

HOLOGIC INC
Form 10-K
November 17, 2016
Table of Contents

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

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended: September 24, 2016

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
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Common Stock, \$.01 par value	The NASDAQ Stock Market LLC
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Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically 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 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.

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

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

The aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant as of March 26, 2016 was \$9,587,876,939 based on the price of the last reported sale on Nasdaq Global Select Market on that date. As of November 11, 2016, 278,215,876 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 24, 2016 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 24, 2016

TABLE OF CONTENTS

	Page
<u>PART I</u>	
Item 1. <u>Business</u>	4
Item 1A. <u>Risk Factors</u>	15
Item 1B. <u>Unresolved Staff Comments</u>	31
Item 2. <u>Properties</u>	32
Item 3. <u>Legal Proceedings</u>	33
Item 4. <u>Mine Safety Disclosures</u>	33
<u>PART II</u>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	34
Item 6. <u>Selected Financial Data</u>	36
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	37
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	65
Item 8. <u>Financial Statements and Supplementary Data</u>	66
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	66
Item 9A. <u>Controls and Procedures</u>	67
Item 9B. <u>Other Information</u>	70
<u>PART III</u>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	71
Item 11. <u>Executive Compensation</u>	71
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	71

Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>71</u>
Item 14. <u>Principal Accounting Fees and Services</u>	<u>72</u>
<u>PART IV</u>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	<u>73</u>
Item 16. <u>Form 10-K Summary</u>	<u>78</u>

2

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 on our business and results of operations;
- the coverage and reimbursement decisions of third-party payors and the guidelines, recommendations, and studies published by various organizations relating to the use of our products and treatments;
- the uncertainty of the impact of cost containment efforts and federal healthcare reform legislation on our business and results of operations;
- the ability to successfully manage ongoing organizational and strategic changes, including our ability to attract, motivate and retain key employees;
- the impact and anticipated benefits of completed acquisitions and acquisitions we may complete in the future;
- the ability to consolidate certain of our manufacturing and other operations on a timely basis and within budget, without disrupting our business and to achieve anticipated cost synergies related to such actions;
- our goal of expanding our market positions;
- the development of new competitive technologies and products;
- regulatory approval and clearances for our products;
- production schedules for our products;
- the anticipated development of markets for 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 our debt agreements;
- anticipated trends relating to our financial condition or results of operations, including the impact of interest rates and foreign currency exchange rate fluctuations; and
- our capital resources and the adequacy thereof.

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

TRADEMARK NOTICE

Hologic is a trademark of Hologic, Inc. Other trademarks, logos, and slogans registered or used by Hologic and its divisions and subsidiaries in the United States and other countries include, but are not limited to, the following: 3D, 3D Mammography, Affirm, Aptima, Aptima Combo 2, ATEC, Celero, Cervista, C-View, Dimensions, DirectRay, Discovery, DTS, Eviva, Fluoroscan, Genius, Gen-Probe, Horizon, Interlace, Invader, MultiCare, MyoSure, NovaSure, Panther, PreservCyt, Progensa, SecurView, Selenia, StereoLoc, ThinPrep, Tigris, TLI IQ, and TMA.

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. The Company operates in four segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health. We sell and service our products through a combination of direct sales and service personnel and a network of independent distributors and sales representatives.

We offer a wide range of diagnostic products which are used primarily to aid in the diagnosis of human diseases and screen donated human blood and plasma. Our primary diagnostics products include our Aptima family of assays, which run on our advanced instrumentation systems (Panther and Tigris), our ThinPrep system, the Rapid Fetal Fibronectin Test and our Procleix blood screening assays. The Aptima family of assays is used to detect the infectious microorganisms that cause the common sexually transmitted diseases, or STDs, chlamydia and gonorrhea, certain high-risk strains of human papillomavirus, or HPV, and *Trichomonas vaginalis*, the parasite that causes trichomoniasis. The ThinPrep System is primarily used in cytology applications, such as cervical cancer screening, and the Rapid Fetal Fibronectin Test assists physicians in assessing the risk of pre-term birth. In blood screening, we develop and manufacture the Procleix family of assays, which are used to detect various infectious diseases. The Procleix blood screening assays also run on our Panther and Tigris systems. These blood screening products are marketed worldwide by our blood screening collaborator, Grifols S.A., or Grifols, under Grifols' trademarks.

Our Breast Health products include a broad portfolio of breast imaging and related products and accessories, including digital mammography systems, computer-aided detection, or CAD, for mammography and minimally invasive breast biopsy devices, breast biopsy site markers, and breast biopsy guidance systems. Our most advanced breast imaging platform, Dimensions, utilizes a technology called tomosynthesis to produce 3D images that show multiple contiguous slice images of the breast, which we refer to as the Genius 3D Mammography exam, as well as conventional 2D full field digital mammography images. Our clinical results for FDA approval demonstrated that conventional 2D digital mammography with the addition of 3D tomosynthesis is superior to 2D digital mammography alone for both screening and diagnostics.

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

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

Available Information

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

These SEC reports can be accessed through the investor relations section of our website. The information found on our website is not part of this or any other report we file with or furnish to the SEC.

Investors and others should note that we announce material financial information to our investors using our investor relations website (<http://investors.hologic.com>), SEC filings, press releases, public conference calls and webcasts. We use these channels as well as social media to communicate with our members and the public about our company, our services and other issues. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on the social media channels listed on our investor relations website. Hologic has used, and intends to continue to use, our investor relations website, as well as our Twitter account (@Hologic), as means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD.

Further corporate governance information, including our certificate of incorporation, bylaws, governance guidelines, board committee charters, and code of business conduct and ethics, is also available on our investor relations website under the heading “Corporate Governance.” 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.

4

Table of Contents

You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy and information statements, and other information regarding Hologic and other issuers that file electronically with the SEC. The SEC's Internet website address is <http://www.sec.gov>.

Products

We view our operations and manage our business in four principal reporting segments: Diagnostics, Breast Health, GYN Surgical and Skeletal Health. Financial information concerning these segments is provided in Note 13 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 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 HBV, HCV and 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 and we are seeking approval of these viral load assays for sale and marketing in the U.S. Our Aptima products integrate various proprietary technologies, including our target capture technology, our Transcription Mediated Amplification, or TMA, technology, and our hybridization protection assay, or HPA, and dual kinetic assay, or DKA, technologies, to produce highly refined amplification assays that increase assay performance, improve laboratory efficiency and reduce laboratory costs. Each of these technologies is described in greater detail below.

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

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

Hybridization Protection Assay (HPA) and Dual Kinetic Assay (DKA) Technologies. With our patented HPA technology, we have simplified testing, further increased test sensitivity and specificity, and increased convenience. In the HPA process, the acridinium ester, or AE, molecule is protected within the double-stranded helix that is formed when the probe binds to its specific target. Prior to activating the AE molecule, known as "lighting off," a chemical is added that destroys the AE molecule on any unhybridized probes, leaving the label on the hybridized probes largely unaffected. When the "light off" or detection reagent is added to the specimen, only the label attached to the hybridized

probe is left to produce a signal indicating that the target organism's DNA or RNA is present. All of these steps occur in a single tube and without any wash steps, which were required as part of conventional probe tests. Our DKA technology uses two types of AE molecules-one that "flashes" and another one that "glows." By using DKA technology, we have created nucleic acid test, or NAT, assays that can detect two separate targets simultaneously.

5

Table of Contents

Procleix Family of Assays for Blood Screening

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

Instrumentation

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

Our instrumentation includes the Tigris system, an integrated, fully-automated testing instrument for high-volume laboratories which is approved for use with a number of our Aptima and Procleix assays, the Panther instrument system, an integrated, fully-automated testing instrument capable of serving both high- and low-volume laboratories, and our semi-automated direct tube sampling, or DTS, instruments which are used to run a number of infectious disease assays. In the fourth quarter of fiscal 2014, we also introduced our Tomcat instrument, a fully-automated general purpose instrument designed to improve pre-analytical sample processing by eliminating the inefficient and error-prone activities associated with manually transferring samples from one tube to another.

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

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

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

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

specimens (e.g., sputum or brushing of respiratory tracts) and ancillary testing (e.g., cell blocks, immunocytochemistry or special stains).

6

Table of Contents

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 a mammography gantry incorporating our DirectRay digital detector capable of performing both 2D and tomosynthesis image acquisition and display. When operating in tomosynthesis mode, the system acquires a series of low dose x-ray images taken in a scanning motion at various angles. The images are mathematically processed into a series of small slices, allowing for visualization of the breast in multiple contiguous slices. We believe by revealing the internal structure of the breast, the more subtle architecture of various types of suspicious lesions may be able to be better interpreted, which may ultimately increase cancer detection and reduce unnecessary patient callbacks. Our clinical results for FDA approval demonstrated that conventional 2D digital mammography with the addition of our Genius 3D Mammography is superior to 2D digital mammography alone for both screening and diagnostics.

C-View System

Our C-View product provides a 2D image that is mathematically synthesized from the data within a tomosynthesis exam. Our current recommended clinical practice involves what we refer to as a "combo" exam involving a tomosynthesis exam and a conventional digital 2D exam, but performed under the same breast compression. The C-View product allows for the mathematical construction of a 2D image from the tomosynthesis data, without the need for an actual 2D exposure. Elimination of the 2D exposure reduces the breast compression time and patient dose compared to the current combo exam.

Selenia

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

SecurView Workstation

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

CAD (Computer Aided Detection) Systems

We have developed CAD software tools for our mammography products and visualization tools for magnetic resonance imaging, or MRI. Mammography CAD is used by radiologists as "a second pair of eyes" when reading a woman's mammogram. Use of this technology provides reviewers with the potential to detect findings that might otherwise be overlooked during the review process, thus potentially increasing cancer detection. We also market an MRI visualization product, which manages the data set from an MRI procedure, designed to improve data workflow for the physician and provide analytical tools to aid in the identification and evaluation of the extent of disease.

Stereotactic Breast Biopsy Systems

We provide clinicians with the flexibility of choosing upright or prone systems for breast biopsy by offering three minimally invasive stereotactic breast biopsy guidance systems: the MultiCare Platinum dedicated, prone breast

biopsy table, the StereoLoc II upright attachment, and the Affirm upright attachment. The StereoLoc II attachment is used in conjunction with our Selenia systems. The Affirm upright attachment is employed with our Dimensions systems. These breast biopsy systems provide an alternative to open surgical biopsy and can be performed as an outpatient procedure under local

7

Table of Contents

anesthesia, allowing shorter recovery times. The Affirm tomosynthesis option provides faster lesion targeting and reduced patient procedure time compared to traditional stereotactic biopsy procedures. The Affirm system is pre-programmed for use with our Eviva and ATEC vacuum-assisted breast biopsy devices.

Breast Biopsy Products

We offer a wide range of minimally invasive products for breast biopsy and biopsy site marking. Our breast biopsy portfolio includes two types of tethered vacuum-assisted breast biopsy products, the Automated Tissue Excision Collection, or ATEC, and Eviva devices. Each tethered device is a disposable biopsy tool that is powered by a console and utilizes our patented fluid management system. The ATEC device can be used under all standard imaging guidance modalities (stereotactic x-ray, ultrasound, MRI and molecular breast imaging) whereas our Eviva device is used exclusively under stereotactic x-ray guidance. We also offer the Celero device, a non-tethered (no separate console), vacuum-assisted, spring-loaded, disposable core biopsy device, which is used exclusively under ultrasound-guidance.

GYN Surgical Products

NovaSure

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

MyoSure

The MyoSure system is designed to provide efficient and effective hysteroscopic removal of fibroids located just below the lining of the uterus as well as uterine polyps and other pathology within the uterus. Removal of fibroids can provide effective relief of heavy menstrual bleeding commonly attributed to such pathology. Unlike other methods of tissue removal, the excavated tissue samples remain intact, which allows them to be tested for abnormalities.

The MyoSure system consists of a tissue removal device, control unit, and hysteroscope. The MyoSure tissue removal device is single-use and features simultaneous tissue cutting and removal. The device incorporates a rapidly rotating cutting blade designed to remove a 3 cm fibroid in less than 10 minutes. During the procedure, the tissue removal device is inserted through the MyoSure hysteroscope. This tissue removal device is powered by a control unit, which features a simple user interface and is foot pedal activated.

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 2016, 2015, and 2014, no customer accounted for more than 10% of our consolidated revenues. In fiscal 2016, 2015, and 2014, revenues under our blood screening collaboration agreement, with Grifols, accounted for 18.8%, 20.9% and 18.8% of our Diagnostics segment revenue,

respectively. In addition, in fiscal 2016, revenues from another customer accounted for 10.9% of our Diagnostics segment revenue. No other customer accounted for more than 10% of our revenues in any other business segment in fiscal 2016, 2015, or 2014. In fiscal 2016,

8

Table of Contents

2015, and 2014, international revenues accounted for 22.2%, 25.4% and 26.4% of our product sales, respectively. See Note 13 to our consolidated financial statements contained in Item 15 of this Annual Report for geographical information.

Our U.S. sales force is structured to specifically target the customers in each of our business segments. We maintain distinct teams focused on the Diagnostics, Breast Health, GYN Surgical, and Skeletal Health markets. A critical element of our strategy in the U.S. has been to utilize the results of our clinical trials and expanded FDA labeling to demonstrate safety, efficacy and productivity improvements to our target customers. Our end customers include clinical laboratories, hospitals, healthcare providers and surgeons in both hospital and office settings, and we target various specialists at healthcare entities who use our products, such as ob-gyns, radiologists and breast surgeons. Our U.S. sales efforts also include the use of national account managers focused on obtaining purchasing contracts from large purchasing entities, such as managed care organizations, integrated delivery networks and government healthcare facilities. In addition, in certain regions of the U.S., we use a limited number of independent dealers or distributors to sell and service certain of our products. Internationally, our products are marketed and sold through a combination of a direct sales force and a network of distributors.

Our service organization is responsible for installing our products and providing warranty and repair services, applications training and biomedical training. Products sold by our direct sales force typically carry limited warranties covering parts and labor for twelve months. Products sold through dealers also carry limited warranties that typically last for twelve months and cover only parts and components. We also offer service contracts that generally last one to five years after the original warranty period. We provide both repair services and routine maintenance services under these arrangements, and also offer repair and maintenance services on a time and materials basis to customers that do not have service contracts. Internationally, we primarily use distributors, sales representatives and third parties to provide maintenance service for our products.

Competition

The healthcare industry is highly competitive and characterized by continual change and improvements in technology. This is particularly the case in the market segments in which we operate. A number of companies have developed, or are expected to develop products that compete or will compete with our products. Many of these competitors offer a broader product portfolio and have greater brand recognition than we do, which may make these competitors more attractive to hospitals, radiology clients, group purchasing organizations, laboratories, physicians and other potential customers. Competitors may develop superior products or products of similar quality for sale at the same or lower prices. Moreover, our products could be rendered obsolete by 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.

9

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

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

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

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

GYN Surgical. Our NovaSure system currently faces direct competition from 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 high quality and reliable supply. We have established long-term supply contracts with many of our suppliers and in other instances, we have developed in-house capability to offset potential shortages caused by sole source suppliers. Due to t