to our outstanding debt and $39.7 million related to the step-up in fair value of acquired inventory. These adjustments to net income were partially offset by a gain on the sale of our blood screening business of $899.7 million, the cash from which was included in investing activities, and a decrease in net deferred tax liabilities of $357.2 million, primarily from the amortization of intangible assets and the reversal of deferred taxes related to blood screening intangible assets that were sold. Cash provided by operations included a net cash outflow of $103.2 million from changes in our operating assets and liabilities. Changes in our operating assets and liabilities were driven primarily by an increase in accounts receivable of $41.5 million primarily due to a higher portion of revenues occurring in the last month of fiscal 2017 compared to fiscal 2016 resulting in a slight increase in days sales outstanding, a decrease in accrued expenses of $17.8 million related to the timing of accruals for income and other taxes, and lower accrued compensation, a decrease in accounts payable of $10.6 million primarily due to the timing of payments, a decrease in deferred revenue of $10.6 million primarily due to recognizing amounts previously deferred for not meeting the revenue recognition criteria, and an increase in inventory of $11.6 million primarily due to building up inventory to meet anticipated demand and launch of newer products.

In fiscal 2017, we generated $285.8 million of cash from investing activities, primarily related to $1.865 billion in proceeds from the sale of our blood screening business and $87.1 million in proceeds from the sale of marketable securities. These cash inflows were partially offset by $1.558 billion in net cash used to acquire Cynosure and Medicor and $107.6 million for capital expenditures, which consisted of the placement of equipment under customer usage agreements and purchases of manufacturing equipment and computer hardware.

In fiscal 2017, our financing activities used cash of $309.2 million, primarily for payments of $396.2 million to extinguish and redeem certain of our Convertible Notes, repurchases of common stock of $200.1 million, payments related to our long term debt under our Credit Agreement of $84.4 million and payments of $19.7 million for employee-related taxes withheld for the net share settlement of vested restricted stock units. Partially offsetting these uses of cash were proceeds of $345.0 million borrowed under our revolving line of credit and proceeds of $49.0 million from our equity compensation plans.

Debt

We had total recorded debt outstanding of $3.3 billion at September 30, 2017, which was comprised of amounts outstanding under our Credit Agreement of $1.66 billion (principal $1.67 billion), our 2022 Senior Notes of $1.0 billion and our convertible notes of $484.5 million (principal $447.4 million), which included accretion of principal at 4.0% per annum on the 2013 Notes, and amounts outstanding under the accounts receivable securitization program of $200.0 million.

Credit Agreement

As of September 30, 2017, the credit facilities under the Credit Agreement consisted of:

- A $1.5 billion secured term loan to the Company with a final maturity date of May 29, 2020 or the Term Loan, of which $1.3 billion was outstanding at September 30, 2017; and
- A secured revolving credit facility under which the Borrowers (as defined below) could borrow up to $1 billion, subject to certain sublimits, with a final maturity date of May 29, 2020 or the Revolver, of which $345.0 million was outstanding at September 30, 2017.

Borrowings were secured by first-priority liens on, and a first-priority security interest in, substantially all of the assets of our U.S. subsidiaries, with certain exceptions. For example, borrowings under the Credit Agreement were not secured by those accounts receivable that we transfer to the special purpose entity under our Accounts Receivable Securitization Program. As of September 30, 2017, the interest rate under the Term Loan and Revolver was 2.73% on the outstanding amounts, which was reflective of the Eurocurrency Rate (i.e., Libor) plus the applicable margin of 1.50% per annum as set forth in the Credit

Table of Contents

Agreement. The applicable margin was subject to specified changes depending on the total net leverage ratio as defined in the Credit Agreement.

We were 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 was due at maturity. Any amounts outstanding under the Revolver were due at maturity. In addition, subject to the terms and conditions set forth in the Credit Agreement, we were required to make certain mandatory prepayments from specified excess cash flows from operations (to the extent our net senior secured leverage ratio exceeded 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”). Subject to certain limitations, we could voluntarily prepay any of the credit facilities under the Credit Agreement without premium or penalty.

The Credit Agreement contained 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 contained customary representations and warranties and events of default, including payment defaults, breach of representations and warranties, covenant defaults, cross defaults and an event of default upon a change of control of the company.

The Credit Agreement contained total net leverage ratio and interest coverage ratio financial covenants measured as of the last day of each fiscal quarter and an excess cash flow prepayment requirement measured as of the end of each fiscal year. As of September 30, 2017, we were in compliance with these covenants, and no Mandatory Prepayments were required as of September 30, 2017.

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 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 30, 2017, our convertible notes, in the aggregate original principal amount of $447.4 million, are recorded at $484.5 million, which includes accretion of principal at 4.0% per annum on the 2013 Notes and is net of the unamortized debt discount attributed to the embedded conversion feature of the convertible notes and deferred issuance costs. At September 30, 2017, these notes consisted of:

- $245.4 million original principal amount of our 2.00% Convertible Senior Notes due 2042 issued in March 2012 (2012 Notes); and
-

$202.0 million original principal amount of our 2.00% Convertible Senior Notes due 2043 issued in February 2013 (2013 Notes).

The 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. The 2012 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.

Table of Contents

The 2012 Notes and 2013 Notes have conversion prices of approximately $31.175 and $38.59 of original principal amount, respectively, and are subject in each case to adjustment. Holders of the 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.

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 2012 Notes and 2013 Notes beginning 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 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. On November 14, 2017, we announced that we had elected to redeem, on December 15, 2017, all of the outstanding 2013 Notes (those 2013 Notes not surrendered to us for repurchase on December 15, 2017 or validly submitted for conversion prior to December 15, 2017) at a redemption price equal to 100% of the accreted principal amount of the 2013 Notes to be redeemed. We also announced on November 14, 2017 that as provided in the indenture for the 2013 Notes, we had made an irrevocable election to settle any conversion of the 2013 Notes validly submitted on or after November 14, 2017 in cash.

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.

Accounts Receivable Securitization Program

On April 25, 2016, we entered into a one-year $200.0 million accounts receivable securitization program (the "Securitization Program") with several of our wholly owned subsidiaries and certain financial institutions. Under the terms of the Securitization Program, we and certain of our wholly-owned subsidiaries sell our customer receivables to a bankruptcy remote special purpose entity, which is wholly-owned by us. In addition, we also contributed a portion of our customer receivables to the special purpose entity in connection with its establishment. We retain servicing responsibility. The special purpose entity, as borrower, and we, as servicer, have entered into a Credit and Security Agreement with several lenders pursuant to which the special purpose entity may borrow from the lenders up to $200.0 million, with the loans secured by the receivables. The amount that the special purpose entity may borrow at a given point in time is determined based on the amount of qualifying receivables that are present in the special purpose entity at such point in time. The entire amount available of $200.0 million is outstanding at September 30, 2017. Borrowings outstanding under the Securitization Program bear interest at LIBOR plus the applicable margin of 0.7% and are included as a component of current liabilities in our consolidated balance sheet, while the accounts receivable securing these obligations remain as a component of net receivables in our consolidated balance sheet. As of September 30, 2017, the interest rate under the Securitization Program was 1.24% on the outstanding amounts. We and the special purpose entity are operated and maintained as separate legal entities. The assets of the special purpose entity secure the amounts borrowed and cannot be used to pay our other debts or liabilities. The special purpose entity was not a guarantor under our Credit Agreement and is not a guarantor under our Amended and Restated Credit

Agreement or of our 2022 and 2025 Senior Notes.

Effective April 21, 2017, the Company entered into an amendment to extend the Securitization Program an additional year to April 20, 2018. The amendment allows the Company to continue to borrow up to $200.0 million and due to structural changes to the terms, the borrowing base has fewer limitations.

The Credit and Security Agreement contains customary representations and warranties and events of default, including payment defaults, breach of representations and warranties, covenant defaults, and an event of default upon a change of control.

Table of Contents

In addition, it contains financial covenants consistent with that of the Credit Agreement. As of September 30, 2017, the Company was in compliance with the Credit and Security Agreement covenants.

Subsequent Events

Amended and Restated Credit Agreement

On October 3, 2017, we and certain of our domestic subsidiaries entered into an Amended and Restated Credit and Guaranty Agreement (the "Amended and Restated Credit Agreement") with Bank of America, N.A. in its capacity as Administrative Agent, Swing Line Lender and L/C Issuer, and certain other lenders from time to time party thereto. The Amended and Restated Credit Agreement amends and restates our Credit Agreement. The proceeds under the Amended and Restated Credit Agreement of $1.8 billion were used, among other things, to pay off the Term Loan and Revolver outstanding under the Credit Agreement. Borrowings under the Amended and Restated Credit Agreement are secured by first-priority liens on, and a first-priority security interest in, substantially all of the assets of our U.S. subsidiaries, with certain exceptions.

The credit facilities (the “Amended and Restated Credit Facilities”) under the Amended and Restated Credit Agreement consist of:

- A $1.5 billion secured term loan to the Company (the "Amended Term Loan") with a stated maturity date of October 3, 2022 (which date may spring to April 15, 2022 upon the occurrence of certain conditions set forth in the Amended and Restated Credit Agreement); and
- A secured revolving credit facility (the "Amended Revolver") under which the Borrowers may borrow up to $1.5 billion, subject to certain sublimits, with a stated maturity date of October 3, 2022 (which date may spring to April 15, 2022 upon the occurrence of certain conditions set forth in the Amended and Restated Credit Agreement).

At the closing, we borrowed $345 million under the Amended Revolver, which was subsequently repaid during October 2017.

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

- Amended Term Loan: the Base Rate (as defined in the Amended and Restated Credit Agreement), at the Eurocurrency Rate (as defined in the Amended and Restated Credit Agreement), or at the LIBOR Daily Floating Rate (as defined in the Amended and Restated Credit Agreement),
- Amended Revolver: if funded in U.S. dollars,the Base Rate, Eurocurrency Rate, or LIBOR Daily Floating Rate, and, if funded in an alternative currency, the Eurocurrency Rate; and it requested under the swing line sublimit, the Base Rate.

The applicable margin to the Base Rate, Eurocurrency Rate, or LIBOR Daily Floating Rate is subject to specified changers depending on the total net leverage ratio as defined in the Amended and Restated Credit Agreement. The borrowings of the Amended Term Loan initially bear interest at an annual rate equal to the Eurocurrency Rate (i.e., the LIBOR rate) plus an Applicable Rate equal to 1.50%. The borrowings of the Amended Revolver initially bear interest at a rate equal to the LIBOR Daily Floating Rate plus an Applicable Rate equal to 1.50%. We are also required to pay a quarterly commitment fee calculated on the undrawn committed amount available under the Amended Revolver.

We are required to make scheduled principal payments under the Amended Term Loan in increasing amounts ranging from $9.375 million per three-month period commencing with the three-month period ending on December 29, 2017 to $37.5 million per three-month period commencing with the three-month period ending on December 23, 2021. The remaining balance of the Amended Term Loan and any amounts outstanding under the Amended Revolver are due at maturity. In addition, subject to the terms and conditions set forth in the Amended and Restated Credit Agreement, we are required to make certain mandatory prepayments from the net proceeds of specified types of asset sales (subject to

certain reinvestment rights), debt issuances and insurance recoveries (subject to certain reinvestment rights). These mandatory prepayments are required to be applied by us, first, to the Amended Term Loan, second, to any outstanding amount under any Swing Line Loans (as defined in the Amended and Restated Credit Agreement), third, to the Amended Revolver, fourth to prepay any outstanding reimbursement obligations with respect to Letters of Credit (as defined in the Amended and Restated Credit Agreement) and fifth, to cash collateralize any Letters of Credit. Subject to certain limitations, we may voluntarily prepay any of the Amended and Restated Credit Facilities without premium or penalty.

The Amended and Restated Credit Agreement contains affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants restricting the ability of us, subject to negotiated exceptions, to incur

Table of Contents

additional indebtedness and grant additional liens on our assets, engage in mergers or acquisitions or dispose of assets, enter into sale-leaseback transactions, pay dividends or make other distributions, voluntarily prepay other indebtedness, enter into transactions with affiliated persons, make investments, and change the nature of their businesses. In addition, the Amended and Restated Credit Agreement requires the Borrowers to maintain certain financial ratios. The Amended and Restated 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.

2025 Senior Notes

On October 10, 2017, we completed a private placement of $350 million aggregate principal amount of our 4.375% Senior Notes due 2025 (the “2025 Notes”) at an offering price of 100% of the aggregate principal amount of the 2025 Notes. The 2025 Notes mature on October 15, 2025 and bear interest at the rate of 4.375% per year, payable semi-annually on April 15 and October 15 of each year, commencing on April 15, 2018. The 2025 Notes were not registered under 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 2025 Notes are general senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by certain domestic subsidiaries of Hologic.

We may redeem the 2025 Notes at any time prior to October 15, 2020 at a price equal to 100% of the aggregate principal amount so redeemed, plus accrued and unpaid interest, if any, to the redemption date and a make-whole premium set forth in the Indenture. We may also redeem up to 35% of the aggregate principal amount of the 2025 Notes with the net cash proceeds of certain equity offerings at any time and from time to time before October 15, 2020, at a redemption price equal to 104.375% 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 2025 Notes on or after: October 15, 2020 through October 14, 2021 at 102.188% of par; October 15, 2021 through October 14, 2022 at 101.094% of par; and October 15, 2022 and thereafter at 100% of par. In addition, if we undergo a change of control coupled with a decline in ratings, as provided in the indenture, we will be required to make an offer to purchase each holder’s 2025 Notes at a price equal to 101% of their principal amount, plus accrued and unpaid interest, if any, to the repurchase date.

We intend to use the net proceeds of the 2025 Notes, plus available cash, which includes amounts available under the Revolver, to redeem or repurchase all of our outstanding convertible notes, including exercise of our cash settlement election upon any conversion of those notes. Our election to redeem or repurchase the convertible notes, and/or make an all cash settlement election on conversion of the convertible notes will be in our sole discretion, based upon existing market and business conditions at the time of such determination.

Stock Repurchase Program

On June 21, 2016, the Board of Directors authorized the repurchase of up to an additional $500.0 million of the Company's outstanding common stock over the next five years. There were no repurchases of common stock made under this authorization during fiscal 2016. During fiscal 2017, the Company repurchased 5.3 million shares of its common stock for total consideration of $200.1 million.

Table of Contents

Contractual Obligations

The following table summarizes our contractual obligations and commitments as of September 30, 2017:

Contractual Obligations	Payments Due by Period				
	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Long-Term Debt Obligations (1)	$1,155.2	$1,200.0	$1,000.0	$ —	$3,355.2
Interest on Long-Term Debt Obligations	103.2	171.7	93.9	—	368.8
Operating Leases	20.9	33.2	23.9	27.0	105.0
Capital Leases (2)	2.8	5.6	5.9	17.3	31.6
Finance Leases (3)	2.9	2.4	2.4	1.7	9.4
Purchase Obligations (4)	56.4	5.8	2.2	—	64.4
Pension Obligations (5)	0.4	0.8	0.8	7.9	9.9
Total Contractual Obligations	$1,341.8	$1,419.5	$1,129.1	$ 53.9	$3,944.3

(1) Included within long-term debt obligations are the Term Loan, Revolver, 2022 Senior Notes, borrowings under the Securitization Program, the 2012 Notes and 2013 Notes. The 2012 Notes and 2013 Notes can first be put to us on March 1, 2018 ($245.4 million original principal). The 2013 Notes can first be put to us on December 15, 2017 ($202.0 million original principal) and are convertible by their respective holders because we have elected to redeem such notes in the first quarter of fiscal 2017 as further discussed above. 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. The 2013 Notes also have principal accretion of 4.00% annually, which is included in the principal amount in the less than 1 year column above. The amounts in the table do not include deferred tax liabilities for the recapture of the original issuance discount.

(2) As a result of the Cynosure acquisition, we have capital leases for the buildings at its primary U.S. operating facility and certain equipment and vehicles.

(3) 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.

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

(5) Pension obligations do not include our obligation under our deferred compensation plans of $43.2 million at September 30, 2017, 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 $88.3 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 intend to use the net proceeds from our 2025 Notes, our Amended and Restated Credit Agreement and available cash and borrowings under our Amended Revolver to redeem or repurchase all of our outstanding convertible notes. We also 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 and permitted accounts receivable securitization program will provide us with sufficient funds in order to redeem or repurchase all of our outstanding convertible notes and 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 Amended and Restated Credit Agreement, 2022 Senior Notes, 2025 Senior Notes, convertible notes and accounts receivable securitization program. These capital requirements could be

Table of Contents

substantial. Our operating performance may also be affected by matters discussed under the above-referenced Risk Factors set forth elsewhere in this report. These risks, trends and uncertainties may also adversely affect our long-term liquidity.

Legal Contingencies

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

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

Inventory

Our inventories include material, labor and overhead, and are stated at the lower of cost (first-in, first-out) or market. As a developer and manufacturer of high technology medical equipment and diagnostic test kits, we may be exposed to a number of economic and industry factors that could result in portions of our inventory becoming either obsolete or in excess of anticipated usage. 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.

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

Table of Contents

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 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 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 generally use the income approach in which cash flow projections on an after-tax basis are discounted using a risk adjusted rate to determine the estimated fair value of certain identifiable intangible assets including developed technology, in-process research and development projects, customer relationships, and trade names.

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

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. In the event an indicator of impairment is identified, we perform an analysis comparing the undiscounted cash flows the asset group is expected to generate over its remaining economic life to its carrying value. The undiscounted cash flows are based on management's assumptions on the asset group's use in the future. 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 has 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.

Table of Contents

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 2017 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 July 1, 2017 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 our 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, except our Medical Aesthetics reporting unit, would still have passed Step 1 of the goodwill impairment test. This reporting unit had a fair value as of the measurement date that exceeded its carrying value by 2% with goodwill of $683.5 million. We acquired Cynosure, which is the sole business in Medical Aesthetics, on March 22, 2017. In connection with our annual strategic planning process and annual goodwill impairment test, we have lowered our estimated financial projections for this business as a result of its current operating performance being below expectations, which we primarily attribute to the significant turnover in the U.S. sales force in 2017. In the event, future operating performance is below our forecasted projections, or there are negative changes to long-term growth rates or if discount rates increase, these factors could result in a decline in the fair value of the reporting unit and we may be required to record a goodwill impairment charge.

At September 30, 2017, the Company believes that its other reporting units, with goodwill aggregating $2.49 billion, were not at risk of failing Step 1 of the goodwill impairment test based on the current forecasts.

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.

Revenue Recognition

We generate revenue from the sale of our products, primarily medical imaging systems, aesthetic treatment systems and diagnostic and surgical disposable products, and related services, which are primarily support and maintenance services on its 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, and collection of the resulting receivable is reasonably assured. Generally, our product arrangements for capital equipment sales, primarily in its Breast Health, Medical Aesthetics 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, we believe that these services and undelivered products can be accounted for separately from the delivered product element as the delivered products have value to our customers on a stand-alone basis. Accordingly, revenue for services not yet performed at the time of product delivery 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 for its capital equipment.

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

Table of Contents

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 the Company's 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 computer-aided detection ("CAD") products and C-View and Intelligent 2D products, the software element in its other products is 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 its CAD, C-View and Intelligent 2D components, which are sold by its Breast Health segment, these products are within the scope of the software revenue recognition rules. We evaluated the appropriate revenue recognition treatment of it 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.

We are required to allocate revenue to its 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 prices ("ESP") and services based on vendor-specific objective evidence of selling price ("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 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 relatively 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 ("PCS") has been established, we recognize revenue using the residual method at the time all other revenue recognition criteria have been met.

Within our Diagnostics segment, we manufactured blood screening products according to demand schedules provided by its former collaboration partner, Grifols, S.A. ("Grifols"). In the second quarter of fiscal 2017, we sold its assets in the blood screening business to Grifols. Upon the closing of the transaction, our existing collaboration agreement with Grifols terminated, and a new collaboration agreement was executed as part of this transaction for us to provide certain research and development services to Grifols. In addition, we agreed to provide transition services to Grifols over the next two to three years depending on the nature of the respective service, including the manufacture of inventory, and we are in effect serving as a contract manufacturer of assays to Grifols for a two to three year period. We also agreed to sell Panther instrumentation and certain supplies to Grifols as part of a long term supply agreement. As such, we will generate a level of revenues, but much lower than historical trends. Prior to divestiture, our agreement provided that we would share a portion of Grifols's revenue from screening blood donations. Upon shipment to Grifols, we recognized product revenue at an agreed upon fixed transfer price, which was not refundable, and recorded the related cost of products sold. Based on the terms of our prior collaboration agreement with Grifols, our ultimate share of the net revenue from sales to the end user in excess of the transfer price was not known until it was reported to us by Grifols. On a monthly basis, Grifols reported net revenue generated during the prior month and remitted an additional corresponding net payment to us, which was recorded as revenue at that time. This payment

combined with the transfer price revenues previously recognized represented our ultimate share of net revenue under the prior agreement.

While the majority of our instruments are placed at customer sites, in certain instances we sell instruments to our clinical diagnostics customers and records sales of these instruments upon shipment or delivery, depending on the terms of the arrangement.

Within our Diagnostics business, and to a lesser extent, its GYN Surgical business, we provide our 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. We install the instrumentation or equipment at the customer's site and recover the cost of providing the instrumentation or equipment in the amount we charge for its

Table of Contents

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.

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% as of September 30, 2017 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 and market-based stock units to members of our senior management team. 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. Each recipient of a market based award is eligible to receive between zero and 200% of the target number of shares of our common stock at the end of three years based upon achieving a certain total shareholder return relative to a defined peer group. Since both awards cliff vest, we recognize compensation expense ratably over the required service period, and specifically for performance stock units 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 $68.2 million, $65.4 million and $59.3 million of stock-based compensation expense for employee equity awards in fiscal years 2017, 2016 and 2015, respectively. As of September 30, 2017, there was $21.0 million and $54.6 million of unrecognized compensation expense related to stock options and stock units, respectively, that we expect to recognize over a weighted-average period of 2.5 years and 1.8 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 $964.5 million in net deferred tax liabilities at September 30, 2017 and $973.3 million at September 24, 2016. 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 the character of such income in assessing the need for the valuation allowance,

Table of Contents

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.
At September 30, 2017, we had $90.3 million in gross unrecognized tax benefits excluding interest, of which $70.3 million, if recognized, would reduce our effective tax rate. At September 24, 2016, we had $163.6 million in gross unrecognized tax benefits excluding interest, of which $76.9 million, if recognized, would have reduced the Company's effective tax rate. The gross unrecognized tax benefits decreased by $73.3 million from fiscal 2016, of which $64 million was a balance sheet reclassification resulting from the effective settlement in fiscal 2017 of uncertain tax positions related to the convertible debt exchange that occurred in fiscal 2013 and $6.2 million was the result of the effective settlement in fiscal 2017 of other unrecognized tax benefits. In the next twelve months it is reasonably possible that the Company will reduce its gross unrecognized tax benefits by up to $2.0 million due to expiring statutes of limitations.
In the ordinary course of business, there are many transactions and calculations where the ultimate tax outcome is uncertain. Judgment is required in determining our worldwide income tax provision. In our opinion, we have made adequate provisions for income taxes for all years subject to audit. While we consider our estimates reasonable, no assurance can be given that the final tax outcome will not be different than amounts reflected in our historical income tax provisions and accruals. If our assumptions are incorrect, the differences could have a material impact on our income tax provision and operating results in the period in which such determination is made.
Recent Accounting Pronouncements

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk
Financial Instruments, Other Financial Instruments, and Derivative Commodity Instruments. Financial instruments consist of cash and cash equivalents, accounts receivable, cost-method equity investments, 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 approximate their carrying amount. As of September 30, 2017, we had $447.4 million of principal of convertible notes outstanding, comprised of our 2012 Notes with a principal of $245.4 million, and our 2013 Notes with a principal of $202.0 million. The fair value of our 2012 Notes and 2013 Notes as of September 30, 2017 was approximately $297.3 million and $244.4 million, respectively. The fair value of our 2022 Senior Notes was approximately $1.05 billion. Amounts outstanding under our Credit Agreement and Securitization Program of $1.67 billion and $200.0 million aggregate principal, respectively, as of September 30, 2017 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, as well as under our accounts receivable securitization program. 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 1.50% per annum. Borrowings under our accounts receivable securitization program currently bear interest at Libor plus the applicable margin of 0.7%.
As of September 30, 2017, there was $1.67 billion of aggregate principal outstanding under the Credit Agreement, including the Revolver, and $200.0 million aggregate principal outstanding under the securitization program. Since these debt obligations are variable rate instruments, our interest expense associated with these instruments is subject to change. A 10% adverse movement (increase in LIBOR rate) would increase annual interest expense by approximately $2.3 million. During fiscal 2015 and fiscal 2017, 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 our LIBOR-based borrowings under the 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 which ends on December 31, 2017 and December 28, 2018, respectively.

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.

Table of Contents

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

We conduct business worldwide and maintain sales and service offices outside the United States as well as manufacturing facilities in Costa Rica and the United Kingdom. Our international sales are denominated in a number of currencies, primarily the Euro, U.S. dollar, UK Pound and Renminbi. The majority of our foreign subsidiaries functional currency is the local currency, although certain foreign subsidiaries functional currency is the U.S. dollar based on the nature of their operations or functions. Fluctuations in the foreign currency rates could affect our sales, cost of goods and operating margins and could result in exchange losses. In addition, currency devaluations can result in a loss if we hold deposits of that currency. We have executed forward foreign currency contracts to hedge a portion of results denominated in the Euro, UK Pound, Australian dollar, Japanese Yen and Canadian dollar. These contracts do not qualify for hedge accounting. As a result, we may experience volatility in our Consolidated Statements of Income due to (i) the impact of unrealized gains and losses reported in other income (expense), net on the mark-to-market of outstanding contracts and (ii) realized gains and losses recognized in other income, net, whereas the offsetting economic gains and losses are reported in the line item of the underlying cash flow, for example, revenue. We believe that the operating expenses of our international subsidiaries that are incurred in local currencies will not have a material adverse effect on our business, results of operations or financial condition. Our operating results and certain assets and liabilities that are denominated in foreign currencies are affected by changes in the relative strength of the U.S. dollar against those currencies. Our expenses, denominated in foreign currencies, are positively affected when the U.S. dollar strengthens against those currencies and adversely affected when the U.S. dollar weakens. However, we believe that the foreign currency exchange risk is not significant. We 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 2017, 2016 and 2015, we incurred net foreign exchange gains (losses) of $2.3 million, $(1.0) million, and $(3.0) 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 30, 2017, 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.

71

Table of Contents

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 30, 2017. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (COSO) in Internal Control-Integrated Framework.

Management has excluded from our assessment of and conclusion on the effectiveness of internal control over financial reporting the internal controls of Cynosure Inc. acquired on March 22, 2017, which is included in the consolidated financial statements of Hologic, Inc. as of and for the year ended September 30, 2017 constituting $1.9 billion and $1.4 billion of total assets and net assets, respectively, as of September 30, 2017, and $207.5 million and $96.4 million of revenues and a pre-tax losses, respectively, for the year then ended.

Subject to the foregoing, based on management’s assessment, we believe that, as of September 30, 2017, 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.

Table of Contents

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 30, 2017, 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.

As indicated in the accompanying Report of Management on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Cynosure, Inc., which is included in the 2017 consolidated financial statements of Hologic, Inc. and constituted $1,876 million and $1,424 million of total and net assets, respectively, as of September 30, 2017, and $207.5 million and $96.4 million of revenues and pre-tax loss, respectively, for the year then ended. Our audit of internal control over financial reporting of Hologic, Inc., also did not include an evaluation of the internal control over financial reporting of Cynosure, Inc.

In our opinion, Hologic, Inc. maintained, in all material respects, effective internal control over financial reporting as of September 30, 2017, 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 30, 2017 and September 24, 2016 and the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended September 30, 2017 of Hologic, Inc. and our report dated November 21, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
November 21, 2017

73

Table of Contents

Changes in Internal Control over Financial Reporting
During the quarter ended September 30, 2017, 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.

Table of Contents

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 30, 2017 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)	9,053,180	$ 28.15	6,783,777
Equity compensation plans not approved by security holders	—	$ —	—
Total	9,053,180	$ 28.15	6,783,777

(1) Includes 3,621,422 shares that are issuable upon restricted stock units (RSUs), performance stock units (PSUs) and market stock units (MSUs) vesting. The remaining balance consists of outstanding stock option grants.

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

The additional information required by this item is incorporated by reference to our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the 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.

Table of Contents

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.

Table of Contents

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 Income for the years ended September 30, 2017, September 24, 2016 and September 26, 2015

Consolidated Statements of Comprehensive Income for the years ended September 30, 2017, September 24, 2016 and September 26, 2015

Consolidated Balance Sheets as of September 30, 2017 and September 24, 2016

Consolidated Statements of Stockholders' Equity for the years ended September 30, 2017, September 24, 2016 and September 26, 2015

Consolidated Statements of Cash Flows for the years ended September 30, 2017, September 24, 2016 and September 26, 2015

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
2.2	Asset Purchase Agreement, dated December 14, 2016, by and among Hologic, Inc., Grifols Diagnostic Solutions Inc. and Grifols, S.A.	8-K	12/15/2016
2.3	Agreement and Plan of Merger, dated February 14, 2017, by and among Hologic, Inc., Cynosure, Inc. and Minuteman Merger Sub, Inc.	8-K	02/14/2017
3.1	Certificate of Incorporation of Hologic, with amendments	Filed herewith	
3.2	Certificate of Designation of Series A Junior Participating Preferred Stock of Hologic.	8-K	11/21/2013
3.3	Certificate of Elimination of Series A Junior Participating Preferred Stock of Hologic.	8-K	06/25/2014
3.4	Sixth Amended and Restated Bylaws of Hologic, Inc.	8-K	03/09/2017

4.1	Specimen Certificate for Shares of Hologic's Common Stock (filed in paper format)	8-A	01/31/1990
4.2	Description of Capital Stock (Contained in Hologic's Certificate of Incorporation, as amended, filed as Exhibit 3.1 hereto).	Filed herewith	
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

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Filing Date/ Period End Date
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
4.12	Indenture, dated October 10, 2017, by and among Hologic, the Guarantors party thereto and Wells Fargo Bank, National Association, as Trustee.	8-K	10/10/2017
4.13	Form of 4.375% Senior Note due 2025 (included in Exhibit 4.12)	8-K	10/10/2017
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 Stock Option Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2017).	8-K	11/09/2016
10.11*	Form of Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2014).	8-K	11/12/2013
10.12*	Form of Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2016).	8-K	10/14/2015
10.13*	Form of Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2017).	8-K	11/09/2016
10.14*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2015).	8-K	11/05/2014
10.15*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (adopted fiscal 2016).	8-K	11/06/2015

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.16*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (ROIC) (adopted fiscal 2017).	8-K	11/09/2016
10.17*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (relative TSR) (adopted fiscal 2017).	8-K	11/09/2016
10.18*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (ROIC) (adopted fiscal 2018).	8-K	11/09/2017
10.19*	Form of Performance Stock Unit Award Agreement Under 2008 Equity Incentive Plan (relative TSR) (adopted fiscal 2018).	8-K	11/09/2017
10.20*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan (annual grant, adopted fiscal 2014).	10-K	09/28/2013
10.21*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan (annual grant, adopted fiscal 2015).	10-K	09/27/2014
10.22*	Form of Independent Director Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (annual grant).	10-K	09/28/2013
10.23*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan (initial grant, adopted fiscal 2014).	10-K	09/28/2013
10.24*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan (initial grant, adopted fiscal 2015).	10-K	09/27/2014
10.25*	Form of Independent Director Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan (initial grant).	10-K	09/28/2013
10.26*	Hologic, Inc. 2012 Employee Stock Purchase Plan, As Amended	8-K	03/04/2016
10.27*	Hologic Short-Term Incentive Plan.	8-K	11/06/2015
10.28*	Hologic Amended and Restated Deferred Equity Plan	8-K	12/16/2015
10.29*	Rabbi Trust Agreement.	10-K	09/28/2013
10.30*	Form of Indemnification Agreement (as executed with each director of Hologic).	8-K	03/06/2009
10.31*	Form of Senior Vice President Change of Control Agreement. (1)	10-Q	12/29/2012

10.32*	Employment Agreement dated December 6, 2013 by and between Stephen P. MacMillan and Hologic.	8-K	12/09/2013
10.33*	Amended and Restated Employment Agreement by and between the Company and Stephen P. MacMillan, dated September 18, 2015.	8-K	09/21/2015
10.34*	Amendment No. 1 to Amended and Restated Employment Agreement by and between the Company and Stephen P. MacMillan, dated September 24, 2016.	10-K	11/17/2016
10.35*	Form of Matching Restricted Stock Unit Award Agreement	8-K	12/09/2013
10.36*	Change of Control Agreement dated December 6, 2013 by and between Stephen P. MacMillan and Hologic.	8-K	12/09/2013
10.37*	Offer Letter dated March 9, 2014 by and between Eric B. Compton and Hologic.	8-K	03/14/2014
10.38*	Severance and Change of Control Agreement dated March 9, 2014 by and between Eric B. Compton and Hologic.	10-K	11/19/2015
10.39*	Offer Letter dated May 8, 2014 by and between Robert W. McMahon and Hologic.	8-K	05/13/2014

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Filing Date/ Period End Date
10.40*	Severance and Change of Control Agreement dated May 8, 2014 by and between Robert W. McMahon and Hologic.	10-K	11/19/2015
10.41*	Offer Letter dated May 4, 2014 by and between Peter J. Valenti and Hologic.	10-Q	06/28/2014
10.42*	Senior Vice President Severance Agreement dated May 26, 2014 by and between Peter J. Valenti and Hologic.	10-K	09/27/2014
10.43*	Offer Letter dated August 21, 2014 by and between Thomas A. West and Hologic.	10-K	09/27/2014
10.44*	Senior Vice President Severance Agreement dated October 3, 2014 by and between Thomas A. West and Hologic.	10-K	09/27/2014
10.45*	Severance and Change of Control Agreement dated September 13 2017 by and between Allison Bebo and Hologic.	Filed herewith	
10.46*	Offer Letter dated January 6, 2015 by and between John M. Griffin and Hologic.	10-Q	03/28/2015
10.47*	Severance and Change of Control Agreement dated February 2, 2015 by and between John M. Griffin and Hologic.	10-Q	03/28/2015
10.48	Facility Lease (Danbury) dated December 20, 1995 by and among Melvin J. Powers and Mary P. Powers D/B/A M&N Realty and Lorad (filed in paper format).	Trex Medical Corporation S-1	03/29/1996
10.49	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
10.50	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
10.51	Office Lease dated December 31, 2003 between Cytyc and Marlborough Campus Limited Partnership.	Cytyc Corporation 10-K	12/31/2003
10.52	First Amendment to that Office Lease dated December 31, 2003 between Cytyc and Marlborough Campus Limited Partnership, entered into August 23, 2017, by and between Hines Global REIT Marlborough Campus LLC and Hologic, Inc. (2)	Filed herewith	
10.53		10-K	09/29/2007

	Lease Agreement by and between Zona Franca Coyol S.A. and Cytyc Surgical Products Costa Rica S.A. dated April 23, 2007.		
10.54	Lease Agreement by and between 445 Simarano Drive, Marlborough LLC and Cytyc dated July 11, 2006.	10-K	09/29/2007
10.55	Lease Guaranty dated October 18, 2007 between Bel Marlborough I LLC and Hologic, as guarantor thereunder.	8-K	10/22/2007
10.56	Form of Exchange Agreement.	8-K	02/15/2013
10.57	Amended and Restated Credit and Guaranty Agreement, originally dated May 29, 2015, and amended and restated as of October 3, 2017 among Hologic, Hologic GGO 4 Ltd, each Designated Borrower from time to time party thereto, the Guarantors from time to time party thereto, each Lender from time to time party thereto and Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer.	8-K	10/04/2017
10.58	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
10.59	Supply Agreement for Panther Instrument System effective November 22, 2006 between Gen-Probe Incorporated and STRATEC Biomedical Systems AG. (3)	Gen-Probe 10-Q	09/30/2007

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Form	Filing Date/ Period End Date
10.60	Amendment No. 1 dated June 1, 2011 to Supply Agreement for Panther Instrument System. (3)	10-K	09/24/2016
10.61	Amendment No. 2 dated February 28, 2013 to Supply Agreement for Panther Instrument System. (3)	10-K	09/24/2016
10.62	Intellectual Property License, dated as of January 31, 2017, by and among Hologic, Inc., Gen-Probe Incorporated and Grifols Diagnostics Solutions Inc.	8-K	02/02/2017
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

_____

* Indicates management contract or compensatory plan, contract or arrangement.
(1) List of executive officers to whom provided filed herewith.
(2) Confidential treatment has been requested 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.
(3) 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.

Item 16. Form 10-K Summary
None.

SIGNATURES
Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.
HOLOGIC, INC.

By: /S/ STEPHEN P. MACMILLAN
Stephen P. MacMillan
Chairman, President and Chief Executive Officer
Date: November 21, 2017
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 21, 2017
/S/ ROBERT W. MCMAHON ROBERT W. MCMAHON	Chief Financial Officer (Principal Financial Officer)	November 21, 2017
/S/ KARLEEN M. OBERTON KARLEEN M. OBERTON	Corporate Vice President, Finance and Accounting, Chief Accounting Officer (Principal Accounting Officer)	November 21, 2017
/S/ ELAINE S. ULLIAN ELAINE S. ULLIAN	Lead Independent Director	November 21, 2017
/S/ SALLY W. CRAWFORD SALLY W. CRAWFORD	Director	November 21, 2017
/S/ CHARLES DOCKENDORFF CHARLES DOCKENDORFF	Director	November 21, 2017
/S/ SCOTT T. GARRETT SCOTT T. GARRETT	Director	November 21, 2017
/S/ LAWRENCE M. LEVY LAWRENCE M. LEVY	Director	November 21, 2017
/S/ CHRISTIANA STAMOULIS	Director	November 21, 2017

CHRISTIANA STAMOULIS		
/S/ AMY M. WENDELL AMY M. WENDELL	Director	November 21, 2017

Table of Contents

Hologic, Inc.
Consolidated Financial Statements
Years ended September 30, 2017, September 24, 2016 and September 26, 2015
Contents

Table of Contents

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 30, 2017 and September 24, 2016 and the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended September 30, 2017. 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 30, 2017 and September 24, 2016, and the consolidated results of its operations and its cash flows for each of the three years in the period ended September 30, 2017, 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 30, 2017, 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 21, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
November 21, 2017

Table of Contents

Hologic, Inc.
Consolidated Statements of Income
(In millions, except number of shares, which are reflected in thousands, and per share data)

	Years ended		
	September 30, 2017	September 24, 2016	September 26, 2015
Revenues:			
Product	$2,538.0	$ 2,379.0	$ 2,270.4
Service and other	520.8	453.7	434.6
	3,058.8	2,832.7	2,705.0
Costs of revenues:			
Product	881.8	756.8	755.5
Amortization of intangible assets	297.1	293.4	299.7
Service and other	258.9	219.2	217.1
Gross Profit	1,621.0	1,563.3	1,432.7
Operating expenses:			
Research and development	232.8	232.1	214.9
Selling and marketing	498.6	415.1	363.0
General and administrative	343.3	267.3	261.0
Amortization of intangible assets	62.5	89.7	110.2
Gain on sale of business	(899.7)	—	—
Restructuring and divestiture charges	13.3	10.5	28.5
	250.8	1,014.7	977.6
Income from operations	1,370.2	548.6	455.1
Interest income	3.8	0.7	1.3
Interest expense	(153.2)	(155.3)	(205.5)
Debt extinguishment losses	(3.2)	(5.3)	(62.7)
Other income (expense), net	12.9	26.6	(11.0)
Income before income taxes	1,230.5	415.3	177.2
Provision for income taxes	475.0	84.5	45.6
Net income	$755.5	$ 330.8	$ 131.6
Net income per common share:			
Basic	$2.70	$ 1.18	$ 0.47
Diluted	$2.64	$ 1.16	$ 0.45
Weighted average number of shares outstanding:			